

"The effect of amoxicillin on Morbidity after paediatric Adenotonsillectomy at Kenyatta National Hospital, Nairobi Kenya."

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A thesis submitted in part fulfilment for the Degree of master of
medicine (ENT/HN surgery) of University of Nairobi

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DEDICATION

This book is dedicated to my wife Judy and Son Nick for their understanding and perseverance during my long hours of absence.

ACKNOWLEDGEMENT

I would like to thank the various staff members in ward 5C, ENT clinic and theatre for their co-operation and assistance during the study.

I would also like to thank Glaxo Smithkline for their support especially for the supply of all the amoxil needed for this study.

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ABSTRACT

Tonsillectomy, adenoidectomy and adenotonsillectomy are the most commonly performed operations by Ear, Nose and Throat, Head and Neck (ENT/HN) surgeons especially in the paediatric age group for various indications.

The post-operative period is characterized by odynophagia, otalgia and intermittent fever for which antibiotics are prescribed to reduce these symptoms to avoid post-operative complications especially secondary infection.

A prospective double blind randomised placebo controlled study was done at Kenyatta National Hospital (KNH) in which Amoxil (or placebo) was administered to children under 12 years of age. They were then evaluated for post-operative symptoms and complications during the study period of September 2001 – February 2002. A total of 144 patients were studied – with 72 patients on each mode of treatment. The male to female ratio was 1.7:1. The average age was 3 years with a range of 5 months to 12 years in this study.

The drop out rate was 18.1% (26 patients) mostly due to failure to come for review. However no patient was readmitted due to complications and there was no mortality during the study.

Patients who had adenoidectomy were 61 with 33 in the placebo and 28 in the antibiotic group. 8 (5.7%) patients dropped out. There were 16 tonsillectomies done with 7 in the placebo and 9 in antibiotic group. Only 2 (7.1%) patients did not complete the study. Adenotonsillectomies done were 67 with 32 and 35 patients in the placebo and antibiotic groups respectively. 16 patients (13.5%) did not complete the study.

There was no significant difference after adenoidectomy in the post-operative recovery between the placebo and antibiotic group in this study. Antibiotics (Amoxil) was found to be significantly useful post-operatively in minimizing the incidence of fever and post-operative pain after tonsillectomy and adenotonsillectomy.

Key words : Double – blind Randomised placebo controlled.

: Adenotonsillectomy, tonsillectomy, adenoidectomy

SUMMARY

Adenoidectomy, tonsillectomy or adenotonsillectomy continues to be commonly performed in most Ear, Nose and Throat (ENT) Units especially in the paediatric age group. Though it is generally safe surgery there are potential complications, which the surgeon should be prepared to manage.

The post operative period is characterized by sore throat, otalgia, fever, dehydration, and foul odour from the oral cavity.

Though post-operative sepsis is a potential complication there is no clear guidelines on the use of antibiotics and there is a possibility that antibiotics may be over used. Patients are routinely put on amoxicillin post-operatively after adenotonsillectomy in Kenyatta National Hospital ENT Unit. No study, in our set up has been done to demonstrate the role of antibiotics after adenotonsillectomy. A prospective double blind randomized study was done in Kenyatta National Hospital (KNH) ENT Unit. Amoxicillin (or placebo) was administered to all children undergoing adenoidectomy, tonsillectomy or adenotonsillectomy for a period of one week. The children were then monitored and evaluated for the incidence and severity of post-operative complications if any. All patients were given intra-operative start dose of dexamethasone (0.1mg./kg) and paracetamol (10mg./kg). They continued with paracetamol for one week.

INTRODUCTION

PHARYNGEAL AND PALATINE TONSILS

2.1 ANATOMY

The tonsils are grouped as secondary lymphatic organs and form part of the Waldeyer ring consisting of the palatine, tubal, lingual and pharyngeal (adenoid) tissue (1). The palatine tonsils are masses of lymphoid tissue, which lie in the mucous membrane of the lateral walls of the oral part of the pharynx, between the palatoglossal, and palatopharyngeal arches. They lie opposite the angle of mandible between the back of the tongue and the soft palate. In children they are larger than the fossae between the arches and bulge into the pharynx, and extend superiorly into the soft palate and anteriorly lateral to the palatoglossal arch. The medial free surface is covered by stratified squamous epithelium and has numerous crypts.

A fibrinous connective tissue capsule covers the lateral surface. The relationships are such that the medial surface is free and faces the pharynx. The lateral surface lies on superior constrictor muscle separated by loose connective tissue below which lies the facial artery. The internal carotid artery is also closely related to it. The blood supply is through the tonsillar branches of dorsal lingual artery, ascending palatine and tonsillar arteries of facial artery, ascending pharyngeal artery from external carotid artery, and descending palatine and accessory meningeal arteries from the maxillary artery. Adenoid tissue arises from the junction of the roof and posterior wall of the nasopharynx and is composed of vertical ridges of lymphoid tissue separated by deep clefts. It differs from the palatine tonsil in that it contains no crypts and is not covered by a capsule.

