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[Intervention Review]

Instruments for assisted vaginal birth

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ABSTRACT

Background

Assisted vaginal births are carried out to expedite birth for the benefit of mothers and babies but are sometimes associated with significant morbidity for both. Various instruments are available, broadly divided into forceps and vacuum cups, and choice may be influenced by clinical circumstances, operator preference, experience and availability.

Objectives

To evaluate the different instruments in terms of success in achieving a vaginal birth, and the risk of morbidity for mother and baby.

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register, ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP) (14 May 2021), and reference lists of retrieved studies.

Selection criteria

We selected randomised controlled trials of assisted vaginal birth using different instruments. The review did not include quasi-randomised trials, cluster-randomised trials or cross-over designs. The review included trials for which abstracts alone were available as long as there was sufficient information to assess eligibility.

Data collection and analysis

We used standard Cochrane methods. We used the GRADE approach to assess the certainty of evidence. The main outcomes assessed included failed delivery with allocated instrument, any maternal trauma, third- and fourth-degree tears, postpartum haemorrhage, any neonatal trauma, low Apgar and low umbilical artery pH.

Main results

We included 31 studies involving a total of 5754 women. Risk of bias criteria were largely assessed as 'unclear', due to a lack of detail in trial reports. Blinding would have been challenging for all trials due to their inability to conceal the type of instrument used from either the woman or the operator, which is reflected in the risk of bias assessment.

Any type of forceps versus any type of vacuum cup (12 studies, 3129 women)

Forceps may be less likely to fail in achieving vaginal birth: risk ratio (RR) 0.58, 95% confidence interval (CI) 0.39 to 0.88; 11 studies, 3080 women; low certainty. 'Any maternal trauma' may be slightly more likely with forceps: odds ratio (OR) 1.53, 95% CI 0.98 to 2.40; 5 studies, 1356 women; low certainty; and third- or fourth-degree tears may also be more likely with forceps: RR 1.83, 95% CI 1.32 to 2.55; 9 studies, 2493 women; low certainty. There is no evidence of a difference in the incidence of postpartum haemorrhage (PPH) between the two groups: RR 1.71, 95% CI 0.59 to 4.95; 2 studies, 523 women; low certainty, because the evidence is very imprecise due to a very wide CI. More women in the forceps group reported requiring pain relief.

There is probably no evidence of difference in rates of low Apgar: RR 0.83, 95% CI 0.46 to 1.51; 7 studies, 1644 women; moderate certainty; or low umbilical artery pH in the forceps group compared to any vacuum: RR 1.33, 95% CI 0.91 to 1.93; 2 studies, 789 women; low certainty; both of these outcomes are imprecise and have wide CIs that include both benefit and harm. There were also lower rates of fetal trauma with 'any forceps' (cephalhematoma, retinal haemorrhage and jaundice).

The composite outcome of 'any neonatal trauma' was not reported.

Low-cavity forceps versus any vacuum cup (2 studies, 218 women)

We included two small studies with 218 participants in this comparison, but we judged most of the evidence as very low certainty, hence it was not feasible to make judgements on the difference in the rates of failed delivery, any maternal trauma or third- and fourth- degree tears. PPH and low umbilical artery pH were not reported.

Soft vacuum cup versus any rigid cup (9 studies, 1148 women)

Failed delivery may be more likely in the soft vacuum cup group: RR 1.62, 95% CI 1.21 to 2.17; 9 studies, 1148 women; low certainty. There may be no difference in the rates of 'any maternal trauma': OR 0.63, 95% CI 0.24 to 1.67; 2 studies, 348 women; low certainty, but the confidence interval is wide, indicating possible benefit or harm.

There may be no difference in the rates of third- or fourth-degree tears: RR 0.93, 95% CI 0.35 to 2.44; 4 studies, 619 women; low certainty. There is probably no difference in the rates of PPH: RR 0.89, 95% CI 0.49 to 1.61; 5 studies, 737 women; moderate certainty between the soft and rigid cup groups.

There may be little or no difference in the incidence of low Apgar scores: RR 0.82, 95% CI 0.49 to 1.37; 9 studies, 1148; low certainty; or low umbilical artery pH: RR 0.80, 95% CI 0.47 to 1.36; 1 study, 100 women; low certainty.

Handheld vacuum versus any vacuum cup (4 studies, 968 women)

There may be no difference in the rates of failures with allocated instrument: RR 1.35, 95% CI 0.81 to 2.25; 4 studies, 962 women; low certainty, any maternal trauma: OR 1.16, 95% CI 0.71 to 1.88; 2 studies; 394 women; low certainty, PPH: RR 0.31, 95% CI 0.03 to 2.92; 1 study, 164 women; low certainty, low umbilical artery pH: RR 1.06, 95% CI 0.71 to 1.59; 1 study, 164 women; low certainty, or low Apgar scores: RR 1.25, 95% CI 0.34 to 4.61; 3 studies, 784 women; low certainty) between the two groups.

There is probably no difference in the rates of third- or fourth-degree tears between the 'handheld vacuum' and 'any vacuum cup' groups: RR 1.15, 95% CI 0.62 to 2.12; 4 studies, 962 women; moderate certainty.

Authors' conclusions

This review provides low-certainty evidence that forceps may be more likely to achieve vaginal birth and have lower rates of fetal trauma, but at a greater risk of perineal trauma and higher pain relief requirements compared with vacuum cups. There was low-certainty evidence that rigid vacuum cups may be more likely to achieve a vaginal birth than soft cups but with more fetal trauma, whilst handheld vacuum cups had similar success rates compared to other cups. There was no evidence of a difference in the rates of third- or fourth-degree tears or postpartum haemorrhages between types of cups, but wide confidence intervals around the estimates indicate further research is needed in this area.

PLAIN LANGUAGE SUMMARY

Instruments for assisted vaginal birth

We used evidence from randomised controlled trials to assess the different forceps and vacuum suction cups used to achieve a vaginal birth.

What is the issue?

Late in labour, when the cervix (neck of the womb) is fully dilated, it is sometimes necessary to assist the birth of the baby through the vagina with an instrument. This may be because the mother is exhausted, suspected distress of the baby, or the mother has a medical condition preventing prolonged pushing.

Two types of instruments can be used: forceps or vacuum suction cups. Forceps are further divided into 'ordinary forceps' for when the baby's head is in the correct position and 'rotational forceps', which are used to turn the baby's head into the correct position. Vacuum cups can be divided into ones with rigid or flexible cups and into ones containing a handheld suction device or ones connected to a foot-operated or electric pump by a tube. This choice of instrument is often dictated by the clinical situation, but there is sometimes a choice.

Why is it important?

All types of instruments can cause complications for the mother or baby and all can also fail. It is therefore important to choose the correct instrument for the clinical situation with the best chance of ensuring a successful vaginal birth with the least risk of significant complications.

What evidence did we find?

We conducted a search on 14th May 2021. Our findings are based on 31 studies with a total of 5754 women and their babies.

Twelve studies involving 3129 women compared any type of forceps with any vacuum cup. Forceps were more likely to achieve vaginal birth, but with a greater number of perineal tears including those affecting the anus or rectum (both low-certainty evidence). The was no evidence of a difference in rates of postpartum haemorrhage (heavy bleeding after birth) between groups (low-certainty evidence). There was no evidence of difference in the chances of low Apgar scores (a scoring system used to assess the baby's well-being at 1 and 5 minutes to determine how well they are coping after the birth) and low umbilical artery pH (blood test from the cord to assess the baby's oxygen levels immediately before birth) (both low-certainty evidence). Women who had forceps had higher pain relief requirements, although babies were less likely to be jaundiced.

Two small studies in 218 women compared low forceps to any vacuum cup, but most of the evidence was of very low certainty, so we could draw no meaningful conclusion.

Nine studies involving 1148 women compared rigid cups with soft cups and found that rigid cups may be more likely to result in a successful delivery (low-certainty evidence), whilst there is probably no evidence of a difference in the rates of perineal tears affecting the anus or rectum or postpartum haemorrhages (low- and moderate-certainty evidence). In addition there is no evidence of a difference in the rates of low Apgar and low umbilical artery pH (low-certainty evidence).

In four studies with a total of 962 women we found no evidence of difference in the chances of a failed delivery between the handheld vacuum-cup group compared to the standard vacuum-cup devices (low-certainty evidence). In addition there was no evidence of differences in the risk of maternal rectal tissue trauma (low-certainty evidence). Finally, there was no evidence of difference in the rates of postpartum haemorrhage, low umbilical artery pH or low Apgar between the two groups (low-certainty evidence).

What does this mean?

The decision on which instrument to use is multifactorial and needs to consider the skills and resources available and the urgency for the birth. The clinician needs to choose the instrument that is most likely to achieve a successful birth with the least trauma to the mother and baby.

Summary of findings 1. Any type of forceps compared to any type of vacuum cup for assisted vaginal delivery

Any type of forceps compared to any type of vacuum cup for assisted vaginal delivery

Patient or population: Women in the second stage of labour, requiring an assisted vaginal birth
Setting: Hospital settings in low-, middle- and high-resource countries
Intervention: Any type of forceps
Comparison: Any type of vacuum cup

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with any type of vacuum cup	Risk with any type of forceps				
Failed delivery with allocated instrument (primary)	Study population		RR 0.58 (0.39 to 0.88)	3080 (11 RCTs)	⊕⊕⊖⊖ LOW[a,b]	-
	137 per 1000	79 per 1000 (53 to 120)				
Any maternal trauma (primary)	Study population		OR 1.53 (0.98 to 2.40)	1356 (5 RCTs)	⊕⊕⊖⊖ LOW[c]	-
	925 per 1000	950 per 1000 (924 to 968)				
Any neonatal injury (primary)	Study population		-	(0 RCTs)	-	Outcome not reported by trial authors
	see comment	see comment				
Third- or fourth-degree perineal tear (with or without episiotomy)	Study population		RR 1.83 (1.32 to 2.55)	2493 (9 RCTs)	⊕⊕⊖⊖ LOW[a,d]	-
	82 per 1000	150 per 1000 (108 to 209)				
Postpartum haemorrhage (≥ 500 mL)	Study population		RR 1.71 (0.59 to 4.95)	523 (2 RCTs)	⊕⊕⊖⊖ LOW[e]	-
	20 per 1000	35 per 1000 (12 to 101)				
Low Apgar score at 5 minutes (< 7 or as defined by trial authors)	Study population		RR 0.83 (0.46 to 1.51)	1644 (7 RCTs)	⊕⊕⊕⊖ MODERATE[d]	-
	28 per 1000	23 per 1000				

		(13 to 42)				
Low umbilical artery pH (< 7.2 or as defined by trial authors)	Study population		RR 1.33 (0.91 to 1.93)	789 (2 RCTs)	⊕⊕⊖⊖ LOW[c]	-
	106 per 1000	141 per 1000 (97 to 205)				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a]We downgraded by 1 level for serious inconsistency due to evidence of heterogeneity ($I^2 > 30$; $Tau^2 > 0$; and P value in the $Chi^2 < 0.10$).
[b]We downgraded by 1 level due to high probability of publication bias (funnel plot asymmetry).
[c]We downgraded by 2 levels due to a wide CI that just crosses 1.
[d]We downgraded by 1 level due to a wide CI.
[e]We downgraded by 2 levels due to a very wide CI.

Summary of findings 2. Low-cavity forceps compared to any vacuum cup for assisted vaginal delivery

Low-cavity forceps compared to any vacuum cup for assisted vaginal delivery

Patient or population: Women in the second stage of labour, requiring an assisted vaginal birth
Setting: Hospital settings in low-, middle- and high-resource countries
Intervention: Low cavity forceps
Comparison: Any type of vacuum cup

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with any vacuum cup	Risk with low-cavity forceps				
Failed delivery with allocated instrument (primary)	Study population		RR 0.26 (0.09 to 0.76)	218 (2 RCTs)	⊕⊖⊖⊖ VERY LOW[a,b]	-
	154 per 1000	40 per 1000				

		(14 to 117)				
Any maternal trauma (primary)	Study population		OR 7.44 (0.37 to 147.92)	100 (1 RCT)	⊕⊖⊖⊖ VERY LOW[a,b]	-
	940 per 1000	991 per 1000 (853 to 1000)				
Any neonatal injury (primary)	Study population		-	(0 RCTs)	-	Outcome not reported by trial authors
	see comment	see comment				
Third- or fourth-degree perineal tear (with or without episiotomy)	Study population		RR 1.05 (0.55 to 2.00)	218 (2 RCTs)	⊕⊖⊖⊖ VERY LOW[a,b]	-
	146 per 1000	154 per 1000 (80 to 293)				
Postpartum haemorrhage	Study population		-	(0 RCTs)	-	Outcome not reported by trial authors
	see comment	see comment				
Low Apgar score at 5 minutes (< 7 or as defined by trial authors)	Study population		-	118 (1 RCT)	-	No events
	see comment	see comment				
Low umbilical artery pH (< 7.20 or as defined by trial authors)	Study population		-	(0 RCTs)	-	Outcome not reported by trial authors
	see comment	see comment				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

__CI:__ Confidence interval; __RR:__ Risk ratio; __OR:__ Odds ratio;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a]We downgraded by 1 level for serious risk of bias because Shekhar 2013 was assessed at high risk of selective outcome reporting bias.
[b]We downgraded by 2 levels for very serious imprecision due to small sample size and a wide CI.

Summary of findings 3. Soft cup compared to rigid cup for assisted vaginal delivery

Soft cup compared to rigid cup for assisted vaginal delivery

Patient or population: Women in the second stage of labour, requiring an assisted vaginal birth
Setting: Hospital settings in low-, middle- and high-resource countries
Intervention: Soft vacuum cup
Comparison: Rigid vacuum cup

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with rigid cup	Risk with soft cup				
Failed delivery with allocated instrument (primary)	Study population		RR 1.62 (1.21 to 2.17)	1148 (9 RCTs)	⊕⊕⊖⊖ LOW[a,b]	-
	108 per 1000	174 per 1000 (130 to 234)				
Any maternal trauma (primary)	Study population		OR 0.63 (0.24 to 1.67)	348 (2 RCTs)	⊕⊕⊖⊖ LOW[c]	-
	960 per 1000	937 per 1000 (851 to 975)				
Any neonatal injury (primary)	Study population		-	(0 RCTs)	-	Outcome not reported by trial authors
	see comment	see comment				
Third- or fourth-degree perineal tear (with or without episiotomy)	Study population		RR 0.93 (0.35 to 2.44)	619 (4 RCTs)	⊕⊕⊖⊖ LOW[d]	-
	26 per 1000	24 per 1000 (9 to 63)				
Postpartum haemorrhage (≥ 500 mL or as defined by trial authors)	Study population		RR 0.89 (0.49 to 1.61)	737 (5 RCTs)	⊕⊕⊕⊖ MODERATE[b]	-
	57 per 1000	51 per 1000 (28 to 92)				
Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)	Study population		RR 0.82 (0.49 to 1.37)	1148 (9 RCTs)	⊕⊕⊖⊖ LOW[a,b]	-
	50 per 1000	41 per,000 (25 to 69)				

Low umbilical artery pH (< 7.2 or as defined by trial authors)	Study population		RR 0.80 (0.47 to 1.36)	100 (1 RCT)	⊕⊕⊖⊖ LOW[c]	-
	400 per 1000	320 per 1000 (188 to 544)				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a]We downgraded by 1 level for serious risk of bias because 4/9 studies were assessed as being at a high risk of bias. Hammarström 1986 was assessed at high risk for selection bias due to the process used for random sequence generation and at high risk for selective outcome reporting. Chanwaro 1999 was assessed at high risk for selection bias due to process used for random sequence generation. Afifi 1995 and Hofmeyr 1990 were assessed as being at high risk for selective outcome reporting.
[b]We downgraded by 1 level for serious imprecision due to a wide CI.
[c]We downgraded by 2 levels for very serious imprecision due to small sample size and a wide CI.
[d]We downgraded by 2 levels for very serious imprecision due to a very wide CI.

Summary of findings 4. Handheld vacuum compared to any vacuum cup for assisted vaginal delivery

Handheld vacuum compared to any vacuum cup for assisted vaginal delivery

Patient or population: Women in the second stage of labour, requiring an assisted vaginal birth
Setting: Hospital settings in low-, middle- and high-resource countries
Intervention: Handheld vacuum cup
Comparison: Any vacuum cup

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with any vacuum cup	Risk with handheld vacuum				
Failed delivery with allocated instrument (primary)	Study population		RR 1.35 (0.81 to 2.25)	962 (4 RCTs)	⊕⊕⊖⊖ LOW[a,b]	-
	139 per 1000	188 per 1000 (113 to 313)				

Any maternal trauma (primary)	Study population		OR 1.16 (0.71 to 1.88)	394 (2 RCTs)	⊕⊕⊖⊖ LOW[c]	-
	753 per 1000	779 per 1000 (683 to 851)				
Any neonatal injury (primary)	Study population		-	(0 RCTs)	-	Outcome not reported by trial authors
	see comment	see comment				
Third- or fourth-degree perineal tear (with or without episiotomy)	Study population		RR 1.15 (0.62 to 2.12)	962 (4 RCTs)	⊕⊕⊕⊖ MODERATE[a]	-
	38 per 1000	44 per 1000 (23 to 80)				
Postpartum haemorrhage (≥ 500 mL)	Study population		RR 0.31 (0.03 to 2.92)	164 (1 RCT)	⊕⊕⊖⊖ LOW[c]	-
	38 per 1000	12 per 1000 (1 to 111)				
Low Apgar score at 5 minutes (< 7 or as defined by trial authors)	Study population		RR 1.25 (0.34 to 4.61)	784 (3 RCTs)	⊕⊕⊖⊖ LOW[d]	-
	10 per 1000	13 per 1000 (3 to 47)				
Low umbilical artery pH (< 7.2 or as defined by trial authors)	Study population		RR 1.06 (0.71 to 1.59)	164 (1 RCT)	⊕⊕⊕⊖ LOW[c]	-
	354 per 1000	376 per 1000 (252 to 564)				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a]We downgraded by 1 level for serious imprecision due to a wide CI.
[b]We downgraded by 1 level for serious inconsistency due to evidence of heterogeneity ($I^2 > 30$; $Tau^2 > 0$; and P value in the $Chi^2 < 0.10$).

[c]We downgraded by 2 levels for very serious imprecision due to small sample size and a wide CI.
[d]We downgraded by 2 levels for very serious imprecision due to a very wide CI.

BACKGROUND

Description of the condition

The birth of a baby often needs to be expedited due to concerns about fetal condition, maternal condition or sometimes both. This can be achieved by an assisted vaginal birth using vacuum cup or forceps. Between 10% and 15% of all women giving birth in the UK have an operative vaginal birth (NHS Maternity Statistics 2017), rising to nearly one-third of nulliparous women.

Assisted vaginal birth is indicated in the presence of concerns for fetal or maternal well-being. or both. Maternal indications include exhaustion following prolonged labour, failure to progress in the second stage of labour, medical conditions such as pre-eclampsia, placental abruption and certain maternal cardiac or neurological conditions. Fetal indications include fetal distress in the second stage of labour due to either maternal condition or occurring independently. Birth of the baby may be desired to allow the early treatment of the maternal or fetal concerns.

Description of the intervention

Broadly speaking, there are two classes of instruments widely used for operative vaginal birth: forceps or vacuum cups.

Forceps are further classified depending upon the need to rotate the fetal head or not. Rotational forceps are used to rotate the fetal head and to provide axial traction; non-rotational forceps are used when only linear traction is required.

Rotational forceps (e.g. Kielland forceps) are straight in design with no pelvic curve, while non-rotational forceps (e.g. Simpson, Neville-Barnes or Wrigley forceps) have a pelvic curve. Due to the pelvic curve of the forceps aligning to the natural curve of the woman's pelvis, non-rotational forceps cannot be rotated. 'Soft' forceps have been developed with the fetal aspect of the blades padded with pliable polyurethane pads with self-adhesive backing (Hebertson 1985) or a permanent soft rubber coating covering the blades (Roshan 2005).

Vacuum cups are similarly classified depending upon the requirement to rotate the fetal head or not. They are divided into anterior cups (OA cups) where rotation is not required or posterior cups (OP cups) where rotation to the occiput anterior position is needed (Chalmers 1989). They can also be classified by the material from which they are made, including metal, plastic and silicone.

Many factors, both patient- and operator-dependent, affect the choice of instrument used for an assisted vaginal birth. Operator choice is foremost amongst these, and is influenced by the operator's experience and training; the clinical scenario; local practice; geographical location; and occasionally maternal preference. Clinical factors which must be taken into account are the station and position of the presenting part; moulding of the fetal head; comfort, morale and co-operation of the mother. The choice of instrument is sometimes limited by the clinical circumstances. For example, for face presentation and after-coming head of the breech, only forceps can be used (Patel 2004). Conversely a successful vacuum cup delivery depends on the active participation of the woman to push, and her inability to do so may increase the risk of failure (Patel 2004).

The choice of instrument is a difficult one, as all have their advantages and disadvantages. It was demonstrated in the original review in 2010 that forceps were more likely than vacuum cup to achieve a vaginal birth, but this comes with an increased risk of third- or fourth-degree tears (with or without episiotomy), vaginal trauma, greater analgesia requirement and altered continence. Facial injury was more likely with forceps, whilst cephalhematoma was more likely with vacuum cup births (O'Mahony 2010).

The likelihood of forceps achieving vaginal birth may be explained simply by the ability to direct greater force through forceps when compared to vacuum cup before the cup detaches (O'Brien, 2017). However, the higher failure rate of vacuum cups might be explained by a number of factors not applicable to forceps. These factors include suction failure, and concern over the traction force that can be applied versus the risk of cup detachment.

The higher rates of maternal trauma with forceps can be attributed to the blades of the forceps occupying additional space between the fetal head and the birth canal, and thus impinging on maternal soft tissues (Bofill 1996a). Due to the nature of the instrument placement over a smaller surface area of the blades, forceps may have higher rates of fetal scalp and face abrasions and lacerations (Lapeer 2014). This is counterbalanced by increased risks of fetal chignon, subaponeurotic bleeding and cephalhematoma with vacuum cups.

Both classes of instrument success remain dependent on operator skill. Correct technique with any instrument is key to a successful outcome of a vaginal birth, and misuse can lead to increased maternal and fetal morbidity. Suboptimal placement is associated with an increased risk of neonatal trauma, use of sequential instruments and caesarean birth due to failed assisted vaginal birth.

Simulation training has been shown to improve outcomes, with improved forceps placement accuracy and greater force generated during extraction (Bligard 2019). UK training programmes, for example the RCOG Operative Birth Simulation Training (ROBuST) course, have been developed to address this need. Postgraduate deaneries in the United Kingdom require evidence of training, as this forms part of the trainees' core log-book of clinical skills. Thus there is an ongoing need to achieve and maintain competency in assisted vaginal birth.

From a maternal viewpoint instrument selection is critical to achieve a successful assisted vaginal birth. An operative vaginal birth when associated with severe perineal trauma may result in a negative psychological effect. The woman may experience a sense of personal failure, which can delay bonding with her baby and may impact on the entire family dynamic. Conversely, some women may view assisted vaginal birth as preferable to caesarean section. In some low-income settings, caesarean section is considered a failure. An assisted birth may, by avoiding a caesarean section, help maintain the woman's status within her community.

Historically, the obstetric forceps were the primary instrument used, and in many settings this is still the case. More recently there has been an increasing use of vacuum compared to forceps (O'Connell 2000; Patel 2004). With the introduction of newer instruments, research has been undertaken comparing them with forceps to address the question as to which is the superior instrument.

Given the limitations of forceps and vacuum cups, there are continued developments to try and improve the design of the existing devices. Additionally, new innovations are being developed with the hope of producing a device that would have a high success rate, and low morbidity for both mother and baby whilst requiring minimal training and be accessible to those in low-resource settings. One such device which is being evaluated for safety and feasibility is the new BD Odon Device (O'Brien 2019). When this review is next updated, we hope to include comparative data for such devices if randomised controlled trials have been published.

How the intervention might work

Either forceps or vacuum cups can be used to expedite delivery for either maternal or fetal well-being, or both. This Cochrane Review found that both forceps and vacuum deliveries are associated with maternal and neonatal morbidity. Forceps deliveries were more likely to be successful but associated with an increased risk of perineal trauma, pain and facial injury, while vacuum deliveries were associated with a higher risk of cephalhematoma (O'Mahony 2010).

Why it is important to do this review

The original Cochrane Review '*Choice of instruments for assisted vaginal delivery*' was published in 2010. It included 32 studies, of which 24 were published before 2000. Only four included studies compared the then relatively new handheld vacuum to other devices. Our review provides an up-to-date evidence base which is relevant to current modern practice where the handheld vacuum device is in routine use. This will allow the decision of choice of instrument for operative vaginal birth to be based on the most up-to-date evidence.

OBJECTIVES

To evaluate the different instruments in terms of success in achieving a vaginal birth, and the risk of morbidity for mother and baby.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) comparing any two instruments used for operative vaginal birth in women in the second stage of labour were eligible for inclusion. Trials presented as abstracts were eligible if sufficient information was reported to allow eligibility assessment. Cluster-RCTs, quasi-RCTs and trials using a cross-over design were not eligible for inclusion in this review.

Types of participants

Women in the second stage of labour, requiring an operative vaginal birth for any indication (maternal or fetal, or both).

Types of interventions

Any type of operative delivery instrument (including any forceps, any vacuum, specific type of forceps or specific type of vacuum cup) compared to any other type of operative delivery instrument (including any forceps, any vacuum, specific type of forceps or specific type of vacuum cup).

Types of outcome measures

Because of the complexity of the different interventions and the many different ways in which they might affect the mother or baby, the numbers of secondary outcomes are large. The possibility of spurious statistically significant results among secondary outcomes must be kept in mind.

Primary outcomes

Maternal

1. Failed delivery with allocated instrument (delivery with a second instrument or proceeding to caesarean section)
2. Any maternal trauma (perineal trauma, vulval and vaginal trauma)

Neonatal

3. Any neonatal injury (including any of scalp injury, facial injury, intracranial injury, cephalhematoma and fracture)

Secondary outcomes

Maternal

Short-term

4. Third- or fourth-degree perineal tear (with or without episiotomy)
5. Postpartum haemorrhage (≥ 500 mL or as defined by the trial authors)
6. caesarean section
7. Time from randomisation to delivery
8. Episiotomy
9. Episiotomy or perineal tear requiring suturing
10. Pain, as defined by trial authors
11. Analgesia
12. General anaesthesia
13. Maternal satisfaction, as defined by trial authors

Long-term (timeframe as decided by trial authors).

14. Urinary incontinence
15. Flatus incontinence
16. Faecal incontinence
17. Perineal pain
18. Pain during sexual intercourse

Neonatal

19. Low Apgar score at five minutes (< 7 or as defined by trial authors)
20. Low umbilical artery pH (< 7.20 or as defined by trial authors)
21. Scalp injury
22. Facial injury
23. Intracranial injury
24. Cephalhematoma
25. Subaponeurotic haemorrhage
26. Fracture
27. Retinal haemorrhage
28. Jaundice
29. Anaemia
30. Admission to neonatal intensive care unit
31. Neonatal encephalopathy

32. Death or severe morbidity (neonatal encephalopathy, organ failure, in neonatal intensive care unit for at least seven days)
33. Death
34. Death or childhood developmental impairment

Search methods for identification of studies

The following Methods section of this review is based on a standard template used by Cochrane Pregnancy and Childbirth.

Electronic searches

For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (14 May 2021).

The Register is a database containing over 27,000 reports of controlled trials in the field of pregnancy and childbirth. It represents over 30 years of searching. For full current search methods used to populate Pregnancy and Childbirth's Trials Register including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link.

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE (Ovid);
3. weekly searches of Embase (Ovid);
4. monthly searches of CINAHL (EBSCO);
5. handsearches of 30 journals and the proceedings of major conferences;
6. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, we assign each trial report a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and we then add it to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set that has been fully accounted for in the relevant review sections (Included studies; Excluded studies).

We also searched ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned and ongoing trial reports (14 May 2021), using the search methods detailed in Appendix 1.

Searching other resources

We searched the reference lists of retrieved studies.

We did not apply any language or date restrictions.

Data collection and analysis

Selection of studies

Two review authors independently assessed for inclusion all potential studies identified as a result of the search strategy, resolving any disagreements through discussion or, when required, by consulting a third person. We created a study flow diagram to map out the number of records identified, included, and excluded.

Data extraction and management

Three of the review authors designed and piloted a data extraction form. For eligible studies, at least two review authors extracted the data using the agreed form, resolving discrepancies through discussion, and when required through consultation with a third person. We entered data into Review Manager 5 software (RevMan 5) and checked them for accuracy (RevMan 2020). When information about any of the above was unclear, we tried to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed risks of bias for each study, using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved disagreements by discussion or by involving a third assessor.

(1) Random sequence generation (checking for possible selection bias)

For each included study, we describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We rated the method as:

1. low risk of bias (any truly random process, e.g. random-number table; computer random-number generator);
2. high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
3. unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

For each included study we note the method used to conceal allocation to interventions prior to assignment and we assess whether intervention allocation could have been foreseen in advance of or during recruitment, or changed after assignment was described.

We assess the methods as:

1. low risk of bias (e.g. telephone or central randomisation; consecutively-numbered sealed opaque envelopes);
2. high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
3. unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

For each included study we describe the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We rated studies at low risk of bias if they were blinded, or if we judged that the lack of

blinding would be unlikely to affect results. Blinding was assessed separately for different outcomes or classes of outcomes.

We assessed the methods as:

1. low, high or unclear risk of bias for participants;
2. low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

For each included study we describe the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We rated methods used to blind outcomes as:

1. low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

For each included study, and for each outcome or class of outcomes, we describe the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or supplied by the trial authors, we re-included missing data in the analyses that we undertook.

We assessed methods as:

1. low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
2. high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation);
3. unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

1. low risk of bias (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
2. high risk of bias (where not all the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
3. unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We describe for each included study any important concerns we had about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

1. low risk of other bias;
2. high risk of other bias;
3. unclear whether there is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we present results as a summary risk ratio with a 95% confidence interval. As the incidence of 'any maternal trauma' was higher than 90% in the control groups, we have reported these as an OR (odds ratio) and not RR (risk ratio), following feedback from the statistical editor.

Continuous data

For continuous data, we used the mean difference (MD) if outcomes were measured in the same way between trials. We used the standardised mean difference (SMD) to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

There were no cluster-randomised trials included in this systematic review.

Cross-over trials

Cross-over trials were not considered eligible for inclusion in this systematic review.

Studies with multiple treatment groups

Trials with multiple treatment groups were eligible for inclusion. As recommended in section 23.3.4 of the *Cochrane Handbook for Systematic Reviews of Intervention* (Higgins 2021), we planned to combine groups of two or more arms of the study if they needed to be part of the same meta-analysis. Where it was possible to include two of the arms in a separate comparison without incurring a unit-of-analysis error by 'double-counting', we did this. One of the included studies (Dell 1985) had three arms; Mytivac vacuum cup, Silastic vacuum cup and forceps. We included the results in three comparisons. For two of the comparisons, namely any type of forceps versus any vacuum cup and low forceps versus any vacuum cup, we combined the results for the two vacuum cups, and in

the 'any soft vacuum cup versus any soft vacuum cup' group we included the results of the two soft cups in the meta-analysis.

Dealing with missing data

For included studies, we noted levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial is the number randomised minus any participants whose outcomes are known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the Tau^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if I^2 is greater than 30% and either Tau^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If there were 10 or more studies in the meta-analysis, we investigated reporting biases (such as publication bias) using funnel plots. We assessed funnel plot asymmetry visually. If asymmetry was suggested by a visual assessment, we performed exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using the Review Manager 5 software (RevMan 2020). We used a fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect, i.e. where trials were examining the same intervention, and we judged the trials' populations and methods to be sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if we found substantial statistical heterogeneity, we used a random-effects meta-analysis to produce an overall summary if we considered an average treatment effect across trials to be clinically meaningful. We treat the random-effects summary as the average of the range of possible treatment effects and we have discussed the clinical implications of treatment effects differing between trials. Where average treatment effect was not clinically meaningful we did not combine trials.

Where we used random-effects analyses, we present the results as the average treatment effect with 95% confidence intervals, and the estimates of Tau^2 and I^2.

We reported our findings in accordance with the EPOC 2018 guideline.

Subgroup analysis and investigation of heterogeneity

If we identified substantial heterogeneity, we investigated it using subgroup analyses and sensitivity analyses. We considered whether an overall summary was meaningful, and if it was, we used random-effects analysis to produce it.

We had planned to carry out the following subgroup analyses.

1. Epidural analgesia versus no epidural analgesia.
2. Countries with low perinatal mortality rate (less than 20 per 1000) versus high perinatal mortality rate (at least 20 per 1000).
3. Non-rotational delivery versus rotational delivery.

For this update, we were able to carry out subgroup analyses by country perinatal mortality rate (PMR). We used a World Health Organization-produced document (*Neonatal and perinatal mortality: country, regional and global estimates*. World Health Organization; WHO 2006) to confirm the PMR unless more reliable information was available for a country. We performed subgroup analysis for the primary outcomes:

1. Failed delivery with allocated instrument (delivery with a second instrument or proceeding to caesarean section).
2. Any maternal trauma.
3. Any neonatal injury.

We assessed subgroup differences by interaction tests available within RevMan 2020. We report the results of subgroup analyses quoting the Chi^2 statistic and P value, and the interaction test I^2 value.

None of the studies presented data for the above outcomes in accordance with epidural use or rotational or non-rotational deliveries, nor did any of the studies solely include participants from one of these subgroups. All studies for these subgroups therefore formed part of the 'mixed or undefined' subgroups and the meta-analyses were identical to those for the primary outcomes without subgroups, and hence these are not reported separately in the results. For future updates, if possible, we will include both these subgroup analyses.

Sensitivity analysis

We planned to carry out sensitivity analyses to explore the effect of risk of bias assessed by concealment of allocation, high attrition rates, or both, with studies at high or unclear risk of bias for these domains being excluded from the analyses in order to assess whether this makes any difference to the overall result.

Summary of findings and assessment of the certainty of the evidence

We assessed the quality of the evidence using the GRADE approach, as outlined in the GRADE handbook, in order to assess the evidence relating to the following seven outcomes for four of our planned comparisons: any forceps versus any vacuum cup; low forceps versus any vacuum cup; soft cup versus rigid cup; and handheld vacuum versus any vacuum cup.

1. Failed delivery with allocated instrument (delivery with a second instrument or proceeding to caesarean section)
2. Any maternal trauma (perineal trauma, vulval and vaginal trauma)
3. Any neonatal injury (including any of scalp injury, facial injury, intracranial injury, cephalhematoma and fracture)
4. Third- or fourth-degree perineal tear (with or without episiotomy)
5. Postpartum haemorrhage (≥ 500 mls or as defined by the trial authors)

6. Low Apgar score at five minutes (< 7 or as defined by trial authors)
7. Low umbilical artery pH (< 7.20 or as defined by trial authors)

We used the GRADEpro Guideline Development Tool to import data from Review Manager 5, and created summary of findings tables. We produced a summary of the intervention effect and a measure of quality for each of the above outcomes using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from 'high quality' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

We applied the same principles outlined in the GRADE approach to additional outcomes not included in the summary of findings tables where these principles were likely to support interpretation of these additional findings.

RESULTS

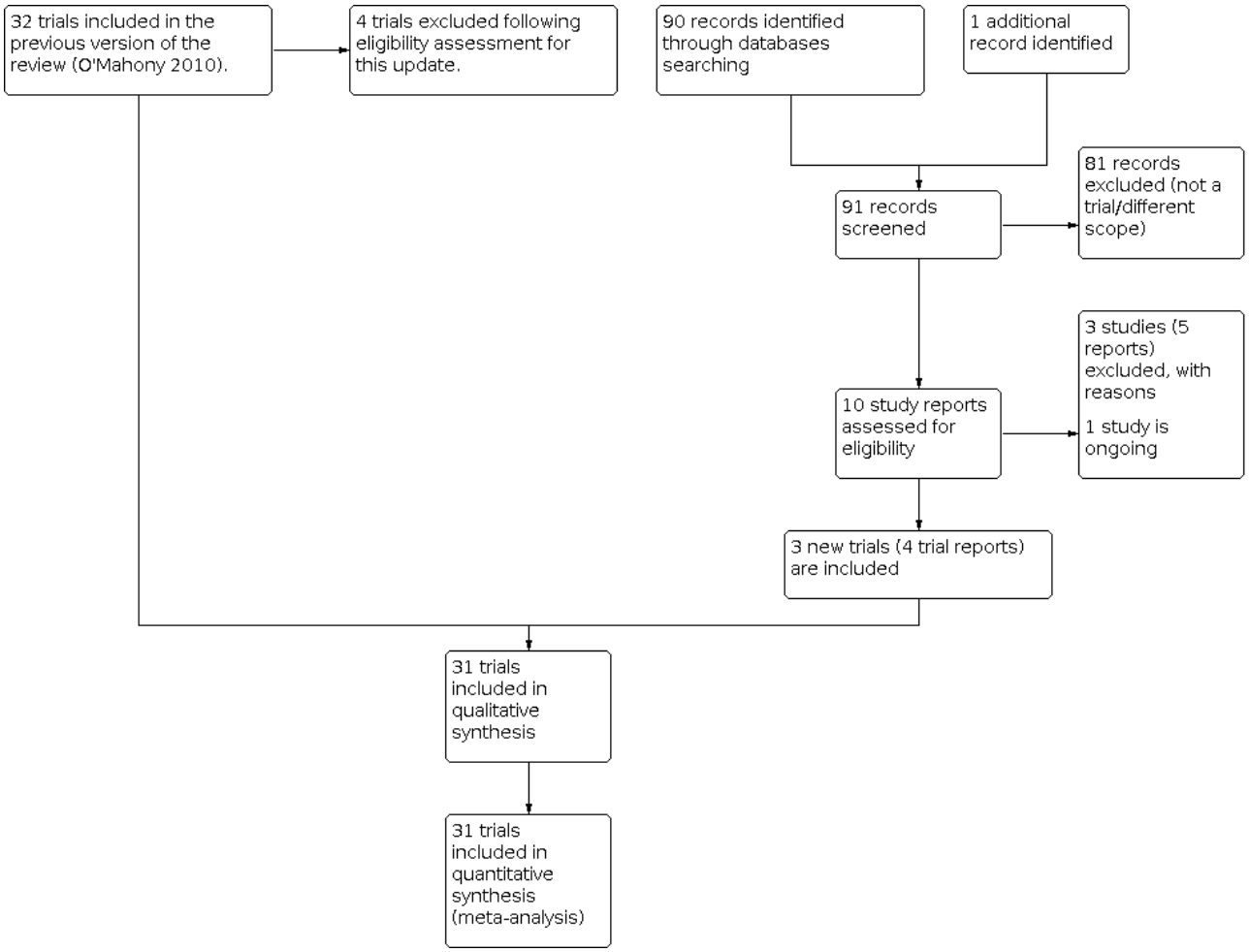
Description of studies

Results of the search

We included 32 studies in the previous version of this review (O'Mahony 2010). A search carried out on 14 May 2021 identified nine study reports to assess in full. In addition, we identified one more study (Suwannachat 2011). We assessed both the previously-included studies and the newly-identified studies against our eligibility criteria to make a decision about inclusion and carried out the complete process of risk of bias assessment and data extraction. We include three new studies (four reports) in this update (Equy 2015; Mola 2010; Shekhar 2013). Four of the studies included in the 2010 update (Loghis 1992; Maleckiene 1996; Mustafa 2002; Lim 1997) and three of the studies (five reports) identified from the new search for this update have been excluded (Mejido 2019; Romero 2021; Suwannachat 2011). See 'Characteristics of excluded studies' table for justifications for the excluded studies. There is one study still in the planning stage (Schvartzman 2012).

See: Figure 1.

Figure 1. Study flow diagram.



Included studies

Methods

All included studies were parallel randomised controlled trials with two study arms, with the exception of Dell 1985, which had three arms. Most of the studies were single-centre, six were multicentre (Cohn 1989; Hebertson 1985; Hofmeyr 1990; Johanson 1989; Johanson 1993;Warwick 1993), whilst the setting for two of the trials was unclear (Kuit 1993; Shekhar 2013).

Participants

All participants were singletons in labour with a cephalic presentation and with a maternal or fetal indication for an instrumental delivery. Most trials included women at or over 36 completed weeks of pregnancy. The gestational cut-off was between 34 and 36 completed weeks in four trials (Bofill 1996a; Johanson 1989; Johanson 1993; Williams 1993). All women included in the trials were in the second stage of labour, but two studies specified that not all included women were fully dilated (Chenoy 1992; Cohn 1989).

Interventions and comparisons

Twelve of the included studies with a total of 3129 participants compared forceps with vacuum cups and were analysed in the 'any forceps versus any vacuum cup' comparison. Two of these studies were stipulated as being low forceps and were also analysed in the 'low forceps versus any vacuum cup' group (Dell 1985; Shekhar 2013). A wide range of instruments were used, often various types within the same comparison. Details of the specific instruments are described in the Characteristics of included studies tables.

Twenty studies compared various vacuum cups. One of these (Dell 1985) was a three-armed study comparing a low-forceps group and two soft-cup groups to each other and was therefore also included in the above-mentioned groups. Nine of these with a total of 1148 participants compared soft vacuum cups to rigid vacuum cups. Four compared handheld vacuum cups to other vacuum cups; of these two had comparator groups of mixed soft and rigid cups (Attilakos 2005; Groom 2006) and two used a comparator group of rigid cups only (Ismail 2008; Mola 2010). The latter two studies were included in the 'any rigid cup' versus 'any rigid cup' comparison along with three additional studies (Carmody 1986; Equy 2015; Thiery 1987). Two studies (Dell 1985; Warwick 1993) with a total of 178 participants compared soft cups to soft cups.

Two studies with a total of 201 participants compared soft forceps to regular forceps (Hebertson 1985; Roshan 2005).

Dates of the study, funding sources and declarations of interest of trial authors

Of the 31 included studies, 10 did not provide details of the dates of the study. Those that provided details spanned over five decades, with the earliest (Lasbrey 1964) beginning in 1961 and the latest (Equy 2015) completing in 2010. Nine studies provided some details about study funding, whilst six provided details about conflicts of interest. Specific details for each of these parameters for each study are specified in the Characteristics of included studies tables.

Excluded studies

Of the previously included thirty-two studies, we excluded four following our eligibility assessment. Mustafa 2002 was excluded because there was insufficient evidence to support it being a randomised controlled trial. Although the terms 'randomly allocated' and 'randomly selected' were used in the publication, it also stated "the choice of method was entirely dependent on the judgment of the consultant". Lim 1997 compares rapid versus step-wise application of a metal cup, and we felt that as this study compares application techniques rather than different instruments, it should in fact be excluded. Furthermore a separate Cochrane Review (Suwannachat 2012) including this and another study has already been carried out which specifically focuses on rapid versus stepwise application of the vacuum cup. Loghis 1992 was excluded because one of the publications compared a metal vacuum cup to a silicone cup, whilst another listed under the same study compared forceps to a silicone cup. Close scrutiny of the two studies showed that characteristics and outcomes of the silicone group in both studies were extremely similar without there being any reference to a planned three-armed study. As this made it difficult to support a reliably randomised study, we decided to exclude this study. Finally, Maleckiene 1996 was excluded due to insufficient detail in the abstract, which was the only publication available for this study. Although abstract-only publications were not in our exclusion criteria, this study was excluded because the data were all presented as percentages only and as only significant outcomes were reported it would therefore not have been possible to analyse any of the data for this study. We decided to exclude these four studies after discussion and agreement among four members of the author team.

We excluded two of the newly-identified studies. Romero 2021 was excluded because it compares different vacuum cup handles rather than vacuum cups themselves. One study (Mejido 2019, 2 reports) had been registered as a clinical trial, but contact with the trialist confirmed that the trial never started.

