The cost-effectiveness of introducing Manual Vacuum Aspiration compared to Dilatation and Curettage for incomplete first trimester abortions at a tertiary hospital in Manzini, Swaziland.

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2010-2013

Dissertation submitted in partial fulfilment for the degree of
Master of Science in Clinical Epidemiology
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Abstract

Background: Despite proven efficacy, Manual Vacuum Aspiration (MVA) use for incomplete abortions is low in the Swaziland setting, including Raleigh Fitkin Memorial (RFM) Hospital. Uncertainty in the costs implications of introducing MVA to replace Dilatation and Curettage (D&C) is the major hindrance to change. This study aimed to evaluate the cost-effectiveness of introducing MVA as an evacuation method for first trimester incomplete miscarriages as well as assess the implications of the introduction of MVA to the entire post-abortion care budget at RFM Hospital.

Methods: The methods comprised cost-effectiveness and budget impact analyses from a healthcare perspective based on a theoretical cohort. Clinical outcomes data for procedures were obtained from relevant literature. Costs were collated from prospective suppliers and then compared for the two treatment modalities. Future numbers of annual evacuations were extrapolated from previous annual figures. First trimester miscarriages were in turn extrapolated from proportions found in previous studies. Total budgets were calculated under the current scenario, as well as if MVA had to be introduced.

Results: With initial capital costs of ZAR11 093.00, introduction of MVA for first trimester incomplete abortions will cut post-abortion care costs by 34.7%. MVA would cost ZAR819.86 per procedure while D&C costs ZAR1 255.40 per procedure. An estimated 26 MVA procedures done instead of D&C will compensate for the initial capital investment. Introduction of MVA into the post-abortion care programme will save the hospital about ZAR516 115.30 annually, with at least similar clinical outcomes compared to D&C.

Conclusions: MVA should be considered as the first option in first trimester post abortion care.

Keywords: Dilatation and Curettage, Manual Vacuum Aspiration, cost-effectiveness analysis, budget impact analysis, post-abortion care

Attestation

I understand the nature of plagiarism, and I am aware of the University's policy on this.

I certify that this dissertation reports original work by me during my University project except for the following:

- Table 1 which was adapted from a WHO document of the same title.
- Table 2 which was reproduced with permission of the Postabortion Care Consortium.
- Table 3 which was adapted from Greenslade et al, 1993 and acknowledged accordingly.

Signature **Date 22/07/13**

Acknowledgements

My sincere thanks go to my co-supervisors at the SHSPH, Drs Saiendhra Moodley and Jacqui Miot who gave me step-by-step guidance since the very first day of this project. The encouragements of Professor Paul Rheeder at the SHSPH as well as management and colleagues from Raleigh Fitkin Memorial hospital also went a long way in shaping this project up to this point. Special thanks go to Sister Thelma Mabuza who assisted in some aspects of data collection.

1. Introduction

Having been known for over a half-a-century since its introduction in the 1960's[1], Vacuum Aspiration (MVA) continues to lag behind Dilatation and Curettage (D &C) in some developing countries in its use for first-trimester miscarriage. Aptly described as something that impresses everyone who has never seen it because of its "cleanness, apparent bloodlessness, speed, and simplicity",[1] this procedure also tends to suit the developing world because of the lesser time it requires, no need for anaesthesia, no need for electricity and additionally, lesser complication rate like reduced blood loss and fewer perforations. In addition, the fact that it can be carried out by junior cadres, the senior ones being more scarce in these settings makes it very viable for resource-restrained settings.[1,2]

Uncertainty about costs to be incurred and a general resistance to change may be some of the factors behind a delay in some settings' taking up MVA usage in first trimester incomplete abortions.

1.1. Miscarriage

Pre-viability pregnancy loss, also known as miscarriage or abortion,[3,4] is a significant contributor to morbidity and mortality. As much as 13% of maternal deaths are attributable to miscarriages[5], approximating to over seventy-eight thousand deaths worldwide.[6] The majority of these deaths occur in the developing world, most likely due to resource-limitation. It is every health setting's goal to provide the most-effective management protocols for miscarriage cases, and especially those associated with complications.[7] Timely and effective definitive management protocols are known to reduce mortality due to pre-viability pregnancy loss by as much as 20%.[8]

Epidemiology

Viability is a function of a particular healthcare setting although it generally tends to fall in the window 20-24 weeks, with the World Health Organisation (WHO) using a cut-off of the of 500 grams foetal weight.[3] In resource-limited settings, however, 28 weeks is considered by many to be a more practical cut-off as survival below this gestational age is less likely.[9] Studies using highly sensitive pregnancy markers have shown that about 25% of all conceptions miscarry within six weeks of the Last Normal Menstrual Period (LNMP).[10] An additional 8% of pregnancies are lost afterwards with about 85% of clinically recognisable spontaneous pregnancy losses occurring before 12 weeks of gestation.[11] About 15% of recognisable pregnancies are miscarried, either induced or spontaneously.[12] Although overall miscarriage rates are comparable in different regions, unsafe abortions rates tend to be higher in the developing world.[13] Table 1 shows estimates of unsafe abortions in developing countries in comparison to those in the developed regions of the world.

Table 1: Impact of unsafe abortions by regions

Region	UA (1000s)	UA /1000 women 15-49	Deaths UA	Mortality UA/ 100,000 live births	Case fatality /100 UA	Risk of death
More developed countries	2340	8	600	4	0.03	1 in 3700
Less developed countries	17620	17	69000	55	0.4	1 in 250
Africa	3740	26	23000	83	0.6	1 in 150

Adapted from: Unsafe abortion: global and regional estimates of the incidence of unsafe abortion and associated mortality in 2000. 4th. Geneva, Switzerland: World Health Organization, 2004.

Unsafe abortion accounts for an eighth of pregnancy-related deaths,[14-16] with a case fatality rate of 0.4 per 100 live births.[6]

Risk factors

Several risk factors for spontaneous miscarriage are known, with interplay between various factors common. Some of these factors include maternal age above 30 years, increased parity, smoking, alcohol and illicit drug use, previous uterine surgery and uterine abnormalities, connective tissue disorders, systemic metabolic syndromes and immunosuppressive disorders among a host of others.[17]

Classification of miscarriages

Presentation of patients with miscarriage depends on the stage at presentation as well as any interventions that would have been done. While patients may present with any of the several types of miscarriage from the 'safe' end of missed miscarriage to the other extreme of septic miscarriage, it is the threatened, inevitable, incomplete and septic variants (Table 2) that need speedy and effective emergency intervention if morbidity, mortality, pain and anxiety are to be kept at the minimum possible.

