The Use of Antibiotics Post–Tonsillectomy at Dr George Mukhari Hospital (DGMH): Is it of benefit?

By

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2011

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Submitted in part fulfilment for the degree of Master of Medicine in Otorhinolaryngology of University of Limpopo.

2011

This dissertation is dedicated

To

My wife,

Bagagametse Sekole

And

My son,

Molatelo Sekole

DECLARATION

CANDIDATE

This dissertation is my original work and has not been presented for a degree, or other academic award, in any other university or institution of higher learning.

Signed: _____

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ACKNOWLEDGEMENTS

- Professor D Le C. Stolp my supervisor and academic head for guidance throughout the preparation.
- Dr I P Olwoch for enthusiasm in supervising this project, support, encouragement, and valuable criticism.
- Prof O A Towobola for assistance with statistical evaluation of the data.
- All my fellow registrars for the support.
- The staff at DGMH.
    1. ENT outpatients department
    2. ENT wards
    3. ENT operating theatre
    4. National Health Laboratory Service

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ABSTRACT

Aims: The purpose of this study was to assess if the use of post-operative antibiotics have any beneficial effects in reducing morbidity following elective tonsillectomy in children with age range of 1-13 years.

Objectives: To assess the degree of post-tonsillectomy pain, determine the incidence of secondary haemorrhage, establish the time period to the resumption of a normal diet, document adverse effects of the use of antibiotics (e.g. skin rash, anaphylaxis, diarrhoea and vomiting), determine the bacteriology in tonsil removed and make recommendations on post-tonsillectomy treatment protocol at DGMH.

Methods: This prospective study was conducted at DGMH on 81 children with an age range of 1-13years (mean 5.7years). At total of 40 children received paracetamol 15mg/kg/day (Group A) in three divided doses for seven days, and 41 received amoxicillin 40 mg/kg/day and paracetamol (Group B) for the same duration. The post operative morbidity and bacteriology of the two treatment groups were compared. Primary outcomes measured included the incidence and severity of pain, use of analgesia, resumption of normal diet, incidence of heamorrhage, fever, vomiting and adverse reactions.

Results: All patients in this study experienced a degree of pain. The majority of patients in both treatment groups used the analgesics three times a day. Patients with antibiotics consumed less additional analgesics and were able to tolerate normal diet sooner. These

findings did not show any significant difference between the two treatment groups ($p>0.05$).

The incidence of bleeding and vomiting was higher in patients who received antibiotics. Fever was much higher in the non-antibiotics group. These findings were not statistically significant ($p>0.05$).

No major adverse reactions were reported in our study. With regard to minor adverse reactions, only 5% of patients in both groups gave a history of skin rash that developed during the study period.

The most frequently isolated microorganism in both groups was *S. aureus* (38.2%), followed by *H .influenzae* (12.3%). There was no significant difference in the aerobes isolated from the two treatment groups. The facultative anaerobe cultured was *E. coli* (2.5%). The patients with more than one microorganism were twice as high in group B (20.0%) than in group A (9.8%). This was not statistically significant.

Conclusion: There is no evidence from the results of our study that routine use of post-operative amoxicillin is justified in paediatric tonsillectomies. Amoxicillin did not have any impact on postoperative pain, bleeding and the time period to the resumption of a normal diet. However, amoxicillin may be effective in reducing the incidence of post-operative fever but further studies will be needed to evaluate this property. It is possible that different antibiotics would be more effective in reduction of post-tonsillectomy morbidities but any alternative would have to be effective to justify its routine use. Therefore in DGMH we do not recommend the use of antibiotics after tonsillectomy.

TITLE

The use of antibiotics post-tonsillectomy at Dr George Mukhari Hospital (DGMH): Is it of benefit?

INTRODUCTION

Tonsillectomy is one of the most commonly performed surgical operations in children in otolaryngology practice[1]. It is a surgical procedure to remove the palatine tonsils, usually done under general anaesthesia[2].

The common indications for tonsillectomy include:

1. Airway obstruction due to large tonsils
2. Recurrent tonsillitis
3. Suspicion of a tonsillar neoplasm
4. Dysphagia due to large and obstructive tonsils
5. Peritonsillar abscess
6. Severe halitosis unresponsive to other non-surgical measures[3-6].

Removal is typically achieved using a scalpel and blunt dissection or with electrocautery. Laser, coblation and harmonic scalpel have also been used[6-10]. Intra operative bleeding is stopped with electrocautery, ligation with sutures and the use of topical thrombin-a protein that induces blood clotting. The tonsillar fossa is left open to heal by secondary intention[11, 12].

Although this procedure is usually simple and uncomplicated if well performed, it is still not without significant morbidity and mortality. Short-term morbidity after tonsillectomy is very common, with an estimated incidence rate ranging from 1.5% to 14%. Usually pain, dysphagia, decreased oral intake, fever, trismus and halitosis occur. Some of these post-operative problems are thought to be associated with infections[13]. Dehydration and weight loss may occur secondary to decreased oral intake. Mortality after tonsillectomy is uncommon, with the incidence reported to be between 1:10.000 and 1:35.000, and it is usually related to complications from anaesthesia and post-operative haemorrhage[14].

Pain following the tonsillectomy is common and may increase the length of hospital stay. Recovery from pain may take from 10 to 20 days, during which analgesic medication is typically prescribed[15]. Although patients are reluctant to swallow anything during the first few days after surgery, they are usually encouraged to maintain a diet of liquid and very soft foods for several days following surgery. Rough textured, acidic or spicy foods may cause local irritation and aggravate pain, and therefore should be avoided. Proper hydration is very important post tonsillectomy, since dehydration can increase throat pain and leading to vicious circles of poor fluid intake[16, 17]. In the post operative period patients are usually advised to drink as much cold fluids as possible, as this is thought to help in bringing down local swelling and fever. Bleeding may occur when scabs begin sloughing off from the surgical sites. The bleeding might stop spontaneously or else mild intervention (e.g. gargling cold water) may be needed[11, 12].

After surgery the tonsillar fossa is left open to heal by secondary intention and is contaminated by oropharyngeal bacteria. Some authors argue that this predisposes to an

inflammatory reaction and infection, which may contribute to post operative morbidity**.** They therefore recommend the use of prophylactic antibiotics to reduce morbidity[18].

Many otolaryngologists choose to prescribe antibiotics following tonsillectomy. It is thought that the use of antibiotics will lessen the bacterial content of the tonsillar fossa and thus reduce the incidence of infection and minimize the duration and intensity of pain[19].

There is conflicting evidence in the literature regarding the use of antibiotics after tonsillectomy in the paediatric population[17]. Some studies have shown antibiotics to be beneficial in reducing post tonsillectomy morbidity and recommended the use of prophylactic antibiotics[16, 20, 21], however there is still no consensus on the matter and opinions remain divided. There are those centers that discourage the use of prophylactic antibiotics[22-25] and those that are ambivalent[13, 26, 27]. Part of the disagreement and the debate arises from lack of well designed clinical trials[28].

Post tonsillectomy treatment protocols used in the management of patients varies between centers[18]. DGMH is a large referral hospital servicing the population of Gauteng and North West Provinces in South Africa. There is high volume and priority for tonsillectomy in otorhinolaryngology at DGMH. In our center antibiotics are not routinely prescribed as part of post-tonsillectomy management. This may be due to lack of standardized treatment protocol. A good number of patients in our center have poor follow up due to multiple factors such as lack of money or lack of transport. This could be one of the reasons we do not know if the use of antibiotics after tonsillectomy is of benefit. The decision to conduct this study was prompted by the need to know the bacteriology associated with tonsillitis, to determine if

the use of peri-operative antibiotics is of benefit and to develop a treatment protocol at DGMH's ENT department. To the best of our knowledge, no previous study exists that looked at the effectiveness of antibiotics in facilitating recovery post-tonsillectomy in the paediatric population before in DGMH.

