

**OUTCOME OF CHRONIC SUPPURATIVE OTITIS MEDIA SURGERY IN TWO
TEACHING HOSPITALS IN KENYA.**

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This thesis is submitted to The University of Nairobi in partial fulfilment for the award of the degree of Master of Medicine in Otolaryngology – Head and Neck Surgery.

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DECLARATION

I declare that this thesis is my original work and has not been presented for the award of any degree in any Research institution or University.

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ABREVIATIONS

ABG	Air Bone Gap
AC	Air Conduction
AOM	Acute otitis Media
BC	Bone Conduction
CHL	Conductive Hearing Loss
CSOM	Chronic Suppurative Otitis Media
dB	decibel
ENT	Ear Nose and Throat
IREC	Institutional Research and ethics Committee
KNH	Kenyatta National Hospital
KNH-UoN ERC	KNH/UoN Ethics and research Committee
MTRH	Moi Teaching and referral Hospital
MUCHS	Moi University College of Health science
OED	Operation Ear Drop
PTA	pure Tone Audiometry
SPSS	Statistical package for social sciences
SNHL	Sensorineural Hearing Loss
TM	Tympanic Membrane
UoN	The University of Nairobi

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ABSTRACT

Background

Chronic suppurative otitis media (CSOM) is among the most common childhood infections. CSOM is the main cause of hearing loss among children in developing countries including Kenya. Operation Ear drop (OED) is an international charity that has been focused on improving care for Kenyan patients with CSOM by sponsoring surgeries and providing the necessary training for Otolaryngologists.

Aim

To determine the outcome of chronic suppurative otitis media surgeries in a training programme in Kenya.

Methods

Study period: September 2016 to September 2017

Study site: ENT departments of Kenyatta National Hospital (KNH) and Moi Teaching and Referral Hospital (MTRH).

Study design and procedure: This is a prospective descriptive study. Patients who underwent tympanoplasty and/or mastoidectomy for chronic suppurative otitis media sponsored by OED, and consented to being included in the study were subjected to preoperative history taking, preoperative and postoperative physical examination, video-otoscopy and pure tone audiometry (PTA) at 250, 500, 1000, 2000, 4000 and 8000 Hz. The Demographic, clinical and PTA data was then collected on a preformatted questionnaire. The outcome measures were Tympanic membrane graft take rate, dry middle ear cavity and change in Pure Tone Audiometry (PTA). Data was analysed using SPSS version 20. Descriptive statistics was used for the population socio-demographic characteristics.

Results

In 50.8% and 61.5% of the cases the tympanic membrane was intact at 3 months and 6 months postoperative period respectively. The graft take rate was not significantly affected by the period of last discharge, perforation size, age of the patient, the expertise of the surgeon or the hospital where the surgery was performed. There was progressive improvement in hearing.

Conclusion

Chronic suppurative otitis media surgery is beneficial in correcting anatomical defect in the tympanic membrane, achieving a dry non-discharging ear and reducing the effect of hearing loss.

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BACKGROUND

Introduction

Chronic suppurative otitis media (CSOM) is a common disease of the ear, especially affecting children ^(1,2). It is defined as chronic infection of the middle ear and mastoid cavity presenting as a persistent discharge through a perforation in the tympanic membrane (TM) ⁽³⁾. It commonly occurs as a sequel of persistent acute otitis media (AOM) in childhood ⁽⁴⁾, but the point at which AOM changes to CSOM is controversial with different authors giving different period of time, ranging from two weeks to more than three months ^(3,5,6,7). CSOM usually affects children but may persist in adulthood. Chronic persistent (non-infected) fluid in the middle ear in the absence of discharge through a perforation in the tympanic membrane is termed as chronic otitis media with effusion.

The development of CSOM is associated with poor socioeconomic conditions, overcrowded environments, exposure to smoke, poor hygiene, family history as well as a history of previous tympanostomy tube insertion ^(8,9,10).

About 65 to 330 million individuals suffer from CSOM, 60% (39-200 million) of whom have clinically significant hearing impairment. Over 90% of the burden is borne by disadvantaged populations in the developing world ⁽¹¹⁾.

CSOM is the main cause of disabling hearing loss among children of the sub-Saharan Africa. A Kenyan study put the prevalence of hearing loss among children with CSOM at 64% versus only 3.4% in those without CSOM ⁽¹²⁾. CSOM prevalence in Kenya is 1.1% ⁽¹²⁾. The main interventions in the management of CSOM are either medical or surgical.