2.2. PHYSIOLOGY

The full details of immunological functions of the tonsils are as yet not totally understood. This Waldeyer's ring of lymphoid tissue surrounds the entrance of the aerodigestive inlet and thus provides initial contact with incoming organisms. The crypts and folds of the adenoids and tonsils serve to collect antigens for immune processing. Sensitized 'B' lymphocytes produce IgA locally (and other) sites whilst T-lymphocytes are part of the immune system against certain viruses. But tonsils and adenoids constitute only a small part of the lymphoid system and, accordingly have only a small part in the production of immune bodies, and that only in the first few years of life. Although Waldeyer's ring forms a barrier of sorts, it frequently breaks down so that tonsils and adenoids themselves become foci of troublesome infections. The palatine tonsil contains 10% lymphatic cells and constitute approximately 0.2% of all lymphocytes in the adult. Cytologically these are subdivided into small lymphocytes (45%) centrocytes (35%), Centroblasts (15%) and plasma cells 2.5%. The centrocytes and

Centroblasts are germinal center cells and produce Immunoglobulins. Proliferation of lymphocytes is induced by contact with antigens or polyclonal activators. Chemically it is suggested that tonsillar hypertrophy is a physiological process indicating B-lymphocytes proliferation while sunken atrophic tonsils indicate a collapse of defence process (3). It may be therefore small atrophic tonsils which are often the seat of infection of a chronic sort and as such have become redundant and worth removing. Hypertrophy will mainly cause obstruction.

2.3 PATHOLOGY

The main pathological problems associated with tonsils are infection, hypertrophy and malignant change. Recurrent infection of tonsils is a major cause of ill health and absenteeism from school in children. Attacks of recurrent tonsillitis (i.e. 3 attacks per year for three years or 5 attacks per year for two years or 7 episodes in one year) is usually an indication for tonsillectomy. Hypertrophy mainly causes obstruction and sleep disturbance.

Tonsils and adenoids are frequently involved in immuno-suppression due to HIV infection. Recurrent tonsillitis and obstructive enlargement are a common occurrence. Grave effects of adenotonsillar hypertrophy in an AIDS situation is sleep apnoea and exhaustion of a patient whose reserves for stress reaction are already compromised. Hence when performing adenotonsillectomy in patients with immunosuppression secondary to HIV infection close attention must be directed to the patient's general condition, coagulation status, the situation of the healing processes, the stage of the illness using CD4 counts, the viral load and the presence of opportunistic infections (30).

2.4 ADENOTONSILLECTOMY

This operation is the surgical procedure most commonly performed in many ENT Units. The indication for tonsillectomy has become better defined over the last 30 years (4). The indications for tonsillectomy are upper airway obstructive symptoms and alveolar hypoventilation, cor pulmonale, malignancy and uncontrollable hemorrhage from tonsillar blood vessels and chronic recurrent tonsillitis.

Adenoidectomy is indicated in upper airway obstruction, with/without secondary cardiopulmonary complications. Other indications include chronic nasal obstruction with obligate mouth breathing, failure to thrive, Eustachian tube obstruction with OME and conductive hearing loss and abnormal speech (especially Hyponasality). Relative contraindications are cleft palate and velopharyngeal insufficiency.

2.5 COMPLICATIONS OF ADENOTONSILLECTOMY

This is generally safe surgery, but complication may occur. Post-operative sepsis is a potential complication and does occur occasionally. Post-operative haemorrhage usually responds to local measures of pressure and cauterization but can be life-threatening though pre-operative coagulation profile screening appears unnecessary. Anaesthetic complications are possible though with modern anaesthetic techniques these have gone down (5). Aspiration and pulmonary oedema sometimes occur. Nasopharyngeal valving may be altered by altered velopharyngeal incompetence, nasopharyngeal or pharyngeal stenosis as a result of excessive trauma. Sore throat, otalgia, fever, dehydration and uvular Oedema, are more common. Less common complications include atlantoaxial subluxation, condylar fracture, Eustachian tube injury and psychological trauma. Localized subacute inflammation of the pharyngeal wall or tonsillar fossae is not uncommon following adenotonsillectomy but usually respond to symptomatic therapies such as warm saline lavages. (19).

3. LITERATURE REVIEW

ANTIBIOTIC USE IN ADENOTONSILLECTOMY

Although the indications for adenotonsillectomy have come under close scrutiny, it is still the most frequent otolaryngological operation performed in most ENT Units in the pediatric age group as well as in selected adults for various indications (6). The morbidity experienced by the patients is well known to the surgeon. The post-operative period can be protracted and characterized by intermittent sore throat, odynophagia with poor oral intake, foul odour from the mouth, secondary infection, otalgia, hemorrhage as well as psychological trauma for which many surgeons attempt to minimize by use of antibiotics and anaesthetics. Most surgeons have felt antibiotics have no role and/or play little role unless overt infection is identifiable (7). The first week after surgery can be difficult for the patient and the family as a whole, this is worse if the recovery period is prolonged or unusually uncomfortable especially if infections were to set in. Although most surgical wounds are contaminated with bacteria from skin or from sources external to the patient very few wounds become infected (8). Adenoidectomy, tonsillectomy or adenotonsillectomy is generally considered safe surgery and complications especially post-operative infection is extremely rare (9). Post-operatively the tonsillar fossa contains a whitish slough which one would expect to be an ideal culture medium for bacteria, in fact the fossae rarely get seriously infected (10). When infection does occur it can be recognized by increasing pain around the end of the first post-operative week with otalgia and pyrexia. Secondary hemorrhage, though rare is a constant threat and may be the first sign of infection for which antibiotic therapy will be necessary. There is therefore need for careful attention to post-operative nutrition and infection.