LITERATURE REVIEW

Tonsillectomy is a surgical procedure to remove the palatine tonsils, usually done under general anaesthesia. This involves removing the tonsil from the tonsillar fossa by separating it from the underlying subcapsular plane[2]. The rise in tonsillectomy procedure is one of the major phenomenons of modern surgery, for it has been estimated that 200,000 tonsillectomies are performed annually and that tonsillectomy form one third of the number of operations performed under general anaesthesia in the United States[1].` Commonly tonsillectomy is performed in patients for the following indications:

1. Recurrent tonsillitis: Three or more attacks of sore throat per a year, in a period of two to three years and the patient is normal between the episodes.
2. Airway obstruction due to large tonsils: Difficulty in breathing due to obstruction of the upper airway.
3. Dyspahgia: Difficulty in swallowing due to obstruction of the upper digestive tract.
4. Peritonsillar abscess: Collection of pus between the superior constrictor muscle of the pharynx and tonsillar capsule.
5. Halitosis: Noticeable unpleasant smell exhaled secondary to trapped debris in the tonsil crypts unresponsive to other non-surgical measures.
6. Suspicion of tonsillar neoplasm[3-6].

Tonsillectomy is said to be effective in alleviating the above mentioned problems. This procedure is well established in terms of safety, but is often accompanied by pain, post operative bleeding and prolonged recovery. Traditionally, the operation has been performed using cold steel dissection and or electrocautery dissection. Newer methods involve harmonic scalpel, laser and coblation. As yet, no definite consensus has been reached regarding the optimal technique with lowest morbidity rates[6-10, 29, 30].

Operative methods for tonsillectomy

1. Cold steel

This is the traditional method which involves removal of the tonsils by blunt dissection. Sixty percent of both private and state surgeons in South Africa remove tonsils by cold steel method[41]. In DGMH conventional cold steel is the method most often used in conjunction with electrocautery to control bleeding.

2. Electrocautery

This uses radiofrequency energy applied directly to the tissue. It can be bipolar (the current passes between the two tips of the forceps) or monopolar (the current passes between the forceps skin and a plate attached to the patients skin). The heat generated may be used to dissect the tonsil away from the pharyngeal wall and also to promote haemostasis.

3. Laser

Laser both dissects tissues and coagulates blood vessels. Lasers used in tonsillectomy include CO2, KTP and contact diode lasers.

4. Coblation

This involves passing a radiofrequency bipolar electric current though normal saline. The resulting plasma field of sodium ions can be used to dissect tissue by disrupting intercellular bond and causing tissue vaporisation.

5. Harmonic scalpel

This uses sound waves and radiofrequency ablation (such as coblation).

Effects of tonsillectomy technique on post operative morbidity

1. Post operative pain is said to be less with cold steel method and higher with the use of electrocautery. Coblation, harmonic scalpel and laser are also thought to have less post operative pain than electrocatery.

2. Many studies looking at the time taken to return to normal diet favoured cold steel over diathermy. Evidence comparing diathermy with coblation was conflicting.

3. Data from studies looking at post operative bleeding were conflicting. One study found the highest with cold steel and ligature haemostasis. However, a much larger study found the highest rates of post operative bleeding with monopolar diathermy and coblation.

4. Post operative vomiting was found to be higher with diathermy than with cold steel [9, 29, 31, 32].

Despite improvements in surgical and anaesthetic techniques, post-operative morbidity remains a significant clinical problem[26]. The most common problems encountered in the post operative period include:

1. Pain
2. Bleeding
3. Nausea and vomiting
4. Fever
5. Inability to resume normal diet
6. Dehydration[26].

Post operative morbidity

1. <u>Pain</u>

Nearly 50% of children who have had tonsillectomy experience severe pain, defined as a visual analog score of 8 or more (0 =little or no pain.10 =unbearable pain). Pain may affect how patients eat, drink, or sleep. The pain typically manifest as dysphagia, which results from trauma to the pharyngeal muscles. If the pain is prolonged it may

be accompanied by dehydration, fever, and bleeding. Patients may also have referred otalgia that usually subsides within 2 weeks[14, 33].

Bleeding

Mortality from bleeding is estimated to be 2 in 10,000 tonsillectomies. Bleeding followed by hypovolaemic shock is the most common cause of morbidity and mortality among patients undergoing tonsillectomy, affecting an estimated 0.5% to 10%. Most fatal postoperative bleeding occurs 24 hours after tonsillectomy[34-37].

2. Nausea and vomiting

Up to 89% of children undergoing tonsillectomy have post-operative vomiting and nausea. Usually nausea and vomiting occur secondary to inhalation anaesthesia, the use of opiates after surgery and to some extend the type of surgery used has also been implicated [14, 38, 39].

3. Fever

Fever may occur within 18 to 36 hours after tonsillectomy. A postoperative fever after 24hours, accompanied by severe throat pain, suggests emerging pharyngeal infection[40,41].

4. Inability to resume normal diet

Patients are reluctant to swallow anything during the first few days after surgery. Pain is major obstacle for return to an oral diet. Coupling analgesia and timing of oral intake is crucial for a quick recovery[14, 42].

5. Dehydration

Post operative dehydration is uncommon in the average patients. The risk of dehydration is more common among dysphagic children. Post operative dehydration is usually aggravated by vomiting[14, 42].

Strategies to reduce post operative morbidity

The first week post-tonsillectomy can be extremely difficult for both children and parents. Normally, children of school age (about 2-13 years) who undergo tonsillectomy will often miss school for up to a week, whereas adults will be absent from work for about 2 weeks. Therefore minimising morbidity after this procedure will provide excellent care[13].

1. Pain

Dehydration can worsen throat pain, so staying well hydrated will improve pain control. Other steps that can be taken to improve pain control include a humidifier in the patient's room or an ice collar loosely applied to the neck for a short period of time. Chewing gum may help both throat and ear pain[43].

Although high dose acetaminophen with or without codeine, is the most common analgesic prescribed post operatively, its analgesic effect varies widely, so it may need to be administered with other agents. Some physician recommend ibuprofen after tonsillectomy, which is said to provide pain control and it has shown no the risk of post operative bleeding[44].

Web survey in South Africa shows that with regard to the use of local anaesthesia, seventeen per cent of surgeons inject the tonsillar bed with local anaesthetics[49].

Although not believed to benefit postoperative pain, the systematic review seems to show a modest reduction in post operative pain[45].

2. Bleeding

Post operative bleeding is usually controlled by applying local pressure with gauze on the tonsillar bed and if not controlled patient will need to be rushed to theatre. Approximately 1 in 200 patient returns to the operating room so that bleeding can be controlled[34-37].

3. Nausea and vomiting

During surgery, antiemetics are usually administered to reduce the incidence of nausea and vomiting after surgery. Forty per cent of both state and private surgeons in South Africa use perioperative corticosteroids to reduce post operative nausea and vomiting[14, 45].

4. Fever

Some surgeons prescribe prophylactic antibiotics to reduce the risk of infection to the tonsillar fossae and it may also reduce the incidence of fever after surgery. It is thought that drinking as much cold fluids as possible may also help in bringing down fever[40, 41].

5. Inability to resume normal diet

Although patients are reluctant to swallow anything during the first few days after surgery, they are usually encouraged to maintain a diet of liquid and very soft foods for several days following surgery. Rough textured, acidic or spicy foods may cause

local irritation and aggravate pain, and therefore should be avoided. If necessary analgesics are given for pain to facilitate the oral intake[14, 42].

6. Dehydration

Proper hydration is very important post tonsillectomy, since dehydration can increase throat pain leading to vicious circles of poor fluid intake. Patients are usually encouraged to resume oral intake of fluids and when necessary receive analgesia for pain to facilitate the oral intake. Patients may need to be readmitted if unable to achieve better pain relief and restore hydration [14, 42].

The role of post operative antibiotics

Since many of the previously mentioned signs and symptoms associated with *postoperative morbidity are thought to be due to infections, antibiotics are frequently* prescribed in the preoperative and post operative period[13].

After surgery the tonsillar fossa is left open to heal by secondary intention and is contaminated by oropharyngeal bacteria. Some authors argue that this predispose to an inflammatory reaction and infection and contributes to post operative morbidity. They therefore recommend prophylactic antibiotics to reduce morbidity [18].

In South Africa tonsillectomy is a common operation done by ENT surgeons and general practitioners. A web survey was conducted to evaluate tonsillectomy practice among South African ENT surgeons and reported only controversial and interesting aspects. Ninety three surgeons completed the survey, of which 65 were in private practice. Sixty per cent of

surgeons prescribe antibiotics of which 42% prescribe amoxicillin- clavulanate and 38% amoxicillin[45].

