ABSTRACT

Pain, swelling and dry socket formation commonly follow third molar surgery. The objective was to investigate the effect of intrasocket Covomycin D®, an antibiotic/anti-inflammatory medication, on pain, swelling and dry socket following lower third molar removal. Nineteen subjects had bilateral lower third molars removed. The patients were blinded to the side of medication; the opposite side acted as the control; postoperatively a pain visual analogue scale was completed, the side of the worst swelling and the incidence of dry socket noted. The data was analysed using the Wilcoxon matched pairs signed ranks test. Results showed that the pain score was lower for the medicated side in 11 patients on day one and in 16 patients over the six day post-operative period (p<0.6). The swelling was less on the medicated side in fourteen patients. Three dry sockets developed in non-medicated sockets. In conclusion this study shows that the use of intrasocket Covomycin D® favourably influences post-operative sequelae following lower third molar removal.

INTRODUCTION

Third molar surgery may be associated with a number of complications the most common of which are postoperative pain, swelling and trismus, and dry socket formation. The incidence of excessive pain, swelling and trismus is reported as 12.3%, 8.6% and 5.7% respectively. Pain has been correlated to surgical extractions, suturing, bony impactions and the duration of surgery; pain following third molar removal has in fact been used as a useful clinical model for the evaluation of analgesics. Swelling is correlated to surgical extractions, reflection of the mucoperiosteum and the duration of surgery. Trismus is correlated to surgical extractions, the duration of extraction and tooth sectioning. Swelling and trismus have been shown to be reduced with the use of glucocorticosteroids (local and systemic), non-steroidal anti-inflammatory agents and systemic antibiotics although the risk benefit ratio when using systemic antibiotics does not justify their use for the reduction of swelling and trismus on a routine basis. Pain is influenced favourably by the perioperative administration of glucocorticosteroids and non-steroidal anti-inflammatory agents but is unaffected by the perioperative administration of systemic antibiotics.

Dry socket (also known as alveolar osteitis, fibrinolysis alveolitis, localized osteitis, alveolitis sicca dolorosa, alveolar osteomyelitis, extracortical focal suppurative osteomyelitis) most commonly follows the removal of impacted lower third molars and is characterised by: i) constant radiating pain beginning 2 - 4 days postoperatively, which is not relieved by analgesics, ii) partial or total absence of a blood clot, iii) tenderness on palpation, iv) pain relieved by the placement of eugenol iodoform dressing and v) malodour.

The aetiology of dry socket is still not fully understood but fibrinolysis albeit bacterial or as a result of the release of local acute inflammatory mediators is thought to play a major role in dry socket formation. Risk factors that have been shown to predispose to the formation of dry socket include gender (females > males), oral contraceptive use, smoking, the difficulty of the extraction, age (most common in the third and fourth decades) and experience of the surgeon. The morbidity associated with dry socket formation has led to a concerted effort in the literature to delineate treatment modalities that aid in the prevention of this complication which include intra-operative irrigation, placement of clot stabilising factors, topical antibiotics within the socket, antimicrobial rinses and systemic antibiotics. Of these, the best methods of prophylaxis appear to be intra-operative lavage, topical antibiotic placed within the socket or perioperative 0.12 % chlorhexidine rinses.

The use of intrasocket medication is well reported in the literature. Complications following intrasocket medication have been reported. There is however still strong support in the literature for the use of intrasocket medication to promote normal socket healing as the morbidity and amount of work lost for the patient and loss of productive time for the surgeon translates into a potentially large economic loss to society. Others however believe that sockets should be allowed to heal without interference preferring to focus on careful and expeditious surgical technique.

The surgical outcome of third molar surgery can be influenced in the patients favour by using the data obtained from the literature; postoperative sequelae are however still common and the search for treatment modalities that serve to decrease the incidence of these sequelae continues.

The object of this study was to evaluate the effect of a combination topical glucocorticosteroid-antibiotic agent, Covomycin D®, on the postoperative incidence of pain, swelling, and dry socket following the removal of impacted lower third molars.
MATERIALS AND METHODS

The study population was drawn from patients attending a maxillofacial and oral surgery outpatient’s clinic at One Military Hospital. The patients selected for the study fulfilled the following criteria:

- No pericoronal infection preceding the surgery.
- No antibiotics in the period leading up to the surgery.
- No anti-inflammatory medication leading up to the surgery.
- Similar impactions bilaterally as determined from clinical and radiological examination.
- No associated co-morbidity.