The most common isolated microorganisms in CSOM are *Pseudomonas aeruginosa* and *Staphylococcus aureus* ^(13,14,15,16,17,18,19). Aduda et al found in a study in Kenya that *Proteus spp.*, *Enterococcus*, *Staphylococcus aureus* and *Pseudomonas spp* were the most common isolates ⁽²⁰⁾.

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Effect of CSOM on Hearing

CSOM can cause not only conductive hearing loss (CHL) ⁽²¹⁾ but also sensorineural hearing loss (SNHL). ^(11, 22)

CHL results from the disruption of the mechanism of sound transmission from the outer ear to the inner ear. The perforation of the tympanic membrane leads to several effects. It reduces the surface area of the tympanic membrane, hence reduction in the ratio of surface areas of TM to stapes footplate and thus reduction in amplification of sound. It also causes loss of the protection of the round window leading to sound pressure being applied simultaneously to both the round and oval window resulting in an increase in impedance. This leads to the loss of the TM's normal effect that is meant to overcome inner ear impedance. It also causes disruption of ossicular chain ^(23, 21). A study done in Kenya showed relationship between the size and site of TM perforation and severity of CHL. It showed the larger the perforation the more severe the hearing loss ⁽²⁴⁾.

SNHL results either from damage to the cochlear or the neural pathway from the cochlear to the brain. In the case of CSOM, it is due to damage to the cochlear. Inflammatory mediators produced in response to chronic middle ear infection can penetrate through the round window and pass into the inner ear causing cochlear damage ⁽²⁵⁾. Studies have shown loss of outer and inner hair cells as well as atrophy of stria vascularies in patients with CSOM ⁽²⁶⁾. Also bacterial toxins can pass into the cochlear and cause damage directly or indirectly through production of inflammatory mediators ⁽²⁷⁾.

Other complications include mastoiditis and mastoid abscess, erosion of the middle ear and mastoid cavity walls leading to exposure of the facial nerve, the lateral sinus, the jugular vein, and the dura of the middle cranial fossa leading to facial nerve palsy, lateral sinus thrombophlebitis and intracranial abscesses.

Diagnosis and Treatment of CSOM

The diagnosis of CSOM is made clinically from symptoms of chronic discharging ear, combined with the finding of tympanic membrane perforation confirmed on examination of the tympanic membrane through an otoscopy, video-otoscopy, otomicroscopy, or using headlights and otologic speculums ⁽¹⁹⁾. Hearing assessment is done via tuning fork tests and pure tone audiometry (PTA).

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Treatment of CSOM includes medical treatment until a dry ear is achieved and surgery to repair tympanic membrane perforations. Topical antibiotics, steroids and dry mopping, was found to be more effective than dry mopping alone in a study carried out in Kenya ⁽²⁸⁾. Topical quinolones was proven to be more effective than topical antiseptic in another study⁽²⁹⁾. Surgery includes tympanoplasty with or without mastoidectomy.

Tympanoplasty is defined as the repair of tympanic membrane perforation with or without ossicular chain reconstruction ⁽³⁾. It is classified into five types. Type one consists of grafting of the TM in place i.e. on to the handle of malleus (includes patch repair). Type 2 is where the graft is placed on to the incus. In type 3 the graft is placed either directly or indirectly (via the use of ossicular reconstruction prosthesis) on to the head of the stapes. Type 4 is where the graft is placed in such a way to isolate the round window niche to reduce maximum hearing loss, while in type 5 the graft is placed on to a fenestration made on the lateral semi circular canal. The grafting technique can be: underlay; overlay or interlay. Several graft materials have been used since the first description of tympanoplasty. Temporalis fascia graft is the most commonly used graft in our setting ⁽³⁰⁾.

Mastoidectomy involves the removal of mastoid air cells after the exposure of mastoid bone cortex via a post-auricular incision. The removal of mastoid air cells is achieved by the use of electric or pneumatic drills, or in the older days gauge and hammer. It is classified into simple, canal wall up, canal wall down, modified radical, radical mastoidectomy, mastoid obliteration depending on the extent of the procedure ⁽³¹⁾.

Challenges in treatment of CSOM

Timely and effective treatment of CSOM will reduce the sequelae of hearing loss, and intratemporal and intracranial complications. In most of sub-Saharan Africa, this is unfortunately not readily achievable because there is lack of adequate staff trained in the field of ear nose and throat (ENT) capable of adequately managing CSOM as well as lack of functional surgical equipment. Also socioeconomic factors prevent the vast majority of the patients involved from accessing the care available in the few facilities that offer ENT services in the region.