There is a considerable variation in practice worldwide. A recent study from the UK showed that only 12% of otolaryngologists routinely prescribe antibiotics[26], while another study showed a figure of 79% among American otolaryngolgist[19]. Other authors do not favour routine antibiotic administration, citing the lack of evidence to support a direct causal link between infection and postoperative morbidity[27, 46] and hence the subject remains contentious.

There is conflicting evidence in the literature regarding the use of antibiotics after tonsillectomy in the paediatric population[17]. Some studies have shown antibiotics to be beneficial in reducing post tonsillectomy morbidity and recommended the use of prophylactic antibiotics[16, 20, 21]. However there is still no consensus on the matter and opinions remain divided. There are those centers that discourage the use of prophylactic antibiotics[22-25] and those that are ambivalent[13, 26, 27]. Part of the disagreement and the debate arises from lack of well designed clinical trials[28].

Studies that support the use of antibiotics

Telian *et al* conducted a single, randomised, double blind, placebo controlled study in the USA and they had 100 children who underwent adenotonsillectomy. Most children had obstructive sleep apnoea as an indication for tonsillectomy. Study and control groups were well matched for age, sex, number of infections in the past 12 months as an indication for surgery. Excluded were those patients who had antibiotics one week preoperatively, patients with medical condition requiring perioperative antibiotics, or patients who were allergic to

the antibiotic studied. At completion of surgery, amoxicillin one gram for children weighing twenty kilograms or more and five hundred milligram for children weighing less than twenty kilogram was administered. This was followed by equivalent doses at six hour intervals until discharge (usually 24 hours). After discharge oral amoxicillin was given three times a day for seven days, 250 mg for children weighing 20 kg or more and 125 mg for children weighing less than 20 kg. Placebo was given for the control group. This study found the mean number of days with continuous subjective pain to be improved with antibiotic use. They found that antibiotics reduce the number of patients manifesting with fever in the first seven days after tonsillectomy. They therefore concluded that antibiotic therapy is effective on recovery after tonsillectomy in children[16].

In 1992 a single–centre, randomised, double blind placebo controlled study was conducted by Grandis *et al* in USA. The efficacy of perioperative antibiotic therapy on recovery following tonsillectomy was looked at. They had 198 adults and children, aged 12 to 48 years undergoing tonsillectomy or adenotonsillectomy (indication not specified). Study and control groups were well matched for age and sex. Excluded were those patients who received antibiotics one week preoperatively, patients with a medical condition requiring perioperative antibiotic therapy, or patients who were allergic to the antibiotic studied. Patients received intravenous Ticarcillin in combination with Clavulanic acid, intravenous three point one grams at completion of surgery, six and twelve hours after surgery. This followed by amoxicillin- clavulanate two hundred and fifty milligram three times daily orally for seven days. They found a significant reduction of pain, reduction in the mean number of days with fever, and also significant reduction on time taken to resume normal diet and time taken to resume normal activities with the use of antibiotic. Those patients who received antibiotics

fared consistently better in the immediate post- operative period compared with the placebo group. Patients in the antibiotic group experienced significantly less mouth odour, were able to tolerate regular diet sooner and resumed their normal activities earlier than did the patient with placebo. They conclude that antibiotics are effective on recovery after tonsillectomy[20].

Colveary *et al* compared two groups of children in a single-centre, randomised controlled trial that was conducted in Ireland. They had 78 children aged 2 to 12 years undergoing tonsillectomy with or without other lesser surgical procedure. Study and control groups were well matched in terms of age and sex. Excluded were patients who received antibiotics within one week preoperatively, patients with a medical condition requiring perioperative therapy or patients who were allergic to the antibiotic studied. Patients were divided into two equal groups. One group was given amoxicillin-clavulanate to for 1week and the other group on was not given treatment. They found that giving antibiotics to children after tonsillectomy reduces post operative morbidity and this was judged by reduction in the amount of analgesia consumed, time to resume normal diet which showed mean reduction of 2.4 days and significant pain reduction. They therefore recommend the use of perioperative antibiotics[21].

Factors affecting the choice of antibiotics

There have been numerous reports of changing microbiological profiles in tonsillar tissues over the last 10 years[47].

Mevio *et al* make the interesting point that whereas *Streptococcus pyogenes* was once the responsible pathogen in 90% of cases chronic tonsillitis, there has been increasing evidence

in the last decade that *Haemophillus influenzae* and *Staphylococcus aureus* may now play dominant roles. Both of these organisms are β-*lactamase* producers and characterized by multi-resistance to antibiotics. They found amoxicillin-clavulanate to be an effective antibiotic in eradicating these three organisms[47].

Note has been taken of the possible role that anaerobic bacteria may play. Anaerobic bacteria are present as indigenous micro flora in the oral cavity and throat and may cause life-threatening infections such as peritonsillar and retropharyngeal abscess[40].

Colveary *et al* compared two groups of children, one group on amoxicillin-clavulanate and another group on no treatment post tonsillectomy. They compared tonsillar core, surface and post operative tonsillar fossae bacteriology in the two groups. The tonsil core pathogens found included:

1. *H. influenzae* 64% of which 9,3% were β-*lactamase* producers.
2. *Streptococcus viridans* 55,7% .
3. *S. aureus* 37% of which 50% were β-*lactamase* producers [21].

Pereira *et al* did a study to look at selected bacterial recovery in Trinidadian children with chronic tonsillar disease. They examined tonsil surface and tonsil core following elective tonsillectomy in children. Hundred and two Trinidadian children had tonsillectomy done.

The organisms found included:

1. *Streptococcus spp* (51.3%).
2. *Staphylococcus spp*. (42.3%).
3. Gram negative *spp* (6.4%).

Surface and core recovery of *Staphylococci spp* and *Streptococci spp* were similar. More surface than core grew *streptococcus spp* and *α-haemolytic Streptococcus* was higher than *β-haemolytic streptococcus* on the surface. *Klebsiella spp (*6.6%, 2.2%), *Proteus* (4.4%, 4.4%), and *Pseudomonas* (4.4%, 1.1%) grew on the surface and core respectively[48].

Studies that do not recommend the use of antibiotics.

Lee *et al* conducted the study in 1996 in USA. They had 95 paediatric patients with the age range from 3 to 14years. 54 patients received oral amoxicillin for 5 days and 41 did not receive antibiotics at two groups of children post-tonsillectomy. Their outcome showed no significant reduction in otalgia, halitosis, post-operative bleeding, nausea and vomiting .They concluded that there was no reduction in the morbidity in the antibiotic treated group [22].

Khan *et al* in 1994 conducted a single centre, randomised controlled trial conducted in UK. The participants were 90 children and adults, age range 6 to 36 years, undergoing tonsillectomy for recurrent tonsillitis. Study and controlled groups were well matched with age, sex, episode of tonsillitis within previous six months and history of peritonsillar abscess.

Excluded were those patients with poor general medical condition, patients with history of adverse drug reaction including penicillin allergy or patients with concomitant ear nose throat pathology. Patients received one intravenous dose of amoxicillin (appropriate for age and weight) at the time of induction and two further oral doses at six and twelve hours. They found that there was no reduction in the mean number of days of patients presenting with sore throat and otalgia between the two treatment groups. Post operative haemorrhage, time taken to resume normal diet and activities showed no benefits from the use of antibiotic[23].

A single–centre, randomised, double blind, and placebo controlled study was conducted in by Mann *et al* in the USA. The study included 51 adults' patients who were eighteen years and above undergoing tonsillectomy. Their indications for tonsillectomy were tonsillitis, peritonsillar abscess or tonsillithiasis. Patients were randomised into four arms; systemic antibiotics, placebo and two different topical antibiotics. The two arms that studied topical antibiotics were unsuitable for analysis and were therefore excluded, leaving patients in the first two arms (8 in antibiotic and 10 in the controlled arm) who completed the study. Study control groups were well matched with regard to age and sex. Excluded were those with significant medical conditions (i.e. diabetes, chronic lung disease, bleeding disorders), patient who had antibiotics administered one week preoperatively, patient with a medical condition requiring antibiotic therapy or patients who were allergic to antibiotics to be used. Their outcome showed no reduction in pain, time taken to resume normal diet and time taken to resume normal activities. They therefore do not recommend use of antibiotics after tonsillectomy[24].