Risk of bias in included studies

A high proportion of domains assessed during the risk of bias assessment process were assessed as being 'unclear', due to a lack of detailed information about the randomisation and allocation concealment processes and due to insufficient evidence to assess selective outcome reporting. Overall, the risk of bias assessment results were similar for all included studies and we therefore did not carry out a sensitivity analysis excluding studies at high risk of bias. The summary of the risk of bias assessments for each of the included studies can be found in the risk of bias table associated with the Characteristics of included studies tables and Figure 2 and Figure 3.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

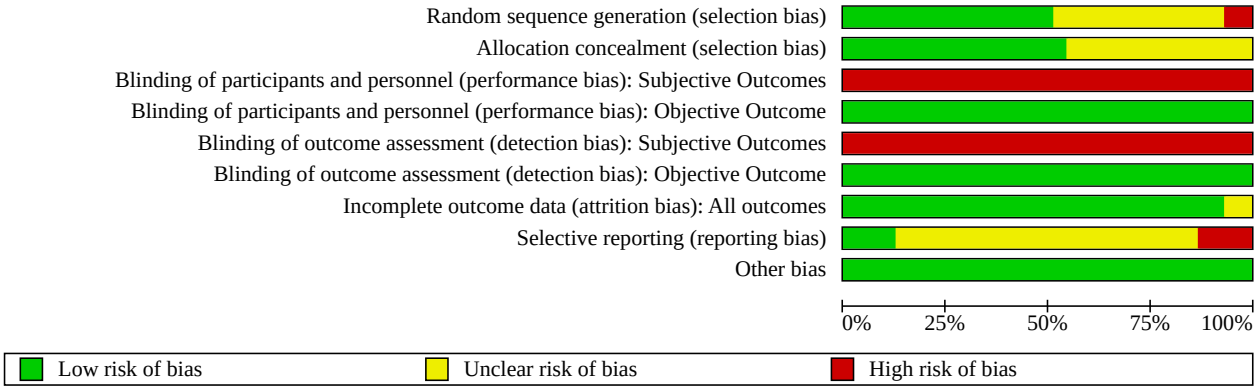


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

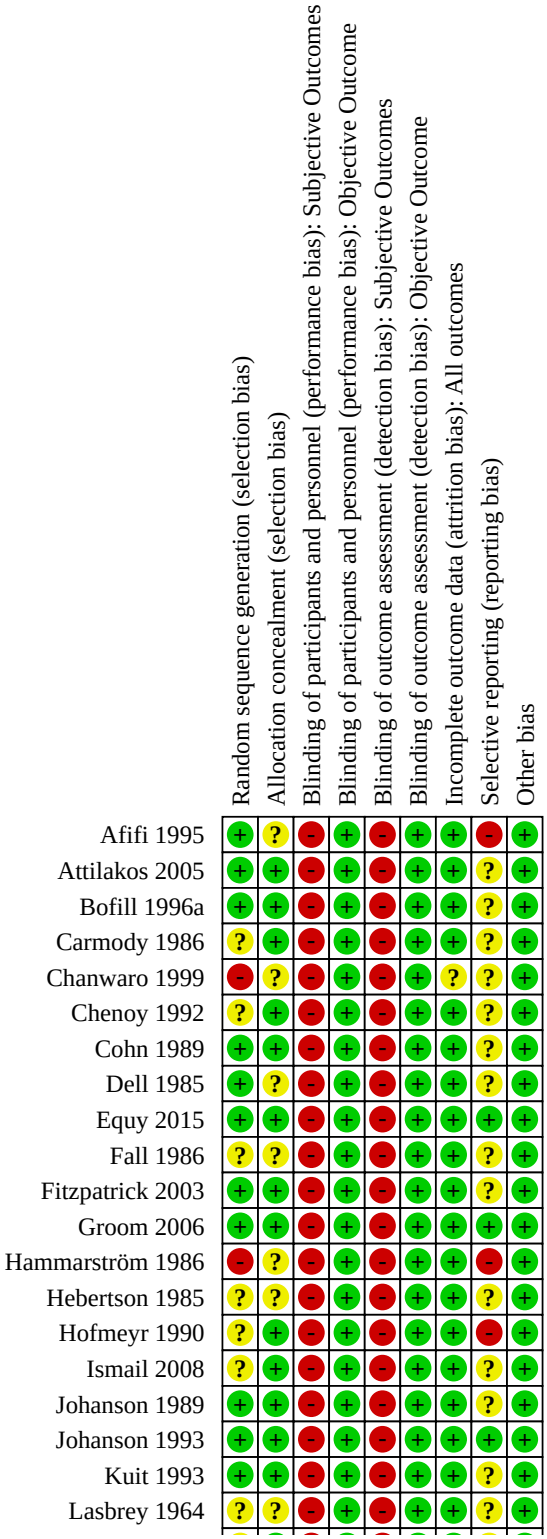
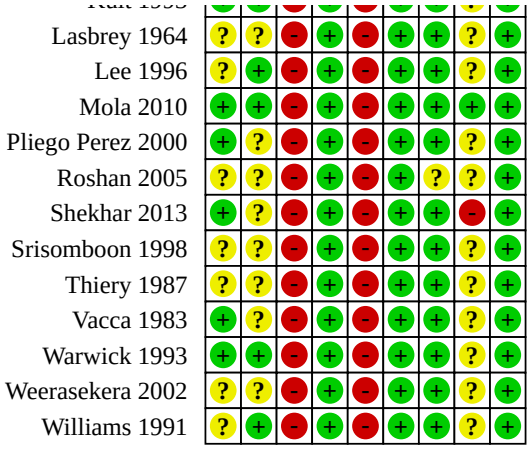


Figure 3. (Continued)



Allocation

Of the 31 included studies, 16 were assessed as low risk for random sequence generation. Centralised electronic randomisation was used by Equy 2015; randomly-generated computer sequence was used by Attilakos 2005; Cohn 1989; Dell 1985; Fitzpatrick 2003; Groom 2006; Mola 2010 and Pliego Perez 2000; serially-numbered envelopes were used in Johanson 1989; Johanson 1993; Shekhar 2013; and Vacca 1983; whilst the final four studies used a random-number table (Afifi 1995; Bofill 1996a; Kuit 1993; Warwick 1993).

Chanwaro 1999 and Hammarström 1986 were assessed as high risk for random sequence generation because they 'used drawing-lots' and randomisation according to date of birth respectively to select the instrument of choice, which are both non-random approaches to allocation.

The remaining 13 studies were assessed as 'uncertain' risk of bias due to insufficient information to allow assessment as either high or low for random-sequence generation.

Allocation concealment was assessed as low risk for 17 studies, as these all used adequate methods such as central allocation or serially-numbered sealed, opaque envelopes. The remaining 14 studies did not provide sufficient information and were assessed as uncertain. Further details are provided in Figure 2, Figure 3 and the Characteristics of included studies.

Blinding

Blinding of participants and personnel would have been challenging for all studies due to their nature. Most immediate maternal and neonatal complications tended to be assessed by those responsible for performing the procedure, potentially opening up their assessment to bias. We therefore divided the outcomes into subjective and objective groups. Risk of both performance and detection bias for subjective outcomes for all the included trials were assessed as high risk, whilst both categories were assessed as low risk for the objective outcomes.

Incomplete outcome data

Twenty-nine studies were assessed as low risk for incomplete outcome data, with most having accounted for most of their participants. Two studies (Chanwaro 1999 and Roshan 2005) were assessed at unclear risk because several of their outcomes were presented as percentages without whole numbers, which made it difficult to evaluate attrition bias.

Selective reporting

Selective reporting bias was assessed as unclear for most of the studies, as protocols were not available for 23 of the 31 included studies.

Four studies were assessed as low risk (Equy 2015; Groom 2006; Johanson 1993; Mola 2010). The study protocol was available for Equy 2015 and all the outcomes stipulated in the protocol were measured and reported in the publication. Mola 2010 stipulated that a protocol was available on request and email correspondence with the author confirmed that there were no deviations between the outcomes stipulated in the protocol and those reported in the study publication. Groom 2006 had clear methods with "predefined outcome measures". Finally, trial registration documentation was available for Johanson 1993, with prespecified outcomes.

We rated the remaining four studies at high risk of selective reporting bias. Afifi 1995 and Hammarström 1986 both reported significant findings in the Results which had not been mentioned in the Methods as part of the outcome measures, Hofmeyr 1990 mentioned a plan to carry out daily neonatal scalp examinations, the results of which were not covered in the full report. Shekhar 2013 presented descriptions of many of their "significant" results without providing supporting numbers.

Other potential sources of bias

All the studies appeared to be free of any additional bias and were all assessed as low risk.

Effects of interventions

See: **Summary of findings 1** Any type of forceps compared to any type of vacuum cup for assisted vaginal delivery; **Summary of findings 2** Low-cavity forceps compared to any vacuum cup for assisted vaginal delivery; **Summary of findings 3** Soft cup compared to rigid cup for assisted vaginal delivery; **Summary of**

findings 4 Handheld vacuum compared to any vacuum cup for assisted vaginal delivery

We included 31 studies (5754 women) in this review, which we analysed in seven of our originally-planned comparisons. We found no studies that compared either mid-cavity forceps to any vacuum delivery or handheld vacuum to forceps. In the previous update for this review (O'Mahony 2010) and again in the plan for this update, subgroup analyses had been planned for epidural use, rotational deliveries and perinatal mortality rate (PMR) by country, but only PMR data were available to be reported separately; we included data for the other two categories in the mixed or undefined groups for the planned subgroup analyses.

As the incidence of 'any maternal trauma' was more than 90% in the control groups, we have reported these as odds ratios (ORs) and not as risk ratios (RRs), as stated in the Methods.

We included 27 of the included studies in single comparisons. Dell 1985, which is a three-armed study, was included in any type of forceps versus any type of vacuum cup, low forceps versus any vacuum, and soft cup versus soft cup. The remaining three studies were included in double comparisons; Shekhar 2013 which has been included in any type of forceps versus any type of vacuum cup and low forceps versus any type of vacuum cup; and Ismail 2008 and Mola 2010, which have both been included in the handheld versus any vacuum and rigid vacuum cup versus rigid vacuum cup groups.

Comparison 1: Any type of forceps versus any type of vacuum cup

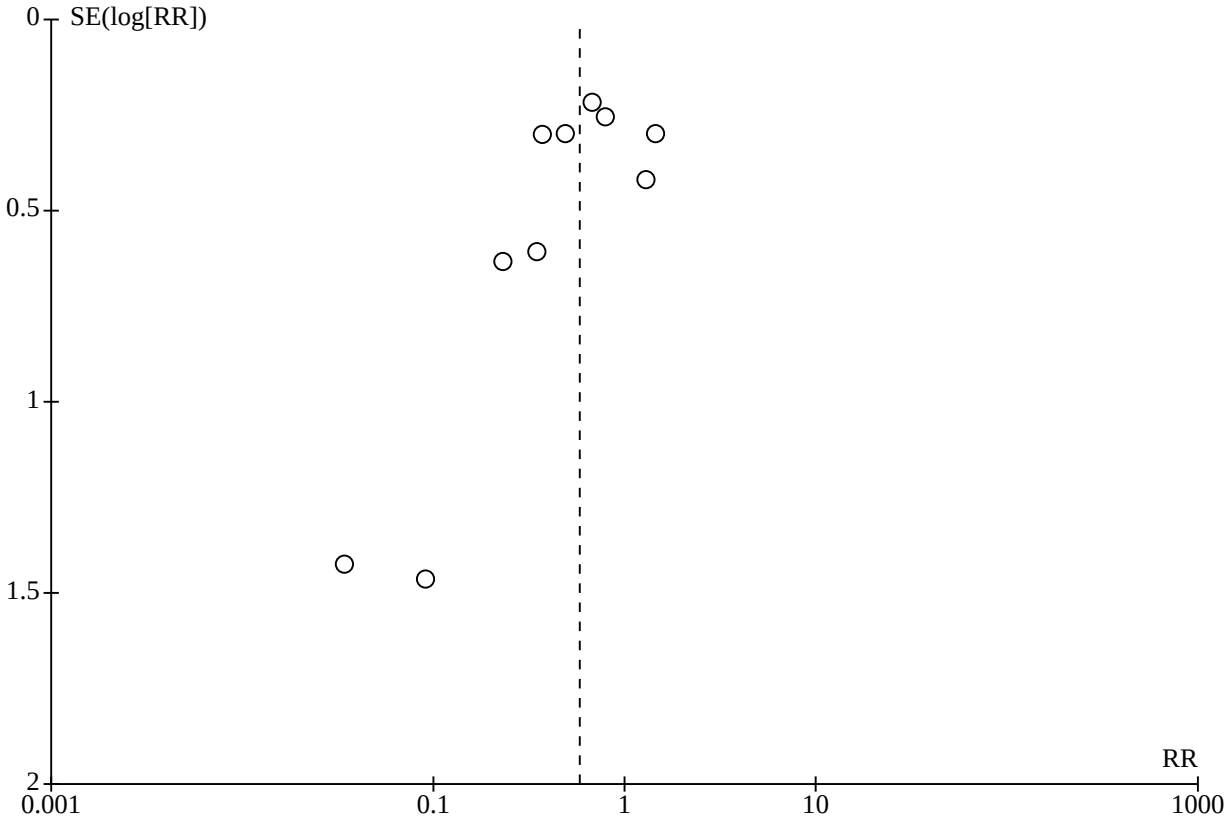
See Summary of findings 1.

Twelve studies (Bofill 1996a; Dell 1985; Fall 1986; Fitzpatrick 2003; Johanson 1989; Johanson 1993; Lasbrey 1964; Pliego Perez 2000; Shekhar 2013; Vacca 1983; Weerasekera 2002; Williams 1991) with a total of 3129 participants compared any type of forceps with any type of vacuum cup. This represents the largest comparison in this review. Bofill 1996a compared the M-cup with forceps. The particular choice of forceps was left to the operator, and types selected included Simpson, Elliot, Laufe divergent, Tucker-McLane, Luikart-Simpson and Kielland. Dell 1985 was a three-armed study comparing the Silastic soft cup and the Mytivac soft cup to the Tucker-McLane forceps. The Silastic and Mytivac arms were used in this comparison against the Tucker-McLane forceps. Johanson 1989 compared the Kobayashi silicone cup ventouse against forceps (Neville Barnes or Kielland). Johanson 1993 compared Ventouse (Silc, Bird anterior or Bird posterior depending on the vacuum extractor policy) with Neville Barnes forceps for OA or Kielland forceps for rotational deliveries. Lasbrey 1964 compared forceps (not specific) with Malmström large or medium vacuum cups. Pliego Perez 2000 compared Simpson's forceps with 65 mm Silc Kobayashi cup. Shekhar 2013 compared a variety of curved forceps and Wrigley's outlet forceps to Bird Modification of Malmström vacuum cups. Vacca 1983 compared anterior and posterior Bird vacuum cups with Haig Ferguson and Kielland forceps. Williams 1991 compared Simpson or Tucker-McLane forceps with CMI Soft Touch Cup, a relatively malleable disposable polyethylene vacuum cup, used with CMI handheld pump. Fall 1986, Fitzpatrick 2003 and Weerasekera 2002 compared vacuum cup to forceps, but did not specify types used.

Primary outcomes

Eleven of the 12 studies (Bofill 1996a; Dell 1985; Fitzpatrick 2003; Johanson 1989; Johanson 1993; Lasbrey 1964; Pliego Perez 2000; Shekhar 2013; Vacca 1983; Weerasekera 2002; Williams 1991) involving 3080 participants presented data for failed delivery with allocated instrument. Forceps may have a lower failure rate than vacuum cup deliveries: risk ratio (RR) 0.58, 95% confidence interval (CI) 0.39 to 0.88; heterogeneity: Tau^2 = 0.24; Chi^2 = 25.48, df = 9 (P = 0.002); I^2 = 65%; 11 studies, 3080 participants; Analysis 1.1, low-certainty evidence. There is statistical heterogeneity in this meta analysis (I^2 > 30% and low P value in the Chi^2 test), so we performed a random-effects analysis. As the meta-analysis involved 11 studies, we generated a funnel plot which is visually asymmetrical, suggestive of publication bias (Figure 4). We conducted subgroup analysis according to country PMR for this outcome (Analysis 1.3) and the results of the subgroup interaction test did not demonstrate a difference between the two subgroups, as P > 0.1 (Chi^2 = 2.09, df = 1 (P = 0.15), I^2 = 52.2%).

Figure 4. Funnel plot of comparison: 1 Any type of forceps versus any type of vacuum cup, outcome: 1.1 Failed delivery with allocated instrument (primary).



Data for 'any maternal trauma' were available in five of the studies (Johanson 1989; Johanson 1993; Shekhar 2013; Vacca 1983; Williams 1991) and it may be slightly more likely in the 'any forceps' group than in the 'any vacuum' group: OR 1.53, 95% CI 0.98 to 2.40; I^2 = 0%; 5 studies, 1356 participants;low-certainty evidence, Analysis 1.5, as the CI is wide and just crosses 1. Subgroup analysis by PMR for this outcome (Analysis 1.7) did not demonstrate a difference in the results for the two subgroups, as P > 0.1 (test for subgroup differences: Chi^2 = 1.13, df = 1 (P = 0.29), I^2 = 11.5%).

There were no suitable data for 'any neonatal injury' in this comparison.

Secondary outcomes included in summary of findings tables

There may be a higher risk of third- or fourth-degree tears with forceps deliveries when compared to vacuum-cup deliveries: RR 1.83, 95% CI 1.32 to 2.55; heterogeneity: Tau^2 = 0.08; Chi^2 = 12.88, df = 8 (P = 0.12); I^2 = 38%; 9 studies, 2493 participants; (Bofill 1996a; Dell 1985; Fitzpatrick 2003; Johanson 1989; Johanson 1993; Lasbrey 1964; Shekhar 2013; Vacca 1983; Williams 1991) Analysis 1.9; low-certainty evidence due to statistical heterogeneity and a wide CI. There is no evidence of a difference in the incidence of postpartum haemorrhage between the two groups: RR 1.71, 95% CI 0.59 to 4.95; heterogeneity: Chi^2 = 0.00, df = 1 (P = 1.00); I^2 = 0%; 2 studies, 523 participants; (Weerasekera 2002; Williams 1991) Analysis 1.10; low-certainty evidence due to wide CI.

There is no evidence of a difference in the incidence of low Apgar at five minutes or low umbilical artery pH between the 'any vacuum cup' and 'any forceps' groups (low Apgar at five minutes: RR 0.83, 95% CI 0.46 to 1.51; 7 studies, 1644 participants; heterogeneity: Chi^2 = 1.02, df = 5 (P = 0.96); I^2 = 0%; (Dell 1985; Fitzpatrick 2003; Johanson 1989; Johanson 1993; Pliego Perez 2000; Vacca 1983; Williams 1991); Analysis 1.11; low-certainty evidence; low umbilical artery pH: RR 1.33, 95% CI 0.91 to 1.93; 2 studies, 789 participants; heterogeneity: Chi^2 = 0.07, df = 1 (P = 0.79); I^2 = 0%; (Johanson 1989; Johanson 1993); Analysis 1.12, low-certainty evidence.

Other short-term maternal outcomes

Caesarean sections may be more likely in the 'any forceps' group than in the 'any vacuum cup' group: RR 1.69, 95% CI 1.00 to 2.87; 7 studies, 2129 participants (Bofill 1996a; Dell 1985; Johanson 1989; Johanson 1993; Shekhar 2013; Vacca 1983 Williams 1991); heterogeneity: Chi^2 = 1.29, df = 4 (P = 0.86); I^2= 0%; Analysis 1.13; low-certainty evidence as CI is wide and reaches 1.

Time from randomisation to delivery in minutes was reported in a single study (Johanson 1989) which showed that there may be little to no difference between the two groups: mean difference (MD) 0.00, 95% CI −2.41 to 2.41; 1 study, 264 participants; heterogeneity: not applicable; Analysis 1.17; low-certainty evidence due to small sample size and wide CI.

Pain at delivery was reported by three studies (Johanson 1989; Johanson 1993; Vacca 1983). For the meta-analysis we pooled the

numbers for "delivery unbearable" (Johanson 1989), "severe pain at delivery" (Johanson 1993) and "extremely painful" (Vacca 1983). There may be no evidence of a difference between the incidence of severe pain between the two groups: RR 1.24, 95% CI 0.77 to 1.99; 3 studies, 542 participants; heterogeneity: $Tau^2 = 0.08$; $Chi^2 = 4.08$, df = 2 (P = 0.13); $I^2 = 51\%$; Analysis 1.15; low-certainty evidence due to statistical heterogeneity and wide CI. This evidence is very uncertain about the effect because the 95% CI is compatible with a wide range of effects that encompass both appreciable benefit and also harm.

The forceps group were less likely to use no analgesia when compared to the vacuum group: RR 0.48, 95% CI 0.34 to 0.66; 5 studies, 1527 participants (Johanson 1989; Johanson 1993; Lasbrey 1964; Shekhar 2013; Vacca 1983); heterogeneity: $Chi^2 = 3.46$, df = 4 (P = 0.48); $I^2 = 0\%$; Analysis 1.32; high-certainty evidence. However, there was little to no difference in epidural use between the two comparisons: RR 1.07, 95% CI 0.96 to 1.19; 6 studies, 2011 participants; (Bofill 1996a; Johanson 1989; Johanson 1993; Shekhar 2013; Vacca 1983; Williams 1991); heterogeneity: $Chi^2 = 4.13$, df = 4 (P = 0.39); $I^2 = 3\%$; Analysis 1.37; high-certainty evidence. There is no evidence of a difference between the use of general anaesthesia between the two groups: RR 2.22, 95% CI 0.57 to 8.62; 4 studies, 1427 participants (Johanson 1989; Johanson 1993; Lasbrey 1964; Vacca 1983); heterogeneity: $Tau^2 = 0.60$; $Chi^2 = 4.36$, df = 3 (P = 0.23); $I^2 = 31\%$; Analysis 1.16; low-certainty evidence due to statistical heterogeneity and wide CI.

Bofill 1996a reported the use of saddle blocks, with no evidence of a difference between the two groups: RR 1.75, 95% CI 0.70 to 4.39; 1 study, 637 participants; heterogeneity: not applicable; Analysis 1.35; low-certainty evidence due very wide CI. Lasbrey 1964 reported the use of inhaled Trichlorethylene with and without local anaesthetic. The study showed that the combination may be more likely to be used for forceps deliveries: RR 18.47, 95% CI 2.52 to 135.56; 1 study, 252 participants; heterogeneity: not applicable; Analysis 1.39, low-certainty evidence due to a very wide CI and small sample size, whilst there may be no difference in the use of inhaled Trichlorethylene alone: RR 1.85, 95% CI 0.34 to 9.90; 1 study, 252 participants; heterogeneity: not applicable; Analysis 1.38; low-certainty evidence due to wide CI and small sample size.

The use of other analgesia modalities including perineal infiltration alone, pudendal blocks alone and the two in combination were reported by studies, but when we conducted meta-analyses we identified very substantial statistical heterogeneity, with I^2 above 70% in each instance, and hence we do not present the pooled results.

Maternal satisfaction was only reported in a single study (Johanson 1993), which reported "disappointed or lack of care". There is no evidence of a difference between the two comparisons: RR 0.90, 95% CI 0.28 to 2.84; 1 study, 185 participants; heterogeneity: not applicable; Analysis 1.14; low-certainty evidence due to small sample size and very wide CI.

Two studies (Bofill 1996a; Fitzpatrick 2003) provided data for episiotomies, but when we conducted a meta-analysis the heterogeneity was very high, with an I^2 of 98% and we therefore do not present pooled results.

None of the studies presented data that were suitable for inclusion under the 'episiotomy or perineal tear requiring suturing' outcome.

Other long-term maternal outcomes

The long-term outcomes reported by Johanson 1993 were measured at five years, while those reported by Fitzpatrick 2003 were measured at three months.

The evidence is very uncertain about long-term incontinence of flatus or urine: flatus incontinence: RR 1.00, 95% CI 0.50 to 2.00; 1 study, 226 participants (Johanson 1993); heterogeneity: not applicable; Analysis 1.19; very low-certainty evidence due to very wide CI and small sample size; urinary incontinence: RR 0.96, 95% CI 0.73 to 1.26; 1 study, 227 participants (Johanson 1993); heterogeneity: not applicable; Analysis 1.18; low-certainty evidence due to wide CI and small sample size. Data were provided for faecal incontinence by two studies but with very substantial heterogeneity of $I^2 = 90\%$, and hence we do not present pooled results.

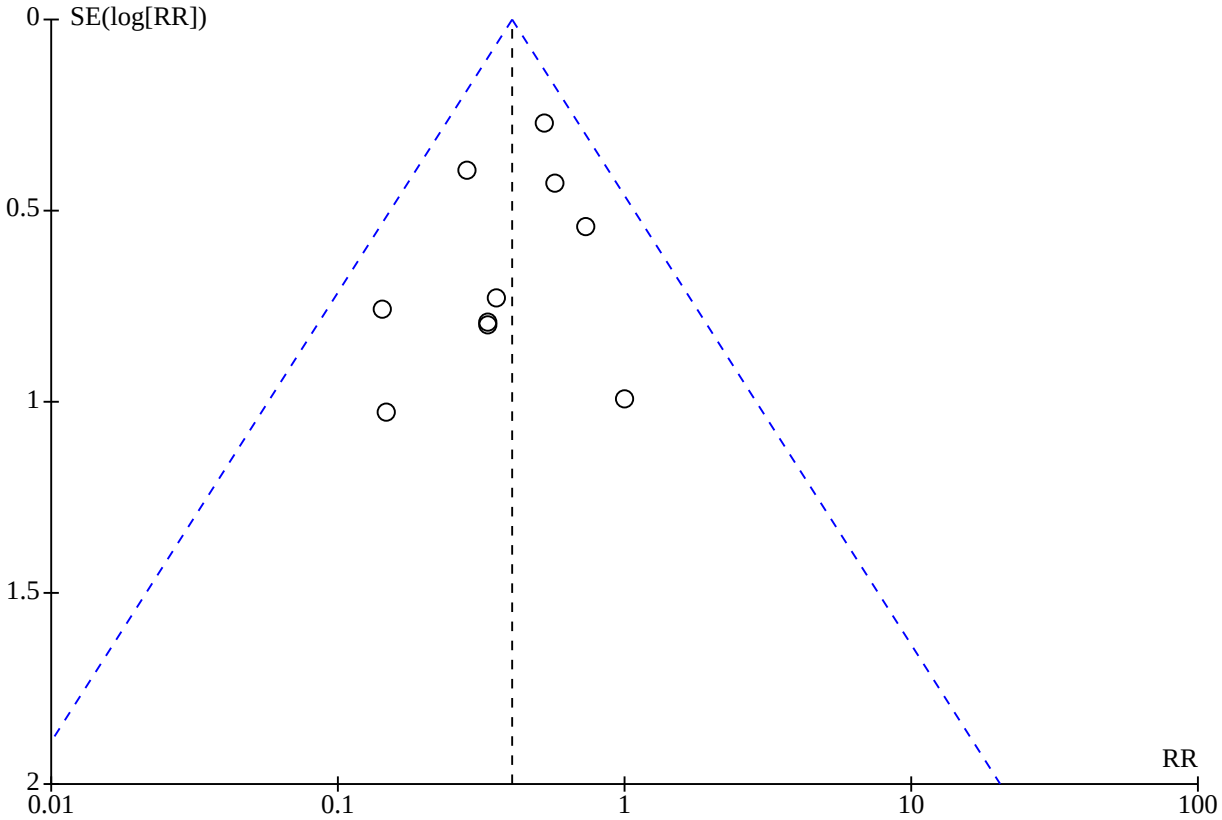
The evidence is very uncertain about the incidence of perineal pain and pain during sexual intercourse between the 'any forceps' and 'any vacuum cup' groups: perineal pain: RR 1.20, 95% CI 0.85 to 1.71; 2 studies, 315 participants (Fitzpatrick 2003; Johanson 1993); heterogeneity: $Chi^2 = 0.00$, df = 1 (P = 0.96); $I^2 = 0\%$; Analysis 1.21, very low-certainty evidence due to small sample size and very wide CI; pain during sexual intercourse: RR 1.37, 95% CI 0.93 to 2.00; 1 study, 185 participants (Johanson 1993); heterogeneity: not applicable; Analysis 1.22; low-certainty evidence due to small sample size and wide CI.

Other neonatal outcomes

There is no evidence of a difference between the two groups in the incidence of scalp, facial and intracranial injury; scalp injury: RR 1.29, 95% CI 0.89 to 1.87; 3 studies, 895 participants; (Bofill 1996a; Dell 1985; Pliego Perez 2000); heterogeneity: $Chi^2 = 0.71$, df = 2 (P = 0.70); $I^2 = 0\%$; Analysis 1.23; low-certainty evidence due to very wide CI; facial injury: RR 7.17, 95% CI 0.92 to 55.71; 1 study, 81 participants; (Williams 1991); heterogeneity: not applicable; Analysis 1.24; low-certainty evidence due to a very wide CI and small sample size; intracranial injury: RR 1.37, 95% CI 0.60 to 3.11; 2 studies, 218 participants (Johanson 1993; Pliego Perez 2000); heterogeneity: $Chi^2 = 0.36$, df = 1 (P = 0.55); $I^2 = 0\%$; Analysis 1.25; low-certainty evidence due to a very wide CI and small sample size.

A cephalhematoma is less likely in the forceps group: RR 0.41, 95% CI 0.30 to 0.56; 10 studies, 2729 participants (Bofill 1996a; Dell 1985; Fall 1986; Johanson 1989; Johanson 1993; Pliego Perez 2000; Shekhar 2013; Vacca 1983; Weerasekera 2002; Williams 1991); heterogeneity: $Chi^2 = 7.43$, df = 9 (P = 0.59); $I^2 = 0\%$; Analysis 1.26; high-certainty evidence. As 10 studies were included in this meta-analysis we generated a funnel plot (Figure 5) which appeared visually symmetrical, so publication bias was undetected.

Figure 5. Funnel plot of comparison: 1 Any type of forceps versus any type of vacuum cup, outcome: 1.33 Cephalhematoma.



Retinal haemorrhages and jaundice are less likely in the forceps group: retinal haemorrhage: RR 0.66, 95% CI 0.46 to 0.94; 5 studies, 386 participants (Fall 1986; Johanson 1989; Johanson 1993; Pliego Perez 2000; Williams 1991); heterogeneity: Chi^2 = 1.31, df = 3 (P = 0.73); I^2 = 0%; Analysis 1.27; high-certainty evidence; jaundice: RR 0.70, 95% CI 0.53 to 0.92; 6 studies, 1600 participants (Bofill 1996a; Johanson 1989; Johanson 1993; Shekhar 2013; Vacca 1983; Williams 1991); heterogeneity: Chi^2 = 3.75, df = 5 (P = 0.59); I^2 = 0%; Analysis 1.28; high-certainty evidence.

There is no evidence of a difference in the rate of admission to neonatal intensive care or neonatal encephalopathy; admission to neonatal intensive care: RR 0.81, 95% CI 0.50 to 1.33; 4 studies, 1140 participants (Fitzpatrick 2003; Johanson 1989; Vacca 1983; Weerasekera 2002); heterogeneity: Chi^2 = 2.09, df = 3 (P = 0.55); I^2 = 0%; Analysis 1.29; moderate-certainty evidence due to wide CI; neonatal encephalopathy: RR 1.75, 95% CI 0.52 to 5.96; 4 studies, 1293 participants (Fitzpatrick 2003; Johanson 1993; Lasbrey 1964; Vacca 1983); heterogeneity: Chi^2 = 2.07, df = 3 (P = 0.56); I^2 = 0%; Analysis 1.30; low-certainty evidence due to very wide CI.

There is no evidence of a difference in neonatal death rate between the two groups: RR 0.82, 95% CI 0.29 to 2.36; 7 studies, 2087 participants (Dell 1985; Johanson 1989; Johanson 1993; Lasbrey 1964; Shekhar 2013; Vacca 1983; Weerasekera 2002); heterogeneity: Chi^2 = 2.06, df = 5 (P = 0.84); I^2 = 0%; Analysis 1.31; low-certainty evidence due to a very wide CI.

It is not possible to determine whether there is a difference in the incidence of subaponeurotic haemorrhage, fracture or anaemia between the two groups, as for each outcome the event only occurred in one case and we therefore decided not to pool these results.

We found no suitable data for the following outcomes.

1. Death or severe morbidity
2. Death or childhood development impairment

Comparison 2: Low-cavity forceps versus any vacuum cup

See Summary of findings 2.

Two small studies (Dell 1985; Shekhar 2013) with a total of 218 participants compared low-cavity forceps with any vacuum cup and were analysed in this group. Dell 1985 was a three-armed study comparing the Silastic soft cup and the Mytivac soft cup to the Tucker-McLane forceps. For this comparison, the Tucker-Mclane forceps were compared against both the Silastic and the Mytivac arms combined. Shekhar 2013 compared a variety of curved forceps and Wrigley's outlet forceps to Bird Modification of Malmström vacuum cups.

Primary outcomes

It is uncertain whether failed delivery with allocated instrument may be more likely in the 'any vacuum cup' group than in the 'low forceps group': RR 0.26, 95% CI 0.09 to 0.76; 2 studies,

218 participants (Dell 1985; Shekhar 2013); heterogeneity: Chi^2 = 0.74, df = 1 (P = 0.39); I^2 = 0%; Analysis 2.1; very low-certainty evidence due to risk of bias assessment, wide CI and small sample size. Dell 1985 was performed in the USA which has a low PMR, whilst Shekhar 2013 was performed in India which has a high PMR and we therefore conducted subgroup analysis. The test for subgroup differences demonstrated no evidence of difference between the two subgroups (Chi^2 = 0.72, df = 1 (P = 0.40), I^2 = 0%).

It is unclear whether there is a difference in the rates of 'any maternal trauma' between the 'any vacuum cup' and 'low forceps groups': OR 7.44, 95% CI 0.37 to 147.92; 1 study, 100 participants (Shekhar 2013); Analysis 2.5; very low-certainty evidence due to the risk of bias assessment, large CI and small sample size. We did not conduct subgroup analysis for 'any maternal trauma' as there was only one study that reported this outcome.

We found no suitable data for 'any neonatal injury'.

Secondary outcomes included in summary of findings tables

It is uncertain if there is a difference between the two groups for rates of third- or fourth-degree tear: RR 1.05, 95% CI 0.55 to 2.00; 2 studies, 218 participants (Dell 1985; Shekhar 2013); heterogeneity: Chi^2 = 1.22, df = 1 (P = 0.27); I^2 = 18%; Analysis 2.9; very low-certainty evidence due to risk of bias assessment, wide CI and small sample size.

Dell 1985 reported no cases of low Apgar score at five minutes in either group, whilst Shekhar 2013 did not report any suitable data for inclusion, so we did not conduct meta-analysis.

We found no suitable data for the following.

1. Postpartum haemorrhage
2. Low umbilical artery pH

Other maternal outcomes

None of the participants in the two included studies underwent a caesarean section, so we did not pool the data.

The use of no analgesia, perineal infiltration alone, perineal infiltration in combination with pudendal block and regional anaesthesia were reported by Shekhar 2013, but no conclusions can be drawn from these data as the evidence is of very low certainty due to a high risk of bias, wide CI and small sample size; no analgesia: RR 0.14, 95% CI 0.01 to 2.70; 1 study, 100 participants; Analysis 2.15; perineal infiltration alone: RR 1.83, 95% CI 1.35 to 2.49; 1 study, 100 participants; Analysis 2.16; perineal infiltration in combination with pudendal block: RR 8.67, 95% CI 2.80 to 26.80; 1 study, 100 participants; Analysis 2.17. Shekhar 2013 reported that no regional anaesthesia was used by any participants in either group, so we did not conduct a meta-analysis.

We found no suitable data for the following maternal outcomes.

1. Time from randomisation to delivery
2. Episiotomy
3. Episiotomy or perineal tear requiring repair
4. Pain
5. General anaesthesia
6. Maternal satisfaction
7. Urinary incontinence
8. Flatus incontinence
9. Faecal incontinence
10. Perineal pain
11. Pain during sexual intercourse

Other neonatal outcomes

There is no evidence of a difference in the rates of scalp injury or neonatal anaemia between the 'low forceps' and 'any vacuum cup' groups; scalp injury: RR 1.17, 95% CI 0.79 to 1.72; 1 study, 118 participants (Dell 1985); heterogeneity: not applicable; Analysis 2.10; low-certainty evidence due to small sample size and wide CI; neonatal anaemia: RR 0.54, 95% CI 0.02 to 12.89; 1 study, 118 participants (Dell 1985); heterogeneity: not applicable; Analysis 2.13; low-certainty evidence due to small sample size and very wide CI.

Cephalhematoma may be less likely in the forceps group; RR 0.22, 95% CI 0.07 to 0.77; 2 studies, 218 participants (Dell 1985; Shekhar 2013); heterogeneity: Chi^2 = 0.42, df = 1 (P = 0.52); I^2 = 0%; Analysis 2.11; low-certainty evidence due to risk of bias assessment and small sample size.

We cannot draw any conclusions about the difference in the incidence of neonatal jaundice and death between the two groups, as the certainty of this evidence is extremely low due to risk of bias assessment, small sample size and wide CI; jaundice: RR 0.60, 95% CI 0.15 to 2.38; 1 study, 100 participants (Shekhar 2013); heterogeneity: not applicable; Analysis 2.12; death: RR 0.33, 95% CI 0.01 to 7.99; 2 studies, 218 participants (Dell 1985; Shekhar 2013); heterogeneity: not applicable; Analysis 2.14.

We found no suitable data for the following secondary outcomes in this comparison.

1. Facial injury
2. Intracranial injury
3. Subaponeurotic haemorrhage
4. Fracture
5. Retinal haemorrhage
6. Admission to neonatal intensive care
7. Neonatal encephalopathy
8. Death of severe morbidity (neonatal encephalopathy, organ failure, in neonatal intensive care for at least seven days)
9. Death or childhood development impairment

Comparison 3: Mid-cavity forceps versus any vacuum cup

We identified no studies relevant to this comparison.

Comparison 4: Soft vacuum cup versus rigid cup

See Summary of findings 3.

Nine studies (Afifi 1995; Chanwaro 1999; Chenoy 1992; Cohn 1989; Hammarström 1986; Hofmeyr 1990; Kuit 1993; Lee 1996; Srisomboon 1998), including a total of 1148 participants, are included in this comparison. Afifi 1995 compared a pliable silicone cup (65 mm Silc cup) with a metal cup (Malmström 50 mm). Chanwaro 1999 compared a Silc cup, size 50 mm, with a Malmström cup, size 50 mm. Chenoy 1992 compared a 6 cm Silc cup (Menox-AB Sweden) attached to a handheld pump

with a 5 cm Malmström metal cup attached to a handheld pump. Cohn 1989 compared a Silc cup with a range of metal cups. 40 to 60 mm Malmström, anterior and posterior Bird, New Gen cup. Hammarström 1986 compared a Silastic cup of Kobayashi with a Malmström diameter 5 cm cup. Hofmeyr 1990 compared a soft cup - Silc or Silastic with a rigid cup - new Bird or O'Neil. Kuit 1993 compared a 55 mm Malmström mushroom-shaped design with tubing attached to the centre of the dome and traction chain passed through the tubing with a Kobayashi Silc cup, with a diameter of 65 mm (Dow Corning Corp., Midland, MI). Lee 1996 compared a 6 cm silicone vacuum cup with a 5 or 6 cm Bird cup. Srisomboon 1998 compared a Silastic silicone rubber cup, 50 mm (Silc cup, Menox AB, Gothenburg, Sweden) with an original 50 mm Malmström mushroom-shaped design with central chain and suction pipe.

Primary outcomes

Failed delivery with allocated instrument may be more likely in the soft vacuum cup group than the rigid vacuum cup group: RR 1.62, 95% CI 1.21 to 2.17; 9 studies, 1148 participants (Afifi 1995; Chanwaro 1999; Chenoy 1992; Cohn 1989; Hammarström 1986; Hofmeyr 1990; Kuit 1993; Lee 1996; Srisomboon 1998); heterogeneity: $Chi^2 = 8.44$, df = 8 (P = 0.39); $I^2 = 5\%$; Analysis 4.1; low-certainty evidence due to high risk of bias and wide CI. Subgroup analysis by country PMR showed similar results in both subgroups and the test for subgroup differences demonstrated no evidence of a difference between them: $Chi^2 = 0.13$, df = 1 (P = 0.71), $I^2 = 0\%$.

There is no evidence of a difference in the rates of 'any maternal trauma' between the soft cup and rigid cup groups: OR 0.63, 95% CI 0.24 to 1.67; 2 studies, 348 participants (Cohn 1989; Srisomboon 1998); heterogeneity: $Chi^2 = 0.50$, df = 1 (P = 0.48); $I^2 = 0\%$; Analysis 4.5; low-certainty evidence due to small sample size and wide CI. There is no evidence of a difference in the incidence of 'any maternal trauma' regardless of country PMR (Analysis 4.7). Test for subgroup differences showed no difference between the two subgroups ($Chi^2 = 0.50$, df = 1 (P = 0.48), $I^2 = 0\%$).

There were no data for 'any neonatal injury'.

Secondary outcomes included in summary of findings tables

There is no evidence of a difference in the rates of third- or fourth-degree tears or postpartum haemorrhage between the soft-cup and rigid-cup groups: third- or fourth-degree tears: RR 0.93, 95% CI 0.35 to 2.44; 4 studies, 619 participants (Chenoy 1992; Cohn 1989; Lee 1996; Srisomboon 1998); heterogeneity: $Chi^2 = 1.84$, df = 3 (P = 0.61); $I^2 = 0\%$; Analysis 4.9; low-certainty evidence due to very wide CI; postpartum haemorrhage: RR 0.89, 95% CI 0.49 to 1.61; 5 studies, 737 participants (Afifi 1995; Chenoy 1992; Cohn 1989; Lee 1996; Srisomboon 1998); heterogeneity: $Chi^2 = 3.73$, df = 4 (P = 0.44); $I^2 = 0\%$; Test for overall effect: Z = 0.39 (P = 0.70); Analysis 4.10; moderate-certainty evidence due to wide CI.

There is no evidence of a difference in the incidence of low Apgar score at five minutes or low umbilical artery pH between the soft-cup and rigid-cup groups: low Apgar score at five minutes: RR 0.82, 95% CI 0.49 to 1.37; 9 studies, 1148 participants (Afifi 1995; Chanwaro 1999; Chenoy 1992; Cohn 1989; Hammarström 1986; Hofmeyr 1990; Kuit 1993; Lee 1996; Srisomboon 1998); heterogeneity: $Chi^2 = 4.59$, df = 7 (P = 0.71); $I^2 = 0\%$; Analysis 4.11; low-certainty evidence due to high risk of bias and wide CI; low umbilical artery pH: RR 0.80, 95% CI 0.47 to 1.36; 1 study, 100 participants (Kuit 1993); heterogeneity: not applicable; Analysis 4.12; low-certainty evidence due to small sample size and wide CI.

Other short-term maternal outcomes

There is no evidence of a difference in the incidence of caesarean sections between the two groups in the comparison: RR 1.40, 95% CI 0.70 to 2.83; 6 studies, 837 participants (Afifi 1995; Chenoy 1992; Cohn 1989; Kuit 1993; Lee 1996; Srisomboon 1998); heterogeneity: $Chi^2 = 1.10$, df = 5 (P = 0.95); $I^2 = 0\%$; Analysis 4.13; low-certainty evidence due to a very wide CI.

There is probably little to no difference in the rates of episiotomy between the two groups: RR 0.98, 95% CI 0.88 to 1.10; 2 studies, 330 participants (Cohn 1989; Lee 1996); heterogeneity: $Chi^2 = 0.83$, df = 1 (P = 0.36); $I^2 = 0\%$; Test for overall effect: Z = 0.33 (P = 0.74); Analysis 4.14; moderate-certainty evidence due to small sample size.

For analgesia there is probably little to no difference in the use of local infiltration between the soft-cup and rigid-cup groups: RR 1.05, 95% CI 0.97 to 1.13; 2 studies, 271 participants (Chenoy 1992; Lee 1996); heterogeneity: $Chi^2 = 0.00$, df = 1 (P = 0.98); $I^2 = 0\%$; Analysis 4.21; moderate-certainty evidence due to small sample size. It is uncertain whether there is a difference in the use of pudendal blocks, paracervical blocks and epidurals, as these data are of very low certainty due to very serious risk of bias, wide CIs and small sample size in the single study (Hammarström 1986) that reported these outcomes; pudendal blocks: RR 2.29, 95% CI 1.03 to 5.07; 1 study, 100 participants; heterogeneity: not applicable; Analysis 4.23; paracervical block: RR 0.33, 95% CI 0.01 to 7.99; 1 study, 100 participants (Hammarström 1986); heterogeneity: not applicable; Analysis 4.24; epidural: RR 0.81, 95% CI 0.65 to 1.01; 1 study, 100 participants (Hammarström 1986); heterogeneity: not applicable; Analysis 4.22.

No appropriate data were available for any of the following short-term maternal outcomes.

1. Time from randomisation to delivery
2. Episiotomy or perineal tear requiring suturing
3. Pain as defined by trial authors
4. General anaesthesia
5. Maternal satisfaction as defined by trial authors

Other long-term maternal outcomes

No appropriate data were available for any of the following long-term maternal outcomes.

1. Urinary incontinence
2. Flatus incontinence
3. Faecal incontinence
4. Perineal pain
5. Pain during sexual intercourse

Other neonatal outcomes

Scalp injury and cephalhematoma rates are probably lower in the soft-cup group; scalp injury: RR 0.63, 95% CI 0.50 to 0.80; 5 studies, 791 participants (Afifi 1995; Chanwaro 1999; Chenoy 1992; Cohn 1989; Lee 1996); heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 5.79$, df = 4 (P =

0.22); I^2 = 31%; Analysis 4.15; moderate-certainty evidence due to statistical heterogeneity; cephalhematoma: RR 0.51, 95% CI 0.28 to 0.95; 5 studies, 710 participants (Afifi 1995; Chanwaro 1999; Cohn 1989; Kuit 1993; Srisomboon 1998); heterogeneity: Chi^2 = 4.01, df = 4 (P = 0.40); I^2 = 0%; Analysis 4.16; moderate-certainty evidence due to wide CI.

Subaponeurotic haemorrhage was reported as having no cases in either group in one study (Kuit 1993) and we therefore did not perform the analysis.

There is no evidence of a difference in the rates of retinal haemorrhage or admission to neonatal unit between the soft-cup and rigid-cup groups, but the evidence is of moderate certainty due to small sample sizes; retinal haemorrhage: RR 0.86, 95% CI 0.60 to 1.24; 1 study, 100 participants (Kuit 1993); heterogeneity: not applicable; Analysis 4.17; admission to neonatal intensive care unit: RR 0.53, 95% CI 0.16 to 1.76; 2 studies, 330 participants (Cohn 1989; Lee 1996); heterogeneity: Chi^2 = 0.41, df = 1 (P = 0.52); I^2 = 0%; Analysis 4.19.

There is probably little to no difference in the rates of jaundice in the two groups: RR 0.98, 95% CI 0.65 to 1.48; 6 studies, 782 participants (Afifi 1995; Chanwaro 1999; Cohn 1989; Kuit 1993; Lee 1996; Srisomboon 1998); heterogeneity: Chi^2 = 4.95, df = 5 (P = 0.42); I^2 = 0%; Analysis 4.18; moderate-certainty evidence due to a wide CI.