The risk of mortality at all ages from Adenotonsillectomy is 1 in 16,000 to 35,000 and mostly from anaesthetic complications and haemorrhage. The incidence of postoperative haemorrhage is 0.1 - 8.1% Transfusion is required in 0.04% of bleeding patients and mortality occurs in 0.002% (with a higher mortality rate in patients with primary haemorrhage). The main causes of post operative haemorrhage are retained adenoid tissue, and damage to posterior pharyngeal wall muscle (11). Careful attention to details of the procedure and sound post-operative care can yield excellent results.

Prophylactic antibiotics are usually administered to uninfected patient who is in jeopardy of acquiring a surgical infection. However there is a lot of controversy regarding prophylactic antibiotics therapy because prophylaxis has not always been as valuable as therapeutic use of Antibiotics. Prophylaxis is given to treat contaminated or potentially contaminated wounds before infection sets in. Though bacterial contamination is a component of every surgical wound, administration of antibiotic agents to prevent infection cannot be substituted for either sound surgical judgement or strict aseptic technique (13). Recommendations by major otolaryngological textbooks regarding use of antibiotics after adenoidectomy, tonsillectomy or adenotonsillectomy are scanty. Many have extensive literature on recommendations regarding post-

operative care but mention of routine use antibiotics leaving the decision to the individual surgeons.

Prophylactic antimicrobial use has no place in clean operative procedures or in those carrying a minimal risk of sepsis but should be considered for operations involving trauma or severe burns and for operations in infected tissue or those associated with heavy contamination e.g. large gut (14). However, chemoprophylaxis is beneficial prior to operations in patients prone to infections because of malnutrition, anaemia, premature infants, the very old, cancer patients, diabetics and those with known pre-existing infection even remote from the operative site. Infection does not necessarily follow contaminated wounds since host versus. Microbial factors play a role. (15).

The flora in upper respiratory airway and oral cavity is varied and is comprised of both aerobic and anaerobic organisms at a ratio of 10:1 (16). At the ENT department in KNH, adenotonsillectomy patients are routinely put on amoxycillin which is quite effective in gram positive aerobes especially streptococci pneumonia but is less effective in such organism like Hemophilus influenza, moraxella catarrhalis and most anaerobes (17) which pre-supposes that only a small proportion of these patients benefit. Antibiotic prophylaxis may not be successful if it is not effective against all pathogens anaerobes and fungus included. (18).

Dehydration aggravates local infection significantly to require antibiotics therapy. (19) Dehydration result from vomiting secondary to anesthesia as well as swallowed blood and decreased oral intake secondary to pain. Younger children are especially prone as they are less co-operative and have less volume reserve. A single intraoperative dose of steroids has been shown to accelerate return to normal diet and decrease post-operative nausea and vomiting (21). Though fever is an accepted complication in the first 36 hours it will increase water loss and predispose to dehydration. Hence just good hydration post-operatively minimizes the need for antibiotics therapy. Excessive manipulation and trauma intra-operatively can predispose to infection; this is minimized by sound surgical techniques. Intra-operative hemorrhage usually responds well to local measures of pressure and minimal cautery. Tissue oedema due to excessive surgical trauma and electrocautery can also predispose to infection. However intra-operative injection of corticosteroids to reduce edema is quite beneficial (20,21,22,23) and significantly reduces chances of infection.

However, Telian et al studied the effectiveness of amoxycillin on recovery after tonsillectomy in children in children's hospital of Philadelphia in 1986 and showed that *there is decrease in incidence and severity of fever as well subjective symptoms of mouth odour, pain and lassitude* (25).

Part of these study results in which 100 patients were assessed is shown in the table below:-

Post- Treatment Factors				Placebo group	Antibiotics group
Echar/Slough (%)				58	54
Weight Loss average % Bwt				-3.3	-3.0
Fever %	One or more episodes T>37.8C%			79	52
	Average	No.	Of	2.9	1.5
	Episodes>37.8C				
	Average	No.	Of	0.23	0.02
Episodes>37.6C					
Oral intake Average No. of days child could not tolerate soft or usual diet				2.3	1.3
Activity Average No. of child could play actively participate in usual activities				5.2	4.2

This first week after surgery can be difficult for the patient and the family. In seeking to provide excellent care surgeons have an obligation in doing whatever is necessary to minimize the morbidity after surgery as well as keeping the expenses as low as possible and hence should avoid administering unnecessary remedies. The goal is not only to prevent complication such as infections, bleeding and dehydration but also try to avoid prolonged periods of discomfort and alteration in diet activities. There is also tremendous amount of potential anxiety when a child is undergoing and recovering from any surgery especially when the recovery period is prolonged or unusually uncomfortable especially if infection were to set in (26).

The tonsils fossae are left open to heal by secondary intention and become covered by fibrinous inflammatory exudates post-operatively, which also confers protection from the digestive enzymes in saliva and invasion by local oropharyngeal bacteria. Unwise selection of medications can create serious problems including fatal side effects and can also be an economic burden to the patient. Therefore benefit versus risk should be considered first (24).

4. JUSTIFICATION FOR THIS STUDY

Adenoidectomy, tonsillectomy and/or adenotonsillectomy is generally safe surgery. There are however potential complications. No major textbook of otolaryngology recommends administration of antibiotics and no controlled study has been done in our set up to demonstrate the effectiveness of antibiotics use post-operatively. Detailed and thorough search in Medline of published English literature revealed that little has been done on use of antibiotics after adenotonsillectomy.