In 2000 a single–centre, randomised controlled, physician-blinded trial conducted in Brazil by Ramos *et al* also showed no benefit for the use of perioperative antibiotics. They had 58 children with the age range not given, who were undergoing tonsillectomy and randomised to 29 each in the antibiotic and control group. Study and control groups well matched with regard to age. Those patients excluded were not specified. The patients were given amoxicillin-clavulanate during and after the operative period for seven days, with dosage calculated according to weight. Their outcome showed no significant reduction in pain and fever with antibiotic use after tonsillectomy[25].

Ambivalent Studies

Srikant Iyer *et al* (2006) did a meta–analysis on a structured search of literature and they retrieved 428 articles. They found 23 potentially appropriate articles. Of these, 18 were able to be located in text form and English. Seven studies directly studied the efficacy of perioperative antibiotics versus no antibiotics in decreasing post operative morbidity. Four of the seven studies had sufficient information to calculate effects estimated and standard deviation for primary outcome and the other three studies did not report on the outcome of interest. The pooled estimate indicated that the antibiotics group returned to normal oral intake 1 day sooner than the control. This difference was found to be statistically significant with a 95% confidence interval of 0.5-1.6 days. An additional assessment of three qualitative reports also suggested the use of perioperative antibiotics for adenotonsillectomy was associated with less post-operative pain. However, these studies varied in terms of study quality, sample size, outcome examined, measure used and antibiotic administered. Authors could not come with a definite conclusion regarding halitosis, fever, activity level, nausea and

vomiting due to the small numbers of studies retrieved. They concluded that antibiotics are beneficial in reduction of time taken for returned to normal oral intake and for other potentially important outcomes, such as post operative pain and bleeding, sufficient data were not available to make any definitive conclusion regarding the effect of antibiotics[13].

A systematic review of trials to find out if antibiotics improve recovery post-tonsillectomy was conducted by Muthuswany *et al*. Only randomised, placebo-controlled, double blind trials attaining preset quality scores were included. Five trials met the eligibility criteria. It was found that antibiotics significantly reduced the number of patients manifesting with fever and halitosis and marginally reduced the time taken to resume normal activity, but had no significant effect in reducing pain score or need for analgesia. Similarly, there was no significant difference in time taken to resume normal diet or incidence of haemorrhage. In the antibiotic group four patients developed an adverse reaction (three cases of rash and one case of oropharyngeal candidiasis), while in the control group one patient had an adverse reaction (rash). Therefore they concluded that antibiotics appear to be effective in reducing some, but not all morbid outcomes following tonsillectomy. Further trials are needed to define role antibiotics following tonsillectomy[26].

A randomised, double blind, placebo controlled study was conducted in USA[27]. The study had 50 children and adults (age range 13 to 40 years) undergoing tonsillectomy primarily for recurrent tonsillitis. Study and controlled groups were all matched in terms of age, sex and number of episodes of tonsillitis prior to surgery. One gram of Cefonicid was administered by intravenous injection before initiation of surgery. Their outcomes showed a significant

reduction in number of patients presenting with fever. However as for pain, time taken to resume normal diet and to resume daily activities no benefit was observed from the use of antibiotics[27].

There is still a debate about the usefulness of post-tonsillectomy antibiotics and opinion varies between different centres. At DGMH antibiotics are not routinely prescribed as part of post-tonsillectomy management. The decision to conduct this study was prompted by the need to know if the use of peri-operative antibiotics is of benefit at DGMH's ENT department. It has also been shown that the bacteriology associated with tonsillitis varies between different centres. This study will also determine bacteriology associated with tonsillitis at this institution and recommend a standardized treatment protocol for the use of antibiotics following tonsillectomy.

AIMS AND OBJECTIVES

The purpose of this study is to assess if the use of antibiotics has any beneficial effects in reducing post-tonsillectomy morbidity.

Objectives

1. To determine the bacteriology in tonsil removed.
2. To assess the degree of pain post-tonsillectomy
3. To determine incidence of secondary haemorrhage post-tonsillectomy
4. To establish when the child should start feeding post-tonsillectomy.
5. To document possible adverse effects of the use of antibiotic - such as skin rash, anaphylaxis, diarrhea and vomiting
6. To make recommendations on post-tonsillectomy treatment protocol at DGMH

MATERIAL AND METHODS

Ethics

This study was approved by the Medunsa Research and Ethics Committee (MREC) and the hospital management of DGMH.

Study Design

The study design was a prospective, randomized, single blind, controlled study.

Study population

The study included 81 selected patients who underwent tonsillectomy at the department of Otorhinolaryngology between 1st March and 31st August 2011.

Inclusion criteria

- Paediatric patients with the age range from 1 to 13 years with indication for elective adenotonsillectomy

Exclusion criteria

- Medical conditions requiring peri-operative antibiotic therapy.
- Antibiotics administered within one week prior to tonsillectomy.
- Patients allergic to penicillins.
- Patients who undergo unilateral tonsillectomy for biopsy.
- Patients for “hot” Tonsillectomy for peritonsillar abscess.

- Patients with concurrent major illness or physical disability (e.g. cerebral palsy, Downs syndrome).
- Patients with concurrent major systemic illness (e.g. malnutrition, electrolyte disorders, diabetes mellitus).

Procedures

- Consecutive patients in the age range of 2-13 years were identified at the ENT out patient clinic. A verbal interview was conducted with the parents/guardians with reasonable involvement of the patients. During the interview the purpose, method, potential risks and benefits of the study were explained to, and discussed with, the parent/guardian. Those parents/guardians who were willing to allow their children to participate in the study were invited to give their written consent (Appendix 1-5).
- Informed consent was obtained from parents/legal guardian prior to entry into the study.
- Pre-operative demographic information was obtained. This included patient age, sex, weight, indication for surgery and area of origin.
- Patients were randomly allocated to one of the two treatment groups.
- The random allocation was done in the following manner: a list of numbers up to 81 was drawn in a note pad which was put in the operating theatre.
- Each consecutive patient was allocated a number prior to surgery.
- Those who fell on odd numbers (Group A) were not to receive any antibiotics and those who fell on the even numbers (Group B) were scheduled to receive antibiotics.

- Amoxicillin was the antibiotic of choice and was administered orally at a daily dose of 40 mg/kg/day in three divided doses for seven days.
- All patients received pain medication, which consisted of oral paracetamol at a daily dose of 15 mg per kilogram of weight in three divided doses for a period of 7 days. Breakthrough pain was managed with additional doses of paracetamol.
- Parents kept diary of the dosage and frequency of pain medication required by their child post- operatively and to note when they felt their child resumed eating a normal diet.
- Patients were allocated to theater according to operative days at DGMH and the operations were carried out by the primary Researcher.
- Operative procedure was cold steel as per departmental policy.
- Hemostasis was ensured with dry gauze packing and/or bipolar diathermy.
- At operation tonsils were removed and immediately transported to the laboratory for culture, microscopy and sensitivity of core tonsillar microorganisms.
- Patients were discharged home on the first day post-tonsillectomy provided there were no complications.
- Patients were reviewed one week later and a detailed questionnaire was filled by the parents/legal guardian interviewed by blinded physician/nurse.

Data Collection

A data collection form was developed which reflected all the variables that were needed for complete information on each patient in the study. One form was used for each patient (Appendix 6).

Data analysis

Data generated from the study was analyzed by descriptive statistics, involving Mean values, Standard Deviation and the determination of levels of significant differences between the two groups. Where appropriate, Odds Ratio and its 95% Confidence Interval will be determined. Fisher's exact test [X^2] was calculated to establish any association between the use of antibiotics and reduction in the occurrence of post-operative infections.

Reliability and validity of study

The design of this study as a randomized, controlled study ensured adequate reliability and validity of results. The investigator (Dr MJ Sekole) was solely responsible for the randomization of patients, performed the procedure of tonsillectomy and recorded all information on study outcomes. Fellow colleagues (Registrars) at the same level of competence to carry out the procedure were briefed on the process of this study but were not involved in the post-tonsillectomy assessment of patients in the study. Statistical derivation of sample size has been applied so as to establish unequivocal findings.