The age of patients ranged from 16 -32 years of age with an average age of 21.4 years of age.

Written consent was obtained following prescribed procedures and each patient received a written post-operative instruction pamphlet. The research was approved by the Ethics Committee of the University of Pretoria.

The patients selected for the study were examined clinically during the week preceding the surgery to ensure that the operation site was not infected. The positions of the impacted teeth to be removed were recorded from the orthopantomogram.

The surgery was carried out under general anaesthesia and adherence to standard sterile procedure was observed. Where indicated a standard mucoperiosteal envelope flap was raised and the necessary bone removal and/or tooth sectioning carried out.

Once the tooth had been removed the surgical field was well irrigated with sterile normal saline solution and any surgical debris removed. The one side was then closed in the standard manner using 3-0 chromic cat gut resorbable sutures following the insertion of an inert gelfoam carrier moistened with one millilitre of normal saline in the surgical site; on the contralateral side (preselected on a random basis by the flip of a coin) one millilitre of Covomycin D® was introduced into the surgical site on an inert gelfoam carrier before standard closure was affected. The inert gelfoam carriers are resorbable and were left in situ.

Covomycin D®, which is a commercially prepared ophthalmological combination medication, was chosen for the purposes of this study. It contains 2.0 mg chloramphenicol, 5.0 mg neomycin sulphate and 0.5 mg dexamethasone per millilitre of preparation. All patients had the following post-operative medication prescribed: analgesic/anti-inflamatory medication six hourly when necessary (Myprodol®), oral antibiotic medication (amoxicillin five hundred milligrams eight hourly or in penicillin allergic patients erythromycin five hundred milligrams six hourly) for five days and a 0.2% chlorhexidine gluconate mouthrinse six hourly for five days.

The post-operative pain was scored using a visual analogue scale for each side with 0 indicating no pain and 10 the worst pain imaginable. The pain scores were recorded at 6-hour intervals from the day of surgery and on subsequent post-operative days up until day six. In the post-operative phase the patients were asked to note the side which swelled the most, the time of onset and disappearance of post-operative swelling, and the time when the swelling reached the maximum for each side.

The patients were examined clinically on day six by an independent surgeon blinded to the side of intrasocket medication. The patients were assessed for postoperative complications including dry socket and post-operative infection. Dry socket was diagnosed if the following criteria were met: i) constant radiating pain beginning 2 - 4 days postoperatively which was not relieved by analgesics, ii) partial or total absence of a blood clot, iii) tenderness on palpation and iv) pain relieved by the placement of eugenol iodoform dressing. Post-operative infection was assessed using the following criteria: i) presence of cellulitis; ii) presence of fluctuance; iii) presence of purulent or non-purulent drainage from the socket; iv) pain and swelling that failed to improve 48 hours after surgery; v) hyperpyrexia > 37.8°C, 48 or more hours after surgery without local signs or symptoms if no other source of infection can be found.

The data was analysed using the Wilcoxon’s matched pairs signed ranks test an appropriate statistical test for the analysis of non-parametric numbers. The level of significance is p<0.6.

RESULTS (see table 1)

Nineteen patients were selected for the study using the criteria mentioned above and all patients underwent surgery within a 6-week time period.

Pain results

Day one

There was a significant difference (p<0.6) in the pain experienced on the non-medicated compared to the medicated side on day one in eleven of the nineteen patients (57.9%). A further two patients had less pain on the medicated side although the difference between the medicated and non-medicated sides was not significant (p>0.6). Four patients (21.1%) had significantly more pain on the medicated side on day one (p<0.6) and a further one had more pain on the medicated side although the difference between the medicated and non-medicated sides was not significant (p>0.6). In one patient the sample size was too small to ever reach statistical significance.

Day two to six

When the data was analysed over the six day period sixteen out of the nineteen patients (84.2%) had significantly less pain on the medicated side compared to the non-medicated side (p<0.6). One patient had less pain on the medicated side although the difference in pain between the medicated and non-medicated sides was not significant (p = 0.882). One patient...
Table 1: Results Summary

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<th>Swelling worst side + day</th>
<th>Dry Socket + side</th>
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KEY:  D1-6  = visual analogue pain scores in the postoperative period
D1  = visual analogue pain scores on the first postoperative day
OC  = oral contraceptive use
Ø time = time taken from the execution of the incision to placement of the last suture;
NCS  = non-covomycin side; CS = covomycin side; day = day of worst swelling; sig = statistically significant difference; γs = no statistically significant difference; ss/γs = sample size to small to reach statistical significance; χ = mean

experienced more pain on the medicated side over this period but again the difference in pain between the medicated and non-medicated sides was not significant (p = 0.107).