Kenyatta National Hospital being a public hospital whereby services are heavily subsidized by the government, amoxycillin is quite safe and most available and affordable antibiotics used. It is also relatively cheap. For this reason, in this study amoxycillin (Amoxil) will be used since most patients are routinely put on it unless there is an indication to use a different class of antibiotics in which case the patient will not meet the inclusion criteria.

5. AIMS AND OBJECTIVES

(1) AIM

To determine the effect of post-operative use of antibiotics on recovery after adenoidectomy, tonsillectomy or adenotonsillectomy.

(2) NULL HYPOTHESIS (H₀)

Post-operative antibiotics after adenotonsillectomy have no effect on recovery.

ALTERNATE HYPOTHESIS (H_A)

Post-operative antibiotics after adenotonsillectomy are useful.

(3) OBJECTIVES

1. Determine effect of post-operative use of amoxycillin on recovery after adenoidectomy, tonsillectomy and adenotonsillectomy.
2. Determine relationship between indication for adenoidectomy, tonsillectomy or adenotonsillectomy and need for post-operative use of amoxycillin.
3. Determine demographic variables with regard to adenotonsillectomy, adenoidectomy and tonsillectomy in Kenyatta National Hospital.

6. ETHICAL CONSIDERATIONS

Information gained during the study will be accessed to patients and the medical fraternity. No unconventional medical techniques whose safety is not ascertained was used during the study. The study proposal was submitted to and approved by Kenyatta National Hospital Ethical Committee.

7. MATERIALS AND METHODS

1. Study Design

This was a double blind Randomized placebo controlled study over a period of (5) months from September 2001 to January 2002

2. Location of Study

Kenyatta National Hospital ENT Department

3. Study Population

All children 12 years and below who underwent adenoidectomy, tonsillectomy or adenotonsillectomy in the ENT unit during the study period and met the inclusion criteria.

4. Sample Size

All children who met admission criteria in the study period:

$$n = \frac{(z_{\alpha} + z_{\beta})^2 4\Pi (1-\Pi)^2}{(\Pi_{\alpha} - \Pi_{\beta})^2}$$

z - power of detecting a relevant difference.

II - Mean

n - Sample size

And also derived from statistical analysis for the behavioral sciences sample sizes for two – sided two – sample Z test significant level =0.005 (27).

Power	Size of difference between P & P (Z & Z)		
	Small	Moderate	Large
0.80	392	63	25
0.85	449	72	28
0.90	525	84	33
0.95	650	104	41
0.99	919	147	57

- Sample size for significant Level of 0.05 and Power of 0.85 for moderate difference between P1 & P2 is 72 for each group hence a total of 144 patients to be randomized.

5. Eligibility Criteria

a) Inclusion Criteria.

- (i) Children 12 years and below undergoing adenoidectomy, tonsillectomy or adenotonsillectomy in the Kenyatta National Hospital (ENT) Unit.
- (ii) American Society of Anaesthesiologist (ASA) Class I and II.
- (iii) Child should not be allergic to penicillin.
- (iv) Child should not have had antibiotics therapy at least one week pre-operatively.

b) Exclusion Criteria

- (i) Obstructive sleep apnoea with cor-pulmonale
- (ii) Any medical condition which may/or may not need active antibiotics therapy post-operatively, e.g. asthmatics, Malnutrition, Rheumatic Heart disease, cerebral palsy, Downs syndrome.
- (iii) Those not meeting the inclusion criteria above.

6. Study Methodology

All patients booked for adenoidectomy, tonsillectomy or adenotonsillectomy in ENT/Ear, Nose and Throat Surgical Unit were pre-operative evaluated by the investigator. Detailed medical history was taken and a thorough medical examination done. Those who met the inclusion criteria for the study were then included in the study. The patients' guardians were informed of the study and informed consent obtained. They were not under any obligation to give consent and no financial inducement was offered or promised. Failure to give consent did not affect the patient's management and eventual follow up.

Once consent was obtained the patients were prepared for theatre in the usual way. A full haemogramme, urea and Electrolytes were determined. Those with acceptable parameters for elective surgery were then operated on. The patients were randomly distributed based on a table of random numbers. Similarly the drugs; Amoxicillin and placebo were similarly assigned numbers as above and the patients' mode of treatment was the one tallying with the number assigned to the drug container.

The operations were done under general anesthesia in the theatres by different surgeons as per duty rota. After intubation all the patients were given intravenous Dexamethasone (0.1mg/kg) and intramuscular paracetamol (10mg/kg.).

Tonsillectomy was done by blunt dissection while adenoidectomy was done by curettage. Haemostasis was by ligature and occasionally electrocautery.

The patients were monitored postoperatively by the investigator in the ward (see appendix II). All patients continued with the appropriate dose of paracetamol for one week post-operatively. The drugs + placebo were coded and packed in similar containers in such a way that the investigator as well as other staff members handling the patients were not aware. The code was only broken for any patient who developed any post-operative signs likely to be due to sepsis like fever persisting for more than 48 hours, increasing pain, persistent foul odour or refusal to take oral fluids by the 3rd post-operative. The patients were then given appropriate treatment.

8. DATA PRESENTATION

This was presented in tabular Bar charts and Pie chart as necessary. Analytical analysis for presentation was also done by use of SSPS and ANOVA computer programmes. Statistical analysis for significance was done by Z-scale and Chi(x²) test.