Bias

No form of bias was evident in this study, as areas that could introduce bias, such as: patient selection, randomization and strict adherence to the methodology were closely guarded. The post-tonsillectomy assessments were performed by departmental colleagues (Registrars) or nurses who were blinded to the treatment received by the patients.

RESULTS

Study population

The study had 81 patients with the age range from 1-13years (mean age of 5.7 years). There were 43 males and 38 females (M:F ratio = 1:0.9). The patients were divided into two treatment groups with similar ($p>0.05$) characteristics (Table 1).

At one week after surgery, all parents and legal guardians returned for the postoperative interview. Data collection forms were completed satisfactorily by the blinded physicians and nurses. All the forms were then collected for statistical analysis and no data was lost to the study.

Table 1: Age and gender distribution of the study population

Demographics		**Group A (no antibiotics)**	**Group B (antibiotics)**
Age (years)	Range	1-13	2-13
	Mean (SD)	5.3 (2.9)	6.4 (3.2)
Gender (Number of patients)	Male (%)	21 (51.2%)	22 (55.0%)
	Female (%)	20 (48.8%)	18 (45.0%)

Pain assessment

Reported pain

All patients completed the post operative pain questionnaire (Table 2). There was no significant difference in both the incidence of reported pain and the pattern of pain severity ($p>0.05$).

Table 2: Comparison of the incidence and severity of postoperative pain

Incidence and severity of pain (number of patients)		**Group A (no antibiotics)**	**Group B (antibiotics)**
Pain	Yes (%)	41 (100%)	40 (100%)
	No (%)	0 (0 %)	0 (0 %)
Pain score	1=No pain	0 (0 %)	0 (0 %)
	2=Mild (%)	0 (0 %)	2 (5.0%)
	3=Moderate (%)	11 (26.8%)	14 (35.0%)
	4=Severe (%)	30 (73.2%)	24 (60.0%)
Mean pain score		3.7	3.6

Consumption of analgesic medication

All patients in the study population received analgesic medication. There was no significant difference between the two treatment groups in the pattern of analgesia consumption ($p>0.05$). The majority of patients in both groups used the medication three times per day. There were more patients in group A (19.0%, n=8) who used breakthrough medication as compared to group B (10.0%, n=4) however, this finding was not statistically significant ($p>0.05$).

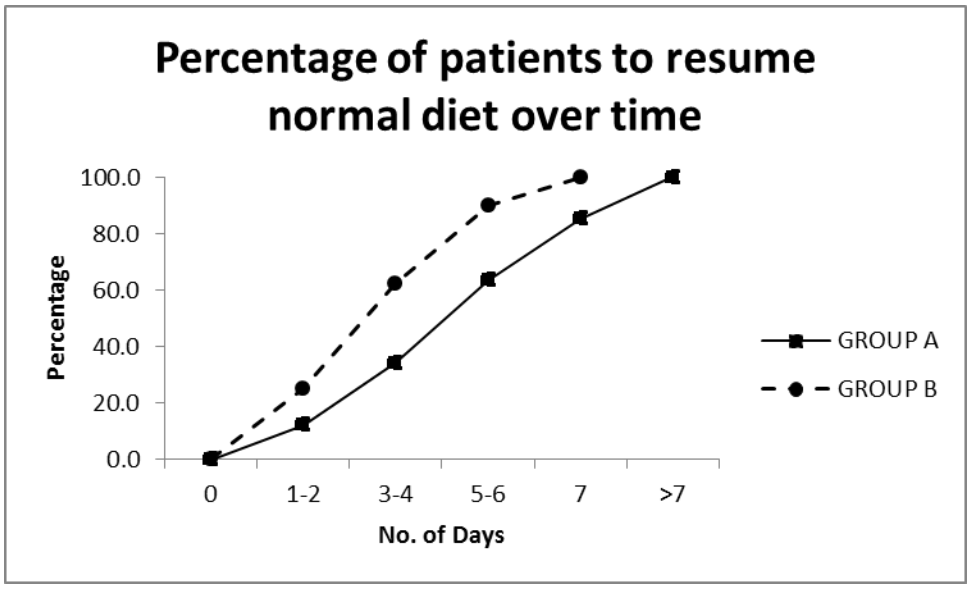
Table 3: Comparison of the number of patients received analgesia and pattern of analgesia consumption

Analgesia consumption		**Group A**	**Group B**
Number of patients who used analgesics		41 (100%)	40 (100%)
Frequency of Daily Dosage	1	0 (0 %)	2 (5.0%)
	2	1 (2.4%)	2 (5.0%)
	3	32 (78.0%)	32 (80.0%)
	4	8 (19.0%)	4 (10.0%)

Resumption of normal diet (Figure 1)

The patients in group B (with antibiotics) resumed normal diet at faster rate than those in group A (without antibiotics). By the seventh day all the patients (100%, n=40) in group B had resumed to normal diet, whereas 6 (14.6%) patients in group A had not yet achieved this. Overall there was no significant difference in the rate at which patients in the two groups resumed their normal diet ($p>0.05$).

Figure 1: Comparison of the time period to the resumption of normal diet.



Postoperative morbidities

There was no significant difference in the frequency of reported postoperative morbidities between the two study groups (Table 4). Patients assigned to the group that did not receive postoperative antibiotics, group A, reported a much higher incidence of fever (24.4%, n=10) than those in group B (10.0%, n=4) who received antibiotics, and a higher incidence of bleeding and vomiting was reported by patients in Group B, but these findings were not statistically significant ($p>0.05$).

Table 4: Comparison of the frequency of reported postoperative morbidity

Post operative morbidities		**Group A**	**Group B**
Bleeding	Yes (%)	2 (4.9%)	5 (12.5%)
	No (%)	39 (95.1%)	35 (87.5%)
Vomiting	Yes (%)	5 (12.2%)	7 (17.5%)
	No (%)	36 (87.5%)	33 (82.5%)
Fever	Yes (%)	10 (24.4%)	4 (10.0%)
	No (%)	31 (75.6%)	36 (90.0%)

Adverse reactions (Table 5)

There were no reported cases of diarrhoea in this study. Five percent of patients in both groups gave a history of skin rash that developed during the study period.

Table 5: Comparison of the frequency of adverse reactions

Adverse reactions		**Group A**	**Group B**
Diarrhoea	Yes (%)	0 (0%)	0 (0%)
	No (%)	41 (100%)	40 (100%)
Skin rash	Yes (%)	2 (4.9%)	2 (5.0%)
	No (%)	39 (95.1%)	38 (95.0%)

Isolated microorganisms (Table 6)

All the patients had culture done on the tonsil tissue removed at surgery. In group A 17.1% (n=7) reported no growth and group B showed 22.5% (n=9) of no growth. The most frequently isolated microorganism in both groups was *S. aureus,* of which 41.5% was isolated from group A (no antibiotics) and 35.0% from group B (antibiotics). There was no significant difference in the aerobes isolated from the two treatment groups. *H .influenzae* (14.6%, 10.0%), *P. aeruginosa (*2.4, 2.5%), *S. viridians* (9.8%, 2.5%), *S. pyogenes* (4.9%, 15.0%), *S. pneumonia* (2.4%, 5.0%), *S. dysenteriae* (2.4%, 2.5*), Group A streptococci* (2.4%, 2.5%) were isolated from group A and group B respectively. The facultative anaerobes cultured was *E. coli,* 2.4% and 2.5% were isolated from group A and group B respectively. The patients with more than one microorganism were twice as high in group B (20.0%) than in group A (9.8%).