Table 2: Stages of abortions

Diagnosis	Bleeding	Cervix	Uterine size	Other signs
Threatened abortion	Slight to moderate	Not dilated	Equal to dates by LMP	Positive pregnancy test Cramping Soft uterus
Inevitable abortion	Moderate to heavy	Dilated (>3cm)	Less than or equal to dates by LMP	Cramping Tender uterus
Incomplete abortion	Slight to heavy	Dilated(soft)	Less than or equal to dates by LMP	Cramping Partial expulsion of POC's
Complete abortion	Little or none	Soft (dilated/closed)	Less than dates by LMP	Less or no cramping Expulsion POC's Firm uterus

Reproduced with permission from the Postabortion Care Consortium[16]

Management of miscarriage

The effectiveness of family planning methods, structure of emergency post-abortion care services and the link between the entire post-abortion care program to the rest of the health care system are the major determinants of post-abortion care programs' success. In the developing world, it is the emergency post abortion care that leaves a lot of room for improvement especially when considering the inaccessibility of care points to the populace[18], and the general staff shortage in the facilities. The choice of management approaches, therefore, is supposed to take into consideration these constraints among other issues, and a particular system may deem pertinent.[6, 14-17]

There are several approaches to the definitive management of incomplete abortions, some being conservative while others are more invasive. The major determining factors are the health setting, resource and infrastructure availability[19], technical and practice limitations of personnel involved in post-abortion care, patient preferences and presence or absence of complications. However, the factors expected to have more influence on the choice of approach are the clinical efficacy and complication rates of a particular method. Well-developed settings may choose less invasive methods as their first option as they can monitor their patients closely. On the other hand, resource-limited settings are likely to prefer more definitive methods as it is difficult to institute close monitoring of patients for possible complications and incomplete evacuation.

With conservative approaches only marginally superior in terms of infection risk[20], the choice in most settings is based on the success rates, giving surgical approaches the edge in most developing countries. In any case, both expectant and medically-managed patients tend to have an increased risk of unplanned admissions and repeat evacuations when compared to those managed surgically.[11,20] Surgical intervention, therefore, remains the most viable option

for most of the developing world where patient follow-up is difficult due to poor accessibility of health service facilities.

A debate continues, however, as to which of the two surgical approaches to use given a health setting, its limitations, expertise as well as what has been going on 'traditionally'. Consequently, there are settings in which the uptake of Manual Vacuum Aspiration (MVA) either as an alternative to or a replacement for Dilatation and Curettage (D&C) was almost instantaneous and yet in other settings there has been a huge delay in the shift despite even local evidence to the contrary.

Being the more invasive of the two procedures, D&C is generally done in theatre, sometimes under general anaesthesia. This already brings in two issues: the need for extra personnel and more pressure on theatre space. In addition, the complexity and the trauma involved in the procedure means it is only the senior clinician who can do it to an acceptable degree of safety. In addition, even the most efficient theatres do have a time lag when compared to procedures that can be done in an emergency department or outpatient setting. In contrast, MVA does not need to be done in theatre nor does it need a highly specialized room.[16]

Comparisons: D&C versus MVA

On clinical efficacy comparison, MVA and D&C have basically the same success rates in terms of complete evacuations, with some studies showing MVA to better D&C in most of the important clinical attributes.[21-24] In addition to being statistically significantly superior to D&C in terms of intra-operative blood loss and post-operative hemoglobin levels, MVA has also been shown to have lesser incidences of uterine and cervical trauma.[21,22] Many other studies have been carried out to compare the two modalities, most of which have shown MVA to be a viable and effective replacement of its age-old predecessor.

In a review of results from 13 studies, the majority showed MVA to be superior to D&C in almost all the major aspects of concern to the post-abortion clinician (Table 3). At least 78% of studies reported MVA to be superior to D&C in terms of pelvic infection and excessive bleeding while above 80% of studies also showed MVA to have lower rates of traumatic injuries to the uterus and the cervix.[23]

Table 3: Summary of studies comparing MVA to D&C

Major Complications Reviewed	Complications with vacuum aspiration per 100 procedures Range of averages (N=95,136)	Complications with D&C per 100 procedures Range of averages (N=17,166)	Studies with lower complication rates for vacuum aspiration than D&C (%)
Excessive blood loss	0 - 15.7	0.5 - 28	10 of 13 (78%)
Pelvic infection	0.2 - 5.4	0.7 - 6	7 of 9 (78%)
Cervical injury	0 - 3.1	0.3 - 6.4	6 of 7 (86%)
Uterine perforation	0 -0.5	0 - 3.3	10 of 12 (83%)

Source: Greenslade et al, 1993.[23]

In a study done at the peak of the MVA-D&C debate, all-complication rates at any gestational age in the first trimester were found to be higher with D&C in comparison to MVA, the rates themselves being significantly higher the higher the gestational age at time of miscarriage.[25] With MVA, rates were noted to increase from under 2 per 100 below 8 weeks

to about 6% beyond 13 weeks while D&C has about 2% complication rates below 8 weeks to about 9% beyond the first trimester.[25]

Clinical outcomes did not change when trained midwives did MVA instead of medical officers[25]. Introduction of MVA into a post-abortion care programme could easily translate to decentralization to lower levels of healthcare with the much-needed improvement in accessibility of healthcare that is currently lacking in most developing countries. In addition, trained midwives doing the procedure could magnify the reduction in human resources costs demonstrated in some studies in addition to the improved client-satisfaction rates that 'non-theatre' procedures tend have over those done in theatre.[26,27] An additional advantage that MVA holds over D&C especially in resource-limited settings is the reduction in length of hospital stay, sometimes by as much as half that of the latter.[28] The introduction of MVA would certainly take pressure off material and human resources.

Client satisfaction may climb as high as 86% with MVA, almost double that of D&C, meaning MVA introduction may significantly alter the health-seeking behaviors of post-abortal women. More so, access to family planning service as part of post-abortion care was found to be significantly improved when MVA was done instead of D&C, a positive attribute given the value of prevention in any pathological processes.[27]

In addition to the clinical parameters outlined, there is always the economic aspect to be considered whenever there is a comparison of any interventions nowadays.