Swelling results
The swelling was worst on day two in all but four patients (see Table 1). Two of the four experienced the worst swelling on day one, one on day three and one on day four. The swelling was worse on the non-medicated side in fourteen out of the nineteen patients (73.7%).

Dry socket results
Dry socket occurred in three patients or three out of thirty eight surgical extraction sites; an overall incidence of 7.9% or an incidence of 0% for the medicated side and an incidence of 15.8% on the non-medicated side. Three out of the nine females included in the study were on the contraceptive pill and one of them developed the complication of dry socket. The other two patients who developed the complication of dry socket were males. All three patients were in the third decade and older than the mean age for the study of 21.4 years.

Other findings
The mean time taken for each surgical removal from the time of the incision to placement of the last suture was eight minutes. There was no significant difference for the time taken on the medicated and the non-medicated sides. Furthermore there was no significant increase in complications in cases where the procedure took longer than the mean. No cases of surgical infection occurred.

Of the 19 patients chosen for the study seven smoked on a regular daily basis (> 10 cigarettes/day) and all dry sockets occurred in this population group.

DISCUSSION
Removal of impacted lower molars invariably causes some degree of pain, swelling and trismus. The appearance of these post-operative sequelae, although affected favourably or unfavourably by surgical technique, mucoperiosteal flap reflection etc. are ultimately related to the manifestations of inflammation in response to tissue injury orchestrated by the mediators of the acute inflammatory response. Surgical trauma, or any other tissue damage due to mechanical, chemical or immunological insult to the body activates the inflammatory response. This
transduction, transmission, modulation of physiologic processes, namely, characterised as consisting of four distinct nociceptive activity in the afferent activity in the afferent nerves is an important factor in the continued sensation of pain after tissue damage; when the nerve endings are sensitised by pro-inflammatory substances, their threshold to activation is lowered and the response to noxious stimuli increases.  

Centrally to the patients’ experience of the acute inflammatory response are the physical manifestations of pain, swelling, loss of function, redness, and warmth.

A pain state is normally generated secondarily to activation of unencapsulated nerve endings that fire in response to stimuli that threaten or actually produce tissue damage; firing frequency is directly related to stimulus intensity. Nociceptive activity in the afferent nerves is responsible for the perception of pain and furthermore induces the synthesis and release of neuropeptides from the peripheral terminals of sensory nerves, a phenomenon known as neurogenic inflammation. The inflammatory response after tissue trauma is a highly complex interaction between substances released from damaged tissues, the blood, the sensory nerves and the immunological cells in the tissue. The changes within the tissues cause the typical symptoms of inflammation, and usually the aim of treatment is to alleviate pain induced by inflammation; this can be achieved by pharmacologic intervention at different levels. Because no agent has yet been identified that specifically inhibits nociception without associated side effects, it has become common practice to employ a polypharmacologic approach to the treatment of postoperative pain. The use of multiple agents in reduced doses to intervene at various points along the nociceptive pathway allows additive or synergistic analgesic effects while minimizing side effects. This notion of balanced analgesia forms the conceptual basis for the effective treatment of acute pain. The mechanism of pain has been characterised as consisting of four distinct physiologic processes, namely, transduction, transmission, modulation, and perception. For the purposes of this discussion it is appropriate to consider the therapeutic modalities that affect transduction as it is at this station along the pain pathway that the topical application of dexamethasone is probably effective.

Agents that serve to alter peripheral transduction include the glucocorticosteroids and the non-steroidal anti-inflammatory agents. The glucocorticosteroids have the capacity to dramatically reduce the manifestations of inflammation and exert their effects in the periphery by a number of different mechanisms. They have profound effects on the concentration, distribution and the function of peripheral leukocytes and to their inhibition of phospholipase A2 activity. After a single dose of short-acting glucocorticosteroid the concentration of neutrophils increases while the lymphocytes (T and B cells), monocytes, eosinophils, and basophils in the circulation decrease in number. The changes are maximal at six hours and are dissipated in 24 hours. The effect of glucocorticosteroids on leukocytes is significant, as it is currently believed that the attraction of these cells to tissues is essential for inflammation; furthermore by influencing the secretion of the abovementioned cytokines glucocorticosteroids modulate the inflammatory response further by interfering with the directional cues for the movement of leukocytes in inflammation.