A survey in Africa found that provision of ENT service is limited due to shortage of personnel and lack of instruments. It also found that there is poor access to audiology, hearing aids and hearing restoration surgeries ⁽³²⁾.

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In Kenya, only the University of Nairobi (UoN) offers Master of Medicine in Otorhinolaryngology Head and Neck surgery training with an average annual output of about 5 Otorhinolaryngologists. There are about 70 Otorhinolaryngologists to serve a population of about 40 million people ^(33, 34).

Chronic suppurative otitis media surgery in Kenya and Operation Ear Drop

Most of the ear surgeries in Kenya are done either at the Kenyatta National Hospital (KNH) or Moi Teaching and Referral Hospital (MTRH). Some of these surgeries are done under the auspices of Operation ear drop (OED), an international charity based in the Netherlands that has been operating in Kenya for the last 30 years. OED not only facilitates the ear surgeries through payment of the necessary fees but also has an inbuilt training in micro-ear surgeries for Postgraduate Otolaryngology students. During the surgical missions postgraduate Otorhinolaryngology students of UoN participate in the surgeries under supervision of qualified Otorhinolaryngologists to gain necessary otologic training. OED also offers a basic and an advanced temporal bone course to postgraduate otorhinolaryngology students of UoN and qualified Otorhinolaryngologists. OED organizes surgical missions twice yearly to both KNH and MTRH. At KNH alone 261 patients underwent surgery of 314 ears between April 2011 to November 2014, with tympanoplasty, mastoidectomy and myringotomy with grommet insertion being the most common surgeries comprising of 208, 47 and 42 surgeries respectively, and chronic otitis media, especially chronic suppurative otitis media the most common diagnosis.

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LITERATURE REVIEW

Two retrospective studies in two teaching Hospitals in Nigeria reviewed data of 68 and 96 ear surgeries, for 5 and 15 years respectively and found that CSOM and mastoiditis are the most common indications for surgery. One of the two studies found that tympanoplasty was the most common surgery performed while the other showed mastoidectomy was the most common. Both found that the bulk of the surgeries were performed by consultants, while postgraduate students did about 5% of the surgeries. One of them had success rate of about 60%, while the other had a failure rate of 60%. They both found that persistent discharging cavity was the most common complication ^(35,36).

A prospective 5 year study by Preben Homøe et al on mobile ear surgery in Greenland found that type 1 tympanoplasty is the most common surgery, and there was greater than 10dB hearing gain in 62% and 56% of patients at one year and two years follow up respectively, while there was deterioration of hearing in 18% and 19% at first and second year after surgery respectively ⁽³⁷⁾. The limitation of this study was that PTA was not conducted in a quiet room and only air conduction was tested. So ABG was not calculated.

Kent D T et al found that perforation size was associated with the graft success rate and no significant difference in the effect of age and repair technique i.e. underlay or overlay. There was improvement in air conduction between 250 to 2000Hz. There was also an improvement in speech reception threshold. The surgeries were done by several attending surgeons assisted by otolaryngology residents. However, they excluded patients with cholesteatoma and ossicular chain discontinuity in their study. They also excluded patients who had surgical failure from postoperative analysis of frequency specific hearing levels ⁽³⁸⁾.

Boronat-Echeverria N E et al found the age of onset of symptoms, the state of contralateral ear, prior adenoidectomy, the cause of perforation, state of mucosa, size of perforation and absence of craniofacial dysmorphism as prognostic factors of tympanoplasty success. They also reported a surgical closure rate of 90% ⁽³⁹⁾.

Sudhakar Vaidya et al in a study on tympanoplasty in a teaching Hospital found a relationship between the size of tympanic membrane perforation and tympanoplasty surgical outcome. They also reported a relationship between postoperative hearing outcome and state of ossicles.

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Temporalis fascia/cartilage graft was used in all the patients. The patients underwent tympanoplasty with/without mastoidectomy. However, the authors did not analyse the outcome in relation to the type of graft used, and whether mastoidectomy was done or not. ⁽⁴⁰⁾.

A study on outcome of tympanoplasty in a teaching hospital in Ethiopia, found that 24 out of 44 surgeries resulted in intact tympanic membrane healing while 12 resulted in reduced tympanic membrane perforation at six months post-operative follow up period with a mean gain of 14 dB hearing level. It also showed that surgeon's training and years of experience did not have a significant impact on the outcome of surgery. In this study all the operations were sponsored by charitable organizations ⁽⁴¹⁾. In a study in Kenya, 42 patients who underwent type 1 tympanoplasty at Kenyatta National Hospital were followed prospectively for 3 months. It found a 76.9% overall graft take rate with 94.4% and 61.9% take rate for surgery done by qualified otolaryngologist and otolaryngology residents respectively. There was audiometric gain of greater than 10dB in 66.6% of the patients, while 5.4% had worsening of hearing ⁽⁴²⁾. In this study, patients who had history of previous tympanoplasty, those who had hearing loss of greater than 50dB with possible ossicular chain disruption, those with cholesteatoma, and those in whom grafts other than temporalis fascia was used were excluded. Patients who had mastoidectomies were also excluded from the study.