From prospective and other costing studies done in Peru, Mexico, Tanzania, Ethiopia, Kenya and Nigeria, MVA was shown to be a cost-saving intervention when introduced to replace D&C for first trimester post-abortion care. As much as a 50% reduction in post-abortion care costs were demonstrated in some of these studies in addition to the reduction of hospital stay, client productivity losses as well as complication rates mentioned earlier.[27-32]

With the above information in mind and considering the fact that MVA is not (yet) in use in Swaziland, it is difficult to rule out the influence of cost uncertainty in the hesitancy to embrace such useful and probably cost-saving technology. Faced with difficulty of generalizing economic evaluation evidence[33], this study aimed to a) assess the cost-effectiveness of introducing MVA in place of D&C in the management of first trimester incomplete abortions at RFM Hospital and, b) evaluate the possible budget implications of the same change to the post-abortion care programme at the facility.

RFM Hospital, based in the city of Manzini, is the second largest public health facility in Swaziland. It is a government-subvented, 350-bed multi-disciplinary facility with an average 20 to 25 deliveries daily as at the end of 2012, and up to 60 daily consultations in the gynaecological outpatients unit alone. Being a central hospital, its catchment area is basically the whole Kingdom, catering for patients of different socioeconomic standing. About 25 incomplete abortions are managed weekly, all using D&C in the main theatre.

2. Aims and Objectives:

Aim:

- To evaluate the overall cost-effectiveness of introducing MVA for first trimester abortions compared to D&C

Objectives:

- To estimate the cost to the health service of carrying out evacuation of retained products of conception using D&C
- To estimate the cost of managing first trimester incomplete abortion using MVA
- To compare the costs of the two treatment modalities
- To estimate the savings that MVA introduction would make for first trimester post-abortion care.

3. Methods

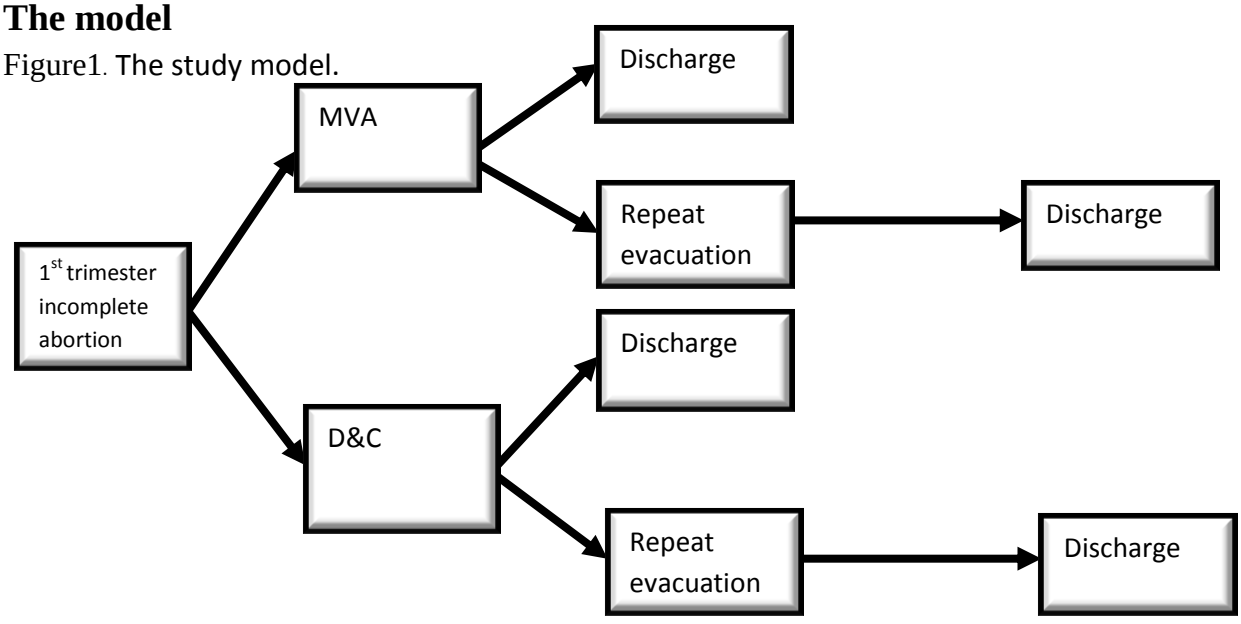
Study design: This is an economic evaluation (cost-effectiveness and budget impact analyses) from a health service perspective based on a theoretical cohort and mixed data sources.

Setting: The study was done at Raleigh Fitkin Memorial (RFM) Hospital, a government-subvented central hospital in Manzini, Swaziland.

Patient inclusion and exclusion criteria: All evacuations for first trimester incomplete miscarriages, regardless of maternal age were included in the comparison. Evacuations for other reasons were excluded.

The model

Figure1. The study model.



Measurements

Efficacy data

Efficacy data was inferred from relevant studies comparing MVA to D&C and is shown in the Table 1 with the sensitivity analysis ranges where appropriate. Sensitivity ranges were taken from extremes found in different studies except in a few instances where arbitrary cut-offs of 20% around a quoted figure were used (Table 1)

Table 4: Clinical outcomes data

Outcome measure	MVA	D&C	Source
	Outcome (Sens. Range)	Outcome (Sens. Range)	
Success rate (%)	100	99.3	Verkuyl &Crowther,1993[22]
All complications (%)	1.2 (1;1.4)	6 (4;10)	Warriner et al, 2006[26] Zhou et al, 2002[34]
**Pre-Op time (min): Nurse*	63.8(±20%)	92.8(±20%)	The Population
Medical Officer	75.1(±20%)	88.1(±20%)	Council,1997[27]
Pelvic infection (%)	1 (0.2;5.4)	4 (0.7;6)	Mahomed et al, 1994[21]
Excessive blood loss (%)	0 (0;15.7)	0.1 (0;28)	Verkuyl &Crowther,1993
Admission (%)	0	100	The Population Council,1997
Percentage **FP-counseled	85.5 (68.5;100)	42.4(33.9;50.9)	The Population Council,1997

*Pre-Op time- time from presentation to procedure commencement in minutes

**FP-Counseled- family planning-counseled

Costing

A cost sheet was designed for each procedure (see Appendix C). All costs, initially in Swaziland Emalangeni were converted into South African Rands (ZAR) at a rate of 1:1 as the Swaziland currency is directly linked to the Rand. Costs, as obtained from various sources, were entered into an excel-based spread sheet and included:

Capital costs: these were exclusive to MVA which is not being done at the moment. D&C is already being done, in the main operating room. Capital costs for MVA included staff-training, purchase of an extra gynaecological bed, speculums and gowns. MVA procedure kits were included under the direct medical costs given their short lifespan.