In addition to their effects on leukocyte function, glucocorticosteroids may influence the inflammatory response by reducing the prostaglandin and leukotriene synthesis. Glucocorticosteroids may also increase the concentration of proteins called lipocortins, who are said to bind the phospholipid substrates of phospholipase A2. This action would also reduce the formation of prostaglandins and leukotrienes. Finally, glucocorticosteroids may reduce the expression of cyclo-oxygenase, thus reducing the amount of enzyme available to produce prostaglandins. Glucocorticosteroids also cause vasoconstriction when applied directly to vessels, and they decrease capillary permeability by inhibiting the action of kinins and bacterial endotoxins and by reducing the amount histamine released by basophils.

The use of local glucocorticosteroid therapy provides means of delivering large amounts of steroid to the diseased tissue with reduced systemic effects. The therapeutic efficacy of topical glucocorticosteroids is based primarily on their anti-inflammatory activity. All absorbable glucocorticosteroids possess the potential to suppress the pituitary-adrenal axis. Iatrogenic Cushing’s syndrome may occur as a result of protracted use of topical glucocorticosteroids in large quantities. However the use of glucocorticosteroids in oral surgery appears not to result in adverse reactions in both topical and systemic forms and the short term administration of glucocorticosteroids is a relatively safe procedure.

Dry socket is another commonly reported complication of third molar removal and most commonly follows the removal of impacted lower third molars. The aetiology of dry socket is still not fully understood but fibrinolysis albeit bacterial or as a result of the release of local acute inflammatory mediators is thought to play a major role in dry socket formation.

Normal healing of an extraction socket passes through a number of phases which can be divided into: (i) the immediate reaction following extraction, (ii) the first week wound, (iii) the second week wound, (iv) the third week wound, and (v) the fourth week wound. Dry socket occurs during the first two phases of healing. Many believe that an increase in fibrinolysis with resultant clot dissolution is responsible for the development of dry socket. Birn hypothesised that partial or complete lysis and destruction of the blood clot was caused by tissue kinases liberated during inflammation resulting in the transformation of plasminogen into plasmin with subsequent lysis of fibrin within the clot and the formation of kinins with the final result being clinical dry socket. The role of an overexuberant inflammatory response was thus considered to be important in the formation of dry socket and the findings that dry socket occurs more commonly following difficult extractions and the use of a dental...
bur for tooth removal would seem to support this theory. The use of modalities that might serve to modify this response were thus investigated and the use of antifibrinolytic agents have shown mixed results.

Since it has been shown that glucocorticosteroids stabilise cellular lysosomal membranes with subsequent inhibition of the release of vasoactive kinins and destructive enzymes it was inevitable that the efficacy of steroids in the prevention of dry socket would be tested. Julius and his co-workers were unable to demonstrate any benefit by the addition of a topical glucocorticosteroid to an antibiotic dressing in the incidence of dry socket formation. Furthermore Chapnick et al. in their review of dry socket report that although glucocorticosteroids decrease immediate post-operative complications they fail to reduce the occurrence of dry socket after extractions.

These results call into question the sole role of inflammatory mediators in the activation of the fibrinolytic system and the subsequent formation of dry socket. It has also been shown that activation of the fibrinolytic system may also be brought about by the action of bacterial pyrogens. Focus thus shifted to the role of bacteria in dry socket formation. The results of studies conducted on the microbiology of intraoral wounds suggest that persons with high preoperative streptococci counts at the wound site have a higher probability of development of dry socket than patients with relatively low counts.

Studies investigating the efficacy of topical intrasocket medication have shown that the use of tetracycline, sulphamides, lincomycin and clindamycin are effective in reducing the incidence of dry socket formation. The rationale for the use of intrasocket bacterial modifying therapies is to reduce the level of bacterial pyrogens which are believed to be the stimulus for fibrinolytic activity with subsequent clot breakdown and dry socket formation. It follows then that the type of antimicrobial selected should possess a spectrum of activity that is appropriate for the local bacterial population i.e. based on the microorganisms most commonly found in extraction sites. Extraction sites are routinely contaminated with microorganisms which commonly include Streptococcus viridans, Corynebacterium xerosis, Staphylococcus lactis, Vibros fusobacteria, Bacteroides melanogenicus, Neisseria pharyngis and Staphylococcus aureus. Although the pattern of aerobic organisms found in extraction sockets is similar to that found in saliva the anaerobic bacteria namely Bacteroides, Vibros and Fusiforms are significantly higher within the socket than within the saliva. Treponema denticola has also been suggested as a possible aetiological agent in the genesis of dry socket. Based on this knowledge an appropriate antibiotic choice would be a broad spectrum antibiotic aimed at gram negative anaerobes.