Olfa Ben Gamra et al in a study on myringoplasty in Egypt found that there was 92.8% overall perforation closure rate and 65% overall hearing improvement while 35% of patients had worsened hearing. They also found: age older than 12 years, absence of allergic rhinitis, dry middle ear, preoperative conductive hearing loss and placement of the graft under the malleus handle, as significant factors influencing the surgical outcome. Also patients with previous history of adenoidectomy/tonsillectomy had better outcomes. However, this was not significant ⁽⁴³⁾. In this study all the patients were aged between the ages of 6 to 16 years.

Sharankumamar Shetty in a study of preoperative and postoperative hearing assessment following tympanoplasty found that type 1 tympanoplasty was the most common type of tympanoplasty performed and there was 94% graft success while 92% had normal hearing postoperatively with a mean post-operative hearing gain of 22.09 dB in all patients. All the patients underwent tympanoplasty with the use of temporalis fascia/tragal cartilage graft. However, the effect of the type of graft was not analysed in this study. All postoperative

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audiograms were done at 12 and 24 weeks after surgery ⁽⁴⁴⁾.

A one year retrospective review of all patients who underwent tympanoplasty with or without mastoidectomy at a hospital in India found complete graft take of 98.6%. Fascia lata, temporalis fascia and tragal perichondrium grafts were compared, and no significant difference was found in outcome between all the types of graft used. They also found improvement in hearing ⁽⁴⁵⁾.

Mwaringa E. C. in a retrospective study of medical records of all patients who underwent myringoplasty at Kenyatta National Hospital in Kenya found that out of a total of 188 myringoplasties done between January 1986 and December 1990, there was 56.08% graft take. He also found that there was an overall improvement in hearing ⁽³⁰⁾.

Adva B. Friedman et al did a retrospective review of all patients who were younger than 13 years who underwent type 1 tympanoplasty. They exclude all patients who had previous cartilage tympanoplasty, those who had cholesteatoma and those who underwent concomitant ossicular chain reconstruction. Conchal or tragal cartilages were used. They found that the graft take was more than 90%, and the average ABG improvement was 12.21dB ⁽⁴⁶⁾.

Maciej Wiatr et al found that the hearing outcome in patients following tympanoplasty was determined by the state of the middle ear mucosa as well as ossicular chain continuity. ABG improved in patients with no findings of granulation tissue in the middle ear at 6 months follow up period after tympanoplasty. They also found no significant difference between ABG done at 6 and 12 months after surgery. ⁽⁴⁷⁾.

Asma binti Abdullah et al in study on outcome of canal wall down mastoidectomy, found 78% healing (dry ear) with 3% recurrence, and ABG improvement in 25% of the patients ⁽⁴⁸⁾.

Gundula Thiel et al followed up patients post modified radical mastoidectomy retrospectively and found a healing rate of 36%, 42%, 53% and 62% respectively at 6 months, 1 year, 18 months and 2 years follow up ⁽⁴⁹⁾.

Melek Uyar et al in a retrospective study of patients who underwent tympanomastoidectomy compared the outcome of canal wall down mastoidectomy and canal wall up mastoidectomy. They also studied the effect of ossicular reconstruction material on outcome. They found that there is postoperative hearing gain in both canal wall up and canal wall down mastoidectomy

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with no significant difference between the two ⁽⁵⁰⁾.

Mahadevaiah A et al retrospectively reviewed patients who underwent tympanoplasty with canal wall up mastoidectomy for cholesteatoma. They found significant improvement in postoperative air conduction and ABG in both short term and long term follow up periods ⁽⁵¹⁾.

A retrospective study to compare the outcome of tympanoplasty with and without mastoidectomy, found that mastoidectomy does not affect tympanoplasty graft take rate but does reduce the number of subsequent ipsilateral otologic surgery. In this study, patients who had abnormal middle ear mucosa, those with granulation tissue in the middle ear, those who had ossicular abnormalities, those who underwent previous tympanoplasty and those who had cholesteatoma were excluded ⁽⁵²⁾.