Human resources costs: A working month comprised of four weeks, with each week comprising of 40 hours. Hourly rates were calculated as monthly salary divided by 160, the 160 being total number of hours that a health worker is expected to be on duty in average month. The personnel components of procedure costs were prorated from times those respective healthcare workers will be caring for the patient against their hourly pay.

Other direct medical costs: These included detergents, anaesthesia and analgesia, antibiotics, procedure kits, family planning consultation and admission (based on Swaziland-specific costs of the hotel-component of admission as per WHO-CHOICE 2008)[35]. The hotel (hospital

stay) component as estimated by the WHO excludes drugs, procedures and diagnostics but includes consultations, meals, nursing and other personnel time outside procedure periods.

Indirect medical/overhead costs: The annual hospital operating expenditure for 2011 that included utility bills, waste disposal, professional services, toilet and cleaning supplies, computer services and transport and vehicle maintenance was divided by the total number of attendances per year at the hospital with an assumption of uniformity in cost distribution. The budgets were requested and obtained from the Financial Controller's office, with the permission of the rest of the Hospital Administration. Other costs that could have been included but were difficult to calculate were wages for non-clinical staff.

Discounting: No discounting was done for costs as these are comparisons of costs borne in the same calendar year.

Analysis of cost-effectiveness

This was done according to the WHO-CHOICE 2005 cost-effectiveness thresholds that are based on the country's Gross Domestic Product (GDP) per capita. The classification of countries by their GDP per capita places Swaziland in the Afro D class (Table 5)

Table 5: Cost-effectiveness thresholds as per WHO-CHOICE 2008

African regions cost effectiveness thresholds:2005		
Threshold value	**Afro D**	**Afro E**
GDP per capita	$1635	$2154
3 X GDP per capita	$5085	$6461
GDP = Gross domestic product; < GDP per capita (Very cost-effective); 1-3 x GDP per capita (cost-effective*); > 3 x GDP per capita (not cost-effective)		

Adapted from WHO-CHOICE 2008[36]

Budget impact analysis

It is estimated that 85 of every 100 abortions occur in the first trimester. It makes sense to further propose the same proportions with incomplete abortions and, by such extrapolation; the total number of incomplete abortions amenable to MVA was calculated. The total budget for first trimester post abortion care was deduced from individual patient cost as calculated in based on per case resource-use. In addition to other variations in the sensitivity analysis, the possibility of having MVA done by trained midwives was explored as well.

Sensitivity analysis

Twenty percent variations were used in the sensitivity analysis of costs as these extremes were considered to represent any possible deviations from quoted figures that could be met in practice. Where available, extremes in sensitivity analyses were taken from the extremes noted in different studies evaluating the respective clinical parameters.

Ethics and Permissions: The study got approval from the University of Pretoria's Faculty of Health Sciences Research Ethics Committee, Swaziland Scientific and Ethics Committee as well as the RFM hospital's Administrator and Chief Executive Officer's offices. No individual files were searched and no individual patient data was collected

4. Results

Miscarriages accounted for over 57% of gynaecological admissions at RFM Hospital during the periods reviewed. Table 6 shows the number of evacuations for years 2009, 2010 and 2011.

There was an 11.42% increase in the number of evacuations for retained products of conception from the year 2009 to 2010. The year 2011 saw a 4.93% increase in the number of incomplete abortions compared to the previous year. An increase of 8.12% in number of evacuations was postulated, being the average of the preceding years' increases. That postulation gave an estimated 1395 evacuations for the year 2012, 1185 of these evacuations presumed being in the first trimester hence amenable to MVA, being 85% of all clinically recognizable pregnancy losses.[11]

Table 6: Number of evacuations for the three years starting 2009

Year	Number all evacuations of products of conception	Percentage change
2009	911	-
2010	1015	+11.42%
2011	1065	+4.93%

Having considered what needs to be put in place in already-available rooms in the ambulatory section of the hospital, it was calculated that a total of ZAR11 092.73 is required to introduce MVA, being the capital costs (Table 7).Once introduced, an MVA procedure costs about ZAR819.86, which represents a 34.7% reduction from the costs of D&C (D&C costs ZAR1255.40 per procedure). The saving means substituting MVA for D&C would require around 26 procedures to have saved enough to compensate for the initial start-up costs and, translated into time, means within a week of its introduction, MVA would have saved enough to cover its own capital costs were it to be introduced in place of D&C.

Table 7: Capital costs for MVA

Item	Cost (ZAR)	Comments
Training	6000	Quotes from Swazipharm for capital items, Training costs obtained from Medecins Sans Frontiers workshop costs.
Gynaecological bed	4278.73	
Speculums	814.27	
Total Capital Costs	**11 092.73**	

Table 8: Major costs for both treatment options

Item	*Cost (ZAR)		Source/Comments
	MVA	D&C	
Direct Medical Costs			Admission and outpatients consultation costs obtained from WHO-CHOICE 2008 Central Medical Stores and Swazipharm for other direct medical costs
Admission	---	191.47	
OPD consultation	72.54	72.54	
Family planning visit	---	72.54	
Procedure consumables	401.17	346.41	
Human Resources			Basic salaries were obtained from the hospital Personnel Department and pro-rated with time spent with patient. Times were inferred from the Mexico Population Council study.
Medical Officer	244.95	312.26	
Nurse	117.67	185.26	
Anaesthetist	---	15.65	
Others	22.38	25.70	
Indirect medical costs	33.57	33.57	Calculated from annual hospital operating expenditure excluding direct medical expenditure divided by the total number of attendances in the year
Grand Totals	**819.86**	**1255.40**	

*all costs were varied by 20% except for medical officer cost which was varied from 0 to 20% above the quoted value.

Significant reductions in costs if MVA were to be introduced were in human resources (28%) and procedure consumables and medical supplies (41%). An additional family planning visit was deemed to be a requirement with D&C but not with MVA since the latter is a 'day procedure' and this represented a notable contribution to the cost of D&C.

The major contributors to total procedure costs were medical officers and nurses times as well as procedure consumables (Table 9)

Table 9: Major contributors to procedure costs

Item	Percentage contribution	
	MVA	D&C
Medical Officer	29.8	24.9
Nurse	14.4	14.8
Procedure consumables	50.0	27.6
Admission	-	15.3
OPD consultation	8.8	5.8
Family planning consultation	-	5.8

5. Budget impact analysis

From the extrapolated figures for 2012, the total budget for first trimester post-abortion care using D&C stood at about ZAR1 487 649.00 (1185 procedures at ZAR1255.50 per procedure). Introduction of MVA instead of D&C would have brought the figure down to ZAR971 533.70 (1185 procedures at ZAR819.86 per procedure) for the same period, a reduction of 34.7% (ZAR516 115.30).