Chloramphenicol is a broad spectrum antibiotic with gram positive, gram negative and anaerobic activity; most gram positive bacteria are inhibited in concentrations of 1 - 10 µg/ml and many gram -negative bacteria are inhibited in concentrations of 0.2 - 5 µg/ml of chloramphenicol. The systemic use of chloramphenicol is indicated only in certain life threatening infections because of its potential toxicity (i.e. gastrointestinal disturbances and bone marrow disturbances including disturbances in red cell maturation and aplastic anaemia) and the availability of other effective drugs. It is however used topically in the treatment of eye infections because of its wide antimicrobial activity and its penetration of ocular tissues and aqueous humor.

The gastrointestinal side effects are related to high systemic dosing associated with 1,5 - 2,5 grams of chloramphenicol daily. Chloramphenicol causes two types of bone marrow suppression; a dose related, reversible suppression of all elements, which occurs during therapy at the maximal recommended doses (4g/day in adults), and an irreversible aplastic anaemia, which occurs approximately one in every 25000 - 40000 exposures. The irreversible form has been reported to follow all forms of chloramphenicol treatment, including ocular administration and develops months after therapy is discontinued. This irreversible aplastic anaemic reaction probably represents an idiosyncratic genetically determined reaction within the individual and is not related to the dose or time of intake, but does occur more often with prolonged use. The probable incidence of an adverse reaction in the patients chosen for this study was very low. Although the dosage used in intra -socket administration is higher than topical eye administration the dosage used was still relatively low (1ml per socket: 1ml contains 2mg chloramphenicol); furthermore it is a one off dosage not to be repeated. Indeed no adverse reactions occurred in the postoperative period in any of the patients that participated in the study.

Cones, containing a combination of neomycin and bacitracin were tested against a placebo following the removal of impacted third molars and were found to effectively reduce the incidence of postoperative infection and associated pain. Neomycin is an aminoglycoside antibiotic active against gram negative organisms including Escherichia coli, Proteus, Klebsiella and Enterobacter. Parenteral administration results in toxicity but topical use rarely results in detectable serum concentrations. The addition of this agent thus improves the gram-negative spectrum of any preparation without significantly compromising the safety of the preparation.

The results from this study indicate an overall dry socket incidence of 7.9% (3 out of 38 extraction sites) or computed
The incidence of dry socket formation varies greatly from one study to another which is probably due to the criteria used for making the diagnosis, the teeth involved, and the incidental treatment of the socket at the time of surgery. When studies include the removal of all 32 teeth the incidence of dry socket is in the range of 2% to 5%. The reported incidence of dry socket following mandibular third molar removal with no accompanying extractions and no therapeutic intervention is in the range of 9.3% - 38%. The incidence of dry socket formation on the non-medicated side in this study thus compares favourably with that reported in the literature. Improvement of the dry socket incidence from 15.8% on the non-medicated side to 0% on the medicated side was 15.8% (3 out of 19 extraction sites) and that on the non-medicated side was 0% (0 out of 19 extraction sites). The results of this study and a review of the literature seem to indicate that the only factors that adversely affected the dry socket incidence in this study were smoking and the patients age.

CONCLUSION

The results of this study and a review of the literature seem to indicate that the common post-operative complications of lower third molar removal of pain, swelling, and dry socket may be effectively minimised by intraoperative irrigation, perioperative 0.12 % chlorhexidine rinses, and placement of Covomycin D® in the socket. Furthermore, when controlling for the other risk factors traditionally associated with an increased incidence of dry socket formation such as gender (females > males), patients on oral contraceptives, smoking, the time taken for the extraction, and age (most common in the third and fourth decades), the only factors that influence the formation of dry socket include smoking and the age of the patient. Other factors commonly cited as influential in the formation of pain, swelling and dry socket such as time taken for the extraction, gender, and use of oral contraceptive medication appeared not to play a significant role in this pilot study.

REFERENCES