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STUDY JUSTIFICATION

OED has been sponsoring chronic suppurative otitis media surgeries in Kenyan Hospitals for more than 30 years. Most of these surgeries are done either by qualified Otorhinolaryngologist assisted by Otorhinolaryngology postgraduate students of UoN, or the latter under the supervision of the former. The outcome of ear surgeries done under the OED programme has not been prospectively studied previously. This study will serve to establish the surgical and hearing outcomes of these surgeries and in so doing help improve otological training at the University of Nairobi.

STUDY QUESTION

What is the surgical and hearing outcome of tympanoplasty and mastoidectomy for chronic suppurative otitis media at two teaching Hospitals in Kenya?

OBJECTIVES OF THE STUDY

General Objective

To determine the surgical and hearing outcomes of tympanoplasty and mastoidectomy for chronic suppurative otitis media performed at two teaching Hospitals in Kenya under the auspices of OED.

Specific Objectives

To determine tympanic membrane graft take rate as measured by the percentage of intact tympanic membrane graft at 3 and 6 months postoperative visits.

To determine the rate of eradication of disease from the middle ear measured by the proportion of dry non-discharging middle ear cavity at 3 and 6 months postoperatively.

To determine hearing outcomes as measured by comparing the average preoperative and postoperative (3 and 6 months) PTA.

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria.

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All patients who underwent tympanoplasty or mastoidectomy for chronic suppurative otitis media at the two hospitals under the auspices of OED during the period of study, and who consented to participate were included.

Exclusion Criteria.

Patients who did not consent to participate in the study.

Patients who underwent surgery not sponsored by OED.

STUDY METHODS

Study duration

November 2016 to November 2017

Study site and population

The cases were patients who underwent tympanoplasty or mastoidectomy for chronic suppurative otitis media sponsored by Operation Ear Drop at Kenyatta National Hospital, Nairobi, and Moi Teaching and Referral Hospital, Eldoret. All patients who underwent these surgeries during the period of study, and consented to participate in the study were included. Patients who declined to participate in the study were excluded. The patients were aged between 8 to 18 years as per the OED protocol

Study design

This was a prospective descriptive study

Sampling and sample size

Consecutive sampling method was used. The participants were selected during the OED operation weeks at the two Hospitals during the period of the study. There were a total of three OED surgery weeks, two at KNH and one at MTRH. All the patients operated on during the period of study and consented to participate were included in the study. Since the study was not comparing the outcomes of surgeries done at the two Hospitals, there was no particular ratio considered on the distribution of the patients between the two Hospitals.

The sample size was determined considering a conservative success rate level of 50% with a precision of 10%. The use of 10% precision was considered because of the large variation in the

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success rate reported in literature (30,35,36, 39, 41, 42, 43, 44). The total sample size of 96 patients was arrived at using the formula below⁽⁵³⁾.

where: n is the sample size, p is the success rate considered as 50%, d is precision of 10% and 1.96 is normal value corresponding to 5% significance level.

However, a total of 64 patients underwent 68 ear surgeries for chronic suppurative otitis media during the study period and all were included in the study. Three patients were lost to follow up. The sample of 96 patients was not met because the number of operation weeks decreased from the usual two per year at both hospital to a total of three weeks. This is because the OED discontinued its' MTRH project. Also the number of patients per project week decreased due to uncertainties caused by the doctors and nurses' strikes as well as the effect of elections during the study period.

Study procedures

The study was explained to all patients who met the inclusion criteria, and /or their guardians in a language they understood and written consent/assent obtained. Where the patient or guardian did not know how to read or write, the consent/assent was signed in the presence of a literate witness. In such cases the patient or guardian gave consent/assent by way of fingerprint and the witness signed a written witness form. The principal researcher then took participants bio-data and a comprehensive history including presenting symptoms, duration of symptoms, status of the contralateral ear, history of previous adenotonsillectomy and presence of craniofacial dysmorphism. The principal researcher carried out a complete Ear, Nose and Throat (ENT) examination, otoscopy and video-otoscopy of both ears, and tuning fork examination one week prior to surgery.

Pure tone auditory (PTA) test was carried out by a qualified audiologist using supra-aural earphones in a sound proof booth at the following frequencies: 250, 500, 1000, 2000, 4000, 6000 & 8000HZ during the week prior to surgery. Bone conduction (BC) and air conduction (AC) averages of frequencies 500, 1000 and 2000Hz were in calculated decibel (dB). Pure tone air-bone gap (ABG) was then calculated from the above values.