6. Sensitivity analysis

Univariate sensitivity analysis was done for the major components of procedure costs for both treatment methods. An arbitrary 20% variation on most costs was chosen as it was considered enough to cater for any realistic variation that may be encountered in practice. MVA was confirmed to be robustly cost-effective and remained dominant over D&C in all extremes of univariate sensitivity analysis (Tables 8 and 9). As a result, no incremental cost-effectiveness ratios (ICER's) are reported.

Table 10: Univariate sensitivity analysis results for MVA

Cost Parameter	Procedure Cost (ZAR)		Comments
	Upper limit	Lower	
Medical Officer	868.85	574.91	Lower limit was 'no medical officer', upper limit was 20% more on medical officer
Nurse	843.39	796.33	±20% as limits
Other direct Medical Costs (combined)	900.70	740.03	±20% as limits

The above table (Table 8) shows the total cost of each MVA procedure when the respective contributory costs were varied within the limits of the sensitivity analyses as explained under 'comments'.

Table 11: Univariate sensitivity analysis results for D&C

Cost parameter	Procedure cost (ZAR)		Comments
	Upper limit	Lower limit	
Medical Officer	1317.85	1192.95	20% variation
Nurse	1292.45	1218.35	20% variation
Other Direct Medical costs (combined)	1391.99	1118.81	20% variation
Total human resources costs	1363.17	1147.63	20% variation

Table 9 demonstrates how each D&C procedure remains significantly more costly compared with MVA (Table 8) in all ranges of sensitivity analyses.

The biggest influences on costs in the sensitivity analysis were personnel costs particularly medical officer and nurse's time. In addition to its dominance in clinical parameters as well as variation of single items, D&C remained costly compared to MVA even with variation of 'bulk' items such as 'total direct medical costs' and 'total human resources costs'.

A more exciting observation in the sensitivity analysis was the magnitude of savings if nurses were to do evacuations of retained products of conception instead of medical officers. If done by a midwife, MVA introduction would result in a 54.2% reduction in first trimester post abortion care, saving the hospital ZAR680.43 per procedure, and ZAR806 381.00 annually. The rest of the individual component costs were not as influential in the univariate analysis as reflected in the tables above.

7. Discussion

The results indicate that MVA introduction would be a very cost-effective change to the post-abortion care program at RFM hospital. Significant cuts in costs to the hospital, and possibly to patients as well, are likely to be realised especially due to shorter hospital stays and reduced morbidity resulting from MVA in comparison to D&C. Such significant sums saved through the introduction of MVA may actually be enough to fund parallel programs or other components of reproductive health such as unsafe abortion prevention, safe abortion awareness promotion and advocacy.

No incremental cost-effectiveness ratios are reported as they were all negative for positive outcomes implying dominance of MVA over D&C. Furthermore, no statistical analysis was done to demonstrate difference between the two arms being compared as the primary goal of the investigators was to demonstrate practicality of introducing MVA for first trimester miscarriages.

The results in the study have shown some consistency with those from other settings like Peru, Mexico, Kenya, Tanzania, Nigeria and Ethiopia in that MVA is associated with significant reductions in post-abortion care costs.[27-32] The cost of MVA found in our study is similar to that found in a study done in Peru (at US118.73, equivalent to about ZAR950)[28]. Although this observation may be mere coincidence, it is the overall conclusion that is of significance. Heterogeneity is expected in economic evaluations, not necessarily purely due to healthcare and economic setups but differences in technical and professional approaches. It comes as no surprise therefore that some studies have found as little as a tenth of what we found while others found as much as three times our cost values.

In a 1996 Mexican study, D&C was found to cost US$264 (about ZAR 2000) per procedure while MVA cost US$74 (about ZAR600) per procedure.[8] Although this was a prospective study, the bigger reduction found with MVA introduction could have been due to the way costs were collated, quoting subsidized values and use of donor items especially with MVA since it was the phase of its introduction into the setting. The same applies to many settings in which the costs of either or both treatment modalities seemed grossly suppressed. In a Kenyan study, D&C was estimated at US$17 (about ZAR136) per procedure, US$11 more than the cost of MVA[29]. Given that some of the individual items needed for D&C such as intravenous fluids already surpassed this total in our study, it can only be concluded that there is probably unmentioned use of subsidized costs rather than the market costs in arriving at the

costs. The Mexican and Kenyan studies show somewhat contrasting differences from our results, probably as a result of differences in methodology, setting and, maybe more importantly time and its associated economic changes. Of note, however, is the fact that the 28 and 41% decreases in staff and supplies costs respectively tally with reductions found in the Mexican study for the same cost components (33% for staff and 65% for instruments and supplies if MVA was done instead of D&C)

The somewhat smaller overall reduction with MVA introduction noted in the current study compared with the others could be explained by the differences in settings alone. However, the fact that the current study was a desk analysis while the others were prospective studies may also be a cause for the difference. In addition, the use of mixed data sources may have brought in heterogeneity to the whole fray. Furthermore, the other analyses were made much earlier than this study and the time that has elapsed may have influenced the differences.

A notable cost omission from the current study was the opportunity cost of moving patients out of the main operating room, freeing much needed space. Although this could not be expressed in monetary terms, MVA does have a huge operational advantage over D&C in this respect.

Due to similarities in suppliers and the way procedures are done, the results of this study are probably generalisable to the whole of Swaziland including private facilities. The same consideration makes the same findings transferrable to the rest of the region including South Africa as Swaziland and the rest of Sub Saharan Africa, and especially the SADC region, have similar and apposed health care and economical structures. In addition, technical practices and professional attitudes to material and resource conservation are expected to be similar as most of the senior clinical personnel come from the same training institutions. The low set-up costs and the invaluable opportunity of freeing main theatres should make introduction of MVA easy and sustainable.

A prospective study would have given less bias in the results as it would have recorded actual times that these procedures take at RFM Hospital. Furthermore, such a study design could have added valuable clinical information on complication rates and the costs of managing them, repeat evacuations as well as the costs of other services rendered to clients that may be missed from a desk analysis. Especially important in the Swaziland setting is the issue of HIV testing and counseling which, by policy, should be offered to all patients that come into contact with the health setting. It would have been exciting to see how the clinical outcomes as well as costs would differ from other settings given the high HIV infection rates. The material and, maybe more critically, the personnel shortage would definitely make data collection in a prospective study almost impossible given that current staff is already overwhelmed with their routine work.