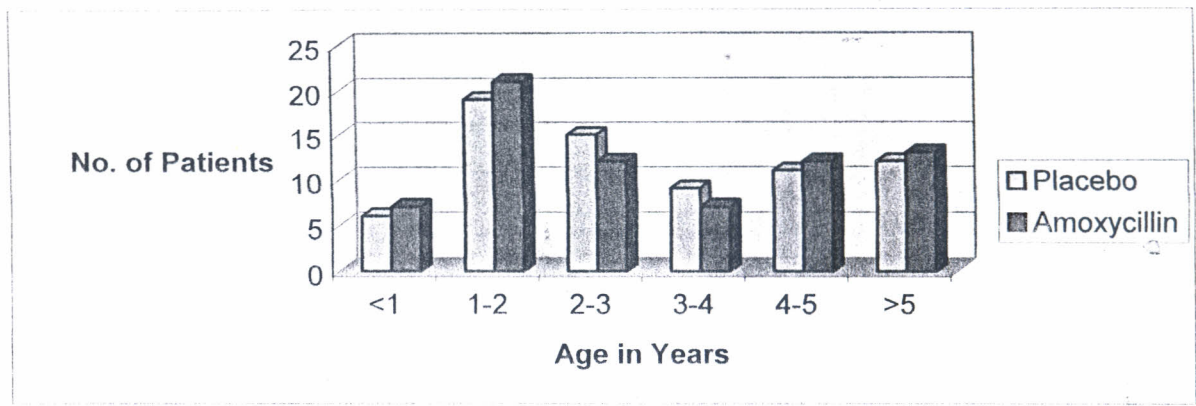
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RESULTS

AGE DISTRIBUTION

- The peak age was between 1 and 2 years of age
- The youngest patient was five months old while the oldest was 12 years.
- The average age of presentation in this study was 3 years.

Table I: Age distribution according to mode of treatment.



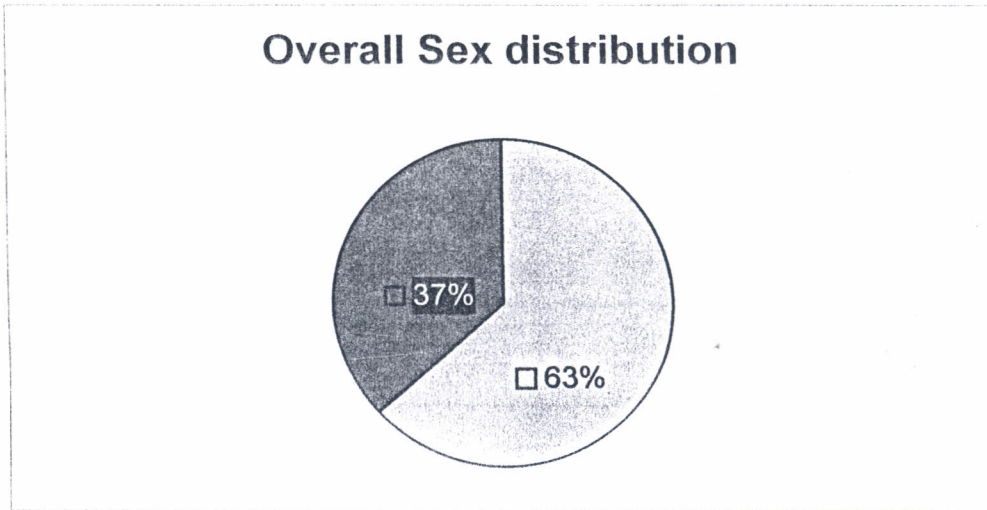
Graph 1: Age distribution according to mode of treatment

SEX DISTRIBUTION

There were 43 Males and 29 Females in the placebo group while in the amoxycillin group 48 were males and 24 were females.

Sex	Placebo	Amoxycillin	Total
Male	43	48	91
Female	29	24	53
Total	72	72	144

Table II: Sex distribution according to mode of treatment.



Key:

 = Females
 = Males

Pie Chart A: Overall Sex Distribution for the study.

PRESENTING COMPLAINS

Out of the 144 patients the commonest presenting complaints were snoring (88.2%) and nasal blockage (71.5%)

	Placebo	Amoxicillin	Total	%
Snoring	65	62	127	88.2
Sleep disturbances	42	46	88	61.1
Recurrent sore-throat	17	18	35	24.3
Nasal blockage	48	55	103	71.5
Mouth breathing	48	55	49	34

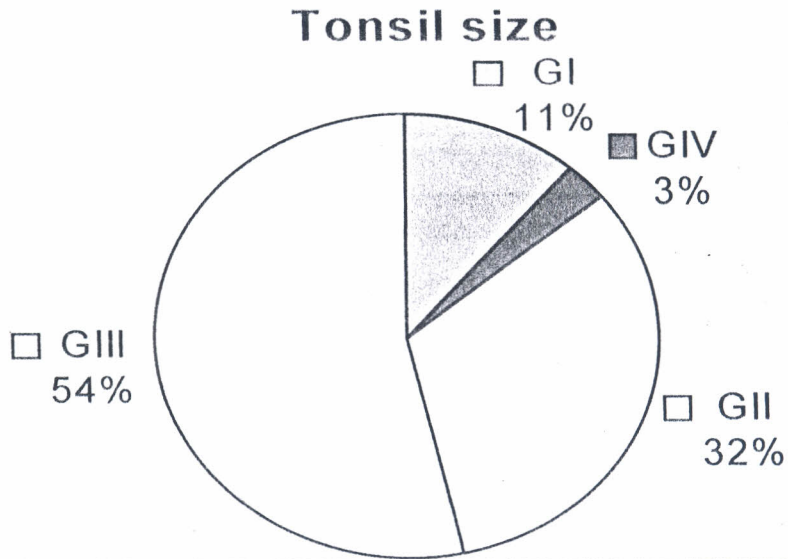
PRESENTING COMPLAINS**AVERAGE DURATION IN MONTHS**