Routine preoperative preparation was done including: blood tests e.g. full haemogram, and urea, electrolytes and creatinine, signing of informed consent/assent for surgery and were subject to

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pre-anaesthesia review by the anaesthetist on the day before surgery. All the surgeries were performed by qualified Otorhinolaryngologist assisted by postgraduate otorhinolaryngology students of UoN, or the latter group under the supervision of the former.

After the surgery the patients were subject to the standard OED postoperative protocol, which includes postoperative per oral antibiotics, analgesics and antiemetics, removal of mastoid dressing at first postoperative day and patient discharged home on first postoperative day. Patients were advised to avoid valsava manoeuvre for six weeks, to keep the ear dry and to visit ENT clinics at the two hospitals in case of any discharge from the ear.

Patients were seen 7 days after surgery, and aural packs and sutures removed as necessary and otoscopy performed. Patients were then seen at 3 months and 6 months postoperatively by the principal investigator who did otoscopy, video-otoscopy, tuning fork tests and pure tone audiometry at both visits. AC, BC and ABG were calculated as above at both visits for each patient. Patients were reminded to attend the clinic by text messages two weeks prior to the date of visit.

All patients were advised to visit ENT clinics at the two hospitals in case of discharge from the ear during the periods between the scheduled visits, and those who developed discharge from the ear were treated as per treatment protocols for discharging ears.

Outcome measures

The surgical outcome was either an intact tympanic membrane graft as at 3 and 6 months postoperatively (in case of tympanoplasty) or achievement of a dry non-discharging ear (in case of mastoidectomy and/or tympanoplasty), or failure to attain the above, as well as postoperative complications. The hearing outcome was the change in hearing after the operation measured by comparing the average preoperative and postoperative (3 and 6 months) PTA values.

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Quality control

To protect the consistency of the data, all the preoperative and postoperative history taking, physical examination, otoscopy, video-otoscopy and tuning fork tests was done by the principal investigator, while all the pure tone audiometry was done by a qualified audiologist.

Data management

Data was collected on questionnaires and entered into Microsoft Excel worksheets which was then be transferred to the statistical package for social sciences (SPSS) version 20 for analysis. All data was cleaned (including checks for completeness and consistency) before commencing analysis. All questionnaires and informed consent forms was stored securely in a lockable drawer. Soft copy versions of the data was stored in a password-protected computer. The data was accessible only to the principal investigator

Data analysis

Data was analysed using SPSS version 20. Descriptive statistics was used for the population socio-demographic characteristics, surgical outcome and audiological outcomes.

ETHICAL CONSIDERATIONS

The study was carried out after approval by the KNH/UON ethics and research committee (KNH/UoN-ERC), and the Institutional research and ethics committee (IREC, constituted jointly by MUCHS and MTRH). Participation in the study was voluntary. No extra cost was incurred by the study participants. Information obtained will be kept confidential. Results of the study will be published and made available to members of the medical fraternity.

CONFLICT OF INTEREST

The authors of this study declare no conflict of interest.

STUDY LIMITATIONS

The sample of 96 patients was not met because the number of operation weeks decreased form the usual two per year at both hospital to a total of three weeks. This is because the OED discontinued its' MTRH project. Despite the failure to recruit the number of patients calculate by

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the sample size formula, the numbers recruited were adequate to give an indication of the outcome of chronic suppurative otitis media surgery at the two teaching hospitals under the auspices of OED during period of study (one year).

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RESULTS

A total of 64 patients underwent 68 ear surgeries for chronic suppurative otitis media sponsored by operation ear drop at the two teaching hospitals during the period of study. Two patients who underwent 3 ear surgeries for CSOM were excluded from the analysis of result because they were lost to follow up. Another patient (operated on the left ear alone) was excluded from the hearing analysis because he had preoperative hearing assessment by use of auditory brain stem response. This patient did not have a PTA done because he was not co-operative enough to do undergo the test. Therefore a total of 62 patients who underwent 65 ear surgeries had their post operative graft take or healing analysed. There were 32 (51.6%) male and 30 (48.4%) female patients.

Patients were aged between 8 and 18 years. The majority were aged 12 years or older. The ratio of those younger than 12 years and those aged 12 years and older is 1:2.1. The mean age was 13.7 years, while the median age was 14 years.

A total of 33 patients had surgery on the left ear alone, 26 on the right ear alone while 3 had surgery on both ears. Left ear surgeries comprised of 55.4% and right was 44.6%. The three patients who underwent bilateral ear surgery had bilateral CSOM with cholesteatoma. Only one patient had adenoidectomy previously, while none of the patients had craniofacial dysmorphism. All the ears operated on had normal appearing pinna. Granulation tissue and aural polyp were preoperatively found in the external ear canal in one case each.