It was difficult to assign care times to other health workers such as porters and cleaners and arbitrary times had to be assigned which may differ from reality. No prospective study was found which took these carers into consideration and may, to a very limited extent though, contribute to differences in our results from other studies. However, these times are relatively

small and may actually be similar in the two arms of the comparison resulting in minimal bias. Other small costs that may have been omitted include transfusions, information on which was not easily accessible as most studies evaluated had no power to evaluate such 'rare' events.

A further limitation of the study was the fact that it used one perspective only. More information on savings could have been obtained if there was an inclusion of the health care user's perspective as it would include information on loss of productivity due to post-abortal and post-procedure morbidity. The health user perspective is one we cannot underestimate or afford to overlook as it has a huge bearing on the accessibility of health care and can easily modify health seeking behavior.

8. Conclusion

MVA, being at least as safe and efficacious as D&C, is a cost-effective replacement of D&C for first trimester miscarriage at RFM Hospital and will save much needed money. We recommend that MVA be considered the first management option for first trimester incomplete miscarriages.

It may be of significant help to the entire Swaziland health sector if MVA could be integrated into the post-abortion care program with subsequent decentralization to lower levels of health care for an improvement in emergency post-abortion care.

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Appendix A: Study assumptions

The study was undertaken under the following major assumptions:

1. Space is already available for MVA and is conducive to the conduction of the procedure. Any room modifications required are of minimal cost and therefore negligible to the total capital costs.
2. Based on the need for post procedure care, all D&Cs are considered 'admitted' while all MVAs are considered dischargeable post procedure.
3. One MVA is proposed to last a conservative 25 procedures before it is considered unusable.
4. Costs of medical supplies as obtained from the Swaziland Central Medical Stores Price List of 2011are accurate and any increases are considered to be parallel to each other and therefore unlikely to impact on the study conclusions.
5. There is equal need for antibiotics amongst the two groups of patients, based on equal infection rates as quoted in literature.
6. A separate family planning visit is required with D&C as it is a more complicated procedure and will not allow enough time for counseling in one visit.
7. No serious complications that warrant long term admission and care are considered in either treatment modality. In addition, no death, permanent disability no sub-fertility were taken into consideration in the study

CHURCH OF THE NAZARENE
Raleigh Fitkin Memorial Hospital

P.O. Box 14,
Manzini, Swaziland,
Southern Africa.
Phone: Manzini
(09268) 505 2211
Fax: (09268) 505 5077
Telex: 2356 WD

16 February 2012

Dr. Costa Maonei
RFM Hospital
P O BOX 14
Manzini

Dear Doctor

RE: AUTHORIZATION TO CARRY OUT A RESEARCH IN THE HOSPITAL

Your application on the fore mentioned endeavors has been duly considered and Authorization granted on the following conditions please;

a). That confidentiality is strictly observed
b). That the hospital receives a copy of the report on the proposed research.

Again thank you for considering the Institution for such a task and wishing you all The best.

Sincerely yours

Leonard S. Dlamini (Mr.)
HOSPITAL ADMINISTRATOR

CC: Chief Medical Officer
Matron 1

Appendix B

Updated 28-02-2007

Permission to access Records ~~/ Files~~ / Data base at
RALEIGH FITKIN MEMORIAL HOSPITAL
~~[Type in name of hospital / government department / hospital / school / company / NGO / etc]~~[1]

TO: MRS FUTHI H. MDLULI [Name][1]
Chief Executive Officer/Information Officer
RFM HOSPITAL
~~[Name of hospital / government dept. / hospital / school / company / NGO / etc]~~[1]

FROM : COSTA MAONEI [Name][1]
Investigator
RFM HOSPITAL
~~[Name of hospital / government dept. / hospital / school / company / NGO / etc OR investigator's home address]~~[1]

Re: Permission to do research at RALEIGH FITKIN MEMORIAL HOSPITAL
~~[Name of hospital / government department / hospital / school / company / NGO / etc]~~[1]

TITLE OF STUDY: THE COST-EFFECTIVENESS OF INTRODUCING MVA COMPARED TO D&C FOR INCOMPLETE FIRST TRIMESTER MISCARRIAGES AT RFM HOSPITAL

This request is lodged with you in terms of the requirements of the Promotion of Access to Information Act. No. 2 of 2000.

I am a researcher / student[2] at the Department of PUBLIC HEALTH at the University of Pretoria / ..... Hospital. I am working with DR S. MOODLEY [Title(s) and surname(s) of ~~co-investigator(s) / supervisor(s)~~][1]. I herewith request permission on behalf of all of us to conduct a study on the above topic on the ~~hospital grounds /~~ at your facility / GYNAE Department[2] This study involves access to ~~patient / client / learner / student /~~ THEATRE[2] records.

The researchers request access to the following information: ~~patient / client / learner / student /~~ THEATRE[2] ~~files,~~ record books and data bases.

We intend to publish the findings of the study in a professional journal and/ or to present them at professional meetings like symposia, congresses, or other meetings of such a nature.

We intend to protect the personal identity of the ~~patients / clients / learners / students /~~.....[2] by assigning each individual a random code number.

We undertake not to proceed with the study until we have received approval from the Faculty of Health Sciences Research Ethics Committee, University of Pretoria.

Yours sincerely

Signature of the Principal Investigator

Permission to do the research study at this institution / facility and to access the information as requested, is hereby approved.

Title and name of Chief Executive Officer: FUTHI H. MDLULI

Name of institution: SWAZILAND NAZARENE HEALTH INSTITUTIONS

Signature:

Date: 14/2/12.

SWAZILAND NAZARENE HEALTH INSTITUTIONS SNHI
Chief Executive Officer
Official Stamp
14 FEB 2012

[1] ~~Delete all highlighted instructions before submitting the form for a signature. Also delete this footnote.~~
[2] ~~Delete which is not applicable and or add a more appropriate description.~~

Appendix B

The Research Ethics Committee, Faculty Health Sciences, University of Pretoria complies with ICH-GCP guidelines and has US Federal wide Assurance.

* **FWA** 00002567, Approved dd 22 May 2002 and Expires 20 Oct 2016.
* **IRB** 0000 2235 IORG0001762 Approved dd 13/04/2011 and Expires 13/04/2014.