	Placebo	Amoxycillin	Group Average
Snoring	26	23	24
Sleep disturbance	29	22	26
Recurrent sore throat	31	31	31
Nasal blockage	27	18	22
Mouth Breathing	31	25	28

Nasal blockage had the shortest duration of presentation of 22 months i.e. 1 year, 10 months while patients who presented with recurrent sore throat had the longest duration of 31 months i.e. 2 years – 7 months.

TONSIL SIZE DISTRIBUTION

Grade III tonsillar hypertrophy was the commonest finding (54.2%) while grade IV was noted in very few patients (2.8%).



INDICATION FOR SURGERY

In the study group the commonest indication for surgery was Adenotonsillar Hypertrophy (44.4%) and adenoidal hypertrophy (42.4%) causing upper airway obstruction.

	Placebo	Antibiotics	Total	Percentage
AH	33	28	61	42.4
TH	4	5	7	4.9
ATH	31	33	64	44.4
CRT	3	4	9	6.3
AH/CRT	1	2	3	2.1
Total	72	72	144	100

Key

- AH - Adenoid Hypertrophy
- TH - Tonsillar Hypertrophy
- ATH - Adenotonsillar Hypertrophy
- CRT - Chronic Recurrent Tonsillitis

TYPES OF SURGERY

The commonest type of surgery performed was adenotonsillectomy (46.6%), while adenoidectomy alone was done in 42.4% of the patients.

	Placebo	Amoxycillin	Total	Percentage
As	33	28	61	42.4
Ts	7	9	16	11.0
AsTs	32	35	67	46.6
Total	72	72	144	100

Key

- As - Adenoidectomy
- Ts - Tonsillectomy
- AsTs - Adenotonsillectomy

DROP OUT

During the study period 26 patients dropped out due to various reasons to give a drop out rate of 18%.

Reason	Total
Fever T $\geq 38^{\circ}\text{C}$	13
Haemorrhage	3
Brochospasms	2
Poor feeding	1
Failure to come for review on 7 th PoD	3
Disqualified	4
Total	26

Four patients were disqualified because they used brufen instead of paracetamol due to communication breakdown with the pharmacist. Thirteen patients dropped out because of fever of 38°C persisting beyond 48 hours. Only three patients dropped out due to significant intraoperative haemorrhage.

SLOUGH

Persisting beyond 7th day post-operatively

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	Placebo	Amoxicillin	Total
Diarthemy used	7	7	14
No diarthemy used	3	0	3
Total	10	7	17

Only 14.4% of the patients had persistent significant slough by seventh post-operative day. In the placebo group 70% of the patient who had slough beyond 7th day post-operatively had electrocautery done for haemostasis, while in the antibiotic group 28% had electrocautery used for haemostasis.

For $\alpha=0.05$ $df=1$ $\chi^2=8.33$ (28) ($\chi^2_{crit}=3.84$)

Hence there is no statistical significance. However the patients on whom diarthemy was used showed higher proportion (53%) of slough persisting beyond seven days post-operatively.

TEMPERATURE.

Temperature		Placebo	Antibiotics	Total
One or more episode T>37.2°C	As	6	3	9
	Ts	2	2	4
	AsTs	7	6	13
One or more episode T>38°C	As	1	2	3
	Ts	0	1	1
	AsTs	4	3	7
Total		20	17	37

24.6% of the patients on placebo developed low grade fever compared to 19.3% in the antibiotic group. It is noteworthy that 32.8% of the placebo group developed fever while only 14.4% in the antibiotic group developed fever.

$\alpha=0.05$ $df=1$ $\chi^2=0.32$. This is statistically significant and hence antibiotics are useful in minimizing fever in this study group.

TIME TAKEN TO RESUME NORMAL ACTIVITY

By 7th operative day 98% patients who had adenoidectomy alone had resumed their normal activities. Only two, one in placebo group and one from the antibiotic group had not resumed their normal activity. Patients who had undergone adenotonsillectomy took longer to resume normal activity. 13.5% had not resumed normal activity and 11.4% of these were from the placebo group. Antibiotic use significantly improved their return to normal activity. Only 21.4% of placebo group compared to 14.3% in the antibiotic group had not resumed their normal activity by the seventh post-operative day after tonsillectomy alone.

The average number of days taken to resume normal activity in the placebo group was 2.93 days while for the Antibiotic group was 2.37 days. This was significant at:

$$\alpha=0.05 \quad df=1 \quad \chi^2=3.74$$

The average number of days the patients could not play actively or participate in the normal activities was 3 and 2 days for placebo and Antibiotics respectively.

DIET (SOFT AND USUAL DIET)

The average number of days the patients took to resume normal or soft diet was 2.9 and 2.7 days for placebo and Antibiotic groups respectively.

This is not significant $Z=0.7, \alpha=0.05, P<0.9442$.