Table 6: Comparison of the frequency distribution of isolated microorganisms

Microorganisms	**Group A** **No (%)**	**Group B** **No (%)**
No growth	7 (17.1)	9 (22.5)
H. influenza	6 (14.6)	4 (10.0%)
P. aeruginosa	1 (2.4)	1 (2.5)
S. aureus	17 (41.5)	14 (35.0)
S. viridians	4 (9.8)	1 (2.5)
S. pyogenes	2 (4.9)	6 (15.0)
S. pneumonia	1 (2.4)	2 (5.0)
S. dysenteriae	1 (2.4)	1 (2.5)
Group A streptococci	1 (2.4)	1 (2.5)
E. coli	1 (2.4)	1 (2.5)

DISCUSSION

Tonsillectomy is a commonly performed operation in children. After surgery virtually all patients experience a significant degree of pain which interferes with their ability to eat a normal diet and to resume their normal daily activities. In addition to surgical trauma, it has been suggested that infection may aggravate the pain and cause fever, diarrhoea, vomiting and bleeding. Post tonsillectomy management invariably requires the use of analgesic medication. What is less certain is whether or not the use of antibiotics will reduce the incidence of infection, reduce risk of bleeding and attenuate the severity of pain following surgery [21].There is no consensus regarding the use of antibiotics after tonsillectomy in the paediatric population and treatment protocols vary between different centres.

This prospective study was conducted at DGMH on 81 children with an age range of 1-13years. Forty children received paracetamol 15mg/kg/day (Group A) in three divided doses for seven days, and 41 received amoxicillin 40 mg/kg/day and paracetamol (Group B) for the same duration. The post operative morbidity and bacteriology of the two treatment groups were compared.

Relief of post-tonsillectomy pain

All patients in this study experienced a degree of pain and severe pain was reported by 73.2% and 60.0% of patients in groups A (paracetamol) and B (amoxicillin-paracetamol) respectively. The use of antibiotics was of no advantage and no difference in the severity of pain was observed between the two groups. Similar findings were shown by O'Reilly *et al* in a randomised placebo controlled study of 31 patients of which 16 patients received

antibiotics. They found that the post-operative pain was worst on day five in both active and placebo groups; thereafter it showed a steady improvement. However the mean sum score was found to be similar for the active and for the placebo group, showing no significant difference between the groups. They concluded that antibiotics did not reduce the total pain nor influence the severity of pain[46].

Some studies have found that the administration of perioperative antibiotics leads to a reduction in pain following tonsillectomy. Colveary *et al* conducted an equivalent study in which they enrolled 78 children with an age range of 2 -12 years (mean 6.2 years). They found that only 25.8% of the patients who received antibiotics experienced severe pain as compared to 58.0% amongst those who had no antibiotics. They suggested that post operative antibiotics were beneficial in that they brought about a significant reduction in pain analogue scores ($p<0.05$)[21]. Intravenous and topical antibiotic regimens were evaluated in a randomized, double-blinded, placebo-controlled pilot study of 36 adult patients undergoing tonsillectomy. Significantly less postoperative pain was reported for the two topical treatment groups, cleocin and augmentin-timentin, when compared with a placebo group ($p<0.05$). The authors did not commit to the use of antibiotics but they suggested that further investigations were warranted[24]. In a placebo controlled study, by Grandis *et al*, on 101 adults with a mean age of 21.7 years, antibiotics were administered to 51 patients. These authors observed that patients who received antibiotics experienced less pain as compared to those that took placebo, however they noted that this finding was not statistically significant ($p>0.05$)[21]. A prospective randomized study was undertaken by Telian *et al*, in which intravenous antibiotics or (placebo) was administered at the time of surgery and for 12 to 24 hours intravenous post operatively. The patients then continued to receive oral antibiotic therapy (or

placebo) for an additional seven days. Their results indicate that antibiotics therapy was effective in minimizing postoperative pain[16].

Need for analgesia

In our study the majority of patients in both treatment groups used the analgesics three times a day. It was found that 19.0% of patients without antibiotics and 10.0% of patients with antibiotics reported consumption of additional analgesics, however this finding did not show any significant difference between the two treatment groups. Similarly O'Relly *et al* reported the use of additional analgesia in 43.0%and 46.0% of patients in the antibiotics and placebo groups respectively, but found no significant difference[46]. Grandis *et al* reported consumption of fewer doses of pain medication in their antibiotic group as opposed to the placebo, but no significant difference was found in mean number of doses of pain medication taken between the two groups ($p>0.05$)[20]. On the other hand, Colveary *et al* found significant reduction in analgesic consumption in the antibiotic group. They reported that the antibiotics group required almost half the amount of analgesia as those not taking antibiotics and this was found to be highly statistically significant ($p<0.038$). They concluded that antibiotics improve pain recovery[21].

Resumption of normal diet

Our study showed that by the seventh day, 100% of the patients in the antibiotics group had resumed a normal diet, whereas 14.6% in non-antibiotic group had not. But the rate at which patients in the two groups resumed their normal diet were not statistically significant ($p>0.05$). A prospective study conducted by Khan *et al* of 106 patients, with 40 on antibiotics and 60 without antibiotics, found that 8.33% of patients who did not received antibiotics

experienced odynophagia as compared to 6.52% amongst those who received antibiotics, but this was not statistically significant. They then recommend not using post operative antibiotics[23].

Colveary et al they reported antibiotic to improve time taken for resumption of normal diet. They found the mean reduction of 2.4 days, (antibiotic group took 2.2 days and no antibiotics took 4.6 days on average), for return to normal diet. This was found to be statistically significant (p=0.0072)[21], while Telian *et al* reported a mean reduction of one day for resumption of normal diet[16].

Haemorrhage

Secondary haemorrhage is widely assumed to be caused by bacterial infection. It is commonly treated with antibiotics, despite scant evidence to support an infective etiology[10, 50]. A more understandable explanation is that sloughing of the primary eschar, which usually occurs between the 5th and 10th day in the postoperative period, manifests as secondary hemorrhage. Our study found that the incidence of bleeding was higher in patients who received antibiotic, (12.5%) compared to those who did not (4.9%), but these findings were not statistically significant (p>0.05). O'Reilly *et al* reported an incidence of bleeding of 23.9% with antibiotic use and 24.5% in a placebo group. However there was no significant difference between the two groups[46]. In contrast, Cannon *et al* in a randomised prospective study of 50 patients, reported that the rate of postoperative haemorrhage was the same in both antibiotic and placebo study groups. Although they did not mention the exact incidence rate, they reported that their findings were not statistically significant and concluded that antibiotics were not effective in reducing the incidence of bleeding after tonsillectomy[27]. A prospective randomized trial of 95 patients (43 with antibiotics and 52 without antibiotics)

conducted by Marja *et al* reported bleeding in 21.0% of patients with antibiotics as compared to 26.8% without antibiotics. All patients who experienced post-tonsillectomy haemorrhage did not require medical attention. They found no statistically significance and concluded that there is no improvement in patients bleeding after tonsillectomy with the use of antibiotics[28].

Fever

Reduction of fever by antibiotic therapy is likely due to the amelioration of bacteremia, which is recognized to occur during and immediately after tonsillectomy[51]. Our study showed an incidence of fever of 24.4% in the non-antibiotics group and 10.0% in antibiotic group. Although the incidence of fever was much higher in the non-antibiotics group this finding was not statistically significant ($p>0.05$). Telian *et al* reported that antibiotics reduce the number of patients presenting with fever in the first seven days. They found that 79.0% of children in the placebo group had at least one episode of fever, while only 52.0% of those in the antibiotic group had at least one episode of fever. They reported a significant difference in the incidence of postoperative fever ($p<0.05$)[16]. Grandis *et al* reported on only 22 patients in whom 1 or more episode of fever developed, 8 (16.0%) in antibiotic group and 14 (28.0%) on placebo. They reported a reduction in the mean number of days with fever in the antibiotic group, but they found this not statistically significant ($p>0.05$)[20]. Marja *et al* found that 25.6% with antibiotics and 19.2% in the control group had fever until second day of tonsillectomy. They reported that their finding were similar between the two groups[28]. The use of antibiotics showed modest reduction in the incidence of the post operative fever. Although this was not statistical significant. There is a need for further trials with large scale of number of patients before we recommend the use of antibiotics in combating fever.

Vomiting

In our study a higher incidence of 17.5% of vomiting was reported by patients in the antibiotic group compared to12.2% in the non-antibiotic group, but these findings were not statistically significant (p>0.05). Lee *et al* reported the incidence of nausea and vomiting, they had 31.5% in patient with antibiotics and 39.0% without antibiotics and that was not statistically significant (p>0.05). Majra *et al* indicated that nausea and vomiting were reported by 27.9% of patients with antibiotics and 75.0% without antibiotics reported no nausea or vomiting. They reported that their finding was similar between the two groups with no statistically significant (p>0.05)[28].