Neonatal encephalopathy rates were measured in two studies (Chenoy 1992; Srisomboon 1998) but there were no cases, so we did not conduct a meta-analysis.

It is not possible to make a judgement on the differences in death rates between the groups, as the evidence is of very low certainty due to the very small number of events and a CI which crosses the line of no effect; RR 1.85, 95% CI 0.24 to 14.22; 4 studies, 619 participants (Chenoy 1992; Cohn 1989; Lee 1996; Srisomboon 1998); heterogeneity: Chi^2 = 0.16, df = 1 (P = 0.69); I^2 = 0%; Analysis 4.20.

No appropriate data were available for the following neonatal outcomes.

1. Facial injury
2. Intracranial injury
3. Fracture
4. Anaemia
5. Death or severe morbidity
6. Death or childhood development impairment

Comparison 5: Handheld vacuum versus any vacuum cup

See Summary of findings 4.

Four studies with a total of 962 participants (Attilakos 2005; Groom 2006; Ismail 2008; Mola 2010) were included in this comparison. The Kiwi Omnicup was compared with a mixed group of standard soft and metal cups in Attilakos 2005 and Groom 2006, and to the Malmström metal cup only in Ismail 2008. Mola 2010 compared the Vacca re-usable Omnicup with the Bird vacuum cup and was conducted at Port Moresby General national referral and teaching Hospital (PMGH), Papua New Guinea. It reported a much lower background failure rate for vacuum-cup deliveries of 2% to 3% compared to the background rate of 20% in other settings, which may explain the differences in the results for this study.

Primary outcomes

There may be no evidence of a difference in the rates of failures between the handheld vacuum versus the 'any vacuum cup' group; RR 1.35, 95% CI 0.81 to 2.25; 4 studies, 962 participants (Attilakos 2005; Groom 2006; Ismail 2008; Mola 2010); heterogeneity: Tau^2 = 0.11; Chi^2 = 4.62, df = 2 (P = 0.10); I^2 = 57%; Analysis 5.1; low-certainty evidence due to statistical heterogeneity and wide CI. Subgroup analyses (Analysis 5.3) by country PMR revealed that failure is probably more common in the handheld vacuum-cup group in low PMR countries: RR 1.58, 95% CI 1.19 to 2.10; 3 studies, 762 participants (Attilakos 2005; Groom 2006; Ismail 2008); moderate-certainty evidence due to a wide CI; and evidence is uncertain for the study conducted in a high PMR country; RR 0.29, 95% CI 0.06 to 1.34; 1 study, 200 participants (Mola 2010); very low-certainty evidence due to small sample size and a wide CI which just crosses the no-effect line; test for subgroup differences showed a substantial difference between the subgroups as P < 0.1 (Chi^2 = 4.55, df = 1 (P = 0.03), I^2 = 78.0%.

There may be no evidence of a difference in the rate of 'any maternal trauma' between the two groups: OR 1.16, 95% CI 0.71 to 1.88; I^2 = 0%; 2 studies, 394 participants (Attilakos 2005; Mola 2010); Analysis 5.5; low-certainty evidence due to small sample size and wide CI. Subgroup analysis by country PMR shows similar results for both subgroups (Analysis 5.7) as confirmed by the test for subgroup differences (Chi^2 = 0.20, df = 1 (P = 0.65), I^2 = 0%).

No appropriate data were available for 'any neonatal injury'.

Secondary outcomes included in summary of findings tables

There may be no evidence of a difference in the rates of third- or fourth-degree tears between the handheld vacuum and 'any vacuum cup' group: RR 1.15, 95% CI 0.62 to 2.12; 4 studies, 962 participants (Attilakos 2005; Groom 2006; Ismail 2008; Mola 2010); heterogeneity: Chi^2 = 1.65%; df = 3 (P = 0.65); I^2 = 0%; Analysis 5.9; low-certainty evidence due to very wide CI.

There may be no evidence of a difference in the rates of postpartum haemorrhage between the two groups: RR 0.31, 95% CI 0.03 to 2.92; 1 study, 164 participants (Ismail 2008); heterogeneity: not applicable; Analysis 5.10; low-certainty evidence due to small sample size and wide CI.

There may be no evidence of a difference in the number of neonates born with low Apgar scores or with low umbilical artery pH between the two groups: low Apgar: RR 1.25, 95% CI 0.34 to 4.61; 3 studies, 784 participants (Attilakos 2005; Groom 2006; Mola 2010); heterogeneity: Chi^2 = 0.09, df = 2 (P = 0.96); I^2 = 0%; Analysis 5.11; low-certainty evidence due to very wide CI; low umbilical artery pH: RR 1.06, 95% CI 0.71 to 1.59; 1 study, 164 participants (Ismail 2008); heterogeneity: not applicable; Analysis 5.12; low-certainty evidence due to a small sample size and wide CI.

Other maternal outcome

There is no evidence of a difference in the rates of caesarean sections between the handheld vacuum cup and 'any vacuum cup' groups: RR 1.42, 95% CI 0.61 to 3.30; 4 studies, 962 participants (Attilakos 2005; Groom 2006; Ismail 2008; Mola 2010);

heterogeneity: Chi^2 = 3.06, df = 2 (P = 0.22); I^2 = 35%; Analysis 5.13 low-certainty evidence due to heterogeneity and very wide CI.

There is little to no difference in the episiotomy rate between the two groups: RR 1.00, 95% CI 0.89 to 1.13; 3 studies, 798 participants (Attilakos 2005; Groom 2006; Mola 2010); heterogeneity: Chi^2 = 0.76, df = 2 (P = 0.69); I^2 = 0%; Analysis 5.14 high-certainty evidence.6

Two studies provided some data that could be included in meta-analyses related to analgesia use. According to data from a single study (Groom 2006) with a total of 404 participants, there may be no evidence of a difference in the use of 'no analgesia' or Entonox between the two groups; no analgesia: RR 0.38, 95% CI 0.08 to 1.96; Analysis 5.21; low-certainty evidence due to a very wide CI; entonox: RR 1.10, 95% CI 0.41 to 2.97; Analysis 5.22; low-certainty evidence due to a very wide confidence interval. According to a small study (Ismail 2008) with 164 participants there is no evidence of a difference in the use of local anaesthesia between the two groups: RR 1.26, 95% CI 0.94 to 1.69; Analysis 5.23; low-certainty evidence due to small sample size and wide CI. Data pertaining to regional anaesthesia were provided by both the studies, but the heterogeneity was high with I^2 = 77%, so we decided not to pool these results.

Perineal pain was reported by one study (Attilakos 2005), and showed no evidence of a difference: RR 0.79, 95% CI 0.50 to 1.26; 145 participants; Analysis 5.15; low-certainty evidence due to a small sample group and a wide CI.

We found no appropriate data for the following maternal outcomes.

1. Time from randomisation to delivery
2. Episiotomy or perineal tear requiring suturing
3. Pain as defined by trial authors
4. General anaesthesia
5. Maternal satisfaction as defined by trial authors
6. Urinary incontinence
7. Flatus incontinence
8. Faecal incontinence
9. Pain during sexual intercourse

Other neonatal outcomes

There may be no evidence of a difference in the rates of scalp injury and probably no difference in the rates of cephalhematomas between the two groups; scalp injury: RR 4.00, 95% CI 0.46 to 35.16; 1 study, 200 participants (Mola 2010); Analysis 5.16; low-certainty evidence due to small sample size and wide CI; cephalhematomas: RR 0.42, 95% CI 0.11 to 1.59; 2 studies, 604 participants (Groom 2006; Mola 2010); heterogeneity: Chi^2 = 0.49, df = 1 (P = 0.48); I^2 = 0%; Analysis 5.17; moderate-certainty evidence due to wide CI. Subaponeurotic haemorrhages may be less likely in the 'handeld vacuum' group: RR 0.12, 95% CI 0.01 to 0.91; 1 study, 164 participants (Ismail 2008); Analysis 5.18; low-certainty evidence due to small sample size and wide CI. Data for jaundice were provided by two studies (Attilakos 2005; Mola 2010) but we did not pool them due to substantial heterogeneity (Chi^2 = 6.13, df = 1 (P = 0.01); I^2 = 84%), with each study demonstrating an effect in opposite directions.

It is not possible to ascertain whether or not there is a difference in the rates of admission to neonatal intensive care and neonatal death between the two groups, as the evidence is of very low certainty; admission to neonatal unit: RR 0.79, 95% CI 0.33 to 1.91; 3 studies, 558 participants (Attilakos 2005; Ismail 2008; Mola 2010); heterogeneity: Tau^2 = 0.42; Chi^2 = 6.51, df = 2 (P = 0.04); I^2 = 69%; Test for overall effect: Z = 0.05 (P = 0.96); Analysis 5.19; very low-certainty evidence due to substantial heterogeneity and wide CI; death: RR 1.50, 95% CI 0.26 to 8.79; 2 studies, 364 participants (Ismail 2008; Mola 2010); heterogeneity: not applicable; Analysis 5.20; very low-certainty evidence due to small sample size and wide CI.

We found no appropriate data for the following maternal outcomes.

1. Facial injury
2. Intracranial injury
3. Fracture
4. Retinal haemorrhage
5. Anaemia
6. Neonatal encephalopathy
7. Death or severe morbidity
8. Death or childhood developmental impairment

Comparison 6: Regular forceps versus soft forceps

Two of the included studies (Hebertson 1985; Roshan 2005) with a total of 201 participants were included in this comparison. Hebertson 1985 compared standard forceps with a pliable polyurethane pad with self-adherent backing with standard forceps, whilst Roshan 2005 compared Simpson's forceps coated in soft rubber with uncoated Simpson's forceps. Hebertson 1985 randomised its participants into four groups; one group with two padded forceps, one group with a pad on the right blade only, one group with a pad on the left blade only and finally a group with both blades unpadded (see Characteristics of included studies table). The data for facial injury were presented in relation to each forceps blade rather than each baby, so were included as such in the analysis.

We did not produce a summary of findings table for this comparison, as no appropriate data were reported.

Primary outcomes

There were no data provided in either study for the primary outcomes of this review.

Secondary outcomes

Facial injuries were the only outcome that could be included for both the studies. Hebertson 1985 graded facial injuries from one to five, with one being no markings and five being severe. Roshan 2005 reported severe facial markings (requiring repair, suturing or adhesive strips) and 'any other markings'. We created two meta-analyses: one for 'severe facial markings' (Hebertson 1985: grade 5 and Roshan 2005: severe facial markings) and the second for 'other markings' (Hebertson 1985: grades 2 - 4 and Roshan 2005: any other markings).

There is no evidence of a difference in the rates of severe facial injury between the regular and soft forceps groups: RR 3.81, 95% CI 0.65 to 22.19; 2 studies, 306 participants; heterogeneity: Chi^2 = 0.65, df = 1 (P = 0.42); I^2 = 0%; Analysis 6.1; low-certainty evidence due

to small sample size and a very wide CI. Other facial injuries may be more likely in the regular forceps group: RR 1.46, 95% CI 1.16 to 1.84; 2 studies, 306 participants; heterogeneity: $Chi^2 = 1.27$, df = 1 (P = 0.26); $I^2 = 22\%$; Analysis 6.2; low-certainty evidence due to small sample size and wide CI.

There were no data that we could include for the other planned secondary outcomes for either study.

Comparison 7: Any soft vacuum cup versus any soft vacuum cup

Two small studies (Dell 1985; Warwick 1993) with a total of 178 participants compared two soft vacuum cups with each other and were included in this comparison. Dell 1985 was a three-armed study comparing the Silastic soft cup and the Mytivac soft cup to the Tucker-McLane forceps. We used the Silastic and Mytivac arms in this comparison. Warwick 1993 compared Silc cup to Santropene cup. We combined the data for the Silastic and Silc cup for the first arm and the data for the Mytivac and Santropene cups for the second arm of our meta-analysis.

We did not produce a summary of findings table for this comparison, due to the sparse data and accompanying heterogeneity.

Primary outcomes

Failed delivery with allocated instrument was reported in both studies (Dell 1985; Warwick 1993), but there was substantial heterogeneity ($Tau^2 = 1.17$; $Chi^2 = 6.08$, df = 1 (P = 0.01); $I^2 = 84\%$) between the two studies, with the total effects being on opposites sides of the line of no effect. We therefore decided not to pool the results.

We found no data for 'any maternal injury' or 'any neonatal injury'.

Maternal secondary outcomes

Both studies reported third- or fourth-degree tears but there were no events in Warwick 1993. There may be no evidence of a difference in the incidence between the Silastic group and the Mityvac group: RR 2.06, 95% CI 0.86 to 4.89; 2 studies, 178 participants (Dell 1985; Warwick 1993); heterogeneity: not applicable; Analysis 7.1; low-certainty evidence due to small sample size and a very wide CI.

Although both studies reported the rate of caesarean sections there was only one performed across the two included studies and we therefore decided not to pool the results.

Neonatal secondary outcomes

It is unclear whether scalp injury and cephalhematoma may be slightly more likely in the Mytivac group or whether the rate of admission to the neonatal unit may be slightly more likely in the Santropene group, as the evidence is of very low certainty due to an extremely small sample size and wide CI: scalp injury: RR 0.91, 95% CI 0.54 to 1.53; 1 study, 73 participants; (Dell 1985); heterogeneity: not applicable; Analysis 7.2; cephalhematoma: RR 0.86, 95% CI 0.29 to 2.56; 1 study, 73 participants (Dell 1985); heterogeneity: not applicable; Analysis 7.3; admission to neonatal intensive care: RR 0.37, 95% CI 0.04 to 3.41; 1 study, 105 participants (Warwick 1993); heterogeneity: not applicable; Analysis 7.5.

It is unclear whether anaemia may be slightly more likely in the Silastic group, as the evidence is of very low certainty due to an extremely small sample size and a very wide CI: RR 3.08, 95% CI 0.13 to 73.24; 1 study, 73 participants (Dell 1985); heterogeneity: not applicable; Analysis 7.4.

There were no incidences of neonatal death or low Apgar in either study, so we did not conduct meta-analyses for them.

We found no data for the following secondary outcomes.

1. Postpartum haemorrhage
2. Low umbilical artery pH
3. Time from randomisation to delivery
4. Episiotomy
5. Episiotomy or perineal tear requiring suturing
6. Pain as defined by trial author
7. Analgesia
8. General anaesthesia
9. Maternal satisfaction as defines by trial authors
10. Urinary incontinence
11. Flatus incontinence
12. Faecal incontinence
13. Perineal pain
14. Pain during sexual intercourse
15. Facial injury
16. Intracranial injury
17. Subaponeurotic haemorrhage
18. Fracture
19. Retinal haemorrhage
20. Jaundice
21. Neonatal encephalopathy
22. Death or severe morbidity
23. Death or childhood developmental impairment

Comparison 8: Any rigid vacuum cup versus any rigid vacuum cup

Five studies (Carmody 1986; Equy 2015; Ismail 2008; Mola 2010; Thiery 1987) with 1565 participants were included in this comparison. We were careful to place similar cups in the same arm of the meta-analysis to try to minimise heterogeneity. Group 1 is represented by the left-hand column of the data tables and is favoured by the left-hand side of the meta-analyses; it included the 'new generation metal cup' (Carmody 1986), the OA or OP O'Neil cup (Thiery 1987), the iCup, the Kiwi Omnicup and the Vacca re-useable Omni-cup (Equy 2015, Ismail 2008 and Mola 2010 respectively). Group 2 is represented by the right-hand column and is favoured by the right-hand side of the meta-analyses; it includes the Bird cup (Carmody 1986; Mola 2010), Drapier-Faure metal cup (Equy 2015), and Malmström cup (Thiery 1987; Ismail 2008). The results of this comparison need to be interpreted with caution, due to the presence of clinical heterogeneity in the interventions being studied in the different trials. For this reason we did not include a summary of findings table for this comparison.

Primary outcomes

An attempt at pooling data for failed delivery revealed extreme statistical heterogeneity, with an I^2 = 82%, so we decided not to pool these data.

There may be no evidence of a difference in the rates of 'any maternal trauma' between the two rigid-cup groups in the one study (Mola 2010) that reported on this outcome; OR 1.24, 95% CI 0.70 to 2.22; 200 participants; Analysis 8.1; low-certainty evidence due to small sample size and wide CI.

No appropriate data were provided for 'any neonatal injury'.

Secondary maternal outcomes

It is uncertain if there is any difference in the rates of third- or fourth-degree tears or postpartum haemorrhage between the two groups, as the evidence is of very low certainty due to clinical and statistical heterogeneity and a wide CI; third- or fourth-degree tear: RR 0.60, 95% CI 0.17 to 2.05; 3 studies, 942 participants (Equy 2015; Ismail 2008; Mola 2010); heterogeneity: Tau^2 = 0.44; Chi^2 = 3.00, df = 2 (P = 0.22); I^2 = 33%; Analysis 8.5; postpartum haemorrhage: RR 0.96, 95% CI 0.37 to 2.52; 2 studies, 742 participants (Equy 2015; Ismail 2008); heterogeneity: Tau^2 = 0.22; Chi^2 = 1.32, df = 1 (P = 0.25); I^2 = 24%; Analysis 8.6.

Caesarean section rates may be higher in group 1 than group 2; RR 2.49, CI 1.01 to 6.16; 5 studies, 1475 participants (Carmody 1986; Equy 2015; Ismail 2008; Mola 2010; Thiery 1987); heterogeneity: Chi^2 = 3.36, df = 3 (P = 0.34); I^2 = 11%; Analysis 8.9; low-certainty evidence due to clinical heterogeneity and wide CI.

There may be little to no evidence of a difference in the rates of episiotomy between the two groups: RR 1.00, 95% CI 0.95 to 1.06; 2 studies, 610 participants (Mola 2010; Thiery 1987); heterogeneity: Chi^2 = 1.62, df = 1 (P = 0.20); I^2 = 38%; Analysis 8.10 low-certainty evidence due to clinical and statistical heterogeneity.

There may be no evidence of a difference in the use of local anaesthesia and paracervical blocks between the two groups; local anaesthesia: RR 1.26, 95% CI 0.94 to 1.69; 1 study, 164 participants (Ismail 2008); Analysis 8.16; low-certainty evidence due to small sample size and wide CI; paracervical block: RR 0.35, 95% CI 0.04 to 3.34; 1 study, 410 participants (Thiery 1987); Analysis 8.17; low-certainty evidence due to small sample size and a very wide CI.

There is probably little to no difference in epidural use between the two groups: RR 0.89, 95% CI 0.75 to 1.06; 2 studies, 574 participants (Ismail 2008; Thiery 1987); heterogeneity: Chi^2 = 1.02, df = 1 (P = 0.31); I^2 = 2%; Analysis 8.18; moderate-certainty evidence due to clinical heterogeneity.

Secondary neonatal outcomes

There may be no evidence of a difference in the incidence of low Apgar between the groups: RR 1.15, 95% CI 0.56 to 2.37; 4 studies, 1310 participants (Carmody 1986; Equy 2015; Mola 2010; Thiery 1987); heterogeneity: Chi^2 = 1.75, df = 3 (P = 0.63); I^2 = 0%; Analysis 8.7; low-certainty evidence due to a very wide CI and clinical heterogeneity. There is probably little to no difference in the rate of low umbilical artery pH between the two groups: pH: RR 1.07, 95% CI 0.87 to 1.31; 2 studies, 742 participants (Equy 2015; Ismail 2008); heterogeneity: Chi^2 = 0.00, df = 1 (P = 0.98); I^2 = 0%; Analysis 8.8; moderate-certainty evidence due to clinical heterogeneity.

There may be no evidence of a difference in the rates of scalp injury or cephalhematoma between the two groups, but the evidence is of low certainty due to clinical heterogeneity and a wide CI; scalp injury: RR 0.85, 95% CI 0.47 to 1.56; 3 studies, 1188 participants (Equy 2015; Mola 2010; Thiery 1987); heterogeneity: Chi^2 = 2.36, df = 2 (P = 0.31); I^2 = 15%; Analysis 8.11); cephalhematoma: RR 1.29, 95% CI 0.59 to 2.81; 4 studies, 1311 participants (Carmody 1986; Equy 2015; Mola 2010; Thiery 1987); heterogeneity: Chi^2 = 0.19, df = 3 (P = 0.98); I^2 = 0%; Analysis 8.12.

Subaponeurotic haemorrhage may be less likely in group 1, but these data were only presented by one small study: RR 0.12, 95% CI 0.01 to 0.91; 1 study, 164 participants (Ismail 2008); Analysis 8.13; low-certainty evidence due to small sample size and wide CI.

There may be little to difference in the rates of jaundice between the two groups: RR 1.02, 95% CI 0.81 to 1.28; 4 studies, 1311 participants (Carmody 1986; Equy 2015; Mola 2010; Thiery 1987); heterogeneity: Chi^2 = 5.09, df = 3 (P = 0.16); I^2 = 41%; Analysis 8.14; low-certainty evidence due to clinical and statistical heterogeneity.

There may be no evidence of a difference in the incidence of anaemia between the two groups; RR 1.92, 95% CI 0.35 to 10.39; 1 study, 578 participants (Equy 2015); Analysis 8.15; low-certainty evidence due to a very wide CI.

We did not pool data for admission to neonatal intensive care which were reported by Carmody 1986; Equy 2015; Ismail 2008; Mola 2010, nor for death, which was reported by Carmody 1986; Ismail 2008; Mola 2010 and Thiery 1987, due to the afore-mentioned clinical heterogeneity, together with the studies reporting outcomes favouring opposite groups.

We found no appropriate data for the following secondary outcomes.

1. Time from randomisation to delivery
2. Episiotomy or perineal tear requiring suturing
3. Pain as defined by trial authors
4. General anaesthesia
5. Maternal satisfaction
6. Urinary incontinence
7. Flatus incontinence
8. Faecal incontinence
9. Perineal pain
10. Pain during sexual intercourse
11. Facial injury
12. Intracranial injury
13. Fracture
14. Retinal haemorrhage
15. Neonatal encephalopathy
16. Death or severe morbidity
17. Death or childhood developmental impairment

Comparison 9: Handheld vacuum cup versus any forceps

We identified no studies relevant to this comparison.

Subgroup analysis

We conducted subgroup analysis by country PMR where primary outcomes within a comparison were reported by countries with a low and high PMR. These results are presented above in the relevant sections. Data were not available to allow placement of studies in the 'epidural' or 'no epidural' subgroups or in the 'rotational' or 'non-rotational' delivery groups, so for both these subgroups all studies were placed in the mixed or undefined groups.

DISCUSSION

Summary of main results

The main thrust of this review consists of two stages of comparisons. Firstly, whether forceps or vacuum cup is the better instrument and secondly which type of vacuum cup or forceps is preferable.

For this update we were able to carry out subgroup analyses for some of the primary outcomes by the perinatal mortality rate (PMR) of the country in which the trial was performed. The original intention of the authors was to also carry out subgroup analyses by epidural use and rotational or non-rotational deliveries, but there were insufficient data to allow these analyses.

We found no studies for Comparison 3: Mid-cavity forceps versus any vacuum cup, or for Comparison 9: Handheld vacuum cup versus any forceps.

When considering results the following should be noted.

1. Not all comparisons included data on all outcomes. We compiled a comprehensive list of potential outcomes in order not to miss any important events. Very few trials considered more than a few outcomes for either mother or baby. Of the primary outcomes, failed delivery and maternal trauma were the most frequently reported. Of the secondary outcomes, the most reported were the short-term outcomes.
2. Conclusions were largely based on the summary of findings tables and other results thought to be of moderate to high certainty.

Comparison 1: Any forceps versus any vacuum cup

Twelve studies involving 3129 participants were included in this comparison.

See Summary of findings 1.

Forceps may be more likely to achieve 'vaginal birth with the allocated instrument', but failure is more likely to result in a caesarean section. This apparent disparity can be explained, as unsuccessful vacuum-cup deliveries are more likely to be followed by an attempt at forceps delivery. Usually only after failure of this forceps delivery would a caesarean section be contemplated. Conversely, a failed forceps delivery would naturally lead straight on to delivery by caesarean section, without an attempt at vacuum-cup delivery.

'Any maternal trauma' may be slightly more likely in the 'any forceps' group than in the 'any vacuum' group, and higher pain relief requirements are more likely with 'any forceps'. Subgroup analysis showed no measurable differences between low or high PMR countries for either outcome.

Third- or fourth-degree tears may be more likely in the forceps group, whilst there is probably no evidence of a difference in the rates of postpartum haemorrhage, low Apgar at five minutes, or low umbilical artery pH between the two groups. Cephalhematoma, retinal haemorrhage and jaundice are less likely with forceps.

Comparison 2: Low-cavity forceps versus any vacuum cup

Two studies with a total of 218 participants were included in this comparison.

See Summary of findings 2.

The evidence included in this comparison is of very low certainty, due to small sample size and a high risk of bias, and should therefore be interpreted with caution.

Comparison 4: Soft cup versus rigid cup

Nine studies including 1148 participants were included in this comparison.

See Summary of findings 3.

Overall there was a high risk of bias in the studies that reported 'failed delivery with allocated instrument' for this comparison. The pooled data demonstrated that failed delivery may be more likely in the soft vacuum-cup group when compared to the rigid vacuum-cup group. This is not unexpected, as measured traction forces achieved with the metal cup are considerably higher than with the soft cup (Hofmeyr 1990). There may be no evidence of a difference in the incidence of 'any maternal trauma'. Subgroup analyses for both these primary outcomes revealed no measurable difference between the low and high PMR countries.

There is probably no evidence of a difference in the rates of third- or fourth-degree tears or postpartum haemorrhage between the two groups.

There may be no evidence of a difference in the rates of low Apgar score at five minutes or low umbilical artery pH between the soft-cup and rigid-cup groups.

Comparison 5: Handheld vacuum versus any vacuum cup

Four studies with a total of 962 participants were included in this comparison.

See Summary of findings 4.

When all studies in the group are assessed together, there may be no evidence of a difference in the rates of failures between the handheld vacuum versus the 'any vacuum cup' group. However, when assessed as subgroups, failure is probably more common in the handheld vacuum cup group in the subgroup with the low PMR countries, whilst the one study that was conducted in a country with a high PMR (Mola 2010) found that failed delivery may be slightly less likely in the handheld group. Test for subgroup differences showed a substantial difference between the two subgroups.

There may be no evidence of a difference in the rate of 'any maternal trauma' and postpartum haemorrhage, third- or fourth-degree tears, low Apgar score and low umbilical artery pH between the handheld cup and the 'any vacuum cup' groups. The evidence

for all of these outcomes was of low certainty, as illustrated in Summary of findings 4.

Comparison 6: Regular forceps versus soft forceps

Two studies with a total of 201 participants were included in this comparison. We did not produce a summary of findings table, as no appropriate outcomes for inclusion were reported. There may be no evidence of a difference in the rates of severe facial injury, whilst other facial injuries may be more likely in the regular-forceps group. The evidence needs to be interpreted with caution, due to the small sample size.

Comparison 7: Any soft cup versus any soft cup

Two studies with a total of 178 participants were included in this comparison.

We did not produce a summary of findings table due to the presence of substantial heterogeneity and small sample size. We did not pool data for 'failed delivery with allocated instruments', due to the two studies demonstrating effects in opposite directions.

Comparison 8: Any rigid cup versus any rigid cup

Five studies with a total of 1565 participants were included in this comparison. As described above, we took care to pool data for similar interventions together. Despite this, caution is advised in interpreting these results, due to clinical heterogeneity between the studies both in terms of interventions and comparisons. We did not pool data for failed delivery due to extreme statistical heterogeneity. There is probably no evidence of a difference in the rates of 'any maternal trauma' or epidural use.

We rated the evidence for all other reported outcomes as of low or very low certainty.

Overall completeness and applicability of evidence

This review of randomised controlled trials on operative vaginal birth evaluating the different forceps and vacuum cups looked specifically for success in achieving a vaginal birth and the risk of morbidity for mother and baby. The main comparisons are between forceps or vacuum cup. There are also comparisons between different types of vacuum cup. The outcomes which are analysed are the success of the particular instrument in achieving the delivery and the rate of complications for both mother and baby. Not all studies considered all outcomes, and there were differences in the types of complications encountered by mothers and babies.

Although there were 5754 women and their babies in the 31 included trials, some comparisons had larger sample sizes than others. There were no trials which included participants for the comparison of mid-cavity forceps versus any vacuum cup, or handheld vacuum versus any forceps. The largest comparison was for any type of forceps versus any type of vacuum cup, totaling 12 trials and 3129 participants ranging from 36 to 637 participants per trial.

Some of the comparisons did not address all of our primary outcomes and even fewer addressed all of our secondary outcomes. For example, none of the comparisons identified suitable data for 'any neonatal injury'. We found that the definition of a neonatal injury is not standard globally, and on this basis we could not make comparisons between trials.

Just under two-thirds of trials recruited women from the USA and Europe (19 trials) compared to other countries (12 trials). This correlated with low PMR countries (WHO 2006) (20 trials) and high PMR countries (WHO 2006) (11 trials), with the exceptions of Malaysia with a low PMR rate outside of Europe and USA and Russia with a high PMR rate (WHO 2006). Two-thirds were published before the year 2000 (21 trials). Results may not be applicable to all settings or countries worldwide, nor to current clinical practice.

Most studies excluded fetal distress from their randomised controlled trials and therefore decisions as to which instrument is best will depend upon individual situations where the urgency with which the baby needs to be delivered will be balanced against potential risks to the mother and baby.

In general these results show trade-offs between the different instruments, with both advantages and disadvantages in most comparisons. The result is that there can be no simplistic conclusion that one instrument is superior to another. What is important is to be aware of the specific advantages and disadvantages of each instrument, so that the optimal choice can be made for each clinical situation.

It is thus important for clinicians to be trained in the use of a range of instruments, so that appropriate choices can be made.

The trials studied did not directly investigate the benefits of policies involving sequential use of more than one instrument. There is indirect evidence that sequential use of the vacuum cup followed if necessary by forceps may reduce overall failure (the need for caesarean section).

The balance of judgement lies between expediting and achieving a vaginal birth, with the minimum of trauma to both mother and baby. Overall forceps appear to be most effective at achieving vaginal birth, but with the risk of significant maternal trauma. The rigid vacuum cup reduces maternal trauma, but increases the risk of cephalhematoma. The soft vacuum cup reduces the risk of trauma to the baby, but has a higher likelihood of failure.

This discussion cannot be concluded without also taking into account the significant maternal risks of second-stage caesarean sections.

Quality of the evidence

A high proportion of criteria assessed during the risk of bias assessment process were rated as being 'unclear' due to a lack of detailed information about the randomisation and allocation concealment processes and due to insufficient evidence to assess selective outcome reporting. Blinding of participants and personnel and blinding of outcome would have been challenging for all trials due to their inability to conceal the type of instrument used for operative vaginal birth from either the woman or the operator, and therefore the risk of bias was deemed equivocal for all studies. Most immediate maternal and neonatal complications tended to be assessed by those responsible for performing the procedure. Selective reporting bias was assessed as unclear for most studies, as protocols were not available for 22 of the 31 included studies. Overall, the risk of bias assessment results

were similar for all included studies and we therefore did not carry out a sensitivity analysis excluding studies at high risk of bias.

We assessed the certainty of the evidence using the GRADE approach, as outlined in the GRADE handbook, for prespecified outcomes analysed in the main comparisons. Our GRADE assessments of the certainty of the evidence ranged from very low to moderate for our seven primary outcomes, with most of our outcomes rated as low or moderate certainty. Our judgements for downgrading decisions were based on imprecision of the studies, inconsistency, publication bias and limitations in study design such as selective outcome reporting.

Potential biases in the review process

The Information Specialist of Cochrane Pregnancy and Childbirth conducted a detailed, systematic search process, and we also searched both ClinicalTrials.gov and WHO International Clinical Trials Registry Platform for unpublished, planned and ongoing trial reports. Trial registration was available only for Mejido 2019 and Mejido 2019. We found no published results for these studies and there was no response to our attempt to contact the authors. Should such studies be published and subsequent studies identified, we will include them in future updates of this review. The strength of this review update is that we included only randomised controlled trials. To minimise the introduction of bias during the review process, at least two review authors independently assessed both the original trials included in the review and the new potential trials for inclusion. Furthermore, data extraction, assessment of risk of bias and GRADE were done independently by at least two review authors for each of the included trials. One of our author team members (JH) is the author of one the included trials (Hofmeyr 1990). In order to minimise the introduction of bias, he was not involved in the assessment for inclusion, risk of bias, data extraction or interpretation of results relating to this study.

Agreements and disagreements with other studies or reviews

Within the Cochrane Library database, the subtopic of operative vaginal birth consists of five separate reviews. We deemed it important to compare our updated findings to these for consistency of evidence used in clinical practice. The previous review on this topic (O'Mahony 2010) demonstrated similar findings to this review. There were an additional three studies included, (Equy 2015; Mola 2010; Shekhar 2013) in our updated review which had similar findings, as outlined in our Results section.

A review by Suwannachat 2012 compared rapid versus stepwise negative pressure application for vacuum extraction for assisted vaginal birth. They looked at two randomised controlled trials, Lim 1997 and Suwannachat 2011, that compared conventional stepwise method consisting of incremental increases to obtain a final negative pressure versus the rapid method where the negative pressure was applied in a single step. For both randomised controlled trials the instrument used was a Malmström metal cup. Lim 1997 was included in the previous version of our review (O'Mahony 2010), but this time we decided to exclude it as it does not compare different instruments. Suwannachat 2012 concludes that there are no significant differences in maternal and neonatal outcomes between rapid and stepwise negative pressure application.

Majoko 2012 addressed a trial of instrumental delivery in theatre versus immediate caesarean section for anticipated difficult assisted births. Unfortunately the trials included in this review do not stipulate whether the assisted delivery was conducted in the room or in theatre and no comment was made about whether a difficult delivery was anticipated. The review concluded that there is no current evidence from randomised trials to guide practice and states that there is a wide variation in rates of failed trial of instrumental delivery (Majoko 2012). We agree that further research into whether a caesarean section for failure to progress in the second stage has similar maternal and neonatal outcomes to caesarean section after a failed trial of instrumental delivery is required, as some of the serious morbidity associated with caesarean section comes at a subsequent pregnancy and birth (Wood 2017), and some of the morbidity associated with instrumental vaginal birth is long-term.

Our review demonstrates that a vacuum-cup delivery is more likely to be conducted without analgesia compared with a forceps delivery. We were not able to comment on the most appropriate analgesia for assisted vaginal deliveries. This is in keeping with the Nikpoor 2013 review, "analgesia for forceps delivery", which concluded that there was insufficient evidence to make conclusive suggestions on the management of women undergoing a forceps delivery for the most effective and safe analgesic agent/method to use.

It is important to state that the new Liabsuetrakul 2020 review suggests that prophylactic antibiotics have an important effect on reduction of superficial and deep perineal wound infection or serious infectious complications in women undergoing operative vaginal deliveries. This high level of evidence from the Anode 2019 randomised controlled trial goes on to state that prophylactic antibiotics slightly improve perineal pain and health consequences of perineal pain, probably reducing cost. They may also slightly reduce maternal hospital re-admission and improve health-related quality of life. Although our review did not look at antibiotic use for assisted vaginal deliveries, their implication for clinical practice will likely become evident in any future update of this review, reducing the longer-term maternal complications following assisted vaginal deliveries.

AUTHORS' CONCLUSIONS

Implications for practice

Choice of instrument for assisted vaginal birth remains a controversial topic. The variables which have to be considered are: operator skill; choice of instruments available; and clinical setting. These in themselves are dependent on the working environment and access to emergency caesarean section. There is no guaranteed safe instrument for both mother and baby.

This review provides low-certainty evidence that forceps may be more likely to achieve vaginal birth and had lower rates of fetal trauma, but at a greater risk of perineal trauma and higher pain relief requirements compared with vacuum cups. There was low-certainty evidence that rigid vacuum cups may be more likely to achieve a vaginal birth than soft cups but with more fetal trauma, whilst handheld vacuum cups had similar success rates compared to other cups. There was no evidence of a difference in the rates of third- or fourth-degree tears or postpartum haemorrhages between

types of cups, but wide confidence intervals around the estimates indicate further research is needed in this area.

Changing patterns of obstetric care, in particular availability and acceptability of caesarean section and the evidence emerging about maternal morbidity associated with second-stage caesarean sections and the increasing caesarean section rate globally need to be considered in clinical practice. Wood 2017 concluded that caesarean delivery in the second stage of labour was associated with a two-fold increase in the risk of spontaneous preterm birth at less than 32 weeks of gestation in a subsequent birth.

A recently-published BJOG review (Bailey 2017) states that assisted vaginal birth is currently underused precisely in countries where pregnant women continue to face hardships accessing emergency obstetric care and where caesarean delivery can be relatively unsafe. Due to this research, more work within low-cost settings is being conducted to evaluate devices that are more accessible in such environments when other equipment is not as readily available, such as vacuum cup pumps. An example is the ODON device.

Implications for research

Future research on type of instrument for operative vaginal birth is needed to clarify whether particular instruments are better suited to low- or high-resource settings, and the implications these have on reducing maternal and neonatal morbidity. Furthermore, the training of operators and their skills are crucial to the success of an assisted vaginal birth, and further work would be valuable in this area to reduce the prevalence of second-stage caesarean sections and the maternal sequelae.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Afifi 1995

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	118 participants included in the study Inclusion criteria: singleton pregnancy at ≥ 36 weeks' gestation at full dilatation with vertex at mid or low station Exclusion criteria: none defined
Interventions	Intervention: pliable silicone cup (65 mm Silc-cup) = 61 participants Comparison: metal cup (Malmström 50 mm) = 57 participants
Outcomes	Mode of delivery Maternal morbidity: perineal, vaginal or cervical lacerations requiring repair, bladder catheterisation and postpartum fall in haemoglobin Neonatal outcome: cord gases, Apgar score, cutaneous and haemorrhage lesions; neonatal jaundice (max bilirubin level of 12 mg/dl or more and whether phototherapy was required). Cranial USS was done for every newborn within 36 hours of delivery to identify any intracranial lesions
Notes	Setting: single centre Country: Saudi Arabia Hospitals: Northern Area Armed Forces Hospital Dates of study: Jan 1994 - Nov 1994 Study duration: 11 months Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: soft vacuum cup versus any rigid vacuum cup

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Quote - "...done by means of table of random numbers and balanced in groups of six." pg 202
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel, so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias)	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment, so low risk of bias

Afifi 1995 *(Continued)*

Objective Outcome		
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study, those assessing subjective outcomes not blinded to instrument used, so high risk of bias
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes, so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All cases accounted for
Selective reporting (reporting bias)	High risk	No protocol available and inconsistencies noted in outcomes defined in Methods and those reported in the Results sections
Other bias	Low risk	The study appears to be free of other sources of bias

Attilakos 2005

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	200 participants included in the study Inclusion criteria: singleton cephalic > 37 weeks' gestation Exclusion criteria: none defined
Interventions	Intervention: Kiwi Omnicup (handheld) = 100 randomised. 96 analysed, as in 4 cases the envelopes were opened before decision for vacuum cup delivery was made Comparison: conventional vacuum cup - either silastic or metal cup as per operator choice = 100. 98 analysed as in 2 cases the envelopes were opened before the decision for vacuum cup delivery was made
Outcomes	Primary outcome: successful completion of delivery with allocated instrument Secondary outcomes: substantial fetal scalp trauma, defined as the presence of 1 of either cephalhematoma, bruising > 5 cm or laceration, and substantial maternal trauma, defined as third- or fourth-degree tears or extended perineal tears that needed repair in theatre Data were also collected on ease of cup application on a scale of 1 to 10 and perineal pain/discomfort at 24 - 48 hours on a predefined 4-point scale
Notes	Setting: single centre Country: UK Hospitals: Southmead Hospital, Bristol, UK Dates of study: 18th Feb 2002 - 31st Oct 2002 Study duration:8.5 months Funding sources: not reported by trial authors

Attilakos 2005 *(Continued)*

Declaration of interest: 'Conflict of interest - none'.