By day 4 all the patients who underwent adenoidectomy alone had resumed normal diet except one patient on the antibiotic group. Patients undergoing adenotonsillectomy took longer to resume normal diet. 16.4% patient on placebo and 15.7% on antibiotics had not resumed normal diet by the 4th post-operative day after adenotonsillectomy and tonsillectomy.

PAIN

The average number of days the patients had continuous pain or intermittent pain was 4.1 and 3.8 days for placebo and Antibiotics group respectively.

On the 7th post-operative day none of the children who underwent adenoidectomy alone showed significant pain. One patient from the antibiotic group showed significant pain.

Patients who underwent tonsillectomy and adenotonsillectomy showed persistence of pain for longer period. 52% of those who underwent adenotonsillectomy still had pain by the seventh post operative day, 63% of these were from the placebo group compared to 37% from the antibiotic group. This was significant at $\alpha=0.05$ $Z=0.911$ $P<0.9442$. The use of antibiotics after tonsillectomy and adenotonsillectomy reduced the duration of continuous or intermittent pain considerably.

ODOUR FROM MOUTH

Odour from the mouth was not a significant finding in the study. Only 7 patients (6.0%) had foul odour from the mouths by the seventh post-operative day. 4 were in the placebo group and 3 were in the antibiotic group.

The average number of days there was detectable odour was 1.9 and 1.8 days for placebo and Antibiotic group respectively. In only three patients did the parents complain of bad odour by the 7th post operative day. Two of the patients were on placebo and one was on Antibiotics. The parents of these patients had complained of bad odour from the mouth preoperatively. One child was noted to still have bad odour beyond 14th day post operatively.

TRISMUS

Trismus was a rare finding in the study. Only 4 patients (3.4%) had persistent trismus by the end of 7th post-operative day. 3 of these were in the placebo group and all of had had adenotonsillectomy done.

DISCUSSION

During the study period no patients developed severe complication to require readmission in hospital. There was no mortality during the study.

There were 26 patients who could not complete the study due to various reasons and had to be put on alternative form of treatment as necessary.

Of 13 Patients (9%) who developed high fever ($T^{\circ}\text{C} > 38^{\circ}\text{C}$), 6 were on placebo and 7 were on antibiotics. One of the patients who was on placebo had fever of 39.2°C on 3rd post-operative day but on investigation was found to have malaria parasiteamia positive but had already been started on intravenous Augmentin before the blood slide report. He had under gone Adenotonsillectomy.

Another patient had low grade fever on the seventh post operative day despite having been on Amoxicillin. This child was put on zinnat and improved by the 14th post operative day. The other patient developed fever on that operative day despite being on Amoxicillin and was put on Intravenous Crystalline Pencillin and fever cleared within 24 hours.

Three patients had severe intra-operative haemorrhage. Two were for adenoidectomy and had posterior nasal packing and hence were started on antibiotics immediately. The third patient had tonsillectomy and due to obvious excessive diathermy and prolonged intra-operative period was automatically started on antibiotics. He had also blood transfusion. He had persistent slough beyond 14 days. His coagulation profile was normal.

Two patients developed severe brocnhospasms at reversal and were started on parental antibiotics intra-operatively besides other treatment. One child who underwent adenotonsillectomy and was on placebo was found not to feed well and sickly on 7th post-operative day. He had failure to thrive (8.2 kg at 1½ years). He was started on augmentin and nutritional support and referred to the paediatrician for farther evaluation. 3 patients (1 on placebo and 2 in Antibiotic group) never turned up for review on the 7th post-operative day and hence were lost in follow up.

Four patients were disqualified because they had been given brufen instead of paracetamol because of communication break down with the pharmacist. This was where brufen was plenty in stock and needed to be cleared.

A total of 144 patients were enrolled into the study. However only 118 (82%) completed the study with a drop out rate of 18% due to various reasons. This compares well to other related studies:- e.g. Telian in 1986 in children's hospital Philadelphia were

drop out rate was 15%. The commonest presentation was snoring and nasal blockage at 88.2% and 71.5% respectively. This is because parents and guardians perceive them as more serious since they cause disturbance at night.⁽²⁶⁾ Recurrent sore throat had the longest duration of presentation at 31 months. Adenotonsillectomy was the commonest surgery done (46.6%) followed by adenoidectomy whose main indication was upper airway obstruction. Antibiotics (Amoxil) was found useful in Adenotonsillectomy and Tonsillectomy compared to placebo group. Where antibiotics are used Amoxil is adequate and more expensive drugs appear not to offer any added advantage and are not cost effective. There was no significant difference between the antibiotic and placebo group, among those who under went adenoidectomy therefore antibiotics are not necessary after adenoidectomy.

Masinde ⁽²⁹⁾ found that the commonest surgery performed was tonsillectomy but this could be due to the fact that the study included adults while in this study only children up to 12 years were included.

The presence of slough correlated with the day of surgery and most patients did not have significant slough after seven days post-operatively. However those patients on whom diathermy was used for haemostasis had slough persisting beyond seven days irrespective of the mode of treatment. Of course excessive diathermy creates more devitalized tissue which can act as a focus for infection and/or take longer to clear.