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Health Sciences Research Ethics Committee
Fakulteit Gesondheidswetenskappe Navorsingsetiekkomitee

DATE: 29/03/2012

NUMBER	**55/2012**
TITLE OF THE PROTOCOL	The cost-effectiveness of introducing manual vacuum aspiration compared to dilatation and curettage for incomplete first trimester miscarriages at Raleigh Fitkin Memorial Hospital, Manzini, Swaziland
PRINCIPAL INVESTIGATOR	Dr Costa Maonei; RFM Hospital, Manzini, Swaziland MSc Clinical Epidemiology, UP SHSPH **Cell:** +268 76738314 **E-Mail:** cmaonei@yahoo.com
SUB INVESTIGATOR	None
STUDY COORDINATOR	Dr Costa Maonei
SUPERVISOR (ONLY STUDENTS)	Dr Saiendra Moodley **E-Mail:** saiendra.moodley@up.ac.za
STUDY DEGREE	MSc Clinical Epidemiology
SPONSOR COMPANY	Self-sponsored
MEETING DATE	28/03/2012

The Protocol and Informed Consent Document were approved on 28 / 03 /2012 by a properly constituted meeting of the Ethics Committee subject to the following conditions:

1. The approval is valid for 1 year period [till the end of March 2013] , and
2. The approval is conditional on the receipt of 6 monthly written Progress Reports, and
3. The approval is conditional on the research being conducted as stipulated by the details of the documents submitted to and approved by the Committee. In the event that a need arises to change who the investigators are, the methods or any other aspect, such changes must be submitted as an Amendment for approval by the Committee.

Members of the Research Ethics Committee:

Prof M J Bester	(female)BSc (Chemistry and Biochemistry); BSc (Hons)(Biochemistry); MSc(Biochemistry); PhD (Medical Biochemistry)
Prof R Delport	(female)BA et Scien, B Curationis (Hons) (Intensive care Nursing), M Sc (Physiology), PhD (Medicine), M Ed Computer Assisted Education
Prof JA Ker	MBChB; MMed(Int); MD – Vice-Dean (ex officio)
Dr NK Likibi	MBB HM – Representing Gauteng Department of Health) MPH
Dr MP Mathebula	(female)Deputy CEO: Steve Biko Academic Hospital; MBCHB, PDM, HM
Prof A Nienaber	(female) BA(Hons)(Wits); LLB; LLM; LLD(UP); PhD; Dipl.Datametrics(UNISA) – Legal advisor
Mrs MC Nzeku	(female) BSc(NUL); MSc(Biochem)(UCL, UK) – Community representative
Prof L M Ntlhe	MbChB (Natal) FCS (SA)
Snr Sr J Phatoli	(female) BCur(Eet.A); BTec(Oncology Nursing Science) – Nursing representative
Dr R Reynders	MBChB (Prêt), FCPaed (CMSA) MRCPCH (Lon) Cert Med. Onc (CMSA)
Dr T Rossouw	(female) MBChB (cum laude); M.Phil (Applied Ethics) (cum laude), MPH (Biostatistics and Epidemiology (cum laude), D.Phil
Dr L Schoeman	(female) B.Pharm, BA(Hons)(Psych), PhD – Chairperson: Subcommittee for students' research

DR R SOMMERS; MBChB; MMed(Int); MPharmMed.
Deputy Chairperson of the Faculty of Health Sciences Research Ethics Committee, University of Pretoria

♦Tel:012-3541330 ♦Fax:012-3541367 / 0866515924 ♦E-Mail: manda@med.up.ac.za
♦Web: //www.healthethics-up.co.za ♦H W Snyman Bld (South) Level 2-34 ♦ Private Bag x 323, Arcadia, Pta, S.A., 0007

Item	Cost/unit	Quantity	Total cost		
10cc syringe	37/100	1	0.37		
18G needle	9.2825/100	1	0.92825		
22G needle	10.5/100	1	0.105		
Gauze	4.5/5M	0.1	0.09		
Surgical gloves	80.57/50	2	3.2228		
Anaesthesia:					
IV ketamine 50mg/ml vial	104.4/10	1	10.44		
Normal Saline 1L	10.66/L	1	10.66		
Urine bag	2.1 each	1	2.1		
Intracath. FG12	5.9/set	1	5.9		
Sub total				33.81605	
Infusion set:					
IV Catheter 16G	2.34/1	1	2.34		
IV 16G Infusion set	293.41/set	1	293.41		
Subtotal				295.75	
Oxytocin 5IU amp	31.51/5	10u	12.604		
3cc syringe	21.74/100	1	0.2174		
18 gauge needle	9.2825/100	1	0.92825		
Sub total				13.74965	
Procedure Consumables				**346.41**	
Antibiotics:					
IV ceftriaxone 1g vial	5.69/vial	2	11.38		
Doxycycline 100mg tb	67.7/1000	14	0.9478		
Ciprofloxacin 500mg tb.	22.1/100	14	3.094		
Metronidazole 400mg tb.	44.41/500	21	1.86522		
Sub total (0.04 patients)				0.69	
Analgesia:					
Ibuprofen 400mg tb.	80.4/500	15	2.412		
Sub total/patient				2.412	
Family planning visit				72.54	
Outpatient consultation				72.54	
Admission				191.47	
Sheet 1D Total					**387.218**

Costa Maonei 10339460

Cadre	Rate/mont	Duration ir	Amount(ZAR)
Medical Officer	24253.08	2.06	312.26
Pharmacist	16839	0.08	8.42
Anaesthetist	10014.25	0.25	15.65
Nurse	10014.25	2.96	185.26
Porter	3414.58	0.08	1.71
Cleaner	3414.58	0.25	5.34
OT Runner	2039	0.25	3.19
Ward aide	3414.58	0.33	7.04
Sheet 2D Total			**538.87**

Costa Maonei 10339460

Item	Expenditure (ZAR)		
Travel	58905		
Communications	117444		
Car mileage allowance	32025		
Fuel	262284		
Vehicle Maintenance	244054		
Pofessional services	412492		
Auditors remunerations	72452		
Association membership	500		
In-service training	66151		
Contracts:			
Building & works	71164		
Equipment	430393		
Printing	412373		
Computer services	85882		
Utility services:			
Water	1003077		
Electricity	909643		
Interest charges	2125		
Bank chares	158582		
Insurance premiums	85984		
Property taxes	138016		
Hospitality	7701		
Toilet & cleaning supplies	872503		
Uniforms, clothing & textile products	470075		
Other textile products	148328		
Printed material & office supplies	466679		
Maintenance materials	839640		
Total for all patients(219478)		7368472	
Cost for 1 patient			33.5727
Sheet 4D Total			**33.573**