Comparison: handheld vacuum versus any vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote - "…randomly generated computer sequence 1:1 ratio….the computer sequence was prepared prior to the commencement of the trial and was not known to the researchers." pg 1511
Allocation concealment (selection bias)	Low risk	Quote - "consecutively numbered sealed opaque envelopes" pg 1511.
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel, so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment, so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Quote - "neither the neonatal nor the obstetric senior house officer were blinded to the kind of cup used". The SHO assessed outcomes 24 - 48 hours post-delivery. Pg 1152
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes, so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	No attrition for primary outcomes. 5/96 cases missing from Omnicup and 4/98 from standard cup for assessment of perineal pain at 24 - 48 hours
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	The study appears to be free of other sources of bias

Bofill 1996a

Study characteristics

Methods	Single-centre parallel randomised controlled study
Participants	637 participants included in the trial Inclusion criteria: candidates for operative vaginal delivery, ≥ 34 weeks or EFW ≥ 1800 g if gestational age unknown Exclusion criteria: not stated.
Interventions	Intervention: M-cup (Neward Enterprises, Rancho Cucamonga, Calif.) = 322 (half were in the continuous (164) suction group and half were in the intermittent (158) suction group)

Bofill 1996a *(Continued)*

	Comparison: forceps (the particular choice of forceps was left to the operator - types selected = Simpson 221, Elliot 19, Laufe divergent 19, Tucker-McLean 18, Luikart-Simpson 18 and Keilland 8) = 315
Outcomes	Maternal demographics, indication for interventions, analgesia, position, station, degree of asynclitism, fetal caput-moulding and time from application to delivery. Epis and extensions, lacerations and reasons for abandonment, fetal weight, Apgar scores, cord art gases, hyperbilirubinaemia, phototherapy, and any evidence of fetal trauma
Notes	Setting: single centre Country: USA Hospitals: University of Mississippi Medical Center Dates of study: October 1994 – July 1995 Study duration: 10 months Funding sources: manufacturer of the cup donated 300 cups. Supported in part by Vicksburg Hospital Medical Foundation Group Declaration of interest: not reported by trial authors Comparison: any forceps versus any vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote - "An uninvolved third party prepared all the envelopes before the initiation of the study by use of a table of random number" pg 1326
Allocation concealment (selection bias)	Low risk	Quote - "The next in a series of numbered opaque envelopes that contained randomisation slips were opened: This scheme randomised the patient into one of three groups: forceps, continuous vacuum, or intermittent vacuum" pg 1326
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel, so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment, so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study, those assessing subjective outcomes not blinded to instrument used so high risk of bias
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for

Bofill 1996a *(Continued)*

Selective reporting (reporting bias)	Unclear risk	Outcome measures not clear in Methods. No protocol available
Other bias	Low risk	The study appears to be free of other sources of bias

Carmody 1986

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	123 participants included in the study Inclusion criteria: singleton, cephalic, ≥ 37 completed weeks, instrumental assistance required Exclusion criteria: not stated
Interventions	Intervension: 'New generation' metal cup 50 mm size = 60 Comparison: original Bird cup 50 mm = 63
Outcomes	Outcomes: not explicitly described in Methods section. However, following stated: Quote: "Details of each procedure were recorded by the operator immediately after delivery. One of us (FC) examined each baby between 24 and 48 hours after delivery and photographed all trauma. Information about the infant's conditions at birth and in the neonatal periods was obtained from the case notes. At the conclusion of the trial all operators were asked about their confidence in using the different cups and whether they had a preference for one or other type." Pg 96 para 6
Notes	St Mary's Hospital, Portsmouth Setting: single centre. Country: UK. Hospitals: St Mary's Portsmouth. Dates of study: March - June 1983 Study duration: 4 months. Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: any rigid vacuum cup versus any rigid vacuum cup

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Details not provided on how the envelopes were produced
Allocation concealment (selection bias)	Low risk	Quote - "opening the top envelope in a box of serially numbered sealed opaque envelopes" pg 96

Carmody 1986 *(Continued)*

Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel, so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment, so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study, those assessing subjective outcomes not blinded to instrument used, so high risk of bias
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes, so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Unclear risk	No protocol. Generic (not specific) description of outcomes only
Other bias	Low risk	The study appears to be free of other sources of bias

Chanwaro 1999

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	180 participants included in the trial Inclusion criteria: 1. Pregnant women who were in labour room, Chonburi Hospital during June 1, 1996 to May 31, 1997 2. Singleton, cephalic (occiput) presentation 3. Term pregnancy and estimated fetal weight ≥ 2500 g 4. In second stage of labour, rupture membrane and station ≥ +2 5. Presence of indications for vacuum extraction 6. Presence of uterine contraction Exclusion criteria: 1. Previous caesarean section or previous uterine surgery 2. Contra-indication for vaginal delivery, e.g. cephalopelvic disproportion 3. Intrauterine fetal death or anomalies 4. Fetal distress
Interventions	Intervention: Silc cup, size 50 mm = 90 Comparison: Malmström cup, size 50 mm = 90
Outcomes	Rate of fetal scalp injury

Chanwaro 1999 *(Continued)*

	Success rate of vacuum extraction
Notes	Setting: single centre. Country: Thailand Hospital: Chonburi Hospital Dates of study: 01 June 1996 – 31 May 1997 Study duration: 12 months Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: soft versus rigid cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Randomisation by drawing lots
Allocation concealment (selection bias)	Unclear risk	Not stated in text
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Several relevant outcomes presented as percentages without whole numbers
Selective reporting (reporting bias)	Unclear risk	Only rate of fetal scalp injury and success rate of vacuum extraction mentioned as outcome measures in Methods section but many others reported in the Results section
Other bias	Low risk	The study appears to be free of other sources of bias

Chenoy 1992

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	199 participant included in the trial Inclusion criteria: singleton pregnancy of > 37 weeks' gestation, cephalic, instrumental delivery required Exclusion criteria: not stated Not all women included were fully dilated. 1 in Silc cup group and 4 in rigid-cup group were delivered before full dilatation was reached
Interventions	Intervention: 6 cm Silc cup (Menox-AB Sweden) attached to handheld pump = 101 participants Comparison: 5 cm Malmström metal cup attached to handheld pump = 98 participants
Outcomes	Success rate, maternal outcomes and neonatal trauma. Further details not specified in Methods
Notes	Setting: single centre Country: Nepal Hospitals: Kathmandu Maternity Hospital Dates of study: not reported by trial authors Study duration: not reported by trial authors Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: soft cup versus rigid cup

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient data
Allocation concealment (selection bias)	Low risk	Quote - "Sealed envelopes"
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel, so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment, so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes

Chenoy 1992 *(Continued)*

Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	No missing data
Selective reporting (reporting bias)	Unclear risk	No protocol and outcomes generalised in Methods section
Other bias	Low risk	The study appears to be free of other sources of bias

Cohn 1989

Study characteristics	
Methods	Parallel multicentre randomised controlled trial
Participants	258 participants included in trial Inclusion criteria: singleton, cephalic, instrumental required. "Where a vacuum extraction was thought to be suitable" Exclusion criteria: not stated Not all participants were fully dilated
Interventions	Intervention: Silc cup = 131 participants Comparison: range of metal cups. 40 - 60 mm Malmström, ant and post Bird, New Gen cup = 127 participants
Outcomes	- Failed delivery with allocated instrument (failure to deliver with 3 pulls or 2 or more cup detachments was recorded as 'method success outside of study protocol' if the intended cup was eventually successful or 'method failure' if an alternative was used) - Extent of maternal trauma - Estimated blood loss - Scalp injury – markings categorised into none, minor (minor (bruising 5 </= cm or minor abrasions) or major (bruising > 5 cm or cephalhematoma))
Notes	Setting: multicentre Country: UK Hospitals: - Northern General Hospital in Sheffield - Rotherham DGH - Leicester General Hospital - North Staff Maternity Hospital Stoke-on-Trent Dates of study: not reported by trial authors

Cohn 1989 *(Continued)*

	Study duration: not reported by trial authors Funding sources: the Silc cups were provided by Egnell-Ameda Ltd, Unit 2, Belvedere Trading Estate, Taunton, TA1 1GH Declaration of interest: not reported by trial authors Comparison: soft cup versus rigid cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated in blocks of 20, allocated to each participating centre in 60s. Pg 564 para 3
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to the nature of the study subjective outcomes likely to be open to bias for maternal outcomes, but in this study the risk of bias in the assessment of neonatal outcomes would have been low as the paediatrician was blinded
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Objective outcomes are generally open to less bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to the nature of the study subjective outcomes likely to be open to bias for maternal outcomes, but in this study the risk of bias in the assessment of neonatal outcomes would have been low as the paediatrician was blinded
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Objective outcomes are generally open to less bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for. 7/265 excluded after recruitment due to multiple gestation, randomisation error, lost data Remaining 258 participants reported here
Selective reporting (reporting bias)	Unclear risk	No protocol. Lots of data
Other bias	Low risk	The study appears to be free of other sources of bias

Dell 1985

Study characteristics

Methods	Parallel single-centre randomised controlled trial
Participants	118 participants included in the trial Inclusion criteria: ≥ 18 yrs old, gest ≥ 36, no previous pregnancy > 20 weeks, epidural or spinal used for delivery, standard criteria for low forceps met except that sagittal suture need not be directly anteroposterior

Dell 1985 *(Continued)*

	Exclusion criteria: no women were excluded on the basis of medical or obstetric complications, as long as study criteria were met
Interventions	Intervention 1: Mityvac = 37 Intervention 2: Silastic = 36 Comparison: Tucker-McLane forceps = 45
Outcomes	Successful delivery Failed delivery Heads of infants examined at delivery and next morning All postpartum and neonatal complications were recorded Charts for all infants for whom later postnatal examinations were available were reviewed and any abnormalities noted by the examining paediatrician were recorded Significant soft tissue injuries: 3rd/4th degree extensions of episiotomy; vaginal, periurethral, labial laceration requiring repair, vulvovaginal haematoma Neonatal scalp findings: caput, superficial skin changes, cephalhematoma
Notes	Setting: single centre Country: USA Hospital: Earl K Long Hospital, a Division of the Department of Obsterics and Gynaecology of Louisiana State University Medical Center Dates of study: 1st Jan 1984 to 30th June 1984 Study duration: 6 months Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors All but 2 in the group had a midline episiotomy Data included in following comparisons - Comparison 1: any type forceps versus any vacuum cup: Forceps versus Mytivac + Silastic - Comparison 2: low forceps versus any vacuum cup: Forceps versus Mytivac + Silastic - Comparison 7: any soft cup versus any soft cup: Silastic versus Mytivac

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote - "computer generated random numbers"
Allocation concealment (selection bias)	Unclear risk	Quote - "pulling next card of a series". No mention if sealed or opaque envelope
Blinding of participants and personnel (performance bias)	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes

Dell 1985 *(Continued)*

Subjective Outcomes		
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Attrition for long-term follow-up only
Selective reporting (reporting bias)	Unclear risk	No protocol and very generalised description of outcomes
Other bias	Low risk	The study appears to be free of other sources of bias

Equy 2015

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	668 participants randomised but only 578 analysed as explained below Inclusion: age 18 - 45, singleton after 37 weeks, cephalic, vacuum indicated, affiliation to the French social security system or equivalent Exclusion: no informed consent, singleton delivery before 37 weeks, non-cephalic presentation, woman deprived of freedom
Interventions	Intervention: iCup - 335 randomised, 295 analysed (40 of whom were wrongly included (8 with exclusion criteria, 30 not needed vacuum extraction, 2 needing forceps as 1st intention) and subsequently excluded leaving a total of 295 in iCup group) Comparison: Drapier-Faure metal cup - 333 randomised, 283 analysed, (49 wrongly included (7 with exclusion criteria, 41 not needing an instrumental and 1 requiring forceps as the 1st intention) and 1 early withdrawal from the study due to retraction of consent leaving a total of 283 in the comparison)
Outcomes	Primary: composite outcome (3 detachment, other instrument used, caesarean section, caput succedaneum, cephalhematoma, maternal perineal lesions)
Notes	Setting: multicentre Countries: France Hospitals: 6 hospitals 1. University Hospital Besançon 2. University Hospital Caen 3. Hospital Chambéry

Equy 2015 *(Continued)*

4. University Hospital Clermont Ferrand
5. University Hospital Grenoble
6. University Hospital Strasbourg

Dates of study: Oct 2009 - Feb 2013

Study duration: 40 months

Funding sources: grant from the French Health Ministry for Hospital Clinical Research (PHRC 2009)

Declaration of interest: Jean-Patrick Schaal (died during the study period) invented the iCup device and received royalties from GYNEAS (www.iCup-gyneal.com/). No other authors had any conflict of interest to declare

Comparison: any rigid cup versus any rigid cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "electronically randomised by the obstetrician in-charge of delivery...centralised using web server and was stratified by centre (random blocks of 6 on 10 to give equal distribution between both groups at each centre"
Allocation concealment (selection bias)	Low risk	Quote: "electronically randomised by the obstetrician in-charge of delivery...centralised using web server and was stratified by centre (random blocks of 6 on 10 to give equal distribution between both groups at each centre"
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Discrepancy between randomised and analysed number explained in detail. Low attrition
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in the protocol have been measured and reported in the study except for cost effectiveness but this has been suggested as a plan going forward
Other bias	Low risk	The study appears to be free of other sources of bias

Fall 1986

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	36 participants included in trial Inclusion criteria: medically uneventful pregnancy, > 37 completed weeks, vertex, normal heart rate pattern, instrumental indicated Exclusion criteria: women with late or variable decelerations in fetal heart or constant bradycardia or tachycardia, or with meconium
Interventions	Intervention: vacuum cup = 20 Comparison: forceps = 16
Outcomes	Estimated blood loss, umbilical artery and vein pH, pCO2, pO2 and standard bicarb, Apgar at 1 and 5, fundal examination for retinal haemorrhages, standard neurological examination, muscle tonus excitability scores
Notes	Setting: single centre Country: Sweden Hospital: University Hospital Linkoping Dates of study: not reported by trial authors Study duration: not reported by trial authors Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors A non-randomised group of normal deliveries reported as a comparison Comparison: any forceps versus any vacuum cup

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote - "Allocated at random"
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias)	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes

Fall 1986 *(Continued)*

Subjective Outcomes		
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Fitzpatrick 2003

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	130 participants included in the study Inclusion criteria: primiparous (recruited antenatally), spontaneous or induced labour, singleton fetus, cephalic, 37 - 42 weeks, required instrumental delivery Exclusion criteria: diabetes, irritable bowel syndrome, other bowel or neurological syndrome were excluded
Interventions	Intervention: vacuum cup = 69 Comparison: forceps = 61
Outcomes	Quote: "The duration of instrumental delivery, degree of difficulty, fetal position, fetal station" 12-week postpartum dedicated clinic - detailed bowel function questionnaire - faecal continence was documented using a modified continence score (scoring system explained in text) - faecal urgency was noted specifically and deemed significant if the participant was unable to defer defecation for longer than 5 minutes - perineal pain - participant satisfaction with labour - preferred mode of delivery next time
Notes	Setting: single centre Country: Ireland Hospital: National Maternity and Mater Misericordiae Hospital Dates of study: not reported by trial authors Study duration: 1 year

Fitzpatrick 2003 *(Continued)*

	Funding sources: supported by grant from the Irish Health Research Board
	Declaration of interest: not reported by trial authors
	Comparison: any type of forceps versus any vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote - "computer generated random allocations in a ratio of 1:1 in balanced blocks of 10."
Allocation concealment (selection bias)	Low risk	Quote - "numbered opaque sealed envelopes"
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Groom 2006

Study characteristics	
Methods	Parallel single-centre randomised controlled trial. (Randomisation stratified for fetal malposition)
Participants	404 participants included in the trial
	Inclusion criteria: ventouse delivery decided
	Exclusion criteria: lack of time for informed consent, declined consent, language barrier, outside unit protocol for ventouse (< 36 weeks, recognised contraindication such as suspected or confirmed fetal coagulopathy)

Groom 2006 *(Continued)*

Interventions	Intervention: Kiwi Omnicup = 206 participants Comparison: Conventional vacuum cups (Silc/Silastic cup, Malmström metal cup or Bird posterior cup) = 198 participants
Outcomes	Mode of delivery Maternal satisfaction Neonatal trauma Maternal trauma
Notes	Setting: single centre Country: UK Hospitals: Queen Charlottes & Chelsea, London Dates of study: April 2001 – March 2004 Study duration: 3 years Funding sources:: Kiwi Omnicups and administrative costs studied by Clinical Innovations (Murry, UT, USA) Declaration of interest: not reported by trial authors Comparison: handheld vacuum versus any vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation programme, randomising in blocks of 20, stratified for malposition
Allocation concealment (selection bias)	Low risk	Quote - "sealed opaque envelopes, which were kept in delivery suite and only opened after consent during preparation for delivery."
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Quote - "due to nature of the study, both patient and doctor were 'unblinded' to the intervention once the sealed envelope was opened"
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Quote - "due to nature of the study, both patient and doctor were 'unblinded' to the intervention once the sealed envelope was opened"
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for

Groom 2006 *(Continued)*

Selective reporting (reporting bias)	Low risk	Clear methods with "predefined outcome measures"
Other bias	Low risk	The study appears to be free of other sources of bias

Hammarström 1986

Study characteristics	
Methods	Parallel single-centre randomised controlled study
Participants	100 participants included in the trial Inclusion criteria: " women in whom instrumental delivery had to be performed due to fetal asphyxia/uterine inertia", head at or below the spine. Cervix fully dilated Exclusion criteria: not stated
Interventions	Intervention: Silastic cup of Kobayashi.= 50 participants Comparison: Malmström diameter 5 cm = 50 participants
Outcomes	Apgars at 1 and 5 minutes. Apgar ≤ 7 classified as asphyxia. Babies examined at 3 days of age for scalp injuries: redness, haematoma, caput, laceration. 1 or 2 of these changes was classified as mild, 3 or more were classified as severe
Notes	Setting: single centre Country: Sweden Hospitals: Karolinska Hospital, Stockholm. Dates of study: 1983 to 1984 Study duration: not reported by trial authors Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors In Silastic group pressure applied immediately. In Malmström group pressure applied gradually in 6 minutes Comparison: soft cup versus rigid cup

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Quote - "randomised according to birth date"
Allocation concealment (selection bias)	Unclear risk	No details.
Blinding of participants and personnel (performance bias)	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes

Hammarström 1986 *(Continued)*

Subjective Outcomes		
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	High risk	Brief description of planned outcomes did not include time taken to deliver which was reported as a significant finding
Other bias	Low risk	The study appears to be free of other sources of bias

Hebertson 1985

Study characteristics	
Methods	Multicentre parallel randomised controlled trial
Participants	105 participants. 29 in the non-padded group, 22 with both blades padded, 26 with the left blade padded, and 28 with the right blade padded Inclusion criteria: "women who required forceps-assisted delivery...at or near term" Exclusion criteria: not stated
Interventions	Intervention: Tucker-Luikart or Simpson-Luikart forceps with pliable polyurethane pad with self-adherent backing 3 groups (Total 98) 1 – forceps with pad on each blade = 22 + 22 2 - forceps with pad on right blade only = 28 3 – forceps with pad on left blade only = 26 Comparison: Unpadded Tucker-Luikart or Simpson-Luikart forceps Total (112) 1 - both blades unpadded forceps = 29 + 29 2 - forceps with pad on right blade only = 28 3 - forceps with pad on left blade only = 26 (Most were Tucker-Luikart forceps, 5 were Simpson-Luikart)
Outcomes	Facial markings

Hebertson 1985 *(Continued)*

	A - Babies checked by attending physician or circulating nurse few minutes after birth B - 24-hour check by 'blinded' nurse Graded as per arbitrary guidelines. 1) None 2) Minimal – erythema of the skin at the point of forceps contact 3) Moderate – erythema plus a visible outline of the forceps on the skin 4) Severe – erythema with deep distinct forceps marks on the skin but without abrasion 5) Abrasions – severe + blisters and or breaks in the skin
Notes	Setting: single centre Country: USA Hospitals: LDH hospital; University of Utah Hospital Dates of study: not reported by trial authors Study duration: not reported by trial authors Funding sources: not reported by trial authors Declaration of interest: "one of the authors MSS pursued the development of a new type of obstetric forceps pad." Pg 275 Total participants in the study was 105; each blade was reported separately so total number used as 210 Comparison: regular forceps versus soft forceps

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote - "placement in each group was accomplishment prospectively by a random numbering system except for a few initial cases at the outset of the study, which were assigned to one group or another by rotation". Number of those assigned by rotation not stated
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Assumed due to nature of study. Would have been low if 24-hour assessment only for which the nurse was blinded
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Assumed due to nature of study. Would have been low if 24-hour assessment only for which the nurse was blinded

Hebertson 1985 *(Continued)*

Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All cases accounted for
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Hofmeyr 1990

Study characteristics	
Methods	Parallel multicentre randomised controlled trial
Participants	31 participants in included in the trial Inclusion criteria: "Women with healthy term fetuses due for vacuum extractor delivery" Exclusion criteria: not stated
Interventions	Intervention: soft cup - Silc or Silastic = 13 Comparison: rigid cup - new Bird or O'Neil = 18
Outcomes	Perinatal outcomes Traction force 5 minutes after delivery appearance of the baby's scalp was mapped – areas of rim markings, excoriation, oedema, bruising and cephalhematoma
Notes	Setting: multicentre. Country: South Africa Hospitals: Coronation, Baragwanath and Johannesburg Hospitals Dates of study: not reported by trial authors Study duration: not reported by trial authors Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: soft cup versus rigid cup

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "shuffled" sealed cards. No mention of numbering

Hofmeyr 1990 *(Continued)*

Allocation concealment (selection bias)	Low risk	Sealed cards
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Quote: "Due to characteristic appearance of chignon from rigid cup outcome assessors were not blinded"
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Quote: "Due to characteristic appearance of chignon from rigid cup outcome assessors were not blinded"
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	None withdrawn after randomisation
Selective reporting (reporting bias)	High risk	Earlier publications mentioned daily scalp examinations for 5 days in planned outcomes but these were not mentioned in main publication. Cephalhematomas and excoriations mentioned in Methods but Results not reported
Other bias	Low risk	The study appears to be free of other sources of bias

Ismail 2008

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	164 participants included in the trial Inclusion criteria: all patients requiring vacuum assisted delivery Exclusion criteria: multiple pregnancy, prematurity (< 36 weeks), refusal to participate
Interventions	Intervention: Kiwi Omnicup = 85 participants Comparison: Malmström metal cup = 79 participants
Outcomes	Maternal trauma Neonatal trauma
Notes	Setting: single centre Country: Malaysia Hospitals: University Kebangsaan Malaysia Dates of study: June 2005 – May 2006

Ismail 2008 *(Continued)*

	Study duration: 12 months Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparisons: - handheld vacuum versus and vacuum cup - rigid cup versus rigid cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No information
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Johanson 1989

Study characteristics

Methods	Multicentre parallel randomised controlled trial.
Participants	264 participants included in the trial Inclusion criteria: singleton, cephalic, 35 completed weeks

Johanson 1989 *(Continued)*

	Exclusion criteria: "if the doctor felt that a particular instrument was especially indicated for assisted delivery"
Interventions	Intervention: Kobayashi silicone cup ventouse = 132 Comparison: Forceps (Neville Barnes/Kiellands) = 132
Outcomes	"maternal morbidity – maternal perineal trauma, postpartum haemorrhage and maternal discomfort at delivery" "Fetal morbidity – scalp and facial skin trauma, cephalhematoma, retinal haemorrhage, jaundice and acidosis at birth"
Notes	Setting: Multicentre Country: UK Hospitals: North Staffordshire Hospital, Stoke-on-Trent and Billinge Maternity Hospital, Wigan Dates of study: Sept 1987 to Feb 1988 Study duration: 6 months. Funding sources: "financial support made available from Trust Fund sources at NSMH by the Unit Administration" Declaration of interest: not reported by trial authors Comparison: any forceps versus any vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote - "consecutive series of sealed, opaque envelopes prepared at the National Perinatal Epidemiology Unit"
Allocation concealment (selection bias)	Low risk	Quote - "consecutive series of sealed, opaque envelopes prepared at the National Perinatal Epidemiology Unit"
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for

Johanson 1989 *(Continued)*

Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Johanson 1993

Study characteristics	
Methods	Parallel multicentre randomised controlled trial
Participants	607 participants included in the trial Inclusion criteria: singleton, cephalic, at least 35 completed weeks, informed consent Exclusion criteria: "women were recruited only when the operator did not feel that a particular instrument was indicated for assisted delivery"
Interventions	Intervention: ventouse (Silc, Bird ant or Bird post depending on the, vacuum extractor policy)' = 296 Comparison: Neville Barnes for OA, Keillind's for rotational deliveries = 311
Outcomes	Success rate Maternal injury (blood loss, analgesia and anaesthetic requirements, perineal injury). Fetal/neonatal injury (jaundice, bruising, scalp and facial injuries) Criteria for assessments were prespecified Cranial US performed on a small unselected group Fundoscopy performed on a small unselected group Women formally questioned about their delivery and puerperium
Notes	Setting: multi-centre Country: UK Hospitals: - North Staffordshire Maternity Hospital - Royal Shrewsbury Hospital - Stafford District Hospital - New Cross Hospital (Wolverhampton) Dates of study: Sept 1989 to May 1990 Study duration: 9 months Funding sources: 'RB Johanson was funded by a grant from the North Staffordshire Medical Institute with additional financial support being provided by Menox-AB of Gothenberg, the National Perinatal Epidemiology Unit (NPEU), and the City General Hospital Trust Fund Declaration of interest: not reported by trial authors Comparison: any forceps versus and vacuum cup

Johanson 1993 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "prepared independently of the trial organisers. There was a 1:1 randomisation within balanced blocks of varying sizes of 4 to 10"
Allocation concealment (selection bias)	Low risk	Quote: "'consecutive series sealed opaque envelopes"
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Selective reporting (reporting bias)	Low risk	Trial registration available with predefined outcomes
Other bias	Low risk	The study appears to be free of other sources of bias

Kuit 1993

Study characteristics	
Methods	Parallel randomised controlled trial
Participants	100 participants included in the trial Inclusion criteria: "patients who met predetermined criteria for operative vaginal delivery, >/= 37 weeks, single live fetus, required instrumental delivery, ruptured membranes, fully dilated, vertex, low or mid station of descent." Exclusion criteria: not found
Interventions	Intervention: 55 mm Malmström mushroom-shaped design with tubing attached to the centre of the dome and traction chain passed through the tubing = 50 participants Comparison: Silastic silicone plastic cup after Kobayashi, with a diameter of 65 mm (Dow Corning Corp., Midland, MI) = 50 participants

Kuit 1993 *(Continued)*

Outcomes	Time from decision to start of procedure Maternal blood loss, vaginal trauma, Apgar, results of neonatal examination. Particular attention to fetal scalp; the presence of cup marks, bruising, lacerations, or haematoma was described Scalp inspected again at 48 - 72 hours Indirect ophthalmoscopy performed in every neonate within 30 minutes of delivery - Retinal haemorrhages graded in 3 grades. 1) small and relatively few haemorrhages, 2) 1 to 2 large bleeding or many small haemorrhages, 3) haemorrhages involving the central macula or many large haemorrhages Serum bilirubin at 48 to 72 hours Neurological exams as per Prechtl 48 to 72 hours after birth
Notes	Setting: not reported by trial authors Country: Netherlands Hospitals: not reported by trial authors Dates of study: not reported by trial authors Study duration: not reported by trial authors Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: soft cup versus rigid cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote - "randomisation was done by means of a table of random numbers and balanced in groups of 6"
Allocation concealment (selection bias)	Low risk	Quote - "by opening the next of a series of sealed and consecutively numbered envelopes"
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias

Kuit 1993 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Lasbrey 1964

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	252 participants included in trial Inclusion criteria: cervix fully dilated. Indication for expediting delivery existed Exclusion criteria: rapid delivery desirable (e.g. cord prolapse), "undesirable for woman to bear down at all", e.g. very severe pre-eclampsia
Interventions	Intervention: forceps = 131 participants Comparison: Malmström large or medium vacuum cup = 121 participants
Outcomes	Number of pulls, interval between applications and delivery, number of pull-offs, degree of asphyxia (absent, slight, moderate, severe). Vacuum babies examined daily for caput and cap haematoma. (forceps group not examined with equal care)
Notes	Setting: single centre Country: South Africa Hospitals: McCord Zulu Hospital Dates of study: April 1961 – March 1963 Study duration: 24 months Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: any forceps versus any vacuum cup

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote - " a slip of paper was drawn in the approved random-sample manner, to indicate…"
Allocation concealment (selection bias)	Unclear risk	Quote - "a slip of paper was drawn in the approved random-sample manner, to indicate…"

Lasbrey 1964 *(Continued)*

Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	The study appears to be free of other sources of bias

Lee 1996

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	72 participants included in the trial Inclusion criteria: term, singleton, vertex Exclusion criteria: not found
Interventions	Intervention: 6 cm silicone vacuum cup = 32 participants Comparison: 5 or 6 cm Bird cup = 40 participants
Outcomes	Characteristics, Apgar scores, condition of baby, estimated blood loss, mother and baby followed up until discharge
Notes	Setting: single centre Country: Malaysia Hospitals: The Maternity Hospital Kuala Lumpur Dates of study: 1st Dec 1991 to 31st April 1992 Study duration: 5 months Funding sources: not reported by trial authors

Lee 1996 *(Continued)*

	Declaration of interest: not reported by trial authors
	Comparison: soft cup versus rigid cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote - "Envelope drawn from box"; no further detail provided
Allocation concealment (selection bias)	Low risk	Sealed envelope
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Selective reporting (reporting bias)	Unclear risk	Generalised statements made "condition of baby' 'mother and baby followed until discharge" and no protocol available
Other bias	Low risk	The study appears to be free of other sources of bias

Mola 2010

Study characteristics

Methods	parallel single-centre randomised controlled trial
Participants	200 participants included in the study Inclusion criteria: singleton, vertex presentation, gestational age at least 36 completed weeks and where vacuum assistance was required for delivery during the second stage of labour Exclusion criteria: not stated
Interventions	Intervention: Vacca Re-Usable OmniCup = 100 participants Comparison: Bird vacuum delivery system = 100 participants

Mola 2010 *(Continued)*

Outcomes	Primary outcome measure: - Completion of the assisted delivery with the allocated instrument Secondary outcome measures: - Rates of maternal trauma (episiotomy, tears to the maternal genital tract) - Significant fetal scalp trauma (severe abrasions and subgaleal haemorrhage) - Neonatal outcome (Apgar scores of < 7 at 5 minutes, days spent in the special care nursery, and neonatal death)
Notes	Setting: sIngle centre. Country: Papau New Guinea Hospitals: Port Moresby General national referral and teaching Hospital (PMGH) Dates of study: 1st June 2007 – 31st Dec 2007 Study duration: 7 months Funding sources: the Vacca Re-Useable Omnicups used in this study were supplied by Clinical Innovations Inc (Murray, Utah, USA) Declaration of interest: Vacca Re-Usable OmniCup systems and their spare parts were supplied by Clinical Innovations (Murray, Utah, USA). Data analysis was undertaken with the assistance of Drs. James King (of the Royal Women's Hospital, Melbourne) and Paulus Ripa (of the UPNG School of Medicine and Health Sciences). Clinical Innovations Inc. had no involvement in the design of the study, the writing of the protocol, the running of the trial, data analysis or manuscript preparation Comparisons: - handheld vacuum versus any vacuum cup - any rigid cup versus any rigid cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote - "A computer-generated randomisation sequence 1:1 ratio was used – obtained from a dedicated web-based randomisation site, ensuring that the operators were blinded to the allocation prior to opening of the envelope"
Allocation concealment (selection bias)	Low risk	Quote - "pre-packed boxes of opaque envelopes each containing the type of vacuum equipment to be used."
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes

Mola 2010 *(Continued)*

Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Low risk	Contact from author (G Mola) 17 Aug 2020 via email. "No difference between outcomes defined in protocol and those presented in the results".
Other bias	Low risk	The study appears to be free of other sources of bias"

Pliego Perez 2000

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	140 participants included in the study Inclusion criteria: age > 20, > 37 weeks, < 42 weeks, Indication to make the 2nd stage shorter, no contraindication to ventouse or forceps as per ACOG Exclusion criteria: fetal distress, suspected macrosomia, high head, cephalo-pelvic disproportion, face or breech presentation. Prolonged second stage
Interventions	Intervention: Simpson's forceps = 70 participants Comparison: 65 mm Silc Kobayashi cup = 70 participants
Outcomes	Outcomes After the baby and before the administration of prophylactic antibiotics, the uterine cavity and vaginal canal were examined. The data were collected by the doctor performing the procedure. All babies had umbilical cord gases Variables were – cephalhematomas, sub-gleal haemorrhage, cerebral oedema, scalp laceration, retinal haemorrhage, weight of the baby, Apgar at 1 and 5 minutes, arterial blood gas and perineal trauma All babies evaluated by neonatal doctors at 12 and 48 hours for neurological, physical and feeding status Cranial USS - all babies had a cranial US in 1st 12 hours using Dornier 5200. Made a note of any complication the mum or baby had while in hospital Fundoscopy – all babies in 1st 24 hours by ophthalmologist – looking for retinal haemorrhage. Also noted anything else that was found
Notes	Setting: single centre Country: Mexico Hospitals: Central Millitary Hospital, Mexico City Dates of study: 1st Jan 1997 - 31st May 1998 Study duration: 18 months

Pliego Perez 2000 *(Continued)*

	Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: any forceps versus any vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised "the patients were randomised by the computer" pg 455 para 2. "La decision de la aplicacion del instrument se llevo a cabo por el medico de guardia"
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Roshan 2005

Study characteristics

Methods	Parallel single-centre randomised controlled trial
Participants	96 participants included in study Inclusion criteria: ruptured membranes (spontaneous or artificial), fully dilated, vertex presentation, fully engaged, +2 or lower. Cephalopelvic disproportion ruled out in every case Exclusion criteria: not stated

Roshan 2005 *(Continued)*

Interventions	Intervention: 'soft' forceps – gas sterilised Simpson coated with a soft rubber coating = 45 participants Comparison: Simpson's forceps = 51 participants.
Outcomes	Neonatal trauma
Notes	Setting: single centre Country: Russia. Hospitals: National Institute of Maternal Health in Moscow Dates of study: Feb 1999 – March 2003 Study duration: 49 months Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: soft forceps versus regular forceps

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote - "randomly assigned to two groups"
Allocation concealment (selection bias)	Unclear risk	Insufficient information
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information, results reported as percentages so not possible to assess missing data
Selective reporting (reporting bias)	Unclear risk	Insufficient information
Other bias	Low risk	The study appears to be free of other sources of bias

Shekhar 2013

Study characteristics	
Methods	Parallel randomised controlled trial
Participants	100 participants included in the trial Inclusion: "The patients eligible for inclusion in the study were those with singleton pregnancies, a cephalic presentation,and a gestation of at least 37 completed weeks and where instrumental assistance was required for delivery during the second stage of labor." Exclusion: not stated
Interventions	Intervention: Das variety of curved forceps and Wrigley's outlet forceps = 50 participants Comparison: Bird modification of Malmström vacuum cup = 50 participant
Outcomes	Maternal outcome: perineal tears, extension of the episiotomy, vaginal lacerations, cervical tears, or others. Maternal blood loss - measured and also assessed by the haemoglobin decrease Fetal outcome: 1 to 5 minute Apgar score, scalp lesions (chignon, abrasion, and cephalhematoma), facial injuries, jaundice (either clinically appreciable or serum bilirubin level (6 mg/dl), nerve palsies, intracranial haemorrhage, and signs of cerebral irritation, fracture, and mortality
Notes	Setting: not reported by trial authors Country: India (assumed due to institutions of the authors) Hospitals: not reported by trial authors Dates of study: not reported by trial authors Study duration: not reported by trial authors Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparisons: - any type of forceps versus and type of vacuum cup - low-cavity forceps versus any vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote - "random treatment allocation to forceps or vacuum extractor was made by opening the top envelope in a box of serially numbered envelopes"
Allocation concealment (selection bias)	Unclear risk	Quote - "random treatment allocation to forceps or vacuum extractor was made by opening the top envelope in a box of serially numbered envelopes" (? is this random)
Blinding of participants and personnel (performance bias)	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes

Shekhar 2013 *(Continued)*

Subjective Outcomes		
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Most participants accounted for
Selective reporting (reporting bias)	High risk	Protocol not available. Many outcomes reported in text as generalisations but numbers not always provided
Other bias	Low risk	The study appears to be free of other sources of bias

Srisomboon 1998

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	90 participants included in the trial Inclusion criteria: > 37 weeks, single live fetus, ruptured membranes, fully dilated, vertex, low or mid station Exclusion criteria: not stated
Interventions	Intervention: Silastic silicone rubber cup, 50 mm (Silc cup, Menox AB, Gothenburg, Sweden) = 44 participants Comparison: original 50 mm Malmström mushroom-shaped design with central chain and suction pipe = 46 participants
Outcomes	Cup application to delivery Failure - Delivery not achieved with 15 minutes of application - 2 or more cup detachments - Delivery other than intended cup Infant evaluated immediately and at 48 hours - Fetal scalp (cup marks, bruising, laceration or haematoma) Transfer to NNU

Srisomboon 1998 *(Continued)*

	Need for phototherapy
Notes	Setting: single centre Country: Thailand Hospitals: Chiang Mai University Hospital Dates of study: May 1996 – October 1996 Study duration: 6 months Funding sources: grant from faculty of medicine endowment funds, faculty of medicine, Chiang Mai University Declaration of interest: Endomed (Thailand) provided Silc cup Comparison: soft cup versus rigid cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "blocked randomisation". No further details provided
Allocation concealment (selection bias)	Unclear risk	Insufficient detail
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Selective reporting (reporting bias)	Unclear risk	No protocol and described in past tense in methodology
Other bias	Low risk	The study appears to be free of other sources of bias

Thiery 1987

Study characteristics	
Methods	Single-centre parallel randomised controlled trial
Participants	410 participants in the trial Singleton, cephalic, > 38 weeks 210 in the Malmström group and 200 in the O'Neil group Inclusion criteria: ≥ 38 completed weeks, fully dilated, apparently healthy fetus, singleton, cephalic Exclusion criteria: maternal or fetal indication for ventouse
Interventions	Intervention: 55 mm OA or OP O'Neil cup = 200. Comparison: 50 mm Malmström = 210.
Outcomes	"Evaluation of infant status at birth was on clinical and biochemical parameters" Heads of all infants examined between 24 and 48 hours Evaluation of cup position for degree of flexion and synclitism (described fig 4 28a) Immediately after the procedure, details of each procedure recorded by the operator on specially-designed charts
Notes	Single centre: Ghent Setting: single centre Country: Belgium Hospitals: University Hospital, Ghent, Belgium Dates of study: 30 Jan 1984 – 30 Sept 1985 Study duration: 18 months Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: rigid vacuum cup versus rigid vacuum cup

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Allocation of cup was on basis of randomisation". No further details provided
Allocation concealment (selection bias)	Unclear risk	Quote: "Allocation of cup was on basis of randomisation". No further details provided
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias)	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias

Thiery 1987 *(Continued)*

Objective Outcome		
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants accounted for
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	The study appears to be free of other sources of bias

Vacca 1983

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	304 participants included in the trial Inclusion criteria: singleton, vertex, ≥ 37 weeks, instrumental required, second stage Exclusion criteria: not stated
Interventions	Intervention: anterior and posterior Bird vacuum cups = 152 participants Comparison: Haig Ferguson's and Kielland's forceps = 152 participants
Outcomes	Details of each procedure including maternal trauma recorded by operator immediately after delivery. Baby examined at 24 and 48 hours by 1 of the authors and photographed
Notes	Setting: single centre Country: UK Hospitals: St Mary's Hospital Portsmouth Dates of study: May – Dec 1981 Study duration: 8 months Funding sources: "grant from department of health and social security" Declaration of interest: not reported by trial authors Comparison: any forceps versus any vacuum cup

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**

Vacca 1983 *(Continued)*

Random sequence generation (selection bias)	Low risk	Top envelope in box of serially-numbered envelopes in blocks of 6. Blocks prepared by 1 of the authors not directly involved with the study
Allocation concealment (selection bias)	Unclear risk	Concealment details not provided
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Selective reporting (reporting bias)	Unclear risk	No protocol available
Other bias	Low risk	The study appears to be free of other sources of bias

Warwick 1993

Study characteristics	
Methods	Parallel multicentre randomised controlled trial
Participants	105 participants included in the study Inclusion criteria: singleton, cephalic, > 35 weeks, active stage, assisted vaginal delivery indicated Exclusion criteria: not stated
Interventions	Intervention: silicone (Silc-cup, Mennox AB, Sweden) = 50 participants Comparison: Santropene (Mennoc AB, Sweden) = 55 participants
Outcomes	Mode of delivery Neonatal outcomes: Apgar score, degree of caput secundum and admission to neonatal unit Maternal outcomes: perineal trauma and blood loss
Notes	Setting: multicentre

Warwick 1993 *(Continued)*

Country: United Kingdom

Hospitals: North Staffordshire Maternity Hospital and The Royal Shrewsbury Hospital

Dates of study: not reported by trial authors

Study duration: not reported by trial authors

Funding sources: not reported by trial authors

Declaration of interest: not reported by trial authors

Comparison: any soft cup versus any soft cup.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Consecutive sealed, opaque envelopes generated from random number tables
Allocation concealment (selection bias)	Low risk	Consecutive sealed, opaque envelopes generated from random number tables
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Selective reporting (reporting bias)	Unclear risk	No protocol, predefined outcomes unclear
Other bias	Low risk	The study appears to be free of other sources of bias

Weerasekera 2002

Study characteristics

Methods	Parallel single-centre randomised controlled trial
Participants	442 participants included in the trial

Weerasekera 2002 *(Continued)*

	Inclusion criteria: ≥ 37 weeks, head fully engaged in the pelvis, cervix fully dilated, the station of the head below the ischial spines, sagittal suture in the antero-posterior diameter, bladder empty Exclusion criteria: not stated
Interventions	Intervention: forceps = 238 participants Comparison: vacuum = 204 participants
Outcomes	Maternal injuries: 3rd degree tears, cervical tears, ruptured uterus, postpartum haemorrhage (requiring transfusion) Fetal complications: cephalhematoma, baby resuscitation, admitted to NICU, stillbirth or neonatal death Failure of delivery by allocated instrument Time taken to complete procedure
Notes	Setting: single centre Country: Sri Lanka. Hospitals: Teaching Hospital Colombo South Dates of study: January 1999 - December 2000 Study duration: 2 years Funding sources: not reported by trial authors Declaration of interest: not reported by trial authors Comparison: any forceps versus any vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "randomised"; no other details
Allocation concealment (selection bias)	Unclear risk	Quote: "randomised"; no other details
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias)	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias

Weerasekera 2002 *(Continued)*

Objective Outcome		
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Williams 1991

Study characteristics	
Methods	Parallel single-centre randomised controlled trial
Participants	99 participants included in the trial Inclusion criteria: > 18 years, completed 35 weeks, required attempted assisted vaginal delivery, non-emergent procedure as determined by attending physician. cephalic, station +1 to +4, mid, low and outlet cephalic presentation, estimated weight, position and station appropriate for either forceps or vacuum Exclusion criteria: electronic fetal monitoring suggestive of fetal distress, station higher than +1, occipitotransverse position, history of traumatic vaginal delivery
Interventions	Intervention: Simpson or Tucker McLane forceps = 51 participants Comparison: CMI Soft Touch Cup, a relatively malleable disposable polyethylene vacuum cup. Used with CMI handheld pump = 48 participants
Outcomes	Delivery data recorded Cord gases performed Neonates evaluated at 12 - 24 hours by neonates staff - Physical exam, neuro exam, evaluation of feeding activity - Neonates had a intracranial US by 24 weeks - Neonates had an ophthalmology examination at 48 hours. (High level of detail of this examination provided within the text) Mothers - Admission and day 1 Hb and hematocrit - Need for episiotomy, Subsequent extension, other lacerations and birth-related injuries were recorded All mothers and babies observed until discharge. Failure rate, maternal and neonatal morbidity including retinal haemorrhage, fetal acid-base status and incidence of intracranial haemorrhage.
Notes	Setting: single centre Country: USA

Williams 1991 *(Continued)*

Hospitals: Tampa General Hospital, University of South Florida

Dates of study: Jan - Dec 1989.

Study duration: 12 months

Funding sources: not reported by trial authors

Declaration of interest: CMI Soft Touch Cup and CMI hand vacuum pump provided by Columbia Medical and Surgical Inc., Bend, OR.