Though fever was not a big problem during the study patients on placebo showed a higher proportion of fever. Antibiotics significantly reduced incidence of fever especially after tonsillectomy and adenotonsillectomy. This compared and correlated well with previous studies. ⁽²⁵⁾

The time taken by the kids to return to normal activity was relatively shorter in this study than other related study. In the philadelphia study (1986) return to normal activity was 5.2 and 4.2 for placebo and antibiotics respectively as compared in this study which was 2.9 and 2.4 days respectively. This could be due to unsophisticated activities available to children here in Kenya as compared to the west. ⁽¹⁰⁾

The time taken by the patients to resume normal diet was 2.9 and 2.7 days for the placebo and antibiotic groups respectively. This was not statistically significant. This differed considerably from the philadelphia study especially in the antibiotic group which took only 1.3 days to resume soft or normal diet. This could be due to the differences in the diet available for the different study groups.

It was also noted though not depicted statistically that there seemed to be more complications immediately post-operatively depending on the level of the surgeons experience. This study was started at a time when surgery was done by consultants for a

week then for two months by registrars and finally by newer registrars with new theatre staff (nurses). The complications noted increased also in that order before again stabilizing to normal just before the completion of the study.

Study problems and short comings and observation

- ◆ Many parents/guardians could not ascertain confidently the number of times the child had attacks of sore throat and a diagnosis of chronic recurrent tonsillitis may not have been precise as an indication for tonsillectomy.
- ◆ Odour from the mouth was quite subjective both for the parent and the investigator. Odour tended to be more appreciated in the morning as compared to assessment later in the day.
- ◆ Pain was very difficult to assess because most of the operations were done on children most of the time relying on their refusal to feed or irritability. Almost all children would cry when their throats are examined both pre-operatively and post-operatively however presence of odalgia and odynophagia was quite accurately picked by the behaviour of the children
- ◆ There was a very little difference between soft and usual diet especially in those younger children and return to normal or soft diet may have been over estimated especially in those children who were breastfeeding and had recently been weaned hence the reason why children who underwent tonsillectomy appeared to take longer to start normal diet since they were older and their usual diet solid.
- ◆ Return to normal activity may also have been biased by nature of surgery. Adenoidectomy is done more in the younger who would almost be jovial and play about immediately post-operatively as compared to the older patient who tended to take longer to play or resume school irrespective of the operation done and mode of treatment given.
- ◆ Some patients may have over emphasized their trismus because of fear of having their throats examined making trismus more apparent as opposed to the actual situation.
- ◆ Communication breakdown between the investigator and the ward staff leading to some patients treatment being changed without consultation leading to some unwarranted drop outs. Pharmacists interference in which one week's patients operated though prescribed paracetamol were given brufen because it was more in stock and needed to be cleared.

RECOMMENDATIONS

- ◆ Antibiotics are not necessary for uncomplicated adenoidectomy alone.
- ◆ Post-operative use of antibiotics after adenotonsillectomy and tonsillectomy appears necessary especially in reducing the number of days the patients experience pain.
- ◆ Where antibiotics are indicated after adenoidectomy, Adenotonsillectomy and tonsillectomy amoxil was adequate and stronger antibiotics may not offer any additional benefit.
- ◆ Further studies are needed to compare the duration of antibiotic use needed; for single intra-operative, 3 day course, 5 day course and compare with the seven day course given in this study.

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APPENDIX I

9. PRE-OPERATIVE PROFILE

Study Code No.

➤ Name

➤ Age

➤ Sex

➤ Presenting Complains:

	Yes	No	Duration of symptoms
➤ Snoring			
➤ Cough			
➤ Sleep apnoea			
➤ Recurrent Sore Throat			
➤ Nasal Blockage			

➤ Other Medical Problems

➤ **Clinical examination:**

➤ Body weight in Kgs.

➤ General condition: Fair Sick

➤ Throat: Tonsils I II III IV Size (Grade)

▪ State Inflame Not inflamed

➤ Nose: Hypertrophy of inferior Turbinate Yes No

➤ Ears: Tympanic membrane Intact Perforated

Otorrhoea Yes No

OME Yes No

➤ Other findings

Indication for surgery

APPENDIX II

10. POST – OPERATIVE PROFILE

Study Code No.

	DAY 0		D1		D2		D3		D7	
	Present	Absent	Present	Absent	Present	Absent	Present	Absent	Present	Absent
Trismus										
Slough										
Odour from Mouth (Bad)										

ACTIVITY

	D0	D1	D2	D3	D7
Sleepy					
Dull					
Active					

PAIN

	D0	D1	D2	D3	D7
Intermittent					
continuous					
None					

ORAL INTAKE

	LIQUIDS	SOFT DIET	USUAL DIET
Day. 0			
Day. 1			
Day. 2			
Day. 3			
Day. 4			
Day. 5			
Day. 6			
Day. 7			

TEMPERATURE °c

Day	1	2	3	4	5	6	7

Mode of Treatment :

APPENDIX III

CONSENT FORM

Name

Age

Address

Relationship

I do hereby give consent for

To be included in the stud of effect of antibiotics therapy after adenotonsillectomy the nature of which has been explained to me by Dr. Mutune Henry. I understand the study is for academic and improvement of health provision purposes.

Date

Signature of guardian

Date

Signature of Doctor

KIBALI

JINA

UMRI

ANWANI

UHUSIANO

Mimi nakubali

Awemojawapo kwa utafiti wa dawa baada ya upasuaji ambao nimeshaambiwa na Dr. Mutune Henry.

Naelewa kwamba nia yake ni usomaji na kueneza mambo ya utibabu.

Tarehe

Sahihi ya mchunganji

Tarehe

Sahihi ya Daktari