Adverse reactions

The potential for adverse effect also need to be considered while prescribing antibiotics[26]. No major adverse reactions have been reported in our study, but with regard to minor adverse reactions only 5% percent of patients in both groups gave a history of skin rash that developed during the study period. Trials by Grandis *et al* reported four cases manifesting with rash and three with diarrhoea in the antibiotics group, compared to one case with rash and two with diarrhoea in the control group[20]. Telian *et al* reported one case of a patient manifesting with rash in the antibiotic group and three cases in the placebo group. They reported that their finding was not statistically significant (p>0.05)[16].

Isolated microorganisms

The use of antibiotics after tonsillectomy has been found to lessen the bacterial content of the post tonsillectomy fossa and is felt to eradicate bacteria in this open wound thus minimizing infection, stimulating and hastening recovery[20]. The bacteriological profile of tonsils differs between centers. It has been shown that cultures from pharyngeal swabs may not be a true reflection of the pathogens in the tonsil core and organisms such as *S. aureus* may reside as intracellular pathogens [52, 53]. In this study the microbiology of core tonsillar microorganisms was determined. Our study demonstrated that the most frequently isolated microorganism in both study groups (Group A: no antibiotics; Group B: antibiotics) was *S. aureus* (38.2%), followed by *H .influenzae* (12.3%). This finding is in agreement with the results of the studies by Motassim *et al* and Zauntner *et al* both of which identified *S. aureus* as the principle isolate. There was no significant difference in the aerobes isolated from the two treatment groups. The facultative anaerobe cultured was *E. coli* (2.5%). The patients with more than one microorganism were twice as high in group B (20.0%) than in group A (9.8%), but this was not statistically significant. In contrast Colveary *et al* found that *H .influenzae* (64.0%) was the most prominent organism. The next most common organism was *S. viridians* (55.9%) and *S. aureus* (37.0%). They found 25% of anaerobes, of which the commonest was *Bacteroides fragilis*[21]. Pereira *et al* found that *Streptococcus spp* (51.3%) and *Staphylococcus* (42.3%) were the most prevalent aerobes on children tonsils regardless of the site[48].

CONCLUSION

There is no evidence from the results of our study that routine use of post-operative amoxicillin is justified in paediatric tonsillectomies. Amoxicillin did not have any impact on postoperative pain, bleeding and the time period to the resumption of a normal diet. However, amoxicillin may be effective in reducing the incidence of post-operative fever but further studies will be needed to evaluate this property. It is possible that different antibiotics would be more effective in reduction of post-tonsillectomy morbidities but any alternative would have to be effective to justify its routine use. Therefore in our centre, DGMH, we do not recommend the use of antibiotics after tonsillectomy.

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APPENDIX **1**

UNIVERSITY OF LIMPOPO (Medunsa Campus) ENGLISH CONSENT FORM

Statement concerning participation in a ~~Clinical Trial~~/Research Project*.

Name of Project / Study / ~~Trial~~*

THE USE OF ANTIBIOTICS POST-TONSILLECTOMY AT DR GEORGE MUKHARI HOSPITAL (DGMH):….…….

IS IT OF BENEFIT?

.....

.....

I have ~~read the information on~~ */heard the aims and objectives of* the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I know that photographs / electronic images / sound recordings* will be taken of me. I am aware that this material may be used in scientific publications which will be electronically available throughout the world. I consent to this provided that my name / and hospital number* is / are* not revealed. Regarding images of the face, I understand that it may not be possible to disguise my identity, and I consent to the use of these images*.

I understand that participation in this Clinical Trial / Study / Project* is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this Trial / Study / Project* has been approved by the Medunsa Research Ethics Committee (MREC), University of Limpopo (Medunsa Campus) / Dr George Mukhari Hospital. I am fully aware that the results of this results of this Trial / Study / Project* will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Trial / Study / Project*.

....
Name of patient/volunteer Signature of patient or guardian.

....
Place. Date. Witness

Statement by the Researcher

I provided verbal and/or written* information regarding this Trial / Study / Project*
I agree to answer any future questions concerning the Trial / Study / Project* as best as I am able.
I will adhere to the approved protocol.

....……
Name of Researcher Signature Date Place

*Delete whatever is not applicable.

APPENDIX 2

UNIVERSITY OF LIMPOPO (Medunsa Campus) AFRIKAANS CONSENT FORM

Verklaring ten opsigte van deelname aan 'n ~~Kliniese Eksperiment~~/Navorsingsprojek*

Naam van ~~Projek/Studie~~/Eksperiment*

DIE GEBRUIK VAN ANTIBIOTIKA POST-TONSILLEKTOMIE IN DR GEORGE MUKHARI HOSPITAAL (DGMH):

IS DIT VAN WAARDE?.....

.....

Ek het die inligting in verband met die beoogde studie gelees*/het die doelwitte en oogmerke van die beoogde studie aangehoor* en is die geleentheid gegun om vrae te stel asook voldoende tyd toegelaat om oor die aangeleentheid te besin. Die doelwit en oogmerke van die studie is duidelik genoeg vir my. Ek is geensins onder enige druk geplaas om deel te neem nie.

Ek verstaan dat deelname aan hierdie Kliniese Eksperiment/Studie/Projek* geheel en al vrywillig is en dat ek te eniger tyd daarvan kan onttrek sonder om enige redes aan te voer. Dit sal geen invloed hê op die gereelde behandeling van my toestand nie, en sal ook nie die behandeling wat ek van my eie dokter ontvang, beïnvloed nie.

Ek is bewus daarvan dat hierdie Eksperiment/Studie/Projek* goedgekeur is deur die 'Medunsa Research Ethics Committee (MREC)', Universiteit van Limpopo (Medunsa-kampus)/Dr George Mukhari Hospitaal. Ek is ten volle bewus daarvan dat die uitslae van hierdie Eksperiment/Studie/Projek* aangewend sal word vir wetenskaplike doeleindes, en gepubliseer mag word. Ek stem daartoe in, met dien verstande dat my privaatheid gewaarborg is.

Hiermee verleen ek toestemming om deel te neem aan hierdie Eksperiment/Studie/Projek*.

.....	.....
Naam van pasiënt/vrywilliger	Handtekening van pasiënt of voog

.....	.....	.....
Plek	Datum	Getuie

Verklaring deur Navorser

Ek het mondelingse en/of skriftelike* inligting ten opsigte van hierdie Eksperiment/Studie/Projek* voorsien.
Ek verklaar myself bereid om enige toekomstige vrae ten opsigte van die Eksperiment/Studie/Projek* na die beste van my vermoë te beantwoord.
Ek sal myself onderwerp aan die goedgekeurde protokol.

.....	.....	.....	……..
Naam van Navorser	Handtekening	Datum	Plek

*Skrap waar nie van toepassing nie.

APPENDIX 3

UNIVERSITY OF LIMPOPO (Medunsa Campus) SETSWANA CONSENT FORM

Seteitemente se se ka ga go tsaya karolo mo Tekopatlisisong / Porojeke ya Patlisiso*.

Leina la Porojeke / Patlisiso / Tekelelo*

TSHEBEDISO YA DIPILISI TSA GO LWANTHSA KOKWANAHLOKO MO SEPETLELENG SA DR GEORGE …….

MUKHARI KA MORAGO GA OPERESHENE YA GO NTSHA DIKODU: A E KABA LE THUSHO? .....

.....

Ke buisitse tshedimosetso mo */ke utlwile maitlhomo le maikemisetso a* patlisiso e e tshitshintsweng mme ke filwe tšhono ya go botsa dipotso le go fiwa nako e e lekaneng ya go akanya gape ka ntlha e. Maitlhomo le maikemisetso a patlisiso e a tlhaloganyega sentle. Ga ke a patelediwa ke ope ka tsela epe go tsaya karolo.

Ke tlhaloganya gore go tsaya karolo mo Tekopatlisisong e / Patlisiso / Porojeke* ke boithaopo le gore nka ikgogela morago mo go yona ka nako nngwe le nngwe kwa ntle ga go neela mabaka. Se ga se kitla se nna le seabe sepe mo kalafong ya me ya go le gale ya bolwetsi jo ke nang le jona e bile ga se kitla se nna le tlhotlheletso epe mo tlhokomelong e ke e amogelang mo ngakeng ya me ya go le gale.