Comparison: any forceps versus and vacuum cup

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "sequentially numbered"; no other details
Allocation concealment (selection bias)	Low risk	Sealed envelopes drawn containing randomisation slips
Blinding of participants and personnel (performance bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of participants and personnel (performance bias) Objective Outcome	Low risk	Although blinding not possible, objective outcomes have predefined parameters for assessment so low risk of bias
Blinding of outcome assessment (detection bias) Subjective Outcomes	High risk	Due to nature of study not possible to blind participants and personnel so high risk of bias for subjective outcomes
Blinding of outcome assessment (detection bias) Objective Outcome	Low risk	Specific parameters given for measurement of objective outcomes so low risk of bias
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low attrition
Selective reporting (reporting bias)	Unclear risk	No protocol
Other bias	Low risk	The study appears to be free of other sources of bias

Due to the nature of the studies, for most outcomes, blinding would not have been possible. Therefore, where specific information is not provided we have assumed that subjective outcomes would be liable to a high risk of bias whilst objective outcomes are likely to be open to a low chance of bias.
ant: anterior; EFW: estimated fetal weight; NNU: neonatal unit; post: posterior; US(S): ultrasound (scan)

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Carmona 1995	No clinical indication for the intervention
Ehlers 1974	Non-randomised
Gabrawi 1997	Author looked at pump not instrument
George 1992	Registration document only from 1992. No evidence trial took place, not able to contact trialist
Katz 1982	1. Elective intervention for no fetal or maternal indication 2. Second stage only 20 - 30 minutes.
Lim 1997	Comparing method of instrument application, not different instruments themselves
Loghis 1992	Insufficient evidence to support randomisation process. Close look at the 3 study references Loghis 1992 showed that the same group of participants had been analysed in 2 separate studies
Maleckiene 1996	Conference abstract only which did not have sufficient information to allow adequate assessment and data extraction
Maltau 1984	Participants were preterm
Mejido 2019	Email from trialist 8 July 2021 - registered randomised trial never started due to technical problems
Mustafa 2002	Not a randomised controlled trial
Romero 2021	Comparing instrument handles, not different instruments themselves
Schuitemaker 1992	Registration document only from 1992. No evidence trial took place, not able to contact trialist
Suwannachat 2011	Comparing method of instrument application, not different instruments themselves
Williams 1993	No analysis of subset (n = 87) of assisted births
Yancey 1991	No clinical indication for intervention

Characteristics of ongoing studies *[ordered by study ID]*

Schvartzman 2012

Study name	Odon device versus forceps/vacuum extraction
Methods	Multi-country randomised trial
Participants	Women undergoing assisted vaginal delivery for prolonged labour
Interventions	Odon device Vacuum extraction Forceps delivery
Outcomes	Effectiveness of Odon device Newborn infection

Schvartzman 2012 *(Continued)*

Starting date	None as yet - still a planned trial
Contact information	World Health Organization Odon Device Research Group
Notes	

DATA AND ANALYSES

Comparison 1. Any type of forceps versus any type of vacuum cup

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Failed delivery with allocated instrument (primary)	11	3080	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.39, 0.88]
1.2 Failed delivery with allocated instrument (subgroup by epidural)	11	3080	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.39, 0.88]
1.2.1 Epidural	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.2.2 No epidural	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.2.3 Mixed or undefined	11	3080	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.39, 0.88]
1.3 Failed delivery with allocated instrument (subgroup by Country PMR)	11	3080	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.39, 0.88]
1.3.1 Low PMR	7	2146	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.42, 1.10]
1.3.2 High PMR	4	934	Risk Ratio (M-H, Random, 95% CI)	0.38 [0.20, 0.72]
1.3.3 Mixed or undefined	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.4 Failed delivery with allocated instrument (subgroup by rotational or non-rotational delivery))	11	3080	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.39, 0.88]
1.4.1 Non-rotational delivery	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.4.2 Rotational delivery	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.4.3 Mixed or undefined	11	3080	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.39, 0.88]
1.5 Any maternal trauma (primary)	5	1356	Odds Ratio (M-H, Fixed, 95% CI)	1.53 [0.98, 2.40]
1.6 Any maternal trauma (subgroup by epidural)	5	1356	Odds Ratio (M-H, Fixed, 95% CI)	1.53 [0.98, 2.40]
1.6.1 Epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
1.6.2 No epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
1.6.3 Mixed or undefined	5	1356	Odds Ratio (M-H, Fixed, 95% CI)	1.53 [0.98, 2.40]
1.7 Any maternal trauma (subgroup by Country PMR)	5	1356	Odds Ratio (M-H, Fixed, 95% CI)	1.53 [0.98, 2.40]
1.7.1 Low PMR	4	1256	Odds Ratio (M-H, Fixed, 95% CI)	1.44 [0.91, 2.28]
1.7.2 High PMR	1	100	Odds Ratio (M-H, Fixed, 95% CI)	7.44 [0.37, 147.92]
1.7.3 Mixed or undefined	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
1.8 Any maternal trauma (subgroup by rotational or non-rotational delivery)	5	1356	Odds Ratio (M-H, Fixed, 95% CI)	1.53 [0.98, 2.40]
1.8.1 Non-rotational delivery	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
1.8.2 Rotational delivery	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
1.8.3 Mixed or undefined	5	1356	Odds Ratio (M-H, Fixed, 95% CI)	1.53 [0.98, 2.40]
1.9 Third- or fourth-degree perineal tear (with or without episiotomy)	9	2493	Risk Ratio (M-H, Random, 95% CI)	1.83 [1.32, 2.55]
1.10 Postpartum haemorrhage (>/= 500 mL)	2	523	Risk Ratio (M-H, Fixed, 95% CI)	1.71 [0.59, 4.95]
1.11 Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)	7	1644	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.46, 1.51]
1.12 Low Umbilical artery pH (<7.2 or as defined by trial authors)	2	789	Risk Ratio (M-H, Fixed, 95% CI)	1.33 [0.91, 1.93]
1.13 Caesarean section	7	2129	Risk Ratio (M-H, Fixed, 95% CI)	1.69 [1.00, 2.87]
1.14 Maternal satisfaction: 'Disappointed or lack of care'	1	185	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.28, 2.84]

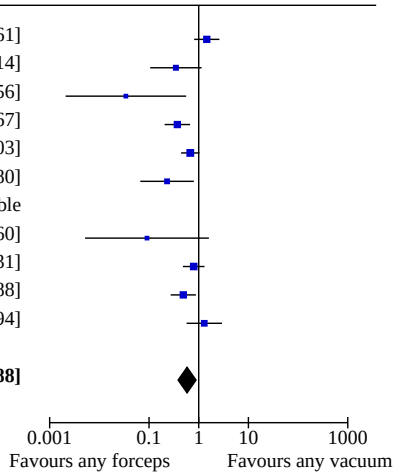
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.15 Pain as defined by trial authors	3	542	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.77, 1.99]
1.16 General anaesthesia	4	1427	Risk Ratio (M-H, Random, 95% CI)	2.22 [0.57, 8.62]
1.17 Time from randomisation to delivery (mins)	1	264	Mean Difference (IV, Fixed, 95% CI)	0.00 [-2.41, 2.41]
1.18 Urinary incontinence	1	227	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.73, 1.26]
1.19 Flatus incontinence	1	226	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.50, 2.00]
1.20 Faecal incontinence	2	356	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.27, 3.47]
1.21 Perineal pain	2	315	Risk Ratio (M-H, Fixed, 95% CI)	1.20 [0.85, 1.71]
1.22 Pain during sexual intercourse	1	185	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [0.93, 2.00]
1.23 Scalp injury	3	895	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [0.89, 1.87]
1.24 Facial injury	1	81	Risk Ratio (M-H, Fixed, 95% CI)	7.18 [0.92, 55.71]
1.25 Intracranial injury	2	218	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [0.60, 3.11]
1.26 Cephalhematoma	10	2729	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.30, 0.56]
1.27 Retinal haemorrhage	5	386	Risk Ratio (M-H, Fixed, 95% CI)	0.66 [0.46, 0.94]
1.28 Jaundice	6	1600	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.53, 0.92]
1.29 Admission to neonatal intensive care unit	4	1140	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.50, 1.33]
1.30 Neonatal encephalopathy	4	1293	Risk Ratio (M-H, Fixed, 95% CI)	1.75 [0.52, 5.96]
1.31 Death	7	2087	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.29, 2.36]
1.32 Analgesia: none	5	1527	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.34, 0.66]
1.33 Analgesia: perineal infiltration	6	2164	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.41, 0.87]
1.34 Analgesia: pudendal	3	1548	Risk Ratio (M-H, Random, 95% CI)	1.86 [0.93, 3.73]
1.35 Analgesia: Saddle block	1	637	Risk Ratio (M-H, Fixed, 95% CI)	1.75 [0.70, 4.39]
1.36 Analgesia: pudendal and perineal	3	971	Risk Ratio (M-H, Random, 95% CI)	2.26 [1.44, 3.55]
1.37 Analgesia: epidural	6	2011	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.96, 1.19]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.38 Analgesia: Trilene inh	1	252	Risk Ratio (M-H, Fixed, 95% CI)	1.85 [0.34, 9.90]
1.39 Analgesia: Trilene inh + local	1	252	Risk Ratio (M-H, Fixed, 95% CI)	18.47 [2.52, 135.56]

Analysis 1.1. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 1: Failed delivery with allocated instrument (primary)

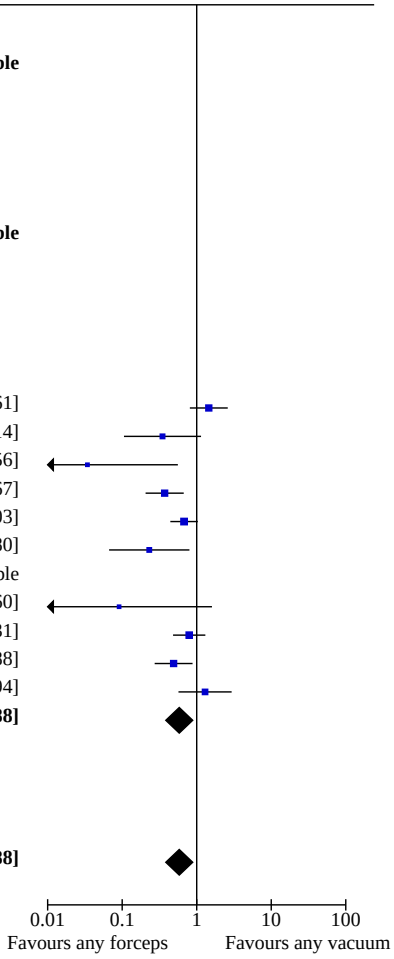
Study or Subgroup	Any forceps Events	Any forceps Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Risk Ratio M-H, Random, 95% CI
Bofill 1996a	25	305	18	319	13.6%	1.45 [0.81 , 2.61]
Dell 1985	3	45	14	73	7.4%	0.35 [0.11 , 1.14]
Fitzpatrick 2003	0	61	16	69	2.0%	0.03 [0.00 , 0.56]
Johanson 1989	13	132	35	132	13.5%	0.37 [0.21 , 0.67]
Johanson 1993	32	311	45	296	15.6%	0.68 [0.44 , 1.03]
Lasbrey 1964	3	131	12	121	7.0%	0.23 [0.07 , 0.80]
Pliego Perez 2000	0	70	0	70		Not estimable
Shekhar 2013	0	50	5	50	1.9%	0.09 [0.01 , 1.60]
Vacca 1983	23	152	29	152	14.7%	0.79 [0.48 , 1.31]
Weerasekera 2002	16	238	28	204	13.6%	0.49 [0.27 , 0.88]
Williams 1991	11	51	8	48	10.8%	1.29 [0.57 , 2.94]
Total (95% CI)		**1546**		**1534**	**100.0%**	**0.58 [0.39 , 0.88]**
Total events:	126		210			

Heterogeneity: Tau² = 0.24; Chi² = 25.48, df = 9 (P = 0.002); I² = 65%
Test for overall effect: Z = 2.55 (P = 0.01)
Test for subgroup differences: Not applicable



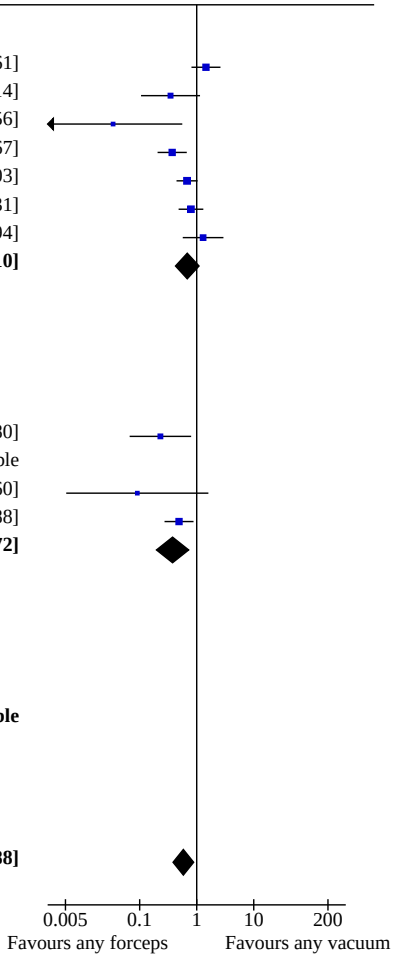
Analysis 1.2. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 2: Failed delivery with allocated instrument (subgroup by epidural)

Study or Subgroup	Any forceps Events	Any forceps Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Risk Ratio M-H, Random, 95% CI
1.2.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.2.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.2.3 Mixed or undefined						
Bofill 1996a	25	305	18	319	13.6%	1.45 [0.81 , 2.61]
Dell 1985	3	45	14	73	7.4%	0.35 [0.11 , 1.14]
Fitzpatrick 2003	0	61	16	69	2.0%	0.03 [0.00 , 0.56]
Johanson 1989	13	132	35	132	13.5%	0.37 [0.21 , 0.67]
Johanson 1993	32	311	45	296	15.6%	0.68 [0.44 , 1.03]
Lasbrey 1964	3	131	12	121	7.0%	0.23 [0.07 , 0.80]
Pliego Perez 2000	0	70	0	70		Not estimable
Shekhar 2013	0	50	5	50	1.9%	0.09 [0.01 , 1.60]
Vacca 1983	23	152	29	152	14.7%	0.79 [0.48 , 1.31]
Weerasekera 2002	16	238	28	204	13.6%	0.49 [0.27 , 0.88]
Williams 1991	11	51	8	48	10.8%	1.29 [0.57 , 2.94]
Subtotal (95% CI)		**1546**		**1534**	**100.0%**	**0.58 [0.39 , 0.88]**
Total events:	126		210			
Heterogeneity: Tau² = 0.24; Chi² = 25.48, df = 9 (P = 0.002); I² = 65%						
Test for overall effect: Z = 2.55 (P = 0.01)						
Total (95% CI)		**1546**		**1534**	**100.0%**	**0.58 [0.39 , 0.88]**
Total events:	126		210			
Heterogeneity: Tau² = 0.24; Chi² = 25.48, df = 9 (P = 0.002); I² = 65%						
Test for overall effect: Z = 2.55 (P = 0.01)						
Test for subgroup differences: Not applicable						



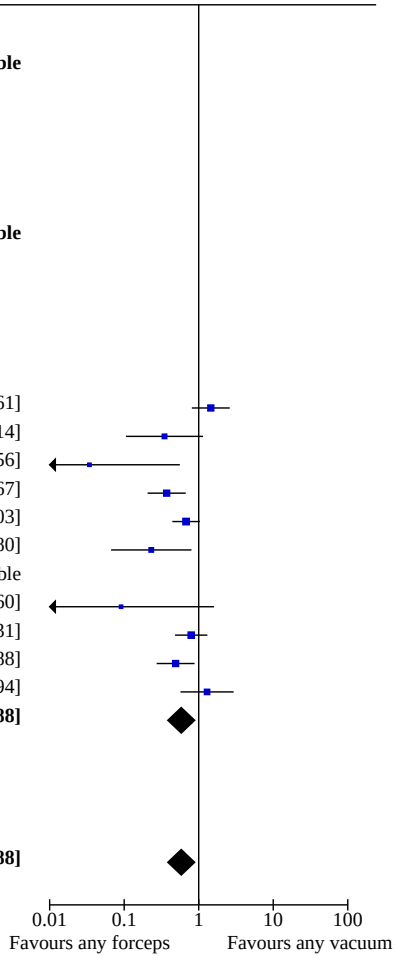
Analysis 1.3. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 3: Failed delivery with allocated instrument (subgroup by Country PMR)

Study or Subgroup	Any forceps Events	Any forceps Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Risk Ratio M-H, Random, 95% CI
1.3.1 Low PMR						
Bofill 1996a	25	305	18	319	13.6%	1.45 [0.81 , 2.61]
Dell 1985	3	45	14	73	7.4%	0.35 [0.11 , 1.14]
Fitzpatrick 2003	0	61	16	69	2.0%	0.03 [0.00 , 0.56]
Johanson 1989	13	132	35	132	13.5%	0.37 [0.21 , 0.67]
Johanson 1993	32	311	45	296	15.6%	0.68 [0.44 , 1.03]
Vacca 1983	23	152	29	152	14.7%	0.79 [0.48 , 1.31]
Williams 1991	11	51	8	48	10.8%	1.29 [0.57 , 2.94]
Subtotal (95% CI)		**1057**		**1089**	**77.5%**	**0.68 [0.42 , 1.10]**
Total events:	107		165			
Heterogeneity: Tau² = 0.24; Chi² = 19.11, df = 6 (P = 0.004); I² = 69%						
Test for overall effect: Z = 1.58 (P = 0.11)						
1.3.2 High PMR						
Lasbrey 1964	3	131	12	121	7.0%	0.23 [0.07 , 0.80]
Pliego Perez 2000	0	70	0	70		Not estimable
Shekhar 2013	0	50	5	50	1.9%	0.09 [0.01 , 1.60]
Weerasekera 2002	16	238	28	204	13.6%	0.49 [0.27 , 0.88]
Subtotal (95% CI)		**489**		**445**	**22.5%**	**0.38 [0.20 , 0.72]**
Total events:	19		45			
Heterogeneity: Tau² = 0.06; Chi² = 2.31, df = 2 (P = 0.31); I² = 13%						
Test for overall effect: Z = 2.94 (P = 0.003)						
1.3.3 Mixed or undefined						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)		**1546**		**1534**	**100.0%**	**0.58 [0.39 , 0.88]**
Total events:	126		210			
Heterogeneity: Tau² = 0.24; Chi² = 25.48, df = 9 (P = 0.002); I² = 65%						
Test for overall effect: Z = 2.55 (P = 0.01)						
Test for subgroup differences: Chi² = 2.09, df = 1 (P = 0.15), I² = 52.2%						



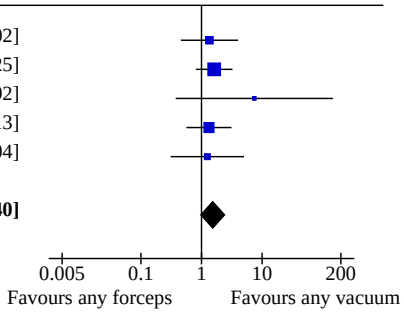
Analysis 1.4. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 4: Failed delivery with allocated instrument (subgroup by rotational or non-rotational delivery))

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.4.1 Non-rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.4.2 Rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.4.3 Mixed or undefined						
Bofill 1996a	25	305	18	319	13.6%	1.45 [0.81 , 2.61]
Dell 1985	3	45	14	73	7.4%	0.35 [0.11 , 1.14]
Fitzpatrick 2003	0	61	16	69	2.0%	0.03 [0.00 , 0.56]
Johanson 1989	13	132	35	132	13.5%	0.37 [0.21 , 0.67]
Johanson 1993	32	311	45	296	15.6%	0.68 [0.44 , 1.03]
Lasbrey 1964	3	131	12	121	7.0%	0.23 [0.07 , 0.80]
Pliego Perez 2000	0	70	0	70		Not estimable
Shekhar 2013	0	50	5	50	1.9%	0.09 [0.01 , 1.60]
Vacca 1983	23	152	29	152	14.7%	0.79 [0.48 , 1.31]
Weerasekera 2002	16	238	28	204	13.6%	0.49 [0.27 , 0.88]
Williams 1991	11	51	8	48	10.8%	1.29 [0.57 , 2.94]
Subtotal (95% CI)		**1546**		**1534**	**100.0%**	**0.58 [0.39 , 0.88]**
Total events:	126		210			
Heterogeneity: Tau² = 0.24; Chi² = 25.48, df = 9 (P = 0.002); I² = 65%						
Test for overall effect: Z = 2.55 (P = 0.01)						
Total (95% CI)		**1546**		**1534**	**100.0%**	**0.58 [0.39 , 0.88]**
Total events:	126		210			
Heterogeneity: Tau² = 0.24; Chi² = 25.48, df = 9 (P = 0.002); I² = 65%						
Test for overall effect: Z = 2.55 (P = 0.01)						
Test for subgroup differences: Not applicable						



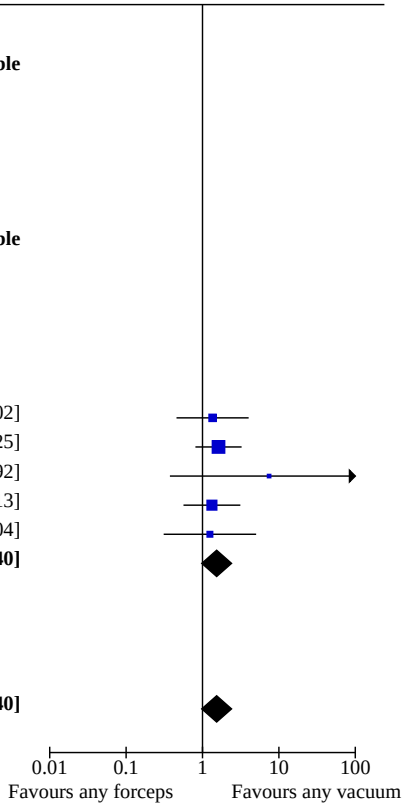
Analysis 1.5. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 5: Any maternal trauma (primary)

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Johanson 1989	126	132	124	132	17.9%	1.35 [0.46 , 4.02]
Johanson 1993	297	311	275	296	40.3%	1.62 [0.81 , 3.25]
Shekhar 2013	50	50	47	50	1.5%	7.44 [0.37 , 147.92]
Vacca 1983	142	152	139	152	29.0%	1.33 [0.56 , 3.13]
Williams 1991	36	40	36	41	11.3%	1.25 [0.31 , 5.04]
Total (95% CI)		**685**		**671**	**100.0%**	**1.53 [0.98 , 2.40]**
Total events:	651		621			
Heterogeneity: Chi² = 1.34, df = 4 (P = 0.86); I² = 0%						
Test for overall effect: Z = 1.87 (P = 0.06)						
Test for subgroup differences: Not applicable						



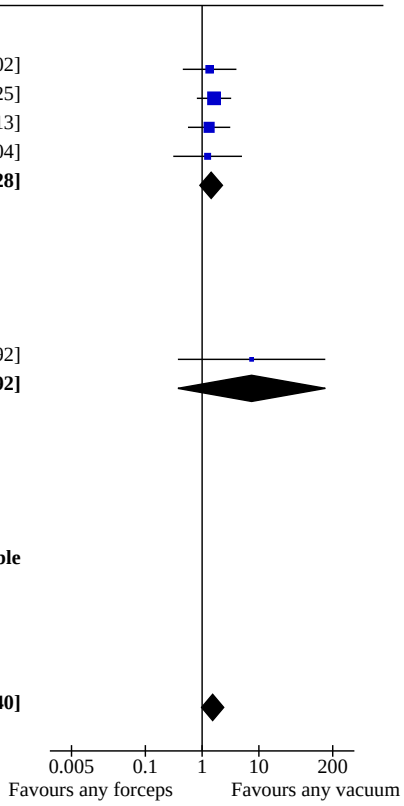
Analysis 1.6. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 6: Any maternal trauma (subgroup by epidural)

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
1.6.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.6.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.6.3 Mixed or undefined						
Johanson 1989	126	132	124	132	17.9%	1.35 [0.46 , 4.02]
Johanson 1993	297	311	275	296	40.3%	1.62 [0.81 , 3.25]
Shekhar 2013	50	50	47	50	1.5%	7.44 [0.37 , 147.92]
Vacca 1983	142	152	139	152	29.0%	1.33 [0.56 , 3.13]
Williams 1991	36	40	36	41	11.3%	1.25 [0.31 , 5.04]
Subtotal (95% CI)		**685**		**671**	**100.0%**	**1.53 [0.98 , 2.40]**
Total events:	651		621			
Heterogeneity: Chi² = 1.34, df = 4 (P = 0.86); I² = 0%						
Test for overall effect: Z = 1.87 (P = 0.06)						
Total (95% CI)		**685**		**671**	**100.0%**	**1.53 [0.98 , 2.40]**
Total events:	651		621			
Heterogeneity: Chi² = 1.34, df = 4 (P = 0.86); I² = 0%						
Test for overall effect: Z = 1.87 (P = 0.06)						
Test for subgroup differences: Not applicable						



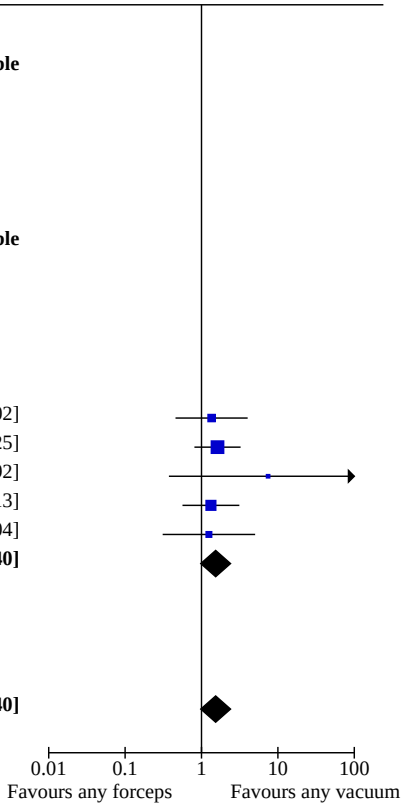
Analysis 1.7. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 7: Any maternal trauma (subgroup by Country PMR)

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
1.7.1 Low PMR						
Johanson 1989	126	132	124	132	17.9%	1.35 [0.46 , 4.02]
Johanson 1993	297	311	275	296	40.3%	1.62 [0.81 , 3.25]
Vacca 1983	142	152	139	152	29.0%	1.33 [0.56 , 3.13]
Williams 1991	36	40	36	41	11.3%	1.25 [0.31 , 5.04]
Subtotal (95% CI)		**635**		**621**	**98.5%**	**1.44 [0.91 , 2.28]**
Total events:	601		574			
Heterogeneity: Chi² = 0.20, df = 3 (P = 0.98); I² = 0%						
Test for overall effect: Z = 1.58 (P = 0.12)						
1.7.2 High PMR						
Shekhar 2013	50	50	47	50	1.5%	7.44 [0.37 , 147.92]
Subtotal (95% CI)		**50**		**50**	**1.5%**	**7.44 [0.37 , 147.92]**
Total events:	50		47			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.32 (P = 0.19)						
1.7.3 Mixed or undefined						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)		**685**		**671**	**100.0%**	**1.53 [0.98 , 2.40]**
Total events:	651		621			
Heterogeneity: Chi² = 1.34, df = 4 (P = 0.86); I² = 0%						
Test for overall effect: Z = 1.87 (P = 0.06)						
Test for subgroup differences: Chi² = 1.13, df = 1 (P = 0.29), I² = 11.5%						



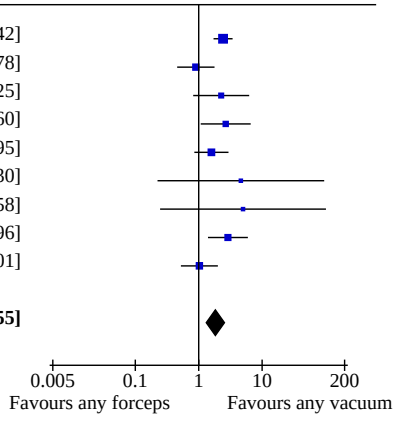
Analysis 1.8. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 8: Any maternal trauma (subgroup by rotational or non-rotational delivery)

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
1.8.1 Non-rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.8.2 Rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
1.8.3 Mixed or undefined						
Johanson 1989	126	132	124	132	17.9%	1.35 [0.46 , 4.02]
Johanson 1993	297	311	275	296	40.3%	1.62 [0.81 , 3.25]
Shekhar 2013	50	50	47	50	1.5%	7.44 [0.37 , 147.92]
Vacca 1983	142	152	139	152	29.0%	1.33 [0.56 , 3.13]
Williams 1991	36	40	36	41	11.3%	1.25 [0.31 , 5.04]
Subtotal (95% CI)		**685**		**671**	**100.0%**	**1.53 [0.98 , 2.40]**
Total events:	651		621			
Heterogeneity: Chi² = 1.34, df = 4 (P = 0.86); I² = 0%						
Test for overall effect: Z = 1.87 (P = 0.06)						
Total (95% CI)		**685**		**671**	**100.0%**	**1.53 [0.98 , 2.40]**
Total events:	651		621			
Heterogeneity: Chi² = 1.34, df = 4 (P = 0.86); I² = 0%						
Test for overall effect: Z = 1.87 (P = 0.06)						
Test for subgroup differences: Not applicable						



Analysis 1.9. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 9: Third- or fourth-degree perineal tear (with or without episiotomy)

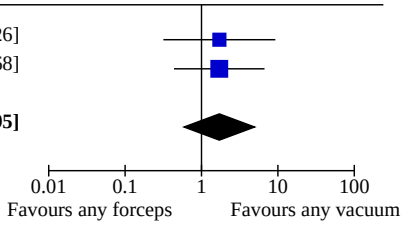
Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Bofill 1996a	90	315	38	322	24.4%	2.42 [1.71 , 3.42]
Dell 1985	10	45	18	73	13.8%	0.90 [0.46 , 1.78]
Fitzpatrick 2003	10	61	5	69	8.0%	2.26 [0.82 , 6.25]
Johanson 1989	16	132	6	132	9.5%	2.67 [1.08 , 6.60]
Johanson 1993	25	311	15	296	15.3%	1.59 [0.85 , 2.95]
Lasbrey 1964	2	131	0	121	1.1%	4.62 [0.22 , 95.30]
Shekhar 2013	2	50	0	50	1.2%	5.00 [0.25 , 101.58]
Vacca 1983	26	152	9	152	12.8%	2.89 [1.40 , 5.96]
Williams 1991	12	40	12	41	14.0%	1.02 [0.52 , 2.01]
Total (95% CI)		**1237**		**1256**	**100.0%**	**1.83 [1.32 , 2.55]**
Total events:	193		103			
Heterogeneity: Tau² = 0.08; Chi² = 12.88, df = 8 (P = 0.12); I² = 38%						
Test for overall effect: Z = 3.60 (P = 0.0003)						
Test for subgroup differences: Not applicable						



Analysis 1.10. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 10: Postpartum haemorrhage (>/= 500 mL)

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Weerasekera 2002	4	238	2	204	42.1%	1.71 [0.32 , 9.26]
Williams 1991	5	40	3	41	57.9%	1.71 [0.44 , 6.68]
Total (95% CI)		**278**		**245**	**100.0%**	**1.71 [0.59 , 4.95]**
Total events:	9		5			

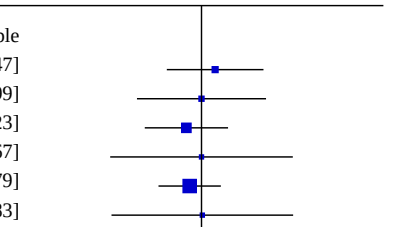
Heterogeneity: Chi² = 0.00, df = 1 (P = 1.00); I² = 0%
Test for overall effect: Z = 0.99 (P = 0.32)
Test for subgroup differences: Not applicable



Analysis 1.11. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 11: Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	0	45	0	73		Not estimable
Fitzpatrick 2003	4	61	3	69	12.3%	1.51 [0.35 , 6.47]
Johanson 1989	2	132	2	132	8.7%	1.00 [0.14 , 6.99]
Johanson 1993	4	311	6	296	26.8%	0.63 [0.18 , 2.23]
Pliego Perez 2000	1	70	1	70	4.4%	1.00 [0.06 , 15.67]
Vacca 1983	7	152	10	152	43.6%	0.70 [0.27 , 1.79]
Williams 1991	1	40	1	41	4.3%	1.02 [0.07 , 15.83]
Total (95% CI)		**811**		**833**	**100.0%**	**0.83 [0.46 , 1.51]**
Total events:	19		23			

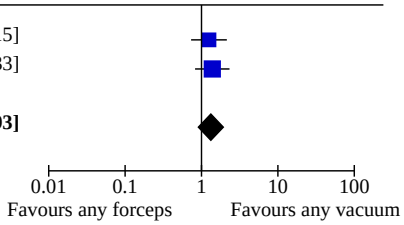
Heterogeneity: Chi² = 1.02, df = 5 (P = 0.96); I² = 0%
Test for overall effect: Z = 0.60 (P = 0.55)
Test for subgroup differences: Not applicable



Analysis 1.12. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 12: Low Umbilical artery pH (<7.2 or as defined by trial authors)

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Johanson 1989	21	83	20	99	44.7%	1.25 [0.73 , 2.15]
Johanson 1993	32	311	22	296	55.3%	1.38 [0.82 , 2.33]
Total (95% CI)		**394**		**395**	**100.0%**	**1.33 [0.91 , 1.93]**
Total events:	53		42			

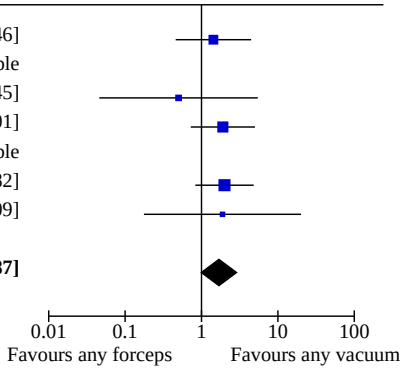
Heterogeneity: Chi² = 0.07, df = 1 (P = 0.79); I² = 0%
Test for overall effect: Z = 1.47 (P = 0.14)
Test for subgroup differences: Not applicable



Analysis 1.13. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 13: Caesarean section

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bofill 1996a	7	315	5	322	23.4%	1.43 [0.46 , 4.46]
Dell 1985	0	45	0	73		Not estimable
Johanson 1989	1	132	2	132	9.5%	0.50 [0.05 , 5.45]
Johanson 1993	12	311	6	296	29.1%	1.90 [0.72 , 5.01]
Shekhar 2013	0	50	0	50		Not estimable
Vacca 1983	14	152	7	152	33.1%	2.00 [0.83 , 4.82]
Williams 1991	2	51	1	48	4.9%	1.88 [0.18 , 20.09]
Total (95% CI)		**1056**		**1073**	**100.0%**	**1.69 [1.00 , 2.87]**
Total events:	36		21			

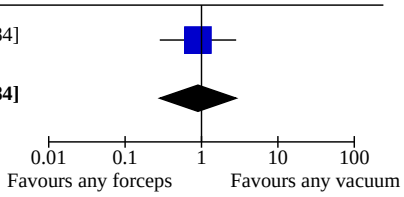
Heterogeneity: Chi² = 1.29, df = 4 (P = 0.86); I² = 0%
Test for overall effect: Z = 1.95 (P = 0.05)
Test for subgroup differences: Not applicable



Analysis 1.14. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 14: Maternal satisfaction: 'Disappointed or lack of care'

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Johanson 1993	5	89	6	96	100.0%	0.90 [0.28 , 2.84]
Total (95% CI)		**89**		**96**	**100.0%**	**0.90 [0.28 , 2.84]**
Total events:	5		6			

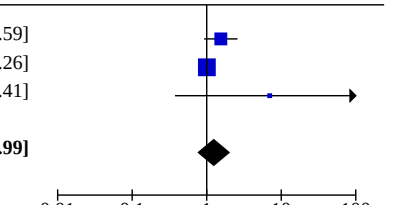
Heterogeneity: Not applicable
Test for overall effect: Z = 0.18 (P = 0.86)
Test for subgroup differences: Not applicable



Analysis 1.15. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 15: Pain as defined by trial authors

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Johanson 1989	28	102	19	107	37.9%	1.55 [0.92 , 2.59]
Johanson 1993	72	137	68	130	59.6%	1.00 [0.80 , 1.26]
Vacca 1983	3	33	0	33	2.5%	7.00 [0.38 , 130.41]
Total (95% CI)		**272**		**270**	**100.0%**	**1.24 [0.77 , 1.99]**
Total events:	103		87			

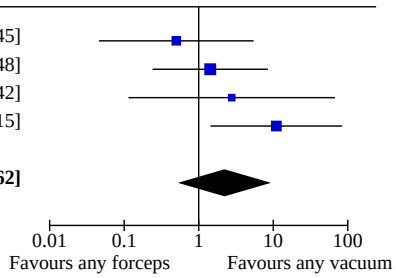
Heterogeneity: Tau² = 0.08; Chi² = 4.08, df = 2 (P = 0.13); I² = 51%
Test for overall effect: Z = 0.90 (P = 0.37)
Test for subgroup differences: Not applicable



Analysis 1.16. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 16: General anaesthesia

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Johanson 1989	1	132	2	132	23.0%	0.50 [0.05 , 5.45]
Johanson 1993	3	311	2	296	33.6%	1.43 [0.24 , 8.48]
Lasbrey 1964	1	131	0	121	14.8%	2.77 [0.11 , 67.42]
Vacca 1983	11	152	1	152	28.6%	11.00 [1.44 , 84.15]
Total (95% CI)		**726**		**701**	**100.0%**	**2.22 [0.57 , 8.62]**
Total events:	16		5			

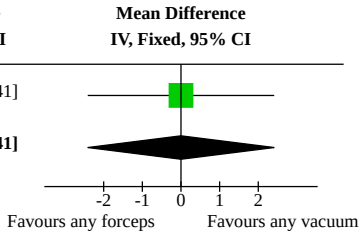
Heterogeneity: Tau² = 0.60; Chi² = 4.36, df = 3 (P = 0.23); I² = 31%
Test for overall effect: Z = 1.15 (P = 0.25)
Test for subgroup differences: Not applicable



Analysis 1.17. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 17: Time from randomisation to delivery (mins)

Study or Subgroup	Any forceps Mean	SD	Total	Any vacuum cup Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Johanson 1989	17	10	132	17	10	132	100.0%	0.00 [-2.41 , 2.41]
Total (95% CI)			**132**			**132**	**100.0%**	**0.00 [-2.41 , 2.41]**

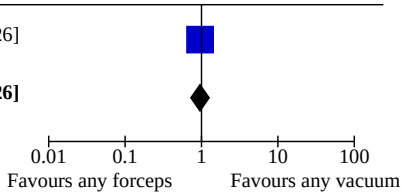
Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)
Test for subgroup differences: Not applicable



Analysis 1.18. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 18: Urinary incontinence

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Johanson 1993	53	115	54	112	100.0%	0.96 [0.73 , 1.26]
Total (95% CI)		**115**		**112**	**100.0%**	**0.96 [0.73 , 1.26]**
Total events:	53		54			

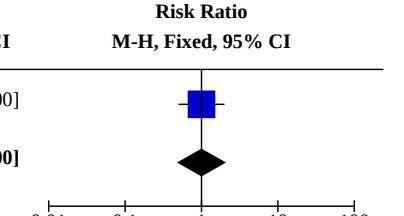
Heterogeneity: Not applicable
Test for overall effect: Z = 0.32 (P = 0.75)
Test for subgroup differences: Not applicable



Analysis 1.19. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 19: Flatus incontinence

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Johanson 1993	14	113	14	113	100.0%	1.00 [0.50 , 2.00]
Total (95% CI)		**113**		**113**	**100.0%**	**1.00 [0.50 , 2.00]**
Total events:	14		14			

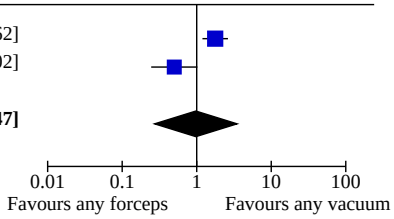
Heterogeneity: Not applicable
Test for overall effect: Z = 0.00 (P = 1.00)
Test for subgroup differences: Not applicable



Analysis 1.20. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 20: Faecal incontinence

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Fitzpatrick 2003	36	61	23	69	52.7%	1.77 [1.19 , 2.62]
Johanson 1993	10	113	20	113	47.3%	0.50 [0.25 , 1.02]
Total (95% CI)		**174**		**182**	**100.0%**	**0.97 [0.27 , 3.47]**
Total events:	46		43			

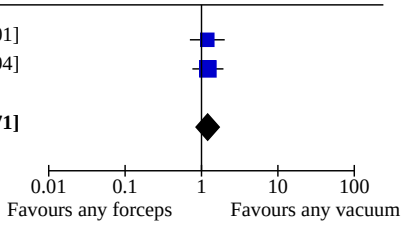
Heterogeneity: Tau² = 0.76; Chi² = 9.79, df = 1 (P = 0.002); I² = 90%
Test for overall effect: Z = 0.04 (P = 0.97)
Test for subgroup differences: Not applicable



Analysis 1.21. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 21: Perineal pain

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Fitzpatrick 2003	20	61	19	69	43.6%	1.19 [0.70 , 2.01]
Johanson 1993	27	89	24	96	56.4%	1.21 [0.76 , 1.94]
Total (95% CI)		**150**		**165**	**100.0%**	**1.20 [0.85 , 1.71]**
Total events:	47		43			

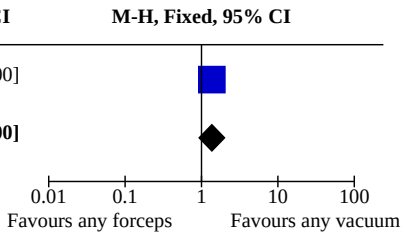
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.96); I² = 0%
Test for overall effect: Z = 1.04 (P = 0.30)
Test for subgroup differences: Not applicable



Analysis 1.22. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 22: Pain during sexual intercourse

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Johanson 1993	38	89	30	96	100.0%	1.37 [0.93 , 2.00]
Total (95% CI)		**89**		**96**	**100.0%**	**1.37 [0.93 , 2.00]**
Total events:	38		30			

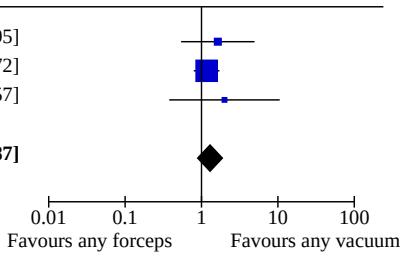
Heterogeneity: Not applicable
Test for overall effect: Z = 1.60 (P = 0.11)
Test for subgroup differences: Not applicable



Analysis 1.23. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 23: Scalp injury

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bofill 1996a	8	315	5	322	15.8%	1.64 [0.54 , 4.95]
Dell 1985	23	45	32	73	77.8%	1.17 [0.79 , 1.72]
Pliego Perez 2000	4	70	2	70	6.4%	2.00 [0.38 , 10.57]
Total (95% CI)		**430**		**465**	**100.0%**	**1.29 [0.89 , 1.87]**
Total events:	35		39			

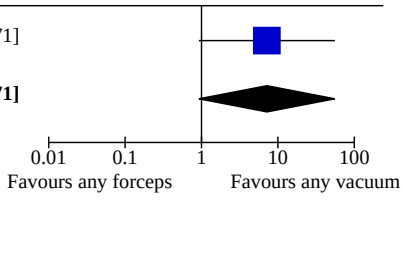
Heterogeneity: Chi² = 0.71, df = 2 (P = 0.70); I² = 0%
Test for overall effect: Z = 1.36 (P = 0.17)
Test for subgroup differences: Not applicable



Analysis 1.24. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 24: Facial injury

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Williams 1991	7	40	1	41	100.0%	7.17 [0.92 , 55.71]
Total (95% CI)		**40**		**41**	**100.0%**	**7.17 [0.92 , 55.71]**
Total events:	7		1			

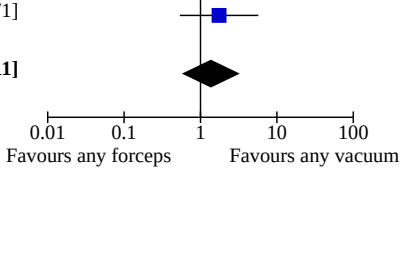
Heterogeneity: Not applicable
Test for overall effect: Z = 1.88 (P = 0.06)
Test for subgroup differences: Not applicable



Analysis 1.25. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 25: Intracranial injury

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Johanson 1993	5	38	5	40	54.9%	1.05 [0.33 , 3.35]
Pliego Perez 2000	7	70	4	70	45.1%	1.75 [0.54 , 5.71]
Total (95% CI)		**108**		**110**	**100.0%**	**1.37 [0.60 , 3.11]**
Total events:	12		9			

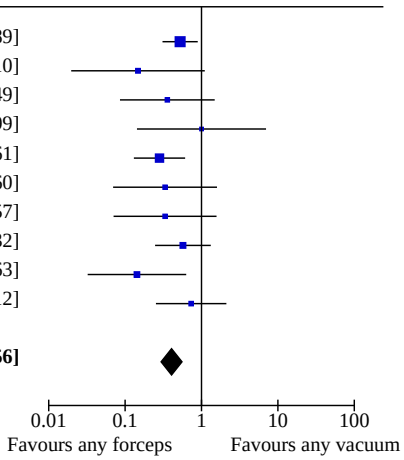
Heterogeneity: Chi² = 0.36, df = 1 (P = 0.55); I² = 0%
Test for overall effect: Z = 0.75 (P = 0.46)
Test for subgroup differences: Not applicable



Analysis 1.26. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 26: Cephalhematoma

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bofill 1996a	19	315	37	322	28.9%	0.52 [0.31 , 0.89]
Dell 1985	1	45	11	73	6.6%	0.15 [0.02 , 1.10]
Fall 1986	2	16	7	20	4.9%	0.36 [0.09 , 1.49]
Johanson 1989	2	132	2	132	1.6%	1.00 [0.14 , 6.99]
Johanson 1993	8	311	27	296	21.8%	0.28 [0.13 , 0.61]
Pliego Perez 2000	2	70	6	70	4.7%	0.33 [0.07 , 1.60]
Shekhar 2013	2	50	6	50	4.7%	0.33 [0.07 , 1.57]
Vacca 1983	8	152	14	152	11.0%	0.57 [0.25 , 1.32]
Weerasekera 2002	2	238	12	204	10.2%	0.14 [0.03 , 0.63]
Williams 1991	5	40	7	41	5.5%	0.73 [0.25 , 2.12]
Total (95% CI)		**1369**		**1360**	**100.0%**	**0.41 [0.30 , 0.56]**
Total events:	51		129			

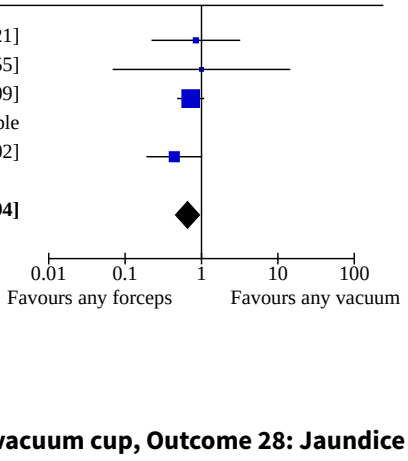
Heterogeneity: Chi² = 7.43, df = 9 (P = 0.59); I² = 0%
Test for overall effect: Z = 5.64 (P < 0.00001)
Test for subgroup differences: Not applicable



Analysis 1.27. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 27: Retinal haemorrhage

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Fall 1986	3	16	4	18	7.9%	0.84 [0.22 , 3.21]
Johanson 1989	1	15	1	15	2.1%	1.00 [0.07 , 14.55]
Johanson 1993	23	59	27	50	61.1%	0.72 [0.48 , 1.09]
Pliego Perez 2000	0	70	0	70		Not estimable
Williams 1991	6	36	14	37	28.9%	0.44 [0.19 , 1.02]
Total (95% CI)		**196**		**190**	**100.0%**	**0.66 [0.46 , 0.94]**
Total events:	33		46			

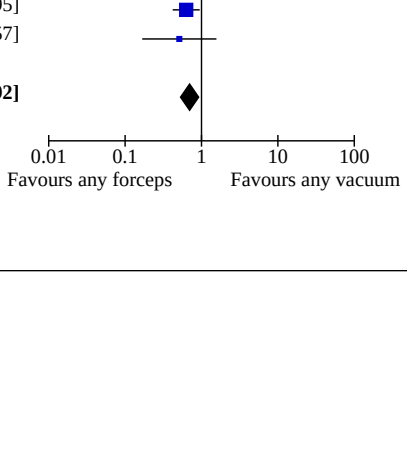
Heterogeneity: Chi² = 1.31, df = 3 (P = 0.73); I² = 0%
Test for overall effect: Z = 2.32 (P = 0.02)
Test for subgroup differences: Not applicable



Analysis 1.28. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 28: Jaundice

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bofill 1996a	18	315	24	322	22.1%	0.77 [0.42 , 1.38]
Johanson 1989	17	111	13	99	12.8%	1.17 [0.60 , 2.28]
Johanson 1993	5	137	11	131	10.4%	0.43 [0.16 , 1.22]
Shekhar 2013	3	50	5	50	4.6%	0.60 [0.15 , 2.38]
Vacca 1983	29	152	46	152	42.7%	0.63 [0.42 , 0.95]
Williams 1991	4	40	8	41	7.3%	0.51 [0.17 , 1.57]
Total (95% CI)		**805**		**795**	**100.0%**	**0.70 [0.53 , 0.92]**
Total events:	76		107			

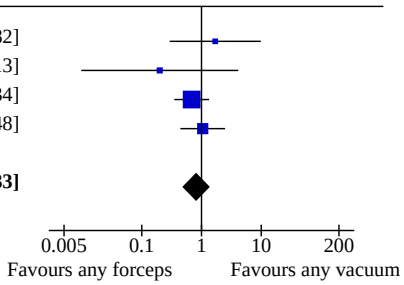
Heterogeneity: Chi² = 3.75, df = 5 (P = 0.59); I² = 0%
Test for overall effect: Z = 2.59 (P = 0.010)
Test for subgroup differences: Not applicable



Analysis 1.29. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 29: Admission to neonatal intensive care unit

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Fitzpatrick 2003	3	61	2	69	5.7%	1.70 [0.29 , 9.82]
Johanson 1989	0	132	2	132	7.6%	0.20 [0.01 , 4.13]
Vacca 1983	13	152	19	152	57.5%	0.68 [0.35 , 1.34]
Weerasekera 2002	11	238	9	204	29.3%	1.05 [0.44 , 2.48]
Total (95% CI)		**583**		**557**	**100.0%**	**0.81 [0.50 , 1.33]**
Total events:	27		32			

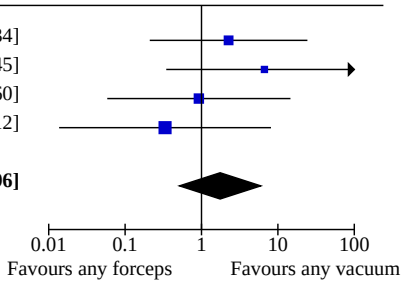
Heterogeneity: Chi² = 2.09, df = 3 (P = 0.55); I² = 0%
Test for overall effect: Z = 0.83 (P = 0.40)
Test for subgroup differences: Not applicable



Analysis 1.30. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 30: Neonatal encephalopathy

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Fitzpatrick 2003	2	61	1	69	23.5%	2.26 [0.21 , 24.34]
Johanson 1993	3	311	0	296	12.8%	6.66 [0.35 , 128.45]
Lasbrey 1964	1	131	1	121	26.1%	0.92 [0.06 , 14.60]
Vacca 1983	0	152	1	152	37.6%	0.33 [0.01 , 8.12]
Total (95% CI)		**655**		**638**	**100.0%**	**1.75 [0.52 , 5.96]**
Total events:	6		3			