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Table 1: Various factors by pre-operative perforation size

VARIABLE		PRE-OPERATIVE PERFORATION SIZE		P VALUE
		≤ 50%	> 50%	
Age (years)	< 12 years	15.0%	85.0%	0.351
	≥12 years	28.9%	71.1%	
Duration of dry ear (Months)	≤3	25.8%	74.2%	1.000
	>3	23.5%	76.5%	
State of contralateral ear	NORMAL	12.2%	87.8%	0.006
	CSOM	45.8%	54.2%	
Sequence of surgery	Primary	19.2%	80.8%	0.069
	Revision	46.2%	53.8%	

A total of 75.4% of the cases had a perforation size of larger than 50% of the tympanic membrane, while only 24.6% had a perforation size of 50% or smaller prior to surgery. The age of the patient, state of contralateral ear and prior surgery affected the preoperative perforation size. However, it is only the effect of the state of contralateral ear that was significant. The anteroinferior quadrant is the most commonly affected part of the tympanic membrane by the perforation both at preoperative and post operative follow up.

Table 2: Graft take rate

Graft take	3 months	6 months
Taken	33 (50.8 %)	40 (61.5 %)
Not Taken	32 (49.2 %)	25 (38.5 %)
Total	65 (100.0 %)	65 (100.0 %)

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Table 3: Effects of various factors on graft take rate

VARIABLE		GRAFT TAKE RATE (%)		P VALUE	
		3 MONTHS	6 MONTHS	3 MONTHS	6 MONTHS
Pre-operative perforation size	≤ 50%	68.8%	75.0%	0.150	0.248
	> 50%	44.9%	57.1%		
Age (years)	< 12 years	45.0%	60.0%	0.598	1.000
	≥12 years	53.3%	62.2%		
Duration of dry ear (Months)	≤3	38.7%	54.8%	0.084	0.318
	>3	61.8%	67.6%		
State of contralateral ear	NORMAL	66.7%	70.8%	0.072	0.296
	CSOM	41.5%	56.1%		
Sequence of surgery	Primary	46.2%	55.8%	0.215	0.065
	Revision	69.2%	84.6%		
Type of surgery	Tympanoplasty	50.0%	62.5%	1.000	0.724
	Tympanomastoidectomy	55.6%	55.6%		
Experience of surgeon	Consultant	47.6%	61.9%	0.794	1.000
	Registrar	52.3%	61.4%		

Legend: consultant; qualified Otorhinolaryngologist , Registrar; postgraduate otorhinolaryngology students of UoN

At 3 months post operative follow up, 50.8% of the patients seen had an intact tympanic membrane graft, while at 6 months follow up the percentage of intact grafts was 61.5%. The smaller the size of the perforation prior to surgery the more likely for the graft to take. Except for

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one case where perforation size increased in size between 3 and 6 months, all the patients had a progressive reduction in the perforation size.

When the graft take rates in patients aged younger than 12 years and those 12 years and older was compared, the older group had a better graft take rate both at 3 months and 6 months post operative follow up. This difference was not statistically significant.

The operated ears have been dry for a period longer than 3 months prior to surgery in 52.31% of the cases, while 47.69% were dry for 3 months or shorter. Those ears that were dry for longer than 3 months prior to surgery had better graft take rate. However, there was no statistically significant relation between graft take rate and the duration of dry ear.

The contralateral ear had chronic suppurative otitis media in 41 (63.07%) of the cases. Patients who had normal contralateral ear had better graft take rate when compared to those with CSOM of the contralateral ear. However, this was not statistically significant.

The operated ears had prior surgery for chronic suppurative otitis in media in 13 (20%) of cases, while 52 (80%) underwent primary surgery. The ears that underwent revision surgery were more likely to have intact tympanic membrane both at 3 and 6 months postoperative follow up. This finding is not statistically significant.

Majority of the ears 56 (86.2%) underwent tympanoplasty alone, while 9 (13.8%) underwent concurrent tympanoplasty and mastoidectomy (tympanomastoidectomy). Type one tympanoplasty was the most common sub-type of surgery performed during the period of study. There was no significant difference in graft take rate between tympanoplasty and tympanomastoidectomy.

The postgraduate otorhinolaryngology students of UoN performed the majority of the surgeries 44 (67.7%). The surgeries performed at the Kenyatta National hospital and at Moi teaching and Referral Hospital comprised 76.9% and 23.1% respectively. There was no statistically significant difference in graft take rate between surgeries performed by qualified Otorhinolaryngologist and those performed by postgraduate otorhinolaryngology students of UoN and between those performed at the two hospitals.