Ke a itse gore Tekopatlisiso / Patlisiso / Porojeke* e e rebotswe ke Patlisiso le Molao wa Maitsholo tsa Khampase ya Medunsa (MREC), Yunibesithi ya Limpopo (Khampase ya Medunsa) / Bookelo jwa Ngaka George Mukhari. Ke itse ka botlalo gore dipholo tsa Tekelelo / Patlisiso / Porojeke* di tla dirisetswa mabaka a saentifiki e bile di ka nna tsa phasaladiwa. Ke dumelana le seno, fa fela go netefadiwa gore se e tla nna khupamarama.

Fano ke neela tumelelo ya go tsaya karolo mo Tekelelong / Patlisiso / Porojeke* e.

....
Leina ka molwetse/moithaopi Tshaeno ya molwetse kgotsa motlamedi.

....
Lefelo. Letlha. Paki

Seteitemente ka Mmatlisisi

Ke tlametse tshedimosetso ka molomo le/kgotsa e e kwadilweng malebana le Tekelelo / Patlisiso / Porojeke* e.
Ke dumela go araba dipotso dingwe le dingwe mo nakong e e tlang tse di amanang le Tekelelo / Patlisiso / Porojeke* ka moo nka kgonang ka teng.
Ke tla tshegetsa porotokolo e e rebotsweng.

....……
Leina la Mmatlisisi Tshaeno Letlha Lefelo

*Phimola sengwe le sengwe se se seng maleba.

APPENDIX 4

UNIVERSITY OF LIMPOPO (Medunsa Campus) SEPEDI CONSENT FORM

Setatamente mabapi le go tšea karolo ka go Protšeke ya Dinyakišišo tša Teko ya Klinikhale *.

Leina la Protšeke / Dinyakišišo / Teko*

TSHOMISHO YA DIPILISI MORAGO GA OPORESHENE YA DIKODU MO BO OKOELONG BJA DR GEORGE …….

MUKHARI: A E NA LE MOHOLA?.....

.....

Ke badile/ke kwele ka ga tshedimošo mabapi le *maikemišetšo le morero wa* dinyakišišo tšeo di šišintšwego gomme ke ile ka fiwa monyetla wa go botšiša dipotšišo gomme ka fiwa nako yeo e lekanego gore ke naganišiše ka ga taba ye. Ke tloga ke kwešiša maikemišetšo le morero wa dinyakišišo tše gabotse. Ga se ka gapeletšwa go kgatha tema ka tsela efe goba efe.

Ke a kwešiša gore go kgatha tema Protšekeng/Dinyakišišong tše tša Teko ya Klinikhale* ke ga boithaopo gomme nka tlogela go kgatha tema nakong efe goba efe ntle le gore ke fe mabaka. Se se ka se be le khuetšo efe goba efe go kalafo yaka ya ka mehla ya maemo a ka gape e ka se huetše le ge e ka ba tlhokomelo yeo ke e humanago go ngaka yaka ya ka mehla.

Ke a tseba gore Teko/Protšeke/Dinyakišišo tše* di dumeletšwe ke Medunsa Research Ethics Committee (MREC), Yunibesithi ya Limpopo (Khamphase ya Medunsa) / Dr George Mukhari Hospital.Ke tseba gabotse gore dipoelo tša Teko/Dinyakišišo/ Protšeke tše * di tla dirišetšwa merero ya saense gomme di ka phatlalatšwa. Ke dumelelana le se, ge fela bosephiri bja ka bo ka tiišetšwa.

Mo ke fa tumelelo ya go kgatha tema Tekong/Dinyakišišong/ Protšekeng *.

.....
Leina la molwetši/ moithaopi Mosaeno wa molwetši goba mohlokomedi.

....
Lefelo. Letšatšikgwedi.
Tlhatse

Setatamente ka Monyakišiši

Ke fana ka tshedimošo ka molomo le/goba yeo e ngwadilwego * mabapi le Teko/Dinyakišišo/ Protšeke ye .*
Ke dumela go araba dipotšišo dife goba dife tša ka moso mabapi le Teko/Dinyakišišo/ / Protšeke ka bokgoni ka moo nka kgonago ka gona.
Ke tla latela melao yeo e dumeletšwego.

....
Leina la Monyakišiši Mosaeno Letšatšikgwedi Lefelo

*Phumola tšeo di sego maleba.

APPENDIX 5

UNIVERSITY OF LIMPOPO (Medunsa Campus) ISIZULU CONSENT FORM

Isitatimende esimaqondana nokuhlanganyela oHlolweni Lokwelashwa/kuPhrojekthi Yocwaningo*

Igama lePhrojekthi/loCwaningo/loHlolo*

UKUSETSHENZISWA KWAMA ANTIBIOTICS EMVA KOKUHLINZWA KWAMATHANSELA ESIBHEDLELA iDR GEORGE MUKHARI: INGABE KUNOMPHUMELA OMUHLE YINNI?.....

.....

Ngilufundile ulwazi*/ngizizwile izinhloso nezinjongo* zocwaningo oluhlongoziwe futhi nganikezwa nethuba lokubuza imibuzo nganikezwa nesikhathi esanele sokuphinde ngicabange ngodaba. Inhloso nenjongo yocwaningo kucace ngokwanele kimi. Azange ngicindezelwe ukuthi ngihlanganyele nganoma iyiphi indlela.

Ngiyaqonda ukuthi ukuhlanganyela kulolu Hlolo/Cwaningo/ kule Projekthi* yoHlolo ngokokuzithandela ngokuphelele nokuthi ngingahoxa kulo noma nini ngaphandle kokunikeza izizathu. Lokhu angeke kube nomthelela ekwelashweni okuvamile kwesimo sami futhi angeke kube nomthelela ekunakekelweni engikuthola kudokotela wami ovamile.

Ngiyazi ukuthi lolu Hlolo/Cwaningo/le Projekthi* igunyazwe yi-Medunsa Research Ethics Committee (MREC), University of Limpopo (Medunsa Campus) / Dr George Mukhari Hospital. Nginolwazi olugcwele lokuthi imiphumela yalolu Hlolo/Cwaningo/yale Projekthi* izosetshenziselwa izinhloso zesayensi futhi ingashicilelwa. Ngiyakuvuma lokhu, uma nje ingasese lami liqinisekisiwe

Lapha nginikeza imvume yokuhlanganyela kulolu *.

....
Igama lesiguli/levolontiya Isignesha yesiguli noma yomgadi.

....
Indawo. Usuku. Ufakazi

Isitatimende somCwaningi

Nginikezele ngolwazi ngomlomo kanye/noma olubhaliwe* maqondana nalolu Hlolo/Cwaningo/nale Phrojekthi*. Ngiyavuma ukuphendula nanoma yimiphi imibuzo yesikhathi esizayo maqondana noHlolo/Cwaningo/ne Phrojekthi* kahle kakhulu kangangoba ngikwazi. Ngizobambelela kusivumelwano senqubo esigunyaziwe

....
Igama loMcwaningi Isignesha Usuku Indawo

* Cisha noma yini engasebenzi.

APPENDIX 6

PATIENT QUESTIONNAIRE

Hospital GT/GP number:

Date of surgery:

Date of birth:

AGE ☐

GENDER ☐ Male ☐ Female ☐

Did the patient experience pain? Yes ☐ No ☐

If yes, was it? Mild ☐ Moderate ☐ Severe ☐

Did the patient receive pain-killers? Yes ☐ No ☐

If yes, how often per day? Once ☐ Twice ☐ Thrice ☐ More than3 ☐

Did the patient have any bleeding? Yes ☐ No ☐

If yes, did you consult for that? Yes ☐ No ☐

Did the patient have any vomiting? Yes ☐ No ☐

Did the patient have any diarrhoea? Yes ☐ No ☐

Did the patient have any skin rash? Yes ☐ No ☐

When did the child start on normal diet? Day 1 ☐ Day 2 ☐ Day 3 ☐

Day 4 ☐ Day 5 ☐ Day 6 ☐

Day 7 ☐ Not yet started ☐

Bacteria cultured? Yes ☐ NO ☐

If yes, what is the organism? ☐