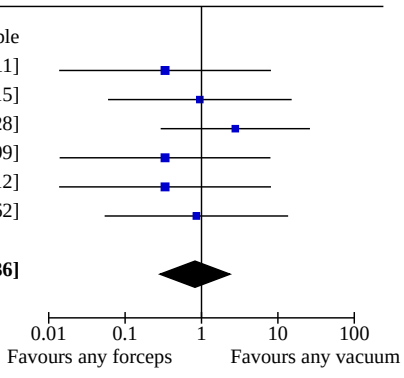
Heterogeneity: Chi² = 2.07, df = 3 (P = 0.56); I² = 0%
Test for overall effect: Z = 0.90 (P = 0.37)
Test for subgroup differences: Not applicable



Analysis 1.31. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 31: Death

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	0	45	0	73		Not estimable
Johanson 1989	0	132	1	132	19.6%	0.33 [0.01 , 8.11]
Johanson 1993	1	311	1	296	13.4%	0.95 [0.06 , 15.15]
Lasbrey 1964	3	131	1	121	13.6%	2.77 [0.29 , 26.28]
Shekhar 2013	0	50	1	50	19.6%	0.33 [0.01 , 7.99]
Vacca 1983	0	152	1	152	19.6%	0.33 [0.01 , 8.12]
Weerasekera 2002	1	238	1	204	14.1%	0.86 [0.05 , 13.62]
Total (95% CI)		**1059**		**1028**	**100.0%**	**0.82 [0.29 , 2.36]**
Total events:	5		6			

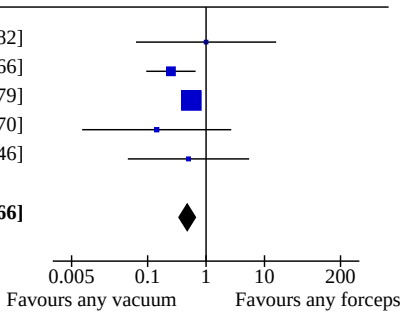
Heterogeneity: Chi² = 2.06, df = 5 (P = 0.84); I² = 0%
Test for overall effect: Z = 0.37 (P = 0.71)
Test for subgroup differences: Not applicable



Analysis 1.32. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 32: Analgesia: none

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Johanson 1989	1	132	1	132	1.2%	1.00 [0.06 , 15.82]
Johanson 1993	5	311	19	296	23.1%	0.25 [0.09 , 0.66]
Lasbrey 1964	34	131	56	121	69.2%	0.56 [0.40 , 0.79]
Shekhar 2013	0	50	3	50	4.2%	0.14 [0.01 , 2.70]
Vacca 1983	1	152	2	152	2.4%	0.50 [0.05 , 5.46]
Total (95% CI)		**776**		**751**	**100.0%**	**0.48 [0.34 , 0.66]**
Total events:	41		81			

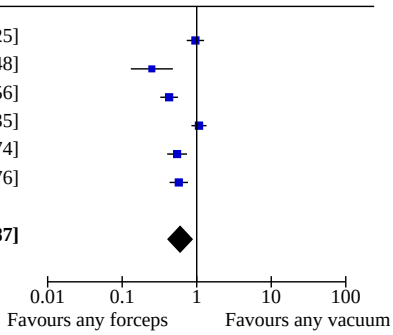
Heterogeneity: Chi² = 3.46, df = 4 (P = 0.48); I² = 0%
Test for overall effect: Z = 4.50 (P < 0.00001)
Test for subgroup differences: Not applicable



Analysis 1.33. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 33: Analgesia: perineal infiltration

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Bofill 1996a	78	315	83	322	17.6%	0.96 [0.74 , 1.25]
Johanson 1989	10	132	40	132	12.2%	0.25 [0.13 , 0.48]
Johanson 1993	56	311	125	296	17.6%	0.43 [0.32 , 0.56]
Lasbrey 1964	72	131	62	121	18.0%	1.07 [0.85 , 1.35]
Shekhar 2013	24	50	44	50	17.1%	0.55 [0.40 , 0.74]
Vacca 1983	46	152	80	152	17.4%	0.57 [0.43 , 0.76]
Total (95% CI)		**1091**		**1073**	**100.0%**	**0.60 [0.41 , 0.87]**
Total events:	286		434			

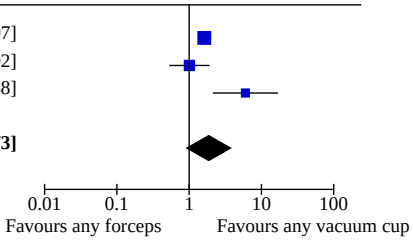
Heterogeneity: Tau² = 0.18; Chi² = 45.74, df = 5 (P < 0.00001); I² = 89%
Test for overall effect: Z = 2.71 (P = 0.007)
Test for subgroup differences: Not applicable



Analysis 1.34. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 34: Analgesia: pudendal

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Bofill 1996a	160	315	101	322	44.4%	1.62 [1.33 , 1.97]
Johanson 1993	18	311	17	296	32.9%	1.01 [0.53 , 1.92]
Vacca 1983	24	152	4	152	22.7%	6.00 [2.13 , 16.88]
Total (95% CI)		**778**		**770**	**100.0%**	**1.86 [0.93 , 3.73]**
Total events:	202		122			

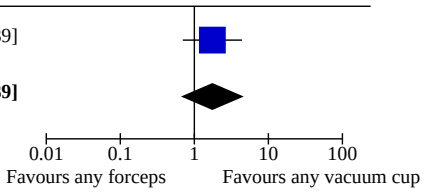
Heterogeneity: Tau² = 0.27; Chi² = 8.36, df = 2 (P = 0.02); I² = 76%
Test for overall effect: Z = 1.76 (P = 0.08)
Test for subgroup differences: Not applicable



Analysis 1.35. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 35: Analgesia: Saddle block

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bofill 1996a	12	315	7	322	100.0%	1.75 [0.70 , 4.39]
Total (95% CI)		**315**		**322**	**100.0%**	**1.75 [0.70 , 4.39]**
Total events:	12		7			

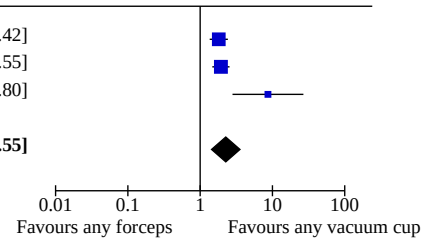
Heterogeneity: Not applicable
Test for overall effect: Z = 1.20 (P = 0.23)
Test for subgroup differences: Not applicable



Analysis 1.36. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 36: Analgesia: pudendal and perineal

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Johanson 1989	76	132	42	132	43.5%	1.81 [1.35 , 2.42]
Johanson 1993	116	311	57	296	44.3%	1.94 [1.47 , 2.55]
Shekhar 2013	26	50	3	50	12.3%	8.67 [2.80 , 26.80]
Total (95% CI)		**493**		**478**	**100.0%**	**2.26 [1.44 , 3.55]**
Total events:	218		102			

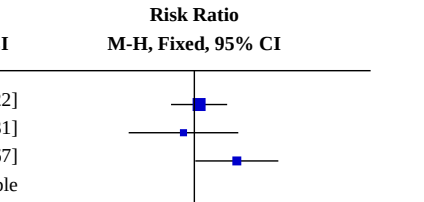
Heterogeneity: Tau² = 0.10; Chi² = 7.29, df = 2 (P = 0.03); I² = 73%
Test for overall effect: Z = 3.54 (P = 0.0004)
Test for subgroup differences: Not applicable



Analysis 1.37. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 37: Analgesia: epidural

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Bofill 1996a	145	315	144	322	38.8%	1.03 [0.87 , 1.22]
Johanson 1989	44	132	47	132	12.8%	0.94 [0.67 , 1.31]
Johanson 1993	102	311	75	296	20.9%	1.29 [1.01 , 1.67]
Shekhar 2013	0	50	0	50		Not estimable
Vacca 1983	69	152	64	152	17.4%	1.08 [0.84 , 1.39]
Williams 1991	36	51	36	48	10.1%	0.94 [0.74 , 1.20]
Total (95% CI)		**1011**		**1000**	**100.0%**	**1.07 [0.96 , 1.19]**
Total events:	396		366			

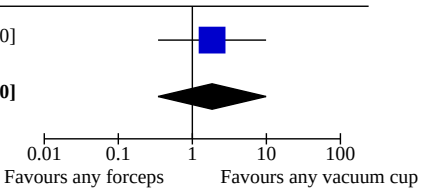
Heterogeneity: Chi² = 4.13, df = 4 (P = 0.39); I² = 3%
Test for overall effect: Z = 1.27 (P = 0.20)
Test for subgroup differences: Not applicable



Analysis 1.38. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 38: Analgesia: Trilene inh

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Lasbrey 1964	4	131	2	121	100.0%	1.85 [0.34 , 9.90]
Total (95% CI)		**131**		**121**	**100.0%**	**1.85 [0.34 , 9.90]**
Total events:	4		2			

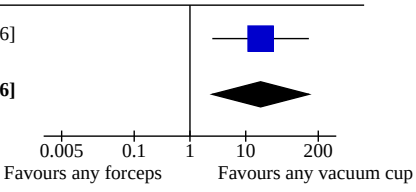
Heterogeneity: Not applicable
Test for overall effect: Z = 0.72 (P = 0.47)
Test for subgroup differences: Not applicable



Analysis 1.39. Comparison 1: Any type of forceps versus any type of vacuum cup, Outcome 39: Analgesia: Trilene inh + local

Study or Subgroup	Any forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Lasbrey 1964	20	131	1	121	100.0%	18.47 [2.52 , 135.56]
Total (95% CI)		**131**		**121**	**100.0%**	**18.47 [2.52 , 135.56]**
Total events:	20		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 2.87 (P = 0.004)
Test for subgroup differences: Not applicable



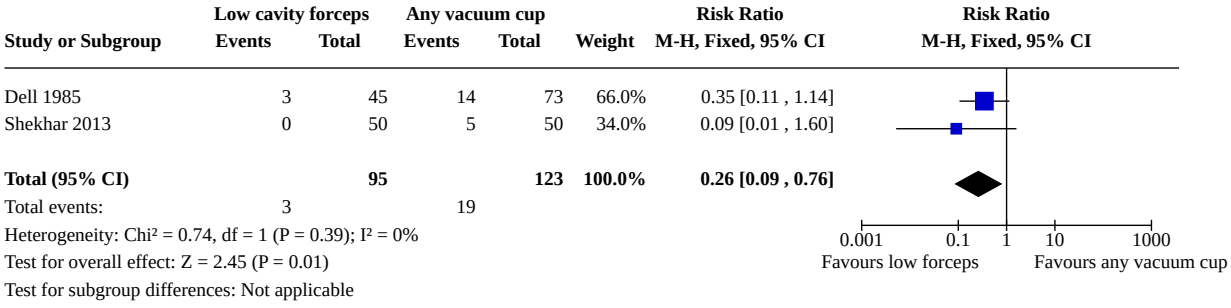
Comparison 2. Low cavity forceps versus any vacuum cup

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Failed delivery with allocated instrument (primary)	2	218	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.09, 0.76]
2.2 Failed delivery with allocated instrument (subgroup by epidural)	2	218	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.09, 0.76]
2.2.1 Epidural	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.2.2 No epidural	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.2.3 Mixed or undefined	2	218	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.09, 0.76]
2.3 Failed delivery by allocated instrument (subgroup by Country PMR)	2	218	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.09, 0.76]
2.3.1 Low PMR	1	118	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.11, 1.14]
2.3.2 High PMR	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.09 [0.01, 1.60]
2.3.3 Mixed or undefined PMR	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.4 Failed delivery by allocated instrument (subgroup by rotational or non-rotational delivery)	2	218	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.09, 0.76]
2.4.1 Non-rotational delivery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.4.2 Rotational delivery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
2.4.3 Mixed or undefined	2	218	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.09, 0.76]
2.5 Any maternal trauma (primary)	1	100	Odds Ratio (M-H, Fixed, 95% CI)	7.44 [0.37, 147.92]
2.6 Any maternal trauma (subgroup by epidural)	1	100	Odds Ratio (M-H, Fixed, 95% CI)	7.44 [0.37, 147.92]
2.6.1 Epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.6.2 No epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.6.3 Mixed or undefined	1	100	Odds Ratio (M-H, Fixed, 95% CI)	7.44 [0.37, 147.92]
2.7 Any maternal trauma (subgroup by Country PMR)	1	100	Odds Ratio (M-H, Fixed, 95% CI)	7.44 [0.37, 147.92]
2.7.1 Low PMR	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.7.2 High PMR	1	100	Odds Ratio (M-H, Fixed, 95% CI)	7.44 [0.37, 147.92]
2.7.3 Mixed or undefined	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.8 Any maternal trauma (subgroup by rotational or non-rotational delivery)	1	100	Odds Ratio (M-H, Fixed, 95% CI)	7.44 [0.37, 147.92]
2.8.1 Non-rotational	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.8.2 Rotational	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
2.8.3 Mixed or undefined	1	100	Odds Ratio (M-H, Fixed, 95% CI)	7.44 [0.37, 147.92]
2.9 Third- or fourth-degree perineal tear (with or without episiotomy)	2	218	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.55, 2.00]
2.10 Scalp injury	1	118	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.79, 1.72]
2.11 Cephalhematoma	2	218	Risk Ratio (M-H, Fixed, 95% CI)	0.22 [0.07, 0.77]
2.12 Jaundice	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.60 [0.15, 2.38]
2.13 Anaemia	1	118	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.02, 12.89]
2.14 Death	2	218	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 7.99]

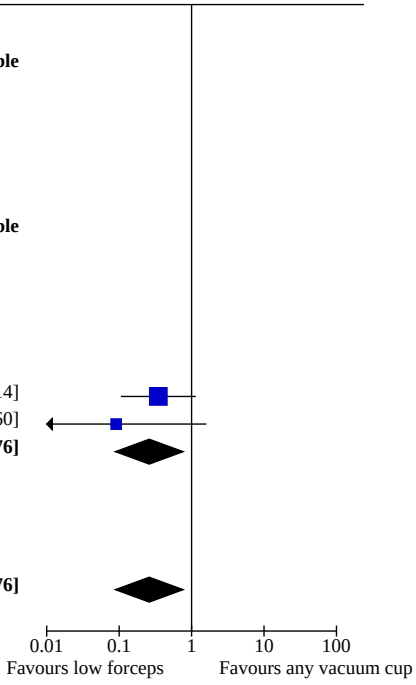
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.15 Analgesia: none	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.14 [0.01, 2.70]
2.16 Analgesia: perineal infiltration only	1	100	Risk Ratio (M-H, Fixed, 95% CI)	1.83 [1.35, 2.49]
2.17 Analgesia: perineal infiltration + pudendal	1	100	Risk Ratio (M-H, Fixed, 95% CI)	8.67 [2.80, 26.80]

Analysis 2.1. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 1: Failed delivery with allocated instrument (primary)



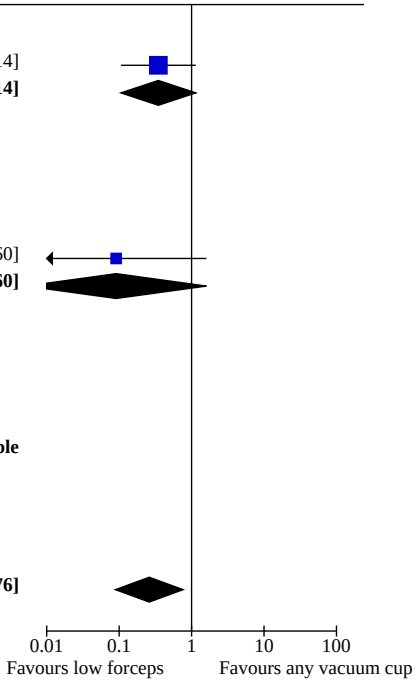
Analysis 2.2. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 2: Failed delivery with allocated instrument (subgroup by epidural)

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.2.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.2.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.2.3 Mixed or undefined						
Dell 1985	3	45	14	73	66.0%	0.35 [0.11 , 1.14]
Shekhar 2013	0	50	5	50	34.0%	0.09 [0.01 , 1.60]
Subtotal (95% CI)		**95**		**123**	**100.0%**	**0.26 [0.09 , 0.76]**
Total events:	3		19			
Heterogeneity: Chi² = 0.74, df = 1 (P = 0.39); I² = 0%						
Test for overall effect: Z = 2.45 (P = 0.01)						
Total (95% CI)		**95**		**123**	**100.0%**	**0.26 [0.09 , 0.76]**
Total events:	3		19			
Heterogeneity: Chi² = 0.74, df = 1 (P = 0.39); I² = 0%						
Test for overall effect: Z = 2.45 (P = 0.01)						
Test for subgroup differences: Not applicable						



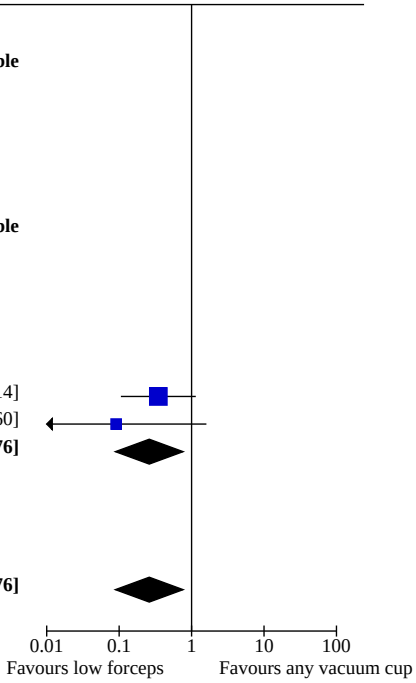
Analysis 2.3. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 3: Failed delivery by allocated instrument (subgroup by Country PMR)

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.3.1 Low PMR						
Dell 1985	3	45	14	73	66.0%	0.35 [0.11 , 1.14]
Subtotal (95% CI)		**45**		**73**	**66.0%**	**0.35 [0.11 , 1.14]**
Total events:	3		14			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.74 (P = 0.08)						
2.3.2 High PMR						
Shekhar 2013	0	50	5	50	34.0%	0.09 [0.01 , 1.60]
Subtotal (95% CI)		**50**		**50**	**34.0%**	**0.09 [0.01 , 1.60]**
Total events:	0		5			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.64 (P = 0.10)						
2.3.3 Mixed or undefined PMR						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)		**95**		**123**	**100.0%**	**0.26 [0.09 , 0.76]**
Total events:	3		19			
Heterogeneity: Chi² = 0.74, df = 1 (P = 0.39); I² = 0%						
Test for overall effect: Z = 2.45 (P = 0.01)						
Test for subgroup differences: Chi² = 0.72, df = 1 (P = 0.40), I² = 0%						



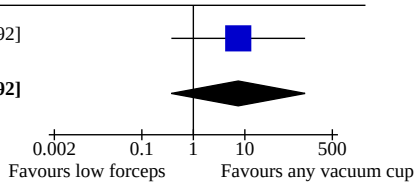
Analysis 2.4. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 4: Failed delivery by allocated instrument (subgroup by rotational or non-rotational delivery)

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.4.1 Non-rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.4.2 Rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.4.3 Mixed or undefined						
Dell 1985	3	45	14	73	66.0%	0.35 [0.11 , 1.14]
Shekhar 2013	0	50	5	50	34.0%	0.09 [0.01 , 1.60]
Subtotal (95% CI)		**95**		**123**	**100.0%**	**0.26 [0.09 , 0.76]**
Total events:	3		19			
Heterogeneity: Chi² = 0.74, df = 1 (P = 0.39); I² = 0%						
Test for overall effect: Z = 2.45 (P = 0.01)						
Total (95% CI)		**95**		**123**	**100.0%**	**0.26 [0.09 , 0.76]**
Total events:	3		19			
Heterogeneity: Chi² = 0.74, df = 1 (P = 0.39); I² = 0%						
Test for overall effect: Z = 2.45 (P = 0.01)						
Test for subgroup differences: Not applicable						



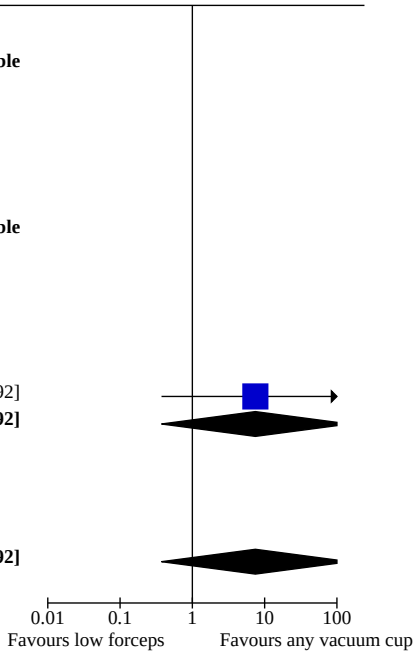
Analysis 2.5. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 5: Any maternal trauma (primary)

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Shekhar 2013	50	50	47	50	100.0%	7.44 [0.37 , 147.92]
Total (95% CI)		**50**		**50**	**100.0%**	**7.44 [0.37 , 147.92]**
Total events:	50		47			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.32 (P = 0.19)						
Test for subgroup differences: Not applicable						



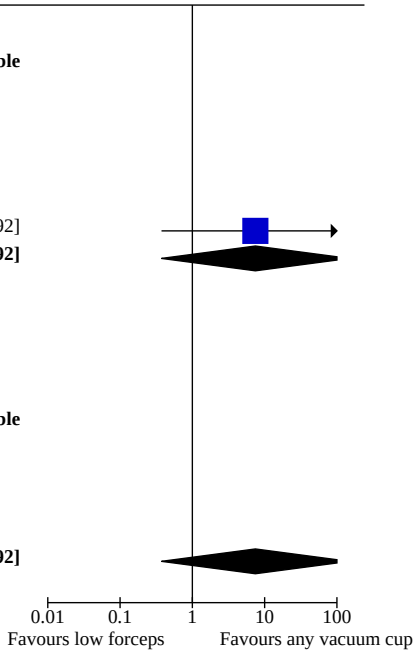
Analysis 2.6. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 6: Any maternal trauma (subgroup by epidural)

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
2.6.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.6.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.6.3 Mixed or undefined						
Shekhar 2013	50	50	47	50	100.0%	7.44 [0.37 , 147.92]
Subtotal (95% CI)		**50**		**50**	**100.0%**	**7.44 [0.37 , 147.92]**
Total events:	50		47			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.32 (P = 0.19)						
Total (95% CI)		**50**		**50**	**100.0%**	**7.44 [0.37 , 147.92]**
Total events:	50		47			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.32 (P = 0.19)						
Test for subgroup differences: Not applicable						



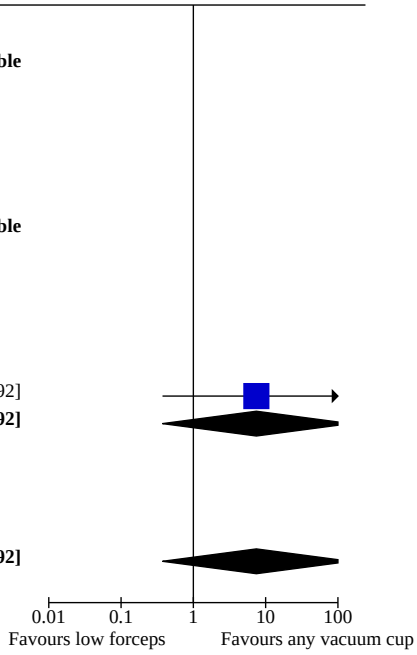
Analysis 2.7. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 7: Any maternal trauma (subgroup by Country PMR)

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
2.7.1 Low PMR						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.7.2 High PMR						
Shekhar 2013	50	50	47	50	100.0%	7.44 [0.37 , 147.92]
Subtotal (95% CI)		**50**		**50**	**100.0%**	**7.44 [0.37 , 147.92]**
Total events:	50		47			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.32 (P = 0.19)						
2.7.3 Mixed or undefined						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)		**50**		**50**	**100.0%**	**7.44 [0.37 , 147.92]**
Total events:	50		47			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.32 (P = 0.19)						
Test for subgroup differences: Not applicable						



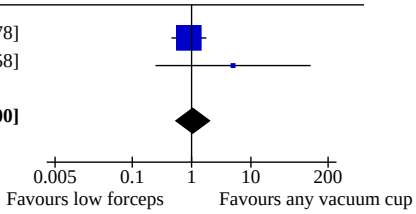
Analysis 2.8. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 8: Any maternal trauma (subgroup by rotational or non-rotational delivery)

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
2.8.1 Non-rotational						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.8.2 Rotational						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
2.8.3 Mixed or undefined						
Shekhar 2013	50	50	47	50	100.0%	7.44 [0.37 , 147.92]
Subtotal (95% CI)		**50**		**50**	**100.0%**	**7.44 [0.37 , 147.92]**
Total events:	50		47			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.32 (P = 0.19)						
Total (95% CI)		**50**		**50**	**100.0%**	**7.44 [0.37 , 147.92]**
Total events:	50		47			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.32 (P = 0.19)						
Test for subgroup differences: Not applicable						



Analysis 2.9. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 9: Third- or fourth-degree perineal tear (with or without episiotomy)

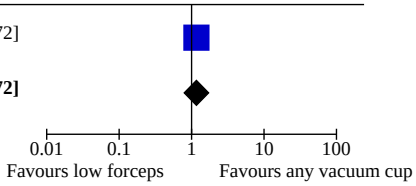
Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	10	45	18	73	96.5%	0.90 [0.46 , 1.78]
Shekhar 2013	2	50	0	50	3.5%	5.00 [0.25 , 101.58]
Total (95% CI)		**95**		**123**	**100.0%**	**1.05 [0.55 , 2.00]**
Total events:	12		18			
Heterogeneity: Chi² = 1.22, df = 1 (P = 0.27); I² = 18%						
Test for overall effect: Z = 0.13 (P = 0.89)						
Test for subgroup differences: Not applicable						



Analysis 2.10. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 10: Scalp injury

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	23	45	32	73	100.0%	1.17 [0.79 , 1.72]
Total (95% CI)		**45**		**73**	**100.0%**	**1.17 [0.79 , 1.72]**
Total events:	23		32			

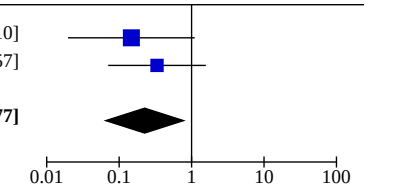
Heterogeneity: Not applicable
Test for overall effect: Z = 0.78 (P = 0.44)
Test for subgroup differences: Not applicable



Analysis 2.11. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 11: Cephalhematoma

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	1	45	11	73	58.3%	0.15 [0.02 , 1.10]
Shekhar 2013	2	50	6	50	41.7%	0.33 [0.07 , 1.57]
Total (95% CI)		**95**		**123**	**100.0%**	**0.22 [0.07 , 0.77]**
Total events:	3		17			

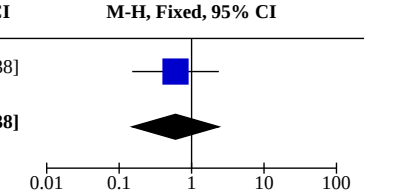
Heterogeneity: Chi² = 0.42, df = 1 (P = 0.52); I² = 0%
Test for overall effect: Z = 2.37 (P = 0.02)
Test for subgroup differences: Not applicable



Analysis 2.12. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 12: Jaundice

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Shekhar 2013	3	50	5	50	100.0%	0.60 [0.15 , 2.38]
Total (95% CI)		**50**		**50**	**100.0%**	**0.60 [0.15 , 2.38]**
Total events:	3		5			

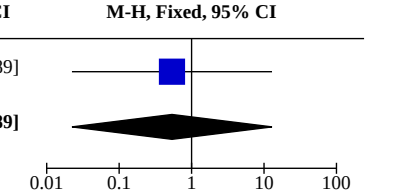
Heterogeneity: Not applicable
Test for overall effect: Z = 0.73 (P = 0.47)
Test for subgroup differences: Not applicable



Analysis 2.13. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 13: Anaemia

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	0	45	1	73	100.0%	0.54 [0.02 , 12.89]
Total (95% CI)		**45**		**73**	**100.0%**	**0.54 [0.02 , 12.89]**
Total events:	0		1			

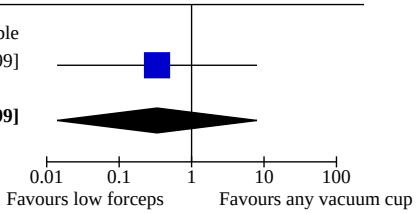
Heterogeneity: Not applicable
Test for overall effect: Z = 0.38 (P = 0.70)
Test for subgroup differences: Not applicable



Analysis 2.14. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 14: Death

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	0	45	0	73		Not estimable
Shekhar 2013	0	50	1	50	100.0%	0.33 [0.01 , 7.99]
Total (95% CI)		**95**		**123**	**100.0%**	**0.33 [0.01 , 7.99]**
Total events:	0		1			

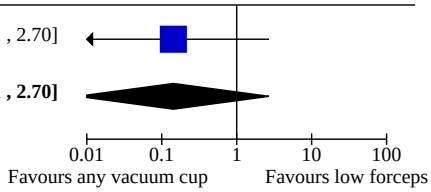
Heterogeneity: Not applicable
Test for overall effect: Z = 0.68 (P = 0.50)
Test for subgroup differences: Not applicable



Analysis 2.15. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 15: Analgesia: none

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Shekhar 2013	0	50	3	50	100.0%	0.14 [0.01 , 2.70]
Total (95% CI)		**50**		**50**	**100.0%**	**0.14 [0.01 , 2.70]**
Total events:	0		3			

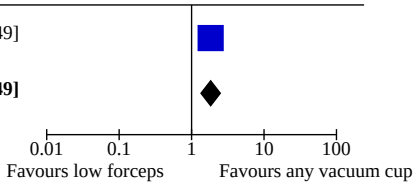
Heterogeneity: Not applicable
Test for overall effect: Z = 1.30 (P = 0.19)
Test for subgroup differences: Not applicable



Analysis 2.16. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 16: Analgesia: perineal infiltration only

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Shekhar 2013	44	50	24	50	100.0%	1.83 [1.35 , 2.49]
Total (95% CI)		**50**		**50**	**100.0%**	**1.83 [1.35 , 2.49]**
Total events:	44		24			

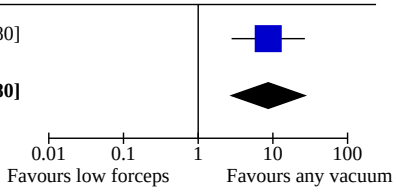
Heterogeneity: Not applicable
Test for overall effect: Z = 3.88 (P = 0.0001)
Test for subgroup differences: Not applicable



Analysis 2.17. Comparison 2: Low cavity forceps versus any vacuum cup, Outcome 17: Analgesia: perineal infiltration + pudendal

Study or Subgroup	Low cavity forceps Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Shekhar 2013	26	50	3	50	100.0%	8.67 [2.80 , 26.80]
Total (95% CI)		**50**		**50**	**100.0%**	**8.67 [2.80 , 26.80]**
Total events:	26		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 3.75 (P = 0.0002)
Test for subgroup differences: Not applicable



Comparison 4. Soft cup versus rigid cup

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Failed delivery with allocated instrument (primary)	9	1148	Risk Ratio (M-H, Fixed, 95% CI)	1.62 [1.21, 2.17]
4.2 Failed delivery with allocated instrument (subgroup by epidural)	9	1103	Risk Ratio (M-H, Fixed, 95% CI)	1.96 [1.48, 2.60]
4.2.1 Epidural	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.2.2 No epidural	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.2.3 Mixed or undefined	9	1103	Risk Ratio (M-H, Fixed, 95% CI)	1.96 [1.48, 2.60]
4.3 Failed delivery with allocated instrument (subgroup by Country PMR)	9	1148	Risk Ratio (M-H, Fixed, 95% CI)	1.62 [1.21, 2.17]
4.3.1 Low PMR	4	530	Risk Ratio (M-H, Fixed, 95% CI)	1.73 [1.11, 2.68]
4.3.2 High PMR	5	618	Risk Ratio (M-H, Fixed, 95% CI)	1.55 [1.05, 2.28]
4.3.3 Mixed or undefined	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.4 Failed delivery with allocated instrument (subgroup by rotational or non-rotational delivery))	9	1148	Risk Ratio (M-H, Fixed, 95% CI)	1.62 [1.21, 2.17]
4.4.1 Non-rotational delivery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.4.2 Rotational delivery	0	0	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
4.4.3 Mixed or undefined	9	1148	Risk Ratio (M-H, Fixed, 95% CI)	1.62 [1.21, 2.17]
4.5 Any maternal trauma (primary)	2	348	Odds Ratio (M-H, Fixed, 95% CI)	0.63 [0.24, 1.67]
4.6 Any maternal trauma (subgroup by epidural)	2	348	Odds Ratio (M-H, Fixed, 95% CI)	0.63 [0.24, 1.67]
4.6.1 Epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
4.6.2 No epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
4.6.3 Mixed or undefined	2	348	Odds Ratio (M-H, Fixed, 95% CI)	0.63 [0.24, 1.67]
4.7 Any maternal trauma (subgroup by Country PMR)	2	348	Odds Ratio (M-H, Fixed, 95% CI)	0.63 [0.24, 1.67]
4.7.1 Low PMR	1	258	Odds Ratio (M-H, Fixed, 95% CI)	0.76 [0.26, 2.26]

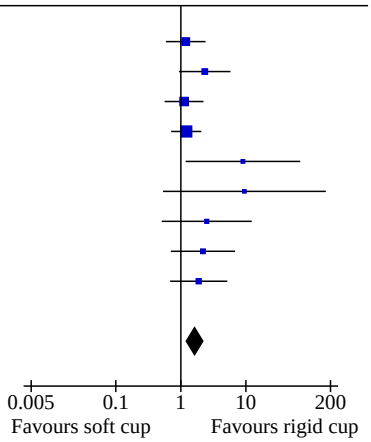
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.7.2 High PMR	1	90	Odds Ratio (M-H, Fixed, 95% CI)	0.30 [0.03, 3.04]
4.7.3 Mixed or undefined	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
4.8 Any maternal trauma (subgroup by rotational or non-rotational delivery)	2	348	Odds Ratio (M-H, Fixed, 95% CI)	0.63 [0.24, 1.67]
4.8.1 Non-rotational delivery	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
4.8.2 Rotational delivery	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
4.8.3 Mixed or undefined	2	348	Odds Ratio (M-H, Fixed, 95% CI)	0.63 [0.24, 1.67]
4.9 Third- or fourth-degree perineal tear (with or without episiotomy)	4	619	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.35, 2.44]
4.10 Postpartum haemorrhage (>/= 500 mL or as defined by trial authors))	5	737	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.49, 1.61]
4.11 Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)	9	1148	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.49, 1.37]
4.12 Low Umbilical artery pH (< 7.2 or as defined by trial authors)	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.47, 1.36]
4.13 Caesarean section	6	837	Risk Ratio (M-H, Fixed, 95% CI)	1.40 [0.70, 2.83]
4.14 Episiotomy	2	330	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.88, 1.10]
4.15 Scalp injury	5	791	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.50, 0.80]
4.16 Cephalhematoma	5	710	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.28, 0.95]
4.17 Retinal haemorrhage	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.60, 1.24]
4.18 Jaundice	6	782	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.65, 1.48]
4.19 Admission to neonatal intensive care unit	2	330	Risk Ratio (M-H, Fixed, 95% CI)	0.53 [0.16, 1.76]
4.20 Death	4	619	Risk Ratio (M-H, Fixed, 95% CI)	1.85 [0.24, 14.22]
4.21 Analgesia: local infiltration	2	271	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.97, 1.13]
4.22 Analgesia: epidural	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.65, 1.01]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.23 Analgesia: pudendal	1	100	Risk Ratio (M-H, Fixed, 95% CI)	2.29 [1.03, 5.07]
4.24 Analgesia: paracervical block	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 7.99]

Analysis 4.1. Comparison 4: Soft cup versus rigid cup, Outcome 1: Failed delivery with allocated instrument (primary)

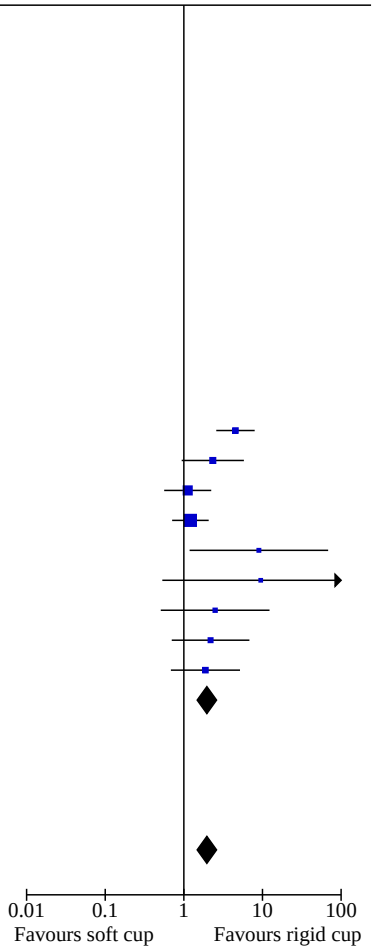
Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Afifi 1995	14	61	11	57	18.1%	1.19 [0.59 , 2.40]
Chanwaro 1999	14	90	6	90	9.6%	2.33 [0.94 , 5.80]
Chenoy 1992	15	101	13	98	21.0%	1.12 [0.56 , 2.23]
Cohn 1989	25	131	20	127	32.4%	1.21 [0.71 , 2.07]
Hammarström 1986	9	50	1	50	1.6%	9.00 [1.18 , 68.42]
Hofmeyr 1990	3	13	0	18	0.7%	9.50 [0.53 , 169.52]
Kuit 1993	5	50	2	50	3.2%	2.50 [0.51 , 12.29]
Lee 1996	7	32	4	40	5.7%	2.19 [0.70 , 6.82]
Srisomboon 1998	9	44	5	46	7.8%	1.88 [0.68 , 5.18]
Total (95% CI)		**572**		**576**	**100.0%**	**1.62 [1.21 , 2.17]**
Total events:	101		62			

Heterogeneity: Chi² = 8.44, df = 8 (P = 0.39); I² = 5%
Test for overall effect: Z = 3.27 (P = 0.001)
Test for subgroup differences: Not applicable



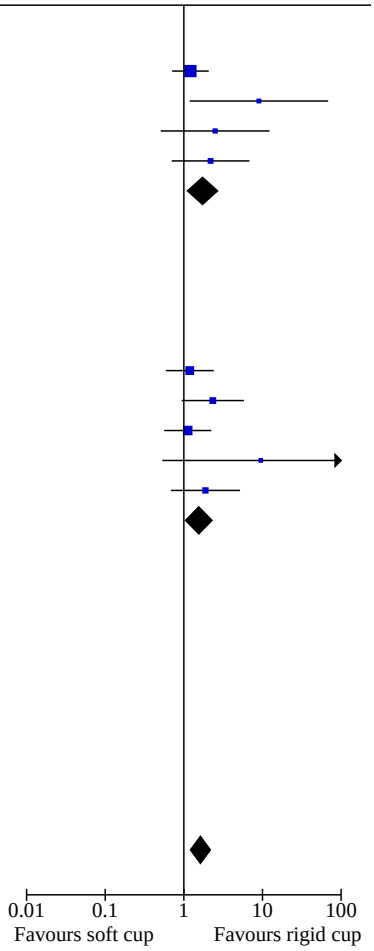
Analysis 4.2. Comparison 4: Soft cup versus rigid cup, Outcome 2: Failed delivery with allocated instrument (subgroup by epidural)

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
4.2.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.2.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.2.3 Mixed or undefined						
Afifi 1995	14	16	11	57	8.6%	4.53 [2.58 , 7.96]
Chanwaro 1999	14	90	6	90	10.7%	2.33 [0.94 , 5.80]
Chenoy 1992	15	101	13	98	23.5%	1.12 [0.56 , 2.23]
Cohn 1989	25	131	20	127	36.1%	1.21 [0.71 , 2.07]
Hammarström 1986	9	50	1	50	1.8%	9.00 [1.18 , 68.42]
Hofmeyr 1990	3	13	0	18	0.8%	9.50 [0.53 , 169.52]
Kuit 1993	5	50	2	50	3.6%	2.50 [0.51 , 12.29]
Lee 1996	7	32	4	40	6.3%	2.19 [0.70 , 6.82]
Srisomboon 1998	9	44	5	46	8.7%	1.88 [0.68 , 5.18]
Subtotal (95% CI)		**527**		**576**	**100.0%**	**1.96 [1.48 , 2.60]**
Total events:	101		62			
Heterogeneity: Chi² = 17.78, df = 8 (P = 0.02); I² = 55%						
Test for overall effect: Z = 4.66 (P < 0.00001)						
Total (95% CI)		**527**		**576**	**100.0%**	**1.96 [1.48 , 2.60]**
Total events:	101		62			
Heterogeneity: Chi² = 17.78, df = 8 (P = 0.02); I² = 55%						
Test for overall effect: Z = 4.66 (P < 0.00001)						
Test for subgroup differences: Not applicable						



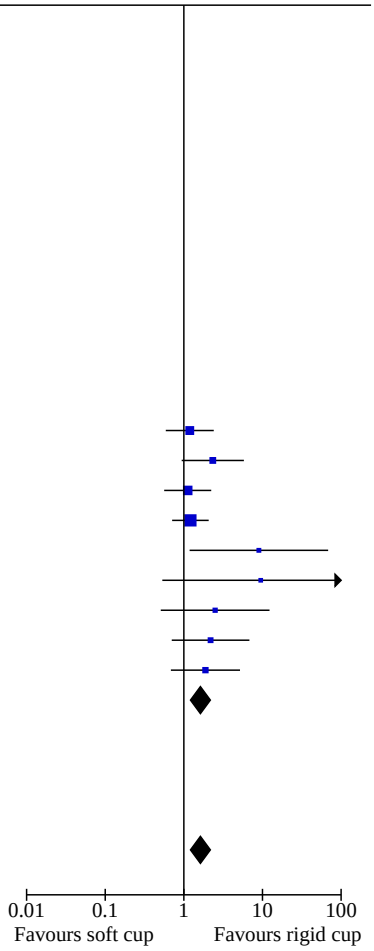
Analysis 4.3. Comparison 4: Soft cup versus rigid cup, Outcome 3: Failed delivery with allocated instrument (subgroup by Country PMR)

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
4.3.1 Low PMR						
Cohn 1989	25	131	20	127	32.4%	1.21 [0.71 , 2.07]
Hammarström 1986	9	50	1	50	1.6%	9.00 [1.18 , 68.42]
Kuit 1993	5	50	2	50	3.2%	2.50 [0.51 , 12.29]
Lee 1996	7	32	4	40	5.7%	2.19 [0.70 , 6.82]
Subtotal (95% CI)		**263**		**267**	**42.8%**	**1.73 [1.11 , 2.68]**
Total events:	46		27			
Heterogeneity: Chi² = 4.60, df = 3 (P = 0.20); I² = 35%						
Test for overall effect: Z = 2.43 (P = 0.01)						
4.3.2 High PMR						
Afifi 1995	14	61	11	57	18.1%	1.19 [0.59 , 2.40]
Chanwaro 1999	14	90	6	90	9.6%	2.33 [0.94 , 5.80]
Chenoy 1992	15	101	13	98	21.0%	1.12 [0.56 , 2.23]
Hofmeyr 1990	3	13	0	18	0.7%	9.50 [0.53 , 169.52]
Srisomboon 1998	9	44	5	46	7.8%	1.88 [0.68 , 5.18]
Subtotal (95% CI)		**309**		**309**	**57.2%**	**1.55 [1.05 , 2.28]**
Total events:	55		35			
Heterogeneity: Chi² = 3.84, df = 4 (P = 0.43); I² = 0%						
Test for overall effect: Z = 2.21 (P = 0.03)						
4.3.3 Mixed or undefined						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)		**572**		**576**	**100.0%**	**1.62 [1.21 , 2.17]**
Total events:	101		62			
Heterogeneity: Chi² = 8.44, df = 8 (P = 0.39); I² = 5%						
Test for overall effect: Z = 3.27 (P = 0.001)						
Test for subgroup differences: Chi² = 0.13, df = 1 (P = 0.71), I² = 0%						



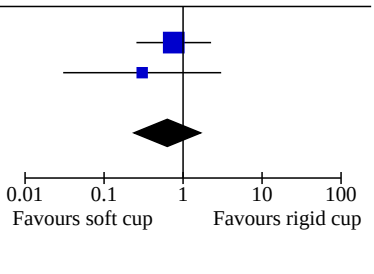
Analysis 4.4. Comparison 4: Soft cup versus rigid cup, Outcome 4: Failed delivery with allocated instrument (subgroup by rotational or non-rotational delivery))

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
4.4.1 Non-rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.4.2 Rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.4.3 Mixed or undefined						
Afifi 1995	14	61	11	57	18.1%	1.19 [0.59 , 2.40]
Chanwaro 1999	14	90	6	90	9.6%	2.33 [0.94 , 5.80]
Chenoy 1992	15	101	13	98	21.0%	1.12 [0.56 , 2.23]
Cohn 1989	25	131	20	127	32.4%	1.21 [0.71 , 2.07]
Hammarström 1986	9	50	1	50	1.6%	9.00 [1.18 , 68.42]
Hofmeyr 1990	3	13	0	18	0.7%	9.50 [0.53 , 169.52]
Kuit 1993	5	50	2	50	3.2%	2.50 [0.51 , 12.29]
Lee 1996	7	32	4	40	5.7%	2.19 [0.70 , 6.82]
Srisomboon 1998	9	44	5	46	7.8%	1.88 [0.68 , 5.18]
Subtotal (95% CI)		**572**		**576**	**100.0%**	**1.62 [1.21 , 2.17]**
Total events:	101		62			
Heterogeneity: Chi² = 8.44, df = 8 (P = 0.39); I² = 5%						
Test for overall effect: Z = 3.27 (P = 0.001)						
Total (95% CI)		**572**		**576**	**100.0%**	**1.62 [1.21 , 2.17]**
Total events:	101		62			
Heterogeneity: Chi² = 8.44, df = 8 (P = 0.39); I² = 5%						
Test for overall effect: Z = 3.27 (P = 0.001)						
Test for subgroup differences: Not applicable						