Costa Maonei 10339460

Item	Cost/unit	Quantity	Total cost	
10cc syringe	37/100	1	0.37	
18G needle	9.2825/100	1	0.92825	
22G needle	10.5/100	1	0.105	
Gauze	4.5/5M	0.1	0.09	
Surgical gloves	80.57/50	2	3.2228	
Subtotal				4.716
Anaesthesia and fluids				
lignocaine 2% vial	13.75/50ml	10ml	2.75	
Normal Saline 1L	10.66/L	1	10.66	
Urine bag	2.1 each	1	2.1	
Intracath. FG12	5.9/set	1	5.9	
Subtotal				21.41
Infusion set:				
IV Catheter 16G	2.34/1	1	2.34	
IV 16G Infusion set	293.41/set	1	293.41	
Subtotal				295.75
Procedure kits				
MVA kit	1472.30each	0.04	58.892	
Kit sterilisation & packaging				
Antibiotics:				
Doxycycline 100mg tb	67.7/1000	14	0.9478	
Ciprofloxacin 500mg tb.	22.1/100	14	3.094	
Metronidazole 400mg tb.	44.41/500	21	1.86522	
Subtotal(0.01 patients)				0.05907
Analgesia:				
Diclofenac 25mg Suppo.	21.4/5	1	4.28	
Ibuprofen 400mg tb.	80.4/500	15	2.412	
Subtotal(0.01 patients)				6.692
OPD consultation				72.54
Sheet Total 1				**401.167**

Costa Maonei 10339460

Comments

Costa Maonei 10339460

Cadre	Rate/month	Duration in minutes	Amount(ZAR)
Medical Officer	24253.08	1.61	244.05
Pharmacist	16839	0.08	8.42
Nurse	10014.25	1.88	117.67
Potter	3414.58	0.08	1.71
Cleaner	3414.58	0.25	5.33
Ward aide	3414.58	0.33	7.04
Sheet 2 Total			**384.22**

Costa Maonei 10339460

Item	Cost/unit	Units Required	Cost (ZAR)
Staff training	3000	2	6000
Gynae exam couch	4278.46each	1	4278.46
Speculums: Auvard	669.27 each	1	669.27
Cuscos	145each	1	145
Sheet 3 Total			**11092.7**

Costa Maonei 10339460

Item	Expenditure (ZAR)		
Travel	58905		
Communications	117444		
Car mileage allowance	32025		
Fuel	262284		
Vehicle Maintenance	244054		
Pofessional services	412492		
Auditors remunerations	72452		
Association membership	500		
In-service training	66151		
Contracts:			
Building & works	71164		
Equipment	430393		
Printing	412373		
Computer services	85882		
Utility services:			
Water	1003077		
Electricity	909643		
Interest charges	2125		
Bank chares	158582		
Insurance premiums	85984		
Property taxes	138016		
Hospitality	7701		
Toilet & cleaning supplies	872503		
Uniforms, clothing & textile products	470075		
Other textile products	148328		
Printed material & office supplies	466679		
Maintenance materials	839640		
Total for all patients(219478)		7368472	
Cost for 1 patient			33.5727
Sheet 4 Total			**33.573**

Costa Maonei 10339460

Dilatation and crettage

Medical Officer		312.26
Pharmacist		8.42
Anaesthetist		15.65
Nurse		185.26
Porter		1.71
Cleaner		5.34
OT Runner		3.19
Ward aide		7.04
10cc syringe	0.37	
18G needle	0.92825	
22G needle	0.105	
Gauze	0.09	
Surgical gloves	3.2228	
Anaesthesia:		
IVDiazepam 10mg amp		
IV pethidine 100mg amp		
IV ketamine 50mg/ml vial		
IV thiopental 1g vial		
lignocaine 2% vial		
Normal Saline 1L	10.66	
Urine bag	2.1	
Intracath. FG12	5.9	
Sub total		33.81605
Infusion set:		
IV Catheter 16G		
IV 16G Infusion set		295.74
Oxytocin 5IU amp		
3cc syringe		
18 gauge needle		
Sub total		13.74965
Blood products		
Packed cells		
Platelet concentrates		
Fresh frozen plasma		
Procedure kits		
MVA kit		
Kit sterilisation & packaging		
D&C kit sterilisation and packaging		
Antibiotics:		
Amoxycillin		
IV ceftriaxone 1g vial		
Doxycycline 100mg tb		
Ciprofloxacin 500mg tb.		
Metronidazole 400mg tb.		
Sub total (0.04 patients)		0.69

 Costa Maonei 10339460

Analgesia:

Diclofenac 25mg Suppo.	
Paracetamol 500mg tb.	
Ibuprofen 400mg tb.	
Diclofenac 50mg tb.	
Sub total/patient	2.412
Family planning visit	72.54
Outpatient consultation	72.54
Admission	191.47
Overhead	33.5727
Totals	**1255.4**

Costa Maonei 10339460

Manual Vacuum Aspiration		
Medical Officer	244.95	
Pharmacist	8.42	
Nurse	117.67	
Potter	1.71	
Cleaner	5.33	
Ward aide	7.04	
Subtotal		385.12
10cc syringe	0.37	
18G needle	0.92825	
22G needle	0.105	
Gauze	0.09	
Surgical gloves	3.2228	
Subtotal	4.716	
Anaesthesia and fluids		
lignocaine 2% vial	2.75	
Normal Saline 1L	10.66	
Urine bag	2.1	
Intracath. FG12	5.9	
Subtotal	21.41	
Infusion set:		
IV Catheter 16G	2.34	
IV 16G Infusion set	293.41	
Subtotal	295.75	
Blood products		
Packed cells		
Platelet concentrates		
Fresh frozen plasma		
Procedure kits		
MVA kit	58.892	
Kit sterilisation & packaging		
Antibiotics:		
Doxycycline 100mg tb	0.9478	
Ciprofloxacin 500mg tb.	3.094	
Metronidazole 400mg tb.	1.86522	
Subtotal(0.01 patients)	0.05907	
Analgesia:		
Diclofenac 25mg Suppo.	4.28	
Ibuprofen 400mg tb.	2.412	
Subtotal(0.01 patients)	6.692	
OPD consultation	72.54	
Total Direct Medical Costs		401.167
overhead		33.5727
Staff training	6000	
Gynae exam couch	4278.46	
Speculums: Auvard	669.27	
Cuscos	145	

Costa Maonei 10339460

Gynae exam light	0	
Sub-Total	**11093**	
annuitised cost		0

819.8598

Costa Maonei 10339460