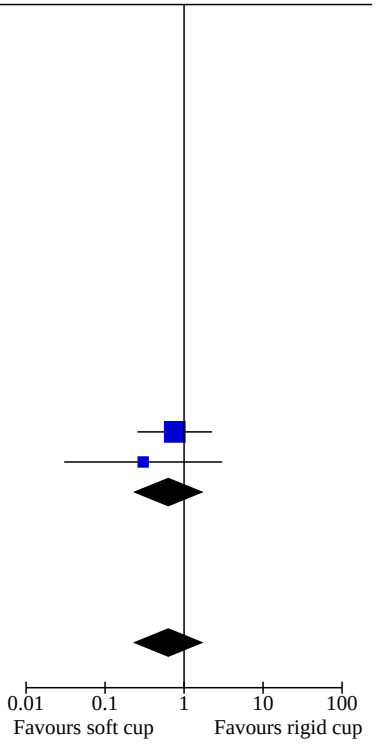
Analysis 4.5. Comparison 4: Soft cup versus rigid cup, Outcome 5: Any maternal trauma (primary)

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Cohn 1989	123	131	121	127	71.4%	0.76 [0.26 , 2.26]
Srisomboon 1998	41	44	45	46	28.6%	0.30 [0.03 , 3.04]
Total (95% CI)		**175**		**173**	**100.0%**	**0.63 [0.24 , 1.67]**
Total events:	164		166			
Heterogeneity: Chi² = 0.50, df = 1 (P = 0.48); I² = 0%						
Test for overall effect: Z = 0.93 (P = 0.35)						
Test for subgroup differences: Not applicable						

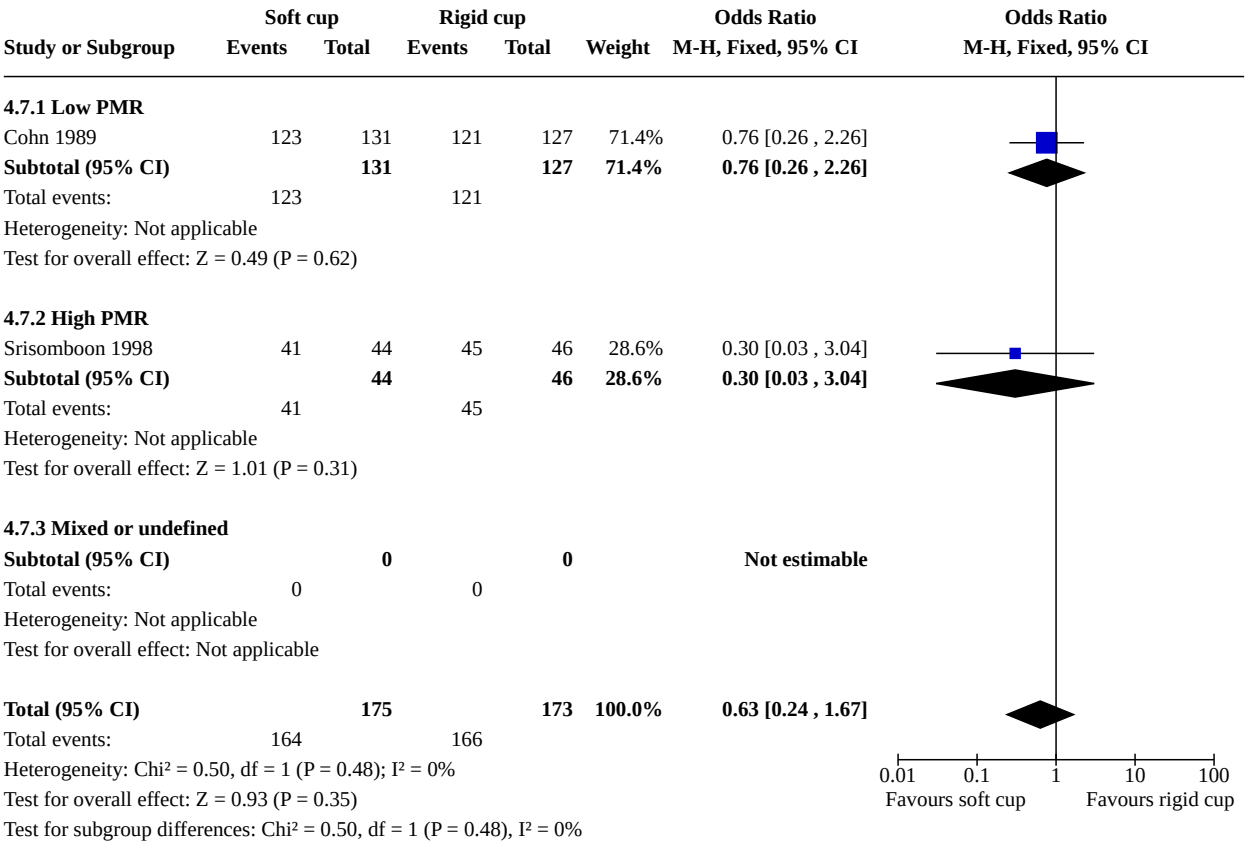


Analysis 4.6. Comparison 4: Soft cup versus rigid cup, Outcome 6: Any maternal trauma (subgroup by epidural)

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Odds Ratio M-H, Fixed, 95% CI
4.6.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.6.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.6.3 Mixed or undefined						
Cohn 1989	123	131	121	127	71.4%	0.76 [0.26 , 2.26]
Srisomboon 1998	41	44	45	46	28.6%	0.30 [0.03 , 3.04]
Subtotal (95% CI)		**175**		**173**	**100.0%**	**0.63 [0.24 , 1.67]**
Total events:	164		166			
Heterogeneity: Chi² = 0.50, df = 1 (P = 0.48); I² = 0%						
Test for overall effect: Z = 0.93 (P = 0.35)						
Total (95% CI)		**175**		**173**	**100.0%**	**0.63 [0.24 , 1.67]**
Total events:	164		166			
Heterogeneity: Chi² = 0.50, df = 1 (P = 0.48); I² = 0%						
Test for overall effect: Z = 0.93 (P = 0.35)						
Test for subgroup differences: Not applicable						

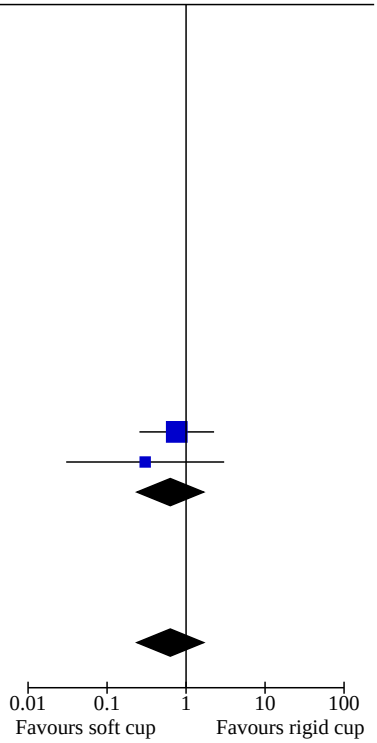


Analysis 4.7. Comparison 4: Soft cup versus rigid cup, Outcome 7: Any maternal trauma (subgroup by Country PMR)



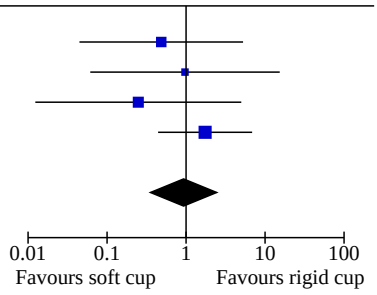
Analysis 4.8. Comparison 4: Soft cup versus rigid cup, Outcome 8: Any maternal trauma (subgroup by rotational or non-rotational delivery)

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Odds Ratio M-H, Fixed, 95% CI
4.8.1 Non-rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.8.2 Rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
4.8.3 Mixed or undefined						
Cohn 1989	123	131	121	127	71.4%	0.76 [0.26 , 2.26]
Srisomboon 1998	41	44	45	46	28.6%	0.30 [0.03 , 3.04]
Subtotal (95% CI)		**175**		**173**	**100.0%**	**0.63 [0.24 , 1.67]**
Total events:	164		166			
Heterogeneity: Chi² = 0.50, df = 1 (P = 0.48); I² = 0%						
Test for overall effect: Z = 0.93 (P = 0.35)						
Total (95% CI)		**175**		**173**	**100.0%**	**0.63 [0.24 , 1.67]**
Total events:	164		166			
Heterogeneity: Chi² = 0.50, df = 1 (P = 0.48); I² = 0%						
Test for overall effect: Z = 0.93 (P = 0.35)						
Test for subgroup differences: Not applicable						



Analysis 4.9. Comparison 4: Soft cup versus rigid cup, Outcome 9: Third- or fourth-degree perineal tear (with or without episiotomy)

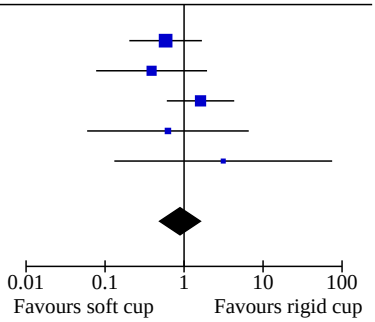
Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Chenoy 1992	1	101	2	98	24.7%	0.49 [0.04 , 5.26]
Cohn 1989	1	131	1	127	12.4%	0.97 [0.06 , 15.33]
Lee 1996	0	32	2	40	27.2%	0.25 [0.01 , 5.00]
Srisomboon 1998	5	44	3	46	35.7%	1.74 [0.44 , 6.86]
Total (95% CI)		**308**		**311**	**100.0%**	**0.93 [0.35 , 2.44]**
Total events:	7		8			
Heterogeneity: Chi² = 1.84, df = 3 (P = 0.61); I² = 0%						
Test for overall effect: Z = 0.15 (P = 0.88)						
Test for subgroup differences: Not applicable						



Analysis 4.10. Comparison 4: Soft cup versus rigid cup, Outcome 10: Postpartum haemorrhage (>/= 500 mL or as defined by trial authors))

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Afifi 1995	5	61	8	57	38.1%	0.58 [0.20 , 1.68]
Chenoy 1992	2	101	5	98	23.4%	0.39 [0.08 , 1.95]
Cohn 1989	10	131	6	127	28.1%	1.62 [0.61 , 4.31]
Lee 1996	1	32	2	40	8.2%	0.63 [0.06 , 6.59]
Srisomboon 1998	1	44	0	46	2.3%	3.13 [0.13 , 74.93]
Total (95% CI)		**369**		**368**	**100.0%**	**0.89 [0.49 , 1.61]**
Total events:	19		21			

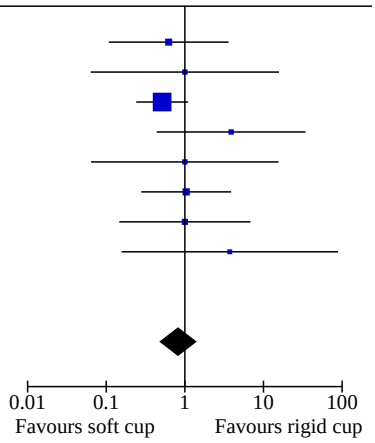
Heterogeneity: Chi² = 3.73, df = 4 (P = 0.44); I² = 0%
Test for overall effect: Z = 0.39 (P = 0.70)
Test for subgroup differences: Not applicable



Analysis 4.11. Comparison 4: Soft cup versus rigid cup, Outcome 11: Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Afifi 1995	2	61	3	57	10.6%	0.62 [0.11 , 3.59]
Chanwaro 1999	1	90	1	90	3.4%	1.00 [0.06 , 15.74]
Chenoy 1992	9	101	17	98	59.1%	0.51 [0.24 , 1.10]
Cohn 1989	4	131	1	127	3.5%	3.88 [0.44 , 34.22]
Hammarström 1986	1	50	1	50	3.4%	1.00 [0.06 , 15.55]
Hofmeyr 1990	3	13	4	18	11.5%	1.04 [0.28 , 3.87]
Kuit 1993	2	50	2	50	6.9%	1.00 [0.15 , 6.82]
Lee 1996	1	32	0	40	1.5%	3.73 [0.16 , 88.53]
Srisomboon 1998	0	44	0	46		Not estimable
Total (95% CI)		**572**		**576**	**100.0%**	**0.82 [0.49 , 1.37]**
Total events:	23		29			

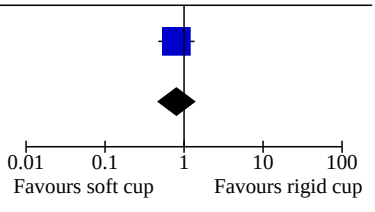
Heterogeneity: Chi² = 4.59, df = 7 (P = 0.71); I² = 0%
Test for overall effect: Z = 0.77 (P = 0.44)
Test for subgroup differences: Not applicable



Analysis 4.12. Comparison 4: Soft cup versus rigid cup, Outcome 12: Low Umbilical artery pH (< 7.2 or as defined by trial authors)

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Kuit 1993	16	50	20	50	100.0%	0.80 [0.47 , 1.36]
Total (95% CI)		**50**		**50**	**100.0%**	**0.80 [0.47 , 1.36]**
Total events:	16		20			

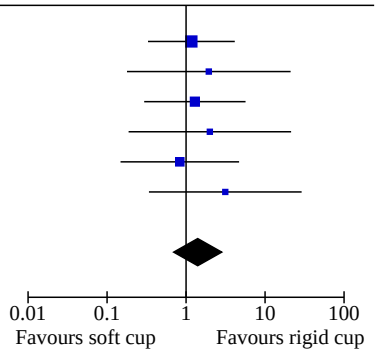
Heterogeneity: Not applicable
Test for overall effect: Z = 0.83 (P = 0.41)
Test for subgroup differences: Not applicable



Analysis 4.13. Comparison 4: Soft cup versus rigid cup, Outcome 13: Caesarean section

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Afifi 1995	5	61	4	57	32.2%	1.17 [0.33 , 4.14]
Chenoy 1992	2	101	1	98	7.9%	1.94 [0.18 , 21.06]
Cohn 1989	4	131	3	127	23.7%	1.29 [0.30 , 5.66]
Kuit 1993	2	50	1	50	7.8%	2.00 [0.19 , 21.36]
Lee 1996	2	32	3	40	20.8%	0.83 [0.15 , 4.69]
Srisomboon 1998	3	44	1	46	7.6%	3.14 [0.34 , 29.03]
Total (95% CI)	**419**		**418**		**100.0%**	**1.40 [0.70 , 2.83]**
Total events:	18		13			

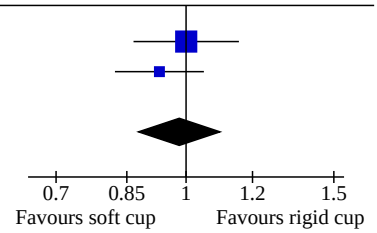
Heterogeneity: Chi² = 1.10, df = 5 (P = 0.95); I² = 0%
Test for overall effect: Z = 0.95 (P = 0.34)
Test for subgroup differences: Not applicable



Analysis 4.14. Comparison 4: Soft cup versus rigid cup, Outcome 14: Episiotomy

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cohn 1989	97	131	94	127	73.4%	1.00 [0.87 , 1.16]
Lee 1996	29	32	39	40	26.6%	0.93 [0.82 , 1.05]
Total (95% CI)	**163**		**167**		**100.0%**	**0.98 [0.88 , 1.10]**
Total events:	126		133			

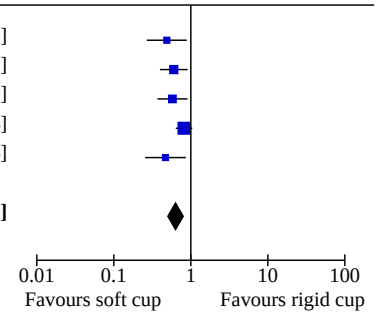
Heterogeneity: Chi² = 0.83, df = 1 (P = 0.36); I² = 0%
Test for overall effect: Z = 0.33 (P = 0.74)
Test for subgroup differences: Not applicable



Analysis 4.15. Comparison 4: Soft cup versus rigid cup, Outcome 15: Scalp injury

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Random, 95% CI
Afifi 1995	12	61	23	57	12.0%	0.49 [0.27 , 0.89]
Chanwaro 1999	24	90	40	90	20.8%	0.60 [0.40 , 0.91]
Chenoy 1992	22	101	37	98	18.6%	0.58 [0.37 , 0.90]
Cohn 1989	54	112	65	110	37.0%	0.82 [0.64 , 1.04]
Lee 1996	9	32	24	40	11.6%	0.47 [0.25 , 0.86]
Total (95% CI)	**396**		**395**		**100.0%**	**0.63 [0.50 , 0.80]**
Total events:	121		189			

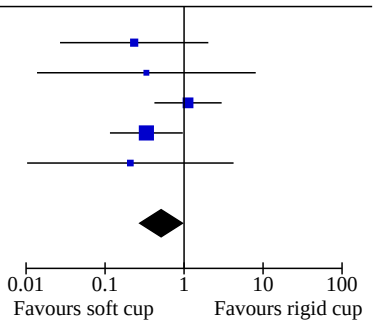
Heterogeneity: Tau² = 0.02; Chi² = 5.79, df = 4 (P = 0.22); I² = 31%
Test for overall effect: Z = 3.92 (P < 0.0001)
Test for subgroup differences: Not applicable



Analysis 4.16. Comparison 4: Soft cup versus rigid cup, Outcome 16: Cephalhematoma

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Afifi 1995	1	61	4	57	15.2%	0.23 [0.03 , 2.03]
Chanwaro 1999	0	90	1	90	5.5%	0.33 [0.01 , 8.08]
Cohn 1989	8	112	7	110	26.0%	1.12 [0.42 , 2.99]
Kuit 1993	4	50	12	50	44.2%	0.33 [0.12 , 0.96]
Srisomboon 1998	0	44	2	46	9.0%	0.21 [0.01 , 4.23]
Total (95% CI)		**357**		**353**	**100.0%**	**0.51 [0.28 , 0.95]**
Total events:	13		26			

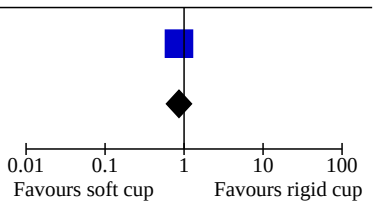
Heterogeneity: Chi² = 4.01, df = 4 (P = 0.40); I² = 0%
Test for overall effect: Z = 2.11 (P = 0.03)
Test for subgroup differences: Not applicable



Analysis 4.17. Comparison 4: Soft cup versus rigid cup, Outcome 17: Retinal haemorrhage

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Kuit 1993	25	50	29	50	100.0%	0.86 [0.60 , 1.24]
Total (95% CI)		**50**		**50**	**100.0%**	**0.86 [0.60 , 1.24]**
Total events:	25		29			

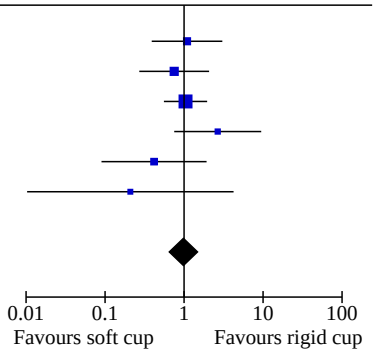
Heterogeneity: Not applicable
Test for overall effect: Z = 0.80 (P = 0.42)
Test for subgroup differences: Not applicable



Analysis 4.18. Comparison 4: Soft cup versus rigid cup, Outcome 18: Jaundice

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Afifi 1995	7	61	6	57	15.1%	1.09 [0.39 , 3.05]
Chanwaro 1999	6	90	8	90	19.5%	0.75 [0.27 , 2.07]
Cohn 1989	17	112	16	110	39.3%	1.04 [0.56 , 1.96]
Kuit 1993	8	50	3	50	7.3%	2.67 [0.75 , 9.47]
Lee 1996	2	32	6	40	13.0%	0.42 [0.09 , 1.93]
Srisomboon 1998	0	44	2	46	5.9%	0.21 [0.01 , 4.23]
Total (95% CI)		**389**		**393**	**100.0%**	**0.98 [0.65 , 1.48]**
Total events:	40		41			

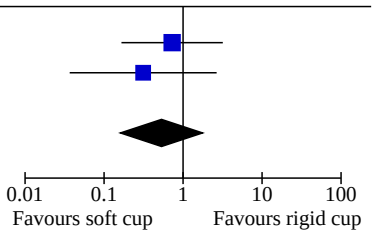
Heterogeneity: Chi² = 4.95, df = 5 (P = 0.42); I² = 0%
Test for overall effect: Z = 0.09 (P = 0.93)
Test for subgroup differences: Not applicable



Analysis 4.19. Comparison 4: Soft cup versus rigid cup, Outcome 19: Admission to neonatal intensive care unit

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Cohn 1989	3	131	4	127	53.3%	0.73 [0.17 , 3.18]
Lee 1996	1	32	4	40	46.7%	0.31 [0.04 , 2.66]
Total (95% CI)		**163**		**167**	**100.0%**	**0.53 [0.16 , 1.76]**
Total events:	4		8			

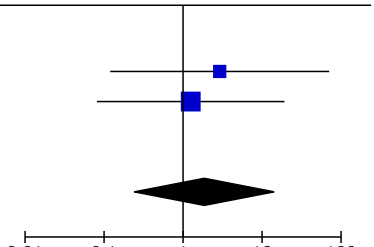
Heterogeneity: Chi² = 0.41, df = 1 (P = 0.52); I² = 0%
Test for overall effect: Z = 1.03 (P = 0.30)
Test for subgroup differences: Not applicable



Analysis 4.20. Comparison 4: Soft cup versus rigid cup, Outcome 20: Death

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Chenoy 1992	0	101	0	98		Not estimable
Cohn 1989	1	131	0	127	36.4%	2.91 [0.12 , 70.75]
Lee 1996	1	32	1	40	63.6%	1.25 [0.08 , 19.22]
Srisomboon 1998	0	44	0	46		Not estimable
Total (95% CI)		**308**		**311**	**100.0%**	**1.85 [0.24 , 14.22]**
Total events:	2		1			

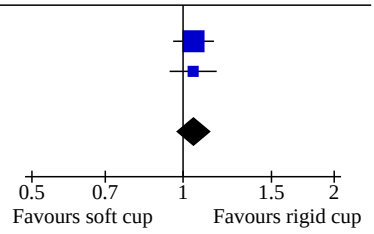
Heterogeneity: Chi² = 0.16, df = 1 (P = 0.69); I² = 0%
Test for overall effect: Z = 0.59 (P = 0.55)
Test for subgroup differences: Not applicable



Analysis 4.21. Comparison 4: Soft cup versus rigid cup, Outcome 21: Analgesia: local infiltration

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Chenoy 1992	93	101	86	98	72.6%	1.05 [0.96 , 1.15]
Lee 1996	31	32	37	40	27.4%	1.05 [0.94 , 1.17]
Total (95% CI)		**133**		**138**	**100.0%**	**1.05 [0.97 , 1.13]**
Total events:	124		123			

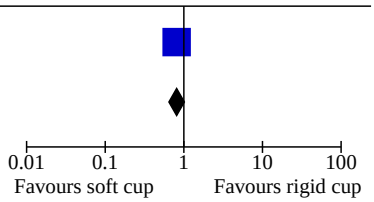
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.98); I² = 0%
Test for overall effect: Z = 1.26 (P = 0.21)
Test for subgroup differences: Not applicable



Analysis 4.22. Comparison 4: Soft cup versus rigid cup, Outcome 22: Analgesia: epidural

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Hammarström 1986	34	50	42	50	100.0%	0.81 [0.65 , 1.01]
Total (95% CI)		**50**		**50**	**100.0%**	**0.81 [0.65 , 1.01]**
Total events:	34		42			

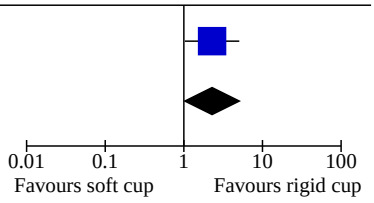
Heterogeneity: Not applicable
Test for overall effect: Z = 1.84 (P = 0.07)
Test for subgroup differences: Not applicable



Analysis 4.23. Comparison 4: Soft cup versus rigid cup, Outcome 23: Analgesia: pudendal

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Hammarström 1986	16	50	7	50	100.0%	2.29 [1.03 , 5.07]
Total (95% CI)		**50**		**50**	**100.0%**	**2.29 [1.03 , 5.07]**
Total events:	16		7			

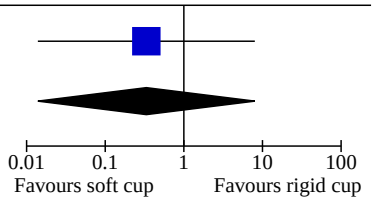
Heterogeneity: Not applicable
Test for overall effect: Z = 2.03 (P = 0.04)
Test for subgroup differences: Not applicable



Analysis 4.24. Comparison 4: Soft cup versus rigid cup, Outcome 24: Analgesia: paracervical block

Study or Subgroup	Soft cup Events	Soft cup Total	Rigid cup Events	Rigid cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Hammarström 1986	0	50	1	50	100.0%	0.33 [0.01 , 7.99]
Total (95% CI)		**50**		**50**	**100.0%**	**0.33 [0.01 , 7.99]**
Total events:	0		1			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.68 (P = 0.50)
Test for subgroup differences: Not applicable



Comparison 5. Handheld vacuum versus any vacuum cup

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Failed delivery with allocated instrument (primary)	4	962	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.81, 2.25]
5.2 Failed delivery with allocated instrument (subgroup by epidural)	4	962	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.81, 2.25]
5.2.1 Epidural	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable

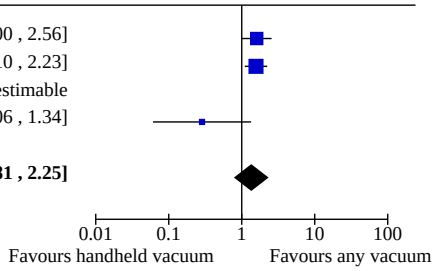
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.2.2 No epidural	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
5.2.3 Mixed or undefined	4	962	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.81, 2.25]
5.3 Failed delivery with allocated instrument (subgroup by Country PMR)	4	962	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.81, 2.25]
5.3.1 Low PMR	3	762	Risk Ratio (M-H, Random, 95% CI)	1.58 [1.19, 2.10]
5.3.2 High PMR	1	200	Risk Ratio (M-H, Random, 95% CI)	0.29 [0.06, 1.34]
5.3.3 Mixed or undefined	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
5.4 Failed delivery with allocated instrument (subgroup by rotational or non-rotational delivery))	4	962	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.81, 2.25]
5.4.1 Non-rotational delivery	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
5.4.2 Rotational delivery	0	0	Risk Ratio (M-H, Random, 95% CI)	Not estimable
5.4.3 Mixed or undefined	4	962	Risk Ratio (M-H, Random, 95% CI)	1.35 [0.81, 2.25]
5.5 Any maternal trauma (primary)	2	394	Odds Ratio (M-H, Fixed, 95% CI)	1.16 [0.71, 1.88]
5.6 Any maternal trauma (subgroup by epidural)	2	394	Odds Ratio (M-H, Fixed, 95% CI)	1.16 [0.71, 1.88]
5.6.1 Epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
5.6.2 No epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
5.6.3 Mixed or undefined	2	394	Odds Ratio (M-H, Fixed, 95% CI)	1.16 [0.71, 1.88]
5.7 Any maternal trauma (subgroup by Country PMR)	2	394	Odds Ratio (M-H, Fixed, 95% CI)	1.16 [0.71, 1.88]
5.7.1 Low PMR	1	194	Odds Ratio (M-H, Fixed, 95% CI)	0.98 [0.40, 2.37]
5.7.2 High PMR	1	200	Odds Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.22]
5.7.3 Mixed or undefined	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.8 Any maternal trauma (subgroup by rotational or non-rotational delivery)	2	394	Odds Ratio (M-H, Fixed, 95% CI)	1.16 [0.71, 1.88]
5.8.1 Non-rotational delivery	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
5.8.2 Rotational delivery	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
5.8.3 Mixed or undefined	2	394	Odds Ratio (M-H, Fixed, 95% CI)	1.16 [0.71, 1.88]
5.9 Third- or fourth-degree perineal tear (with or without episiotomy)	4	962	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.62, 2.12]
5.10 Postpartum haemorrhage (>/= 500 mL)	1	164	Risk Ratio (M-H, Fixed, 95% CI)	0.31 [0.03, 2.92]
5.11 Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)	3	784	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.34, 4.61]
5.12 Low Umbilical artery pH (< 7.2 or as defined by trial authors)	1	164	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.71, 1.59]
5.13 Caesarean section	4	962	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.61, 3.30]
5.14 Episiotomy	3	798	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.89, 1.13]
5.15 Perineal pain	1	145	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.50, 1.26]
5.16 Scalp injury	1	200	Risk Ratio (M-H, Fixed, 95% CI)	4.00 [0.46, 35.16]
5.17 Cephalhematoma	2	604	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.11, 1.59]
5.18 Subaponeurotic haemorrhage	1	164	Risk Ratio (M-H, Fixed, 95% CI)	0.12 [0.01, 0.91]
5.19 Admission to neonatal intensive care unit	3	558	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.33, 1.91]
5.20 Death	2	364	Risk Ratio (M-H, Fixed, 95% CI)	1.50 [0.26, 8.79]
5.21 Analgesia: none	1	404	Risk Ratio (M-H, Fixed, 95% CI)	0.38 [0.08, 1.96]
5.22 Analgesia: entonox	1	404	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.41, 2.97]
5.23 Analgesia: local anaesthetic	1	164	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [0.94, 1.69]

Analysis 5.1. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 1: Failed delivery with allocated instrument (primary)

Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Risk Ratio M-H, Random, 95% CI
Attilakos 2005	33	96	21	98	41.6%	1.60 [1.00 , 2.56]
Groom 2006	62	206	38	198	49.1%	1.57 [1.10 , 2.23]
Ismail 2008	0	85	0	79		Not estimable
Mola 2010	2	100	7	100	9.3%	0.29 [0.06 , 1.34]
Total (95% CI)		**487**		**475**	**100.0%**	**1.35 [0.81 , 2.25]**
Total events:	97		66			

Heterogeneity: Tau² = 0.11; Chi² = 4.62, df = 2 (P = 0.10); I² = 57%
Test for overall effect: Z = 1.15 (P = 0.25)
Test for subgroup differences: Not applicable



Analysis 5.2. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 2: Failed delivery with allocated instrument (subgroup by epidural)

Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Risk Ratio M-H, Random, 95% CI
5.2.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable

5.2.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			

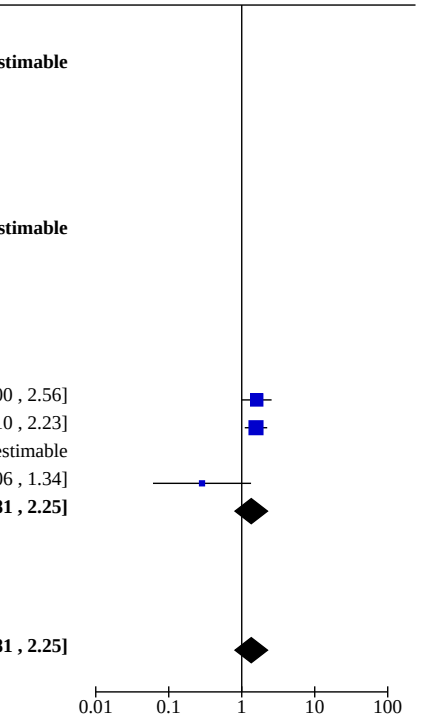
Heterogeneity: Not applicable
Test for overall effect: Not applicable

5.2.3 Mixed or undefined						
Attilakos 2005	33	96	21	98	41.6%	1.60 [1.00 , 2.56]
Groom 2006	62	206	38	198	49.1%	1.57 [1.10 , 2.23]
Ismail 2008	0	85	0	79		Not estimable
Mola 2010	2	100	7	100	9.3%	0.29 [0.06 , 1.34]
Subtotal (95% CI)		**487**		**475**	**100.0%**	**1.35 [0.81 , 2.25]**
Total events:	97		66			

Heterogeneity: Tau² = 0.11; Chi² = 4.62, df = 2 (P = 0.10); I² = 57%
Test for overall effect: Z = 1.15 (P = 0.25)

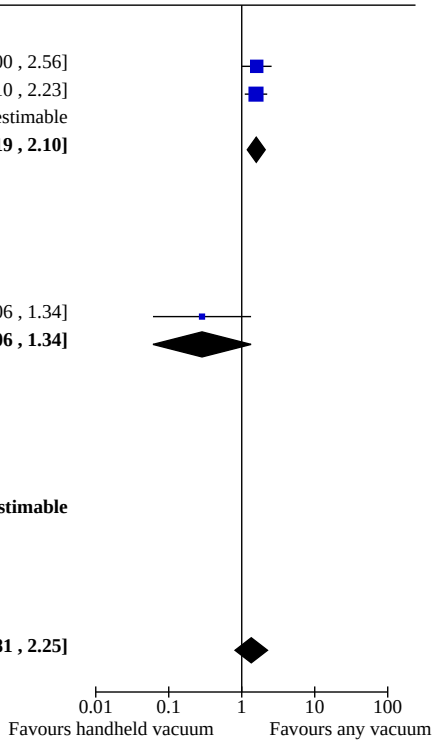
Total (95% CI)		**487**		**475**	**100.0%**	**1.35 [0.81 , 2.25]**
Total events:	97		66			

Heterogeneity: Tau² = 0.11; Chi² = 4.62, df = 2 (P = 0.10); I² = 57%
Test for overall effect: Z = 1.15 (P = 0.25)
Test for subgroup differences: Not applicable



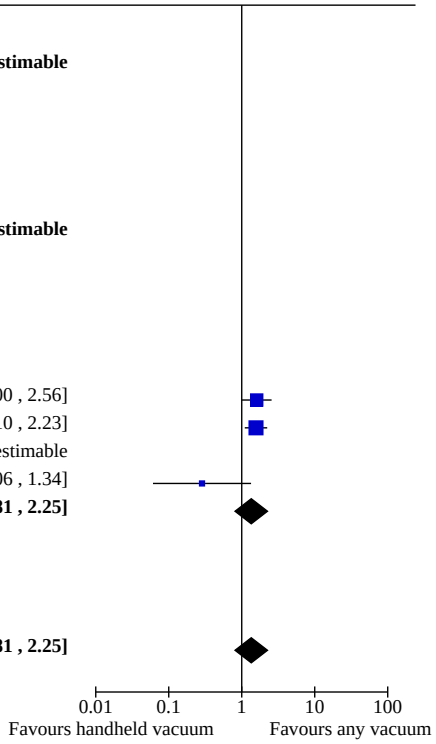
Analysis 5.3. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 3: Failed delivery with allocated instrument (subgroup by Country PMR)

Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Risk Ratio M-H, Random, 95% CI
5.3.1 Low PMR						
Attilakos 2005	33	96	21	98	41.6%	1.60 [1.00 , 2.56]
Groom 2006	62	206	38	198	49.1%	1.57 [1.10 , 2.23]
Ismail 2008	0	85	0	79		Not estimable
Subtotal (95% CI)		**387**		**375**	**90.7%**	**1.58 [1.19 , 2.10]**
Total events:	95		59			
Heterogeneity: Tau² = 0.00; Chi² = 0.01, df = 1 (P = 0.94); I² = 0%						
Test for overall effect: Z = 3.18 (P = 0.001)						
5.3.2 High PMR						
Mola 2010	2	100	7	100	9.3%	0.29 [0.06 , 1.34]
Subtotal (95% CI)		**100**		**100**	**9.3%**	**0.29 [0.06 , 1.34]**
Total events:	2		7			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.59 (P = 0.11)						
5.3.3 Mixed or undefined						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)		**487**		**475**	**100.0%**	**1.35 [0.81 , 2.25]**
Total events:	97		66			
Heterogeneity: Tau² = 0.11; Chi² = 4.62, df = 2 (P = 0.10); I² = 57%						
Test for overall effect: Z = 1.15 (P = 0.25)						
Test for subgroup differences: Chi² = 4.55, df = 1 (P = 0.03), I² = 78.0%						



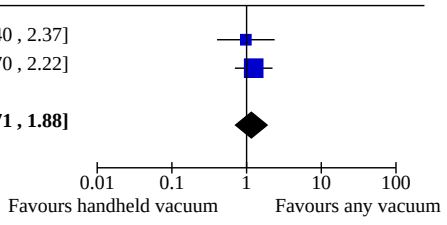
Analysis 5.4. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 4: Failed delivery with allocated instrument (subgroup by rotational or non-rotational delivery))

Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Risk Ratio M-H, Random, 95% CI
5.4.1 Non-rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
5.4.2 Rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
5.4.3 Mixed or undefined						
Attilakos 2005	33	96	21	98	41.6%	1.60 [1.00 , 2.56]
Groom 2006	62	206	38	198	49.1%	1.57 [1.10 , 2.23]
Ismail 2008	0	85	0	79		Not estimable
Mola 2010	2	100	7	100	9.3%	0.29 [0.06 , 1.34]
Subtotal (95% CI)		**487**		**475**	**100.0%**	**1.35 [0.81 , 2.25]**
Total events:	97		66			
Heterogeneity: Tau² = 0.11; Chi² = 4.62, df = 2 (P = 0.10); I² = 57%						
Test for overall effect: Z = 1.15 (P = 0.25)						
Total (95% CI)		**487**		**475**	**100.0%**	**1.35 [0.81 , 2.25]**
Total events:	97		66			
Heterogeneity: Tau² = 0.11; Chi² = 4.62, df = 2 (P = 0.10); I² = 57%						
Test for overall effect: Z = 1.15 (P = 0.25)						
Test for subgroup differences: Not applicable						

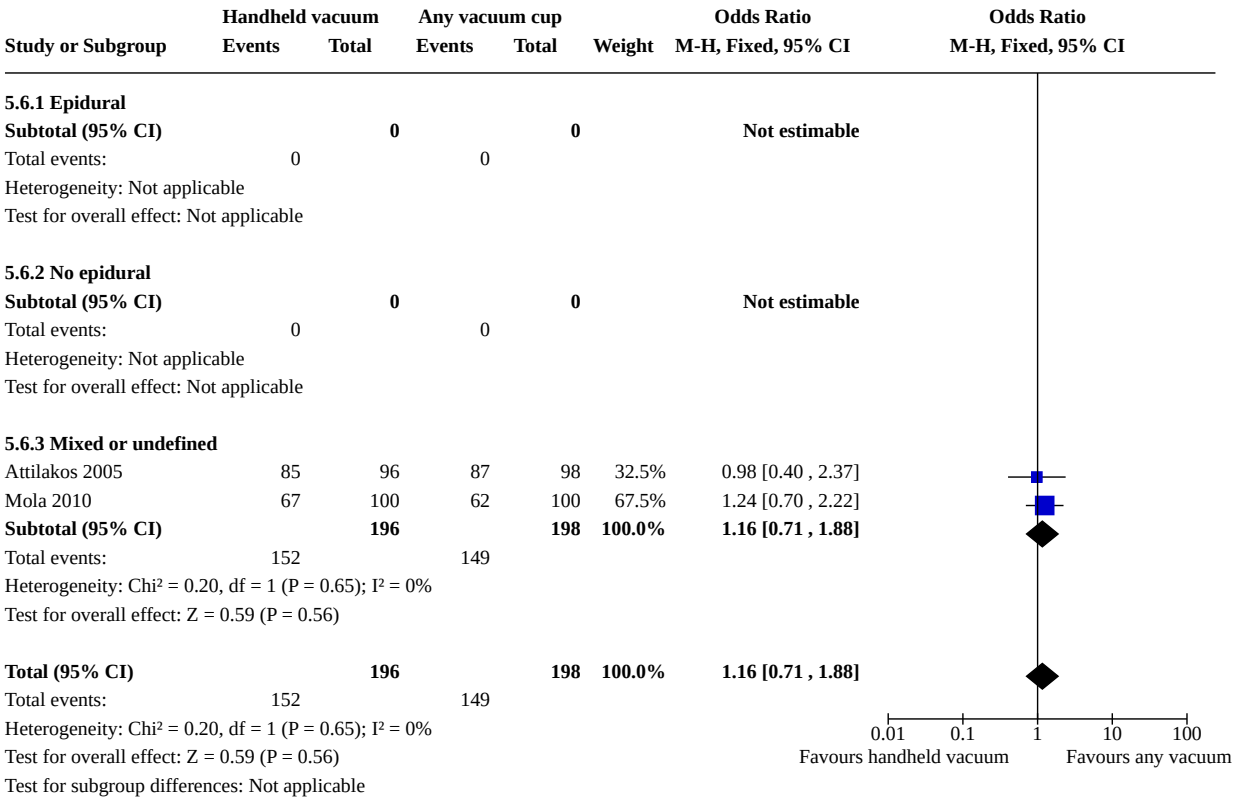


Analysis 5.5. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 5: Any maternal trauma (primary)

Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Attilakos 2005	85	96	87	98	32.5%	0.98 [0.40 , 2.37]
Mola 2010	67	100	62	100	67.5%	1.24 [0.70 , 2.22]
Total (95% CI)		**196**		**198**	**100.0%**	**1.16 [0.71 , 1.88]**
Total events:	152		149			
Heterogeneity: Chi² = 0.20, df = 1 (P = 0.65); I² = 0%						
Test for overall effect: Z = 0.59 (P = 0.56)						
Test for subgroup differences: Not applicable						



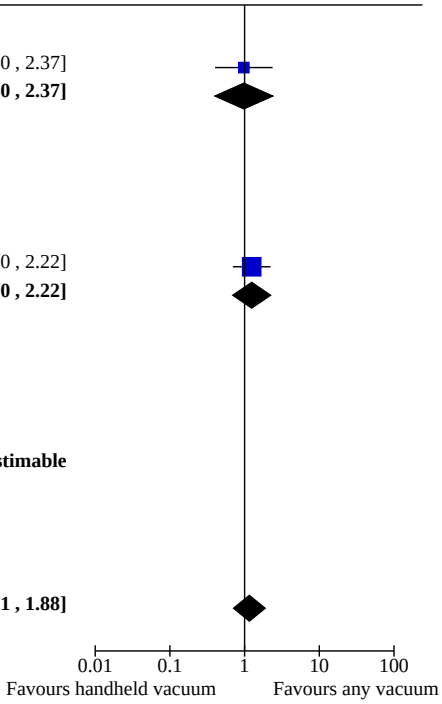
Analysis 5.6. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 6: Any maternal trauma (subgroup by epidural)



Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Odds Ratio M-H, Fixed, 95% CI
5.6.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
5.6.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
5.6.3 Mixed or undefined						
Attilakos 2005	85	96	87	98	32.5%	0.98 [0.40 , 2.37]
Mola 2010	67	100	62	100	67.5%	1.24 [0.70 , 2.22]
Subtotal (95% CI)		**196**		**198**	**100.0%**	**1.16 [0.71 , 1.88]**
Total events:	152		149			
Heterogeneity: $Chi^2 = 0.20$, df = 1 (P = 0.65); $I^2 = 0\%$						
Test for overall effect: Z = 0.59 (P = 0.56)						
Total (95% CI)		**196**		**198**	**100.0%**	**1.16 [0.71 , 1.88]**
Total events:	152		149			
Heterogeneity: $Chi^2 = 0.20$, df = 1 (P = 0.65); $I^2 = 0\%$						
Test for overall effect: Z = 0.59 (P = 0.56)						
Test for subgroup differences: Not applicable						

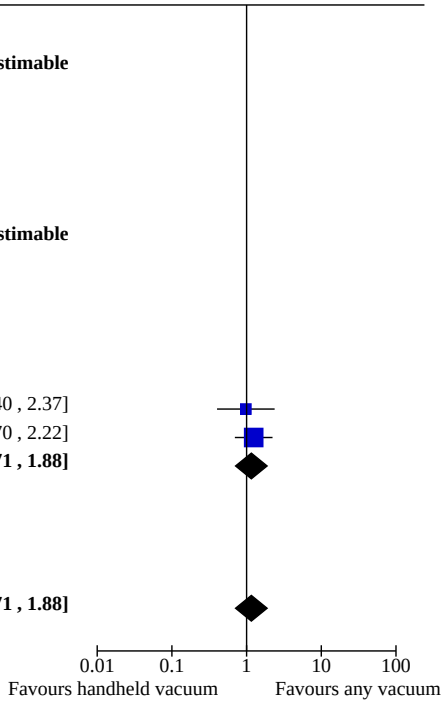
Analysis 5.7. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 7: Any maternal trauma (subgroup by Country PMR)

Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Odds Ratio M-H, Fixed, 95% CI
5.7.1 Low PMR						
Attilakos 2005	85	96	87	98	32.5%	0.98 [0.40 , 2.37]
Subtotal (95% CI)		**96**		**98**	**32.5%**	**0.98 [0.40 , 2.37]**
Total events:	85		87			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.05 (P = 0.96)						
5.7.2 High PMR						
Mola 2010	67	100	62	100	67.5%	1.24 [0.70 , 2.22]
Subtotal (95% CI)		**100**		**100**	**67.5%**	**1.24 [0.70 , 2.22]**
Total events:	67		62			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
5.7.3 Mixed or undefined						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)		**196**		**198**	**100.0%**	**1.16 [0.71 , 1.88]**
Total events:	152		149			
Heterogeneity: Chi² = 0.20, df = 1 (P = 0.65); I² = 0%						
Test for overall effect: Z = 0.59 (P = 0.56)						
Test for subgroup differences: Chi² = 0.20, df = 1 (P = 0.65), I² = 0%						



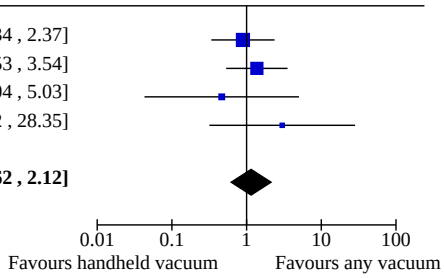
Analysis 5.8. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 8: Any maternal trauma (subgroup by rotational or non-rotational delivery)

Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Odds Ratio M-H, Fixed, 95% CI
5.8.1 Non-rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
5.8.2 Rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
5.8.3 Mixed or undefined						
Attilakos 2005	85	96	87	98	32.5%	0.98 [0.40 , 2.37]
Mola 2010	67	100	62	100	67.5%	1.24 [0.70 , 2.22]
Subtotal (95% CI)		**196**		**198**	**100.0%**	**1.16 [0.71 , 1.88]**
Total events:	152		149			
Heterogeneity: Chi² = 0.20, df = 1 (P = 0.65); I² = 0%						
Test for overall effect: Z = 0.59 (P = 0.56)						
Total (95% CI)		**196**		**198**	**100.0%**	**1.16 [0.71 , 1.88]**
Total events:	152		149			
Heterogeneity: Chi² = 0.20, df = 1 (P = 0.65); I² = 0%						
Test for overall effect: Z = 0.59 (P = 0.56)						
Test for subgroup differences: Not applicable						



Analysis 5.9. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 9: Third- or fourth-degree perineal tear (with or without episiotomy)

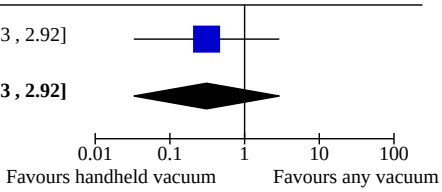
Study or Subgroup	Handheld vacuum Events	Handheld vacuum Total	Any vacuum cup Events	Any vacuum cup Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Attilakos 2005	7	96	8	98	43.7%	0.89 [0.34 , 2.37]
Groom 2006	10	206	7	198	39.4%	1.37 [0.53 , 3.54]
Ismail 2008	1	85	2	79	11.4%	0.46 [0.04 , 5.03]
Mola 2010	3	100	1	100	5.5%	3.00 [0.32 , 28.35]
Total (95% CI)		**487**		**475**	**100.0%**	**1.15 [0.62 , 2.12]**
Total events:	21		18			
Heterogeneity: Chi² = 1.65, df = 3 (P = 0.65); I² = 0%						
Test for overall effect: Z = 0.44 (P = 0.66)						
Test for subgroup differences: Not applicable						



Analysis 5.10. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 10: Postpartum haemorrhage (>/= 500 mL)

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ismail 2008	1	85	3	79	100.0%	0.31 [0.03 , 2.92]
Total (95% CI)		**85**		**79**	**100.0%**	**0.31 [0.03 , 2.92]**
Total events:	1		3			

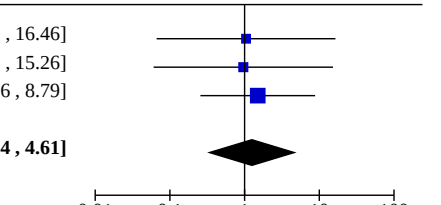
Heterogeneity: Not applicable
Test for overall effect: Z = 1.02 (P = 0.31)
Test for subgroup differences: Not applicable



Analysis 5.11. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 11: Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Attilakos 2005	1	88	1	92	24.5%	1.05 [0.07 , 16.46]
Groom 2006	1	206	1	198	25.5%	0.96 [0.06 , 15.26]
Mola 2010	3	100	2	100	50.0%	1.50 [0.26 , 8.79]
Total (95% CI)		**394**		**390**	**100.0%**	**1.25 [0.34 , 4.61]**
Total events:	5		4			

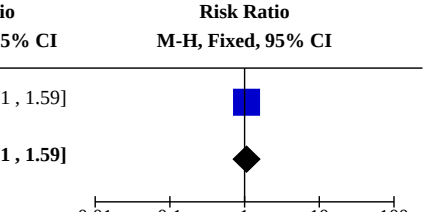
Heterogeneity: Chi² = 0.09, df = 2 (P = 0.96); I² = 0%
Test for overall effect: Z = 0.34 (P = 0.74)
Test for subgroup differences: Not applicable



Analysis 5.12. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 12: Low Umbilical artery pH (< 7.2 or as defined by trial authors)

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ismail 2008	32	85	28	79	100.0%	1.06 [0.71 , 1.59]
Total (95% CI)		**85**		**79**	**100.0%**	**1.06 [0.71 , 1.59]**
Total events:	32		28			

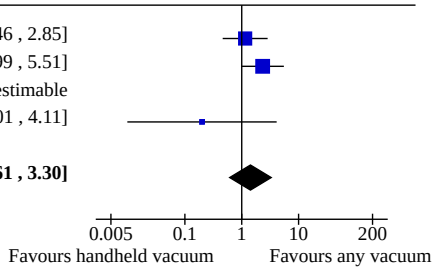
Heterogeneity: Not applicable
Test for overall effect: Z = 0.29 (P = 0.77)
Test for subgroup differences: Not applicable



Analysis 5.13. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 13: Caesarean section

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Attilakos 2005	9	96	8	98	45.0%	1.15 [0.46 , 2.85]
Groom 2006	17	206	7	198	47.8%	2.33 [0.99 , 5.51]
Ismail 2008	0	85	0	79		Not estimable
Mola 2010	0	100	2	100	7.1%	0.20 [0.01 , 4.11]
Total (95% CI)		**487**		**475**	**100.0%**	**1.42 [0.61 , 3.30]**
Total events:	26		17			

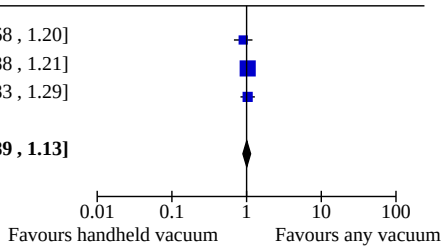
Heterogeneity: Tau² = 0.19; Chi² = 3.06, df = 2 (P = 0.22); I² = 35%
Test for overall effect: Z = 0.82 (P = 0.41)
Test for subgroup differences: Not applicable



Analysis 5.14. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 14: Episiotomy

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Attilakos 2005	45	96	51	98	21.9%	0.90 [0.68 , 1.20]
Groom 2006	127	206	118	198	52.1%	1.03 [0.88 , 1.21]
Mola 2010	62	100	60	100	26.0%	1.03 [0.83 , 1.29]
Total (95% CI)		**402**		**396**	**100.0%**	**1.00 [0.89 , 1.13]**
Total events:	234		229			

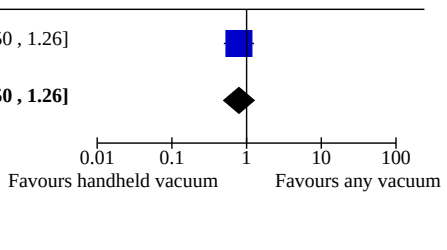
Heterogeneity: Chi² = 0.76, df = 2 (P = 0.69); I² = 0%
Test for overall effect: Z = 0.08 (P = 0.93)
Test for subgroup differences: Not applicable



Analysis 5.15. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 15: Perineal pain

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Attilakos 2005	22	75	26	70	100.0%	0.79 [0.50 , 1.26]
Total (95% CI)		**75**		**70**	**100.0%**	**0.79 [0.50 , 1.26]**
Total events:	22		26			

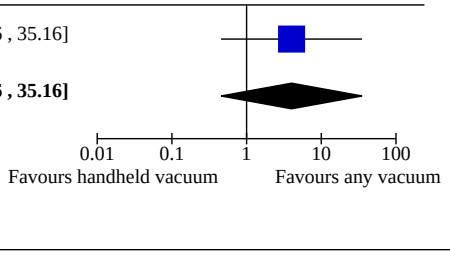
Heterogeneity: Not applicable
Test for overall effect: Z = 0.99 (P = 0.32)
Test for subgroup differences: Not applicable



Analysis 5.16. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 16: Scalp injury

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Mola 2010	4	100	1	100	100.0%	4.00 [0.46 , 35.16]
Total (95% CI)		**100**		**100**	**100.0%**	**4.00 [0.46 , 35.16]**
Total events:	4		1			

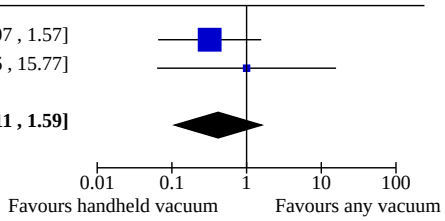
Heterogeneity: Not applicable
Test for overall effect: Z = 1.25 (P = 0.21)
Test for subgroup differences: Not applicable



Analysis 5.17. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 17: Cephalhematoma

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Groom 2006	2	206	6	198	86.0%	0.32 [0.07 , 1.57]
Mola 2010	1	100	1	100	14.0%	1.00 [0.06 , 15.77]
Total (95% CI)		**306**		**298**	**100.0%**	**0.42 [0.11 , 1.59]**
Total events:	3		7			

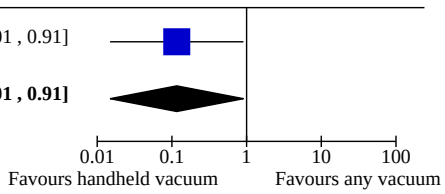
Heterogeneity: Chi² = 0.49, df = 1 (P = 0.48); I² = 0%
Test for overall effect: Z = 1.28 (P = 0.20)
Test for subgroup differences: Not applicable



Analysis 5.18. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 18: Subaponeurotic haemorrhage

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ismail 2008	1	85	8	79	100.0%	0.12 [0.01 , 0.91]
Total (95% CI)		**85**		**79**	**100.0%**	**0.12 [0.01 , 0.91]**
Total events:	1		8			

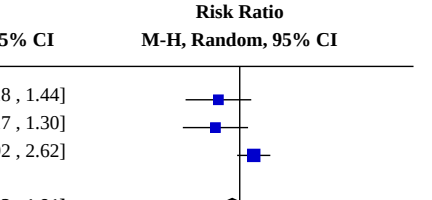
Heterogeneity: Not applicable
Test for overall effect: Z = 2.05 (P = 0.04)
Test for subgroup differences: Not applicable



Analysis 5.19. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 19: Admission to neonatal intensive care unit

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Attilakos 2005	5	96	10	98	29.2%	0.51 [0.18 , 1.44]
Ismail 2008	5	85	10	79	29.3%	0.46 [0.17 , 1.30]
Mola 2010	28	100	18	100	41.5%	1.56 [0.92 , 2.62]
Total (95% CI)		**281**		**277**	**100.0%**	**0.79 [0.33 , 1.91]**
Total events:	38		38			

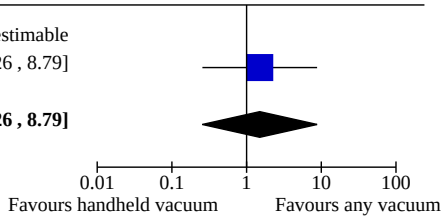
Heterogeneity: Tau² = 0.42; Chi² = 6.51, df = 2 (P = 0.04); I² = 69%
Test for overall effect: Z = 0.53 (P = 0.60)
Test for subgroup differences: Not applicable



Analysis 5.20. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 20: Death

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ismail 2008	0	85	0	79		Not estimable
Mola 2010	3	100	2	100	100.0%	1.50 [0.26 , 8.79]
Total (95% CI)		**185**		**179**	**100.0%**	**1.50 [0.26 , 8.79]**
Total events:	3		2			

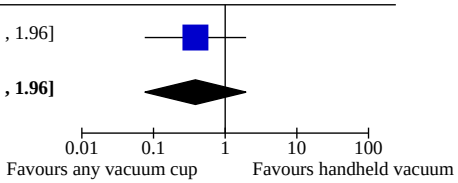
Heterogeneity: Not applicable
Test for overall effect: Z = 0.45 (P = 0.65)
Test for subgroup differences: Not applicable



Analysis 5.21. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 21: Analgesia: none

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Groom 2006	2	206	5	198	100.0%	0.38 [0.08 , 1.96]
Total (95% CI)		**206**		**198**	**100.0%**	**0.38 [0.08 , 1.96]**
Total events:	2		5			

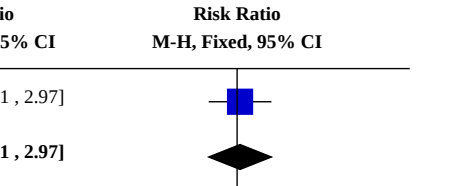
Heterogeneity: Not applicable
Test for overall effect: Z = 1.15 (P = 0.25)
Test for subgroup differences: Not applicable



Analysis 5.22. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 22: Analgesia: entonox

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Groom 2006	8	206	7	198	100.0%	1.10 [0.41 , 2.97]
Total (95% CI)		**206**		**198**	**100.0%**	**1.10 [0.41 , 2.97]**
Total events:	8		7			

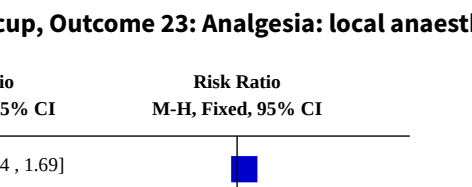
Heterogeneity: Not applicable
Test for overall effect: Z = 0.18 (P = 0.85)
Test for subgroup differences: Not applicable



Analysis 5.23. Comparison 5: Handheld vacuum versus any vacuum cup, Outcome 23: Analgesia: local anaesthetic

Study or Subgroup	Handheld vacuum Events	Total	Any vacuum cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ismail 2008	50	85	37	79	100.0%	1.26 [0.94 , 1.69]
Total (95% CI)		**85**		**79**	**100.0%**	**1.26 [0.94 , 1.69]**
Total events:	50		37			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.52 (P = 0.13)
Test for subgroup differences: Not applicable



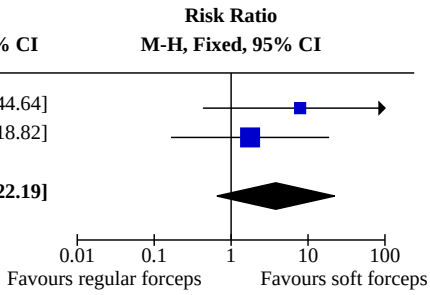
Comparison 6. Regular forceps versus soft forceps

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6.1 Severe facial markings	2	306	Risk Ratio (M-H, Fixed, 95% CI)	3.81 [0.65, 22.19]
6.2 Other facial markings	2	306	Risk Ratio (M-H, Fixed, 95% CI)	1.46 [1.16, 1.84]

Analysis 6.1. Comparison 6: Regular forceps versus soft forceps, Outcome 1: Severe facial markings

Study or Subgroup	Regular forceps Events	Regular forceps Total	Soft forceps Events	Soft forceps Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Hebertson 1985	4	112	0	98	33.4%	7.88 [0.43 , 144.64]
Roshan 2005	2	51	1	45	66.6%	1.76 [0.17 , 18.82]
Total (95% CI)		**163**		**143**	**100.0%**	**3.81 [0.65 , 22.19]**
Total events:	6		1			

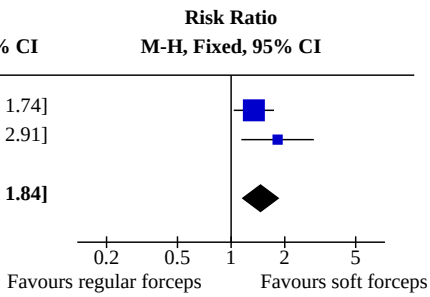
Heterogeneity: Chi² = 0.65, df = 1 (P = 0.42); I² = 0%
Test for overall effect: Z = 1.49 (P = 0.14)
Test for subgroup differences: Not applicable



Analysis 6.2. Comparison 6: Regular forceps versus soft forceps, Outcome 2: Other facial markings

Study or Subgroup	Regular forceps Events	Regular forceps Total	Soft forceps Events	Soft forceps Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Hebertson 1985	69	112	45	98	75.1%	1.34 [1.03 , 1.74]
Roshan 2005	31	51	15	45	24.9%	1.82 [1.14 , 2.91]
Total (95% CI)		**163**		**143**	**100.0%**	**1.46 [1.16 , 1.84]**
Total events:	100		60			

Heterogeneity: Chi² = 1.27, df = 1 (P = 0.26); I² = 22%
Test for overall effect: Z = 3.27 (P = 0.001)
Test for subgroup differences: Not applicable



Comparison 7. Any soft cup versus any soft vacuum cup

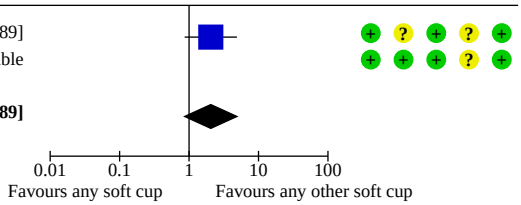
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.1 Third- or fourth-degree perineal tear (with or without episiotomy)	2	178	Risk Ratio (M-H, Fixed, 95% CI)	2.06 [0.86, 4.89]
7.2 Scalp injury	1	73	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.54, 1.53]
7.3 Cephalhematoma	1	73	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.29, 2.56]
7.4 Anaemia	1	73	Risk Ratio (M-H, Fixed, 95% CI)	3.08 [0.13, 73.24]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7.5 Admission to neonatal intensive care unit	1	105	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.04, 3.41]

Analysis 7.1. Comparison 7: Any soft cup versus any soft vacuum cup, Outcome 1: Third- or fourth-degree perineal tear (with or without episiotomy)

Study or Subgroup	Any soft cup Events	Total	Any soft cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	12	36	6	37	100.0%	2.06 [0.86 , 4.89]
Warwick 1993	0	50	0	55		Not estimable
Total (95% CI)		**86**		**92**	**100.0%**	**2.06 [0.86 , 4.89]**
Total events:	12		6			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.63 (P = 0.10)
Test for subgroup differences: Not applicable

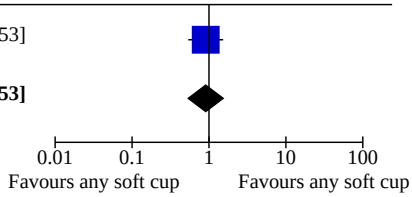


Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Incomplete outcome data (attrition bias)
(D) Selective reporting (reporting bias)
(E) Other bias

Analysis 7.2. Comparison 7: Any soft cup versus any soft vacuum cup, Outcome 2: Scalp injury

Study or Subgroup	Any soft cup Events	Total	Any soft cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	15	36	17	37	100.0%	0.91 [0.54 , 1.53]
Total (95% CI)		**36**		**37**	**100.0%**	**0.91 [0.54 , 1.53]**
Total events:	15		17			

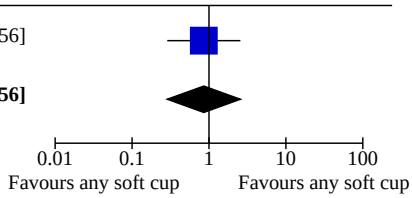
Heterogeneity: Not applicable
Test for overall effect: Z = 0.37 (P = 0.71)
Test for subgroup differences: Not applicable



Analysis 7.3. Comparison 7: Any soft cup versus any soft vacuum cup, Outcome 3: Cephalhematoma

Study or Subgroup	Any soft cup Events	Total	Any soft cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	5	36	6	37	100.0%	0.86 [0.29 , 2.56]
Total (95% CI)		**36**		**37**	**100.0%**	**0.86 [0.29 , 2.56]**
Total events:	5		6			

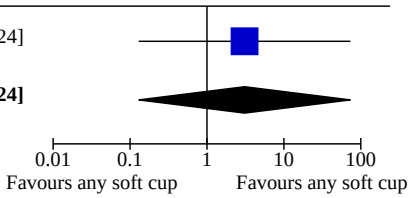
Heterogeneity: Not applicable
Test for overall effect: Z = 0.28 (P = 0.78)
Test for subgroup differences: Not applicable



Analysis 7.4. Comparison 7: Any soft cup versus any soft vacuum cup, Outcome 4: Anaemia

Study or Subgroup	Any soft cup Events	Total	Any soft cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Dell 1985	1	36	0	37	100.0%	3.08 [0.13 , 73.24]
Total (95% CI)		**36**		**37**	**100.0%**	**3.08 [0.13 , 73.24]**
Total events:	1		0			

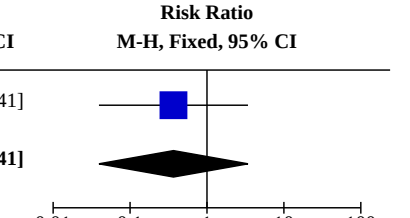
Heterogeneity: Not applicable
Test for overall effect: Z = 0.70 (P = 0.49)
Test for subgroup differences: Not applicable



Analysis 7.5. Comparison 7: Any soft cup versus any soft vacuum cup, Outcome 5: Admission to neonatal intensive care unit

Study or Subgroup	Any soft cup Events	Total	Any soft cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Warwick 1993	1	50	3	55	100.0%	0.37 [0.04 , 3.41]
Total (95% CI)		**50**		**55**	**100.0%**	**0.37 [0.04 , 3.41]**
Total events:	1		3			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.88 (P = 0.38)
Test for subgroup differences: Not applicable



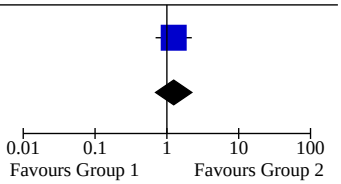
Comparison 8. Any rigid cup versus any rigid cup

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.1 Any maternal trauma (primary)	1	200	Odds Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.22]
8.2 Any maternal trauma (subgroup by epidural)	1	200	Odds Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.22]
8.2.1 Epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
8.2.2 No epidural	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
8.2.3 Mixed or undefined	1	200	Odds Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.22]
8.3 Any maternal trauma (subgroup by Country PMR)	1	200	Odds Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.22]
8.3.1 Low PMR	1	200	Odds Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.22]
8.3.2 High PMR	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
8.3.3 Mixed or undefined	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.4 Any maternal trauma (subgroup by rotational or non-rotational delivery)	1	200	Odds Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.22]
8.4.1 Non-rotational delivery	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
8.4.2 Rotational delivery	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
8.4.3 Mixed or undefined	1	200	Odds Ratio (M-H, Fixed, 95% CI)	1.24 [0.70, 2.22]
8.5 Third- or fourth-degree perineal tear (with or without episiotomy)	3	942	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.17, 2.05]
8.6 Postpartum haemorrhage (>/= 500 mL)	2	742	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.37, 2.52]
8.7 Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)	4	1310	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.56, 2.37]
8.8 Low Umbilical artery pH (< 7.2 or as defined by trial authors)	2	742	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.87, 1.31]
8.9 Caesarean section	5	1475	Risk Ratio (M-H, Fixed, 95% CI)	2.49 [1.01, 6.16]
8.10 Episiotomy	2	610	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.95, 1.06]
8.11 Scalp injury	3	1188	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.47, 1.56]
8.12 Cephalhematoma	4	1311	Risk Ratio (M-H, Fixed, 95% CI)	1.29 [0.59, 2.81]
8.13 Subaponeurotic haemorrhage	1	164	Risk Ratio (M-H, Fixed, 95% CI)	0.12 [0.01, 0.91]
8.14 Jaundice	4	1311	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.81, 1.28]
8.15 Anaemia	1	578	Risk Ratio (M-H, Fixed, 95% CI)	1.92 [0.35, 10.39]
8.16 Analgesia: local anaesthetic	1	164	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [0.94, 1.69]
8.17 Analgesia: paracervical block	1	410	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.04, 3.34]
8.18 Analgesia: epidural	2	574	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.75, 1.06]

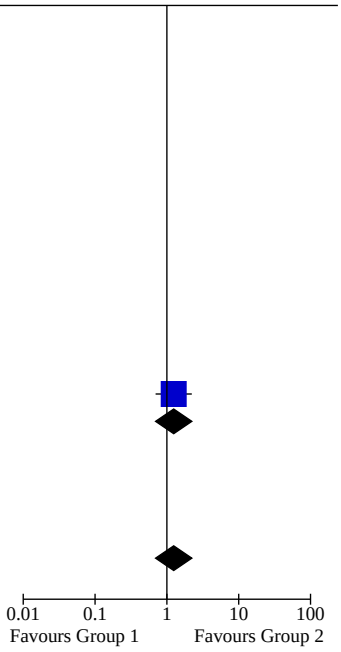
Analysis 8.1. Comparison 8: Any rigid cup versus any rigid cup, Outcome 1: Any maternal trauma (primary)

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
Mola 2010	67	100	62	100	100.0%	1.24 [0.70 , 2.22]
Total (95% CI)		**100**		**100**	**100.0%**	**1.24 [0.70 , 2.22]**
Total events:	67		62			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
Test for subgroup differences: Not applicable						



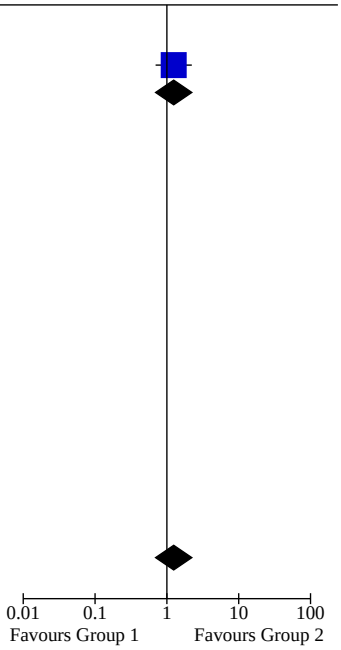
Analysis 8.2. Comparison 8: Any rigid cup versus any rigid cup, Outcome 2: Any maternal trauma (subgroup by epidural)

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
8.2.1 Epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
8.2.2 No epidural						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
8.2.3 Mixed or undefined						
Mola 2010	67	100	62	100	100.0%	1.24 [0.70 , 2.22]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**1.24 [0.70 , 2.22]**
Total events:	67		62			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
Total (95% CI)		**100**		**100**	**100.0%**	**1.24 [0.70 , 2.22]**
Total events:	67		62			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
Test for subgroup differences: Not applicable						



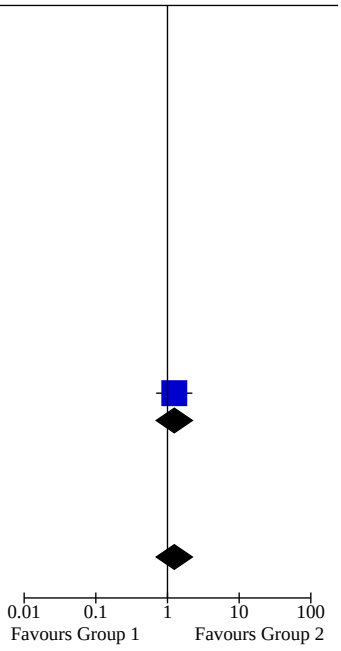
Analysis 8.3. Comparison 8: Any rigid cup versus any rigid cup, Outcome 3: Any maternal trauma (subgroup by Country PMR)

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
8.3.1 Low PMR						
Mola 2010	67	100	62	100	100.0%	1.24 [0.70 , 2.22]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**1.24 [0.70 , 2.22]**
Total events:	67		62			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
8.3.2 High PMR						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
8.3.3 Mixed or undefined						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
Total (95% CI)		**100**		**100**	**100.0%**	**1.24 [0.70 , 2.22]**
Total events:	67		62			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
Test for subgroup differences: Not applicable						



Analysis 8.4. Comparison 8: Any rigid cup versus any rigid cup, Outcome 4: Any maternal trauma (subgroup by rotational or non-rotational delivery)

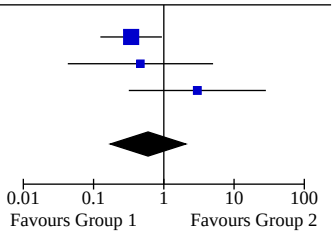
Study or Subgroup	Group 1: Any rigid cup Events	Total	Group 2: Any rigid cup Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
8.4.1 Non-rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
8.4.2 Rotational delivery						
Subtotal (95% CI)		**0**		**0**		**Not estimable**
Total events:	0		0			
Heterogeneity: Not applicable						
Test for overall effect: Not applicable						
8.4.3 Mixed or undefined						
Mola 2010	67	100	62	100	100.0%	1.24 [0.70 , 2.22]
Subtotal (95% CI)		**100**		**100**	**100.0%**	**1.24 [0.70 , 2.22]**
Total events:	67		62			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
Total (95% CI)		**100**		**100**	**100.0%**	**1.24 [0.70 , 2.22]**
Total events:	67		62			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.74 (P = 0.46)						
Test for subgroup differences: Not applicable						



Analysis 8.5. Comparison 8: Any rigid cup versus any rigid cup, Outcome 5: Third- or fourth-degree perineal tear (with or without episiotomy)

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Equy 2015	5	295	14	283	56.6%	0.34 [0.13 , 0.94]
Ismail 2008	1	85	2	79	20.7%	0.46 [0.04 , 5.03]
Mola 2010	3	100	1	100	22.7%	3.00 [0.32 , 28.35]
Total (95% CI)		**480**		**462**	**100.0%**	**0.60 [0.17 , 2.05]**
Total events:	9		17			

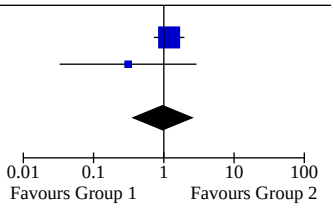
Heterogeneity: Tau² = 0.44; Chi² = 3.00, df = 2 (P = 0.22); I² = 33%
Test for overall effect: Z = 0.82 (P = 0.41)
Test for subgroup differences: Not applicable



Analysis 8.6. Comparison 8: Any rigid cup versus any rigid cup, Outcome 6: Postpartum haemorrhage (>/= 500 mL)

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
Equy 2015	31	295	25	283	84.2%	1.19 [0.72 , 1.96]
Ismail 2008	1	85	3	79	15.8%	0.31 [0.03 , 2.92]
Total (95% CI)		**380**		**362**	**100.0%**	**0.96 [0.37 , 2.52]**
Total events:	32		28			

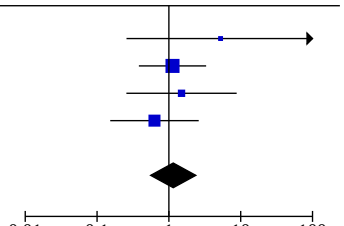
Heterogeneity: Tau² = 0.22; Chi² = 1.32, df = 1 (P = 0.25); I² = 24%
Test for overall effect: Z = 0.08 (P = 0.94)
Test for subgroup differences: Not applicable



Analysis 8.7. Comparison 8: Any rigid cup versus any rigid cup, Outcome 7: Low Apgar score at 5 minutes (less than 7 or as defined by trial authors)

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Carmody 1986	2	60	0	63	3.6%	5.25 [0.26 , 107.07]
Equy 2015	7	294	6	283	45.4%	1.12 [0.38 , 3.30]
Mola 2010	3	100	2	100	14.8%	1.50 [0.26 , 8.79]
Thiery 1987	3	200	5	210	36.2%	0.63 [0.15 , 2.60]
Total (95% CI)		**654**		**656**	**100.0%**	**1.15 [0.56 , 2.37]**
Total events:	15		13			

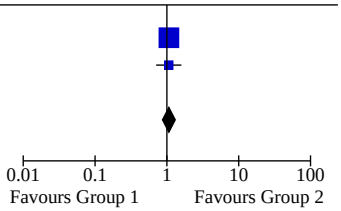
Heterogeneity: Chi² = 1.75, df = 3 (P = 0.63); I² = 0%
Test for overall effect: Z = 0.38 (P = 0.70)
Test for subgroup differences: Not applicable



Analysis 8.8. Comparison 8: Any rigid cup versus any rigid cup, Outcome 8: Low Umbilical artery pH (< 7.2 or as defined by trial authors)

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Equy 2015	99	295	89	283	75.8%	1.07 [0.84 , 1.35]
Ismail 2008	32	85	28	79	24.2%	1.06 [0.71 , 1.59]
Total (95% CI)		**380**		**362**	**100.0%**	**1.07 [0.87 , 1.31]**
Total events:	131		117			

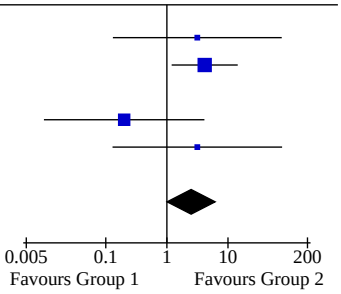
Heterogeneity: Chi² = 0.00, df = 1 (P = 0.98); I² = 0%
Test for overall effect: Z = 0.62 (P = 0.54)
Test for subgroup differences: Not applicable



Analysis 8.9. Comparison 8: Any rigid cup versus any rigid cup, Outcome 9: Caesarean section

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Carmody 1986	1	60	0	63	7.5%	3.15 [0.13 , 75.79]
Equy 2015	13	295	3	283	46.8%	4.16 [1.20 , 14.43]
Ismail 2008	0	85	0	79		Not estimable
Mola 2010	0	100	2	100	38.2%	0.20 [0.01 , 4.11]
Thiery 1987	1	200	0	210	7.5%	3.15 [0.13 , 76.86]
Total (95% CI)		**740**		**735**	**100.0%**	**2.49 [1.01 , 6.16]**
Total events:	15		5			

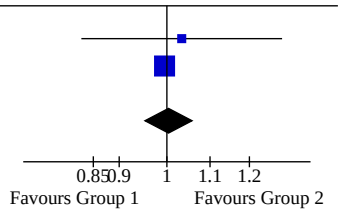
Heterogeneity: Chi² = 3.36, df = 3 (P = 0.34); I² = 11%
Test for overall effect: Z = 1.98 (P = 0.05)
Test for subgroup differences: Not applicable



Analysis 8.10. Comparison 8: Any rigid cup versus any rigid cup, Outcome 10: Episiotomy

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Mola 2010	62	100	60	100	22.6%	1.03 [0.83 , 1.29]
Thiery 1987	199	200	210	210	77.4%	0.99 [0.98 , 1.01]
Total (95% CI)		**300**		**310**	**100.0%**	**1.00 [0.95 , 1.06]**
Total events:	261		270			

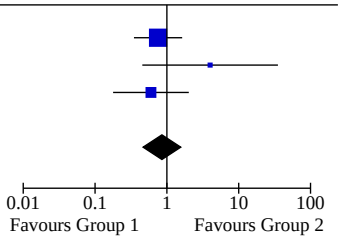
Heterogeneity: Chi² = 1.62, df = 1 (P = 0.20); I² = 38%
Test for overall effect: Z = 0.14 (P = 0.89)
Test for subgroup differences: Not applicable



Analysis 8.11. Comparison 8: Any rigid cup versus any rigid cup, Outcome 11: Scalp injury

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Equy 2015	11	295	14	283	64.6%	0.75 [0.35 , 1.63]
Mola 2010	4	100	1	100	4.5%	4.00 [0.46 , 35.16]
Thiery 1987	4	200	7	210	30.9%	0.60 [0.18 , 2.02]
Total (95% CI)		**595**		**593**	**100.0%**	**0.85 [0.47 , 1.56]**
Total events:	19		22			

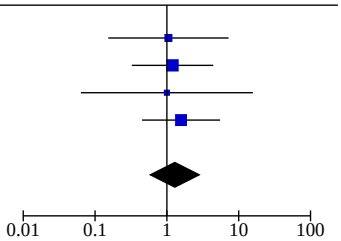
Heterogeneity: Chi² = 2.36, df = 2 (P = 0.31); I² = 15%
Test for overall effect: Z = 0.52 (P = 0.61)
Test for subgroup differences: Not applicable



Analysis 8.12. Comparison 8: Any rigid cup versus any rigid cup, Outcome 12: Cephalhematoma

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Carmody 1986	2	60	2	63	17.8%	1.05 [0.15 , 7.22]
Equy 2015	5	295	4	283	37.3%	1.20 [0.33 , 4.42]
Mola 2010	1	100	1	100	9.1%	1.00 [0.06 , 15.77]
Thiery 1987	6	200	4	210	35.7%	1.57 [0.45 , 5.50]
Total (95% CI)		**655**		**656**	**100.0%**	**1.29 [0.59 , 2.81]**
Total events:	14		11			

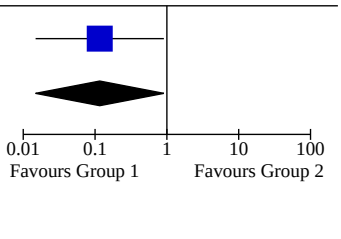
Heterogeneity: Chi² = 0.19, df = 3 (P = 0.98); I² = 0%
Test for overall effect: Z = 0.64 (P = 0.52)
Test for subgroup differences: Not applicable



Analysis 8.13. Comparison 8: Any rigid cup versus any rigid cup, Outcome 13: Subaponeurotic haemorrhage

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ismail 2008	1	85	8	79	100.0%	0.12 [0.01 , 0.91]
Total (95% CI)		**85**		**79**	**100.0%**	**0.12 [0.01 , 0.91]**
Total events:	1		8			

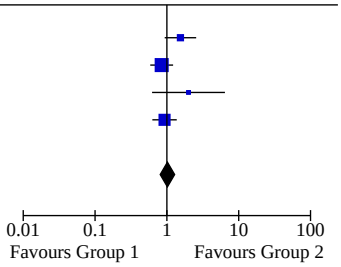
Heterogeneity: Not applicable
Test for overall effect: Z = 2.05 (P = 0.04)
Test for subgroup differences: Not applicable



Analysis 8.14. Comparison 8: Any rigid cup versus any rigid cup, Outcome 14: Jaundice

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Carmody 1986	25	60	17	63	14.5%	1.54 [0.93 , 2.56]
Equy 2015	45	295	51	283	45.4%	0.85 [0.59 , 1.22]
Mola 2010	8	100	4	100	3.5%	2.00 [0.62 , 6.43]
Thiery 1987	38	200	43	210	36.6%	0.93 [0.63 , 1.37]
Total (95% CI)		**655**		**656**	**100.0%**	**1.02 [0.81 , 1.28]**
Total events:	116		115			

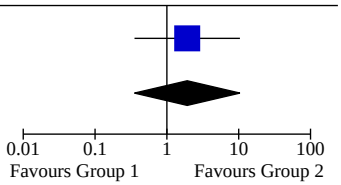
Heterogeneity: Chi² = 5.09, df = 3 (P = 0.16); I² = 41%
Test for overall effect: Z = 0.15 (P = 0.88)
Test for subgroup differences: Not applicable



Analysis 8.15. Comparison 8: Any rigid cup versus any rigid cup, Outcome 15: Anaemia

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Equy 2015	4	295	2	283	100.0%	1.92 [0.35 , 10.39]
Total (95% CI)		**295**		**283**	**100.0%**	**1.92 [0.35 , 10.39]**
Total events:	4		2			

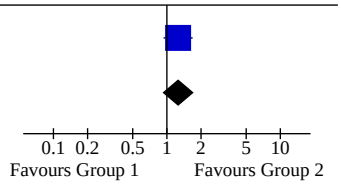
Heterogeneity: Not applicable
Test for overall effect: Z = 0.76 (P = 0.45)
Test for subgroup differences: Not applicable



Analysis 8.16. Comparison 8: Any rigid cup versus any rigid cup, Outcome 16: Analgesia: local anaesthetic

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ismail 2008	50	85	37	79	100.0%	1.26 [0.94 , 1.69]
Total (95% CI)		**85**		**79**	**100.0%**	**1.26 [0.94 , 1.69]**
Total events:	50		37			

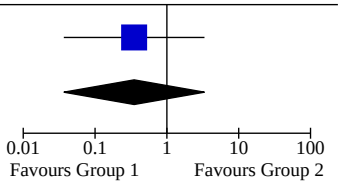
Heterogeneity: Not applicable
Test for overall effect: Z = 1.52 (P = 0.13)
Test for subgroup differences: Not applicable



Analysis 8.17. Comparison 8: Any rigid cup versus any rigid cup, Outcome 17: Analgesia: paracervical block

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Thiery 1987	1	200	3	210	100.0%	0.35 [0.04 , 3.34]
Total (95% CI)		**200**		**210**	**100.0%**	**0.35 [0.04 , 3.34]**
Total events:	1		3			

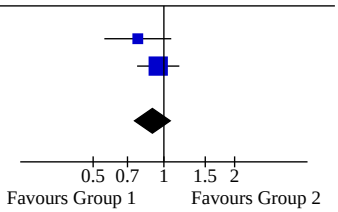
Heterogeneity: Not applicable
Test for overall effect: Z = 0.91 (P = 0.36)
Test for subgroup differences: Not applicable



Analysis 8.18. Comparison 8: Any rigid cup versus any rigid cup, Outcome 18: Analgesia: epidural

Study or Subgroup	Group 1: any rigid cup Events	Total	Group 2: any rigid cup Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Ismail 2008	35	85	42	79	30.6%	0.77 [0.56 , 1.07]
Thiery 1987	91	200	101	210	69.4%	0.95 [0.77 , 1.16]
Total (95% CI)		**285**		**289**	**100.0%**	**0.89 [0.75 , 1.06]**
Total events:	126		143			

Heterogeneity: Chi² = 1.02, df = 1 (P = 0.31); I² = 2%
Test for overall effect: Z = 1.26 (P = 0.21)
Test for subgroup differences: Not applicable



APPENDICES

Appendix 1. Search methods for ICTRP and ClinicalTrials.gov

ICTRP

Each line was run separately

ventouse

vacuum AND delivery

forceps AND delivery

vacuum AND birth

forceps AND birth

instrumental delivery

ClinicalTrials.gov

Advanced search

Interventional Studies | instrumental delivery

Interventional Studies | vacuum delivery

Interventional Studies | forceps delivery

Interventional Studies | ventouse

WHAT'S NEW

Date	Event	Description
14 May 2021	New citation required but conclusions have not changed	The conclusions remain unchanged, but the review has been updated to include GRADE summary of findings tables.
14 May 2021	New search has been performed	Search updated and three new studies included (Equy 2015; Mola 2010; Shekhar 2013). Three studies included in the 2010 update have been excluded in this update (Loghis 1992; Maleckiene 1996; Mustafa 2002). Two new excluded added (Mejido 2019 and Romero 2021).

HISTORY

Protocol first published: Issue 3, 2005
Review first published: Issue 11, 2010

Date	Event	Description
15 April 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

G Verma (GV) and V Vannevel (VV) prepared the first draft of the proposal for update, with contributions from GJ Hofmeyr (GJH) and F O'Mahony (FOM).

GV and J Spalding (JS) and M Wilkinson (MW) piloted the eligibility, risk of bias and data collection forms.

GV and JS contributed to study selection data extraction, data entry and data analysis. FOM resolved any disagreements.

GV, JS and MW drafted the full write-up with contributions from FOM, GJH and VV.

DECLARATIONS OF INTEREST

Ganga L Verma: none known.

Jessica J Spalding: none known.

Marc D Wilkinson: none known.

G Justus Hofmeyr: is author of one trial included in the study, and did not participate in decisions regarding this trial.

Valerie Vannevel: none known.

Fidelma O'Mahony: none known.

SOURCES OF SUPPORT

Internal sources

- University Hospital of North Midlands, UK
- (GJH) Effective Care Research Unit, University of the Witwatersrand, University of Fort Hare, Eastern Cape Department of Health, South Africa

External sources

- (GJH) HRP-UNDP/UNFPA/WHO/World Bank Special Programme in Human Reproduction, Geneva, Switzerland

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We have updated the contents of the review in accordance with the latest *Cochrane Handbook* (Higgins 2021). In particular we have followed the standard formats and subheadings of the Background, Plain language summary and Discussion. We have included greater detail in the 'Characteristics of studies' tables, including setting, dates of studies, funding information and declaration of interests of the authors, in line with the MECIR guidance. We have employed the GRADE approach to evaluate the certainty of the evidence and produced summary of findings table.

For completeness and to avoid variation, we assessed all the previously-included trials for eligibility and re-performed the risk of bias assessment and data-extraction process. We excluded four studies (Lim 1997; Loghis 1992; Maleckiene 1996; Mustafa 2002) that were included in the O'Mahony 2010 review.

We altered the term 'metal' to 'rigid' in the comparisons, to allow the inclusion of rigid non-metal material vacuum cups.

The term 'vaginal birth' is preferred to 'vaginal delivery' in Cochrane Pregnancy and Childbirth review, and this has been reflected in the change of title and throughout the review.

As the incidence of 'any maternal trauma' was greater than 90% in the control groups, we have reported these as odds ratios (ORs) and not risk ratios (RRs), as stated in the Methods, following feedback from the statistical referee.

NOTES

The review replaces three previously-published Cochrane Reviews that addressed forceps versus ventouse and soft cup versus rigid cup ventouse (Johanson 1999; Johanson 2000; O'Mahony 2010).

INDEX TERMS

Medical Subject Headings (MeSH)

*Parturition; *Postpartum Hemorrhage

MeSH check words

Female; Humans; Infant; Infant, Newborn; Pregnancy