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Table 4: Choice of surgery by Surgeon's level of experience

VARIABLE		SURGEON	
		Consultant	Registrar
Sequence of surgery	Primary	26.9%	73.1%
	Revision	53.8%	46.2%
Pre-operative perforation size	≤ 50%	31.2%	68.8%
	> 50%	32.7%	67.3%
Type of surgery	Tympanoplasty	25.0%	75.0%
	Tympanomastoidectomy	77.8%	22.2%

Legend: consultant; qualified Otorhinolaryngologist , Registrar; postgraduate otorhinolaryngology students of UoN

The qualified Otorhinolaryngologist are more likely to perform revision surgeries and more complex surgeries (tympanomastoidectomy).

In the group who had mastoidectomy, 5 (55.6%) had intact graft at 6 months post-operative follow up, while 3(33.3%) had tympanic membrane perforation with non-discharging ear and only 1(11.1%) had persistent discharging ear with cholesteatoma.

Table 5: Pure tone air conduction

dB	Pre-operative		3 months		6 months	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
≤ 25	6	9.4%	28	43.8%	33	51.6%
26 to 40	13	20.3%	11	17.2%	14	21.9%
41 to 60	33	51.6%	18	28.1%	11	17.2%
61 to 80	9	14.1%	6	9.4%	6	9.4%
> 80	3	4.7%	1	1.6%	0	0.0%
Mean (dB)	47.9		35.5		30.8	

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Table 6: Pure tone bone conduction

dB	Pre-operative		3 months		6 months	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
≤ 25	49	76.6%	56	87.5%	61	95.3%
26 to 40	11	17.2%	4	6.3%	1	1.6%
41 to 60	3	4.7%	4	6.3%	2	3.1%
61 to 80	1	1.6%	0	0.0%	0	0.0%
Mean (dB)	13.7		9.4		7.9	

Table 7: Pure tone air-bone gap

dB	Pre-operative		3 months		6 months	
	Frequency	Percentage	Frequency	Percentage	Frequency	Percentage
≤ 15	3	4.7%	24	37.5%	32	50.0%
> 15	61	95.3%	40	62.5%	32	50.0%
Mean (dB)	34.2		25.6		22.8	

Only about 29.7% had normal hearing or mild hearing loss (9.4% and 20.3%) prior to surgery. This improved to 60.9% (43.8% and 17.2%) at 3 months, and 73.4% (51.6% and 21.9%) at 6 months. There was progressive improvement in the mean air conduction, mean bone conduction and mean air bone gap averages.

A patient who underwent type 1 tympanoplasty developed ipsilateral facial nerve palsy (House-Brackmann grade 4). The patients had progressive improvement in the facial nerve function, and had a normal facial nerve function by 6 months postoperative follow up.

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DISCUSION

During the period of study 64 patients underwent 68 ear surgeries under the OED program. The calculated sample size of 96 patients was not met because the number of operation weeks decreased from the usual two per year at both hospital (adding up to four weeks) to a total of three weeks. This is because the OED outreach to MTRH was discontinued. This is not the total number of ear surgeries for chronic suppurative otitis media at the two hospitals since surgeries not sponsored by OED were excluded. This represents a relatively higher rate of these surgeries as compared to other studies in this region ^(35,36). It also shows an increase in the rate of these surgeries in Kenyan Hospital ^(30,42).

There was a 50.8% and 61.5% graft take rate at 3 and 6 months post operative follow up respectively. This is comparable to the short term outcome of a similar surgical mission in this region^{30,41}. However, it is lower than a report of by Mburu P N at Kenyatta national hospital⁴². This is probably because in his study patient selection was different in terms of age, type of surgery and complexity of surgery and severity of disease. It was better than reports from two Nigerian studies, but worse than a report from Egypt ^(35,36,43). These studies are not similar in terms of design and follow up period. There was better surgical outcome at 6 months when compared to 3 months in terms of the percentage of graft take. There was also progressive reduction in perforation size in those with persistent perforation. This indicates that the tympanic membrane continues to grow to cover the remaining perforation. The smaller the size of the perforation, the better the surgical outcome. This is similar to outcome of other studies^(38,39,40). The smaller perforations have better surgical outcomes probably due to the fact that the refreshed edges of the tympanic membrane has a shorter distance to cover over the scaffolding provided by the graft and hence better outcomes.

When grouped into ages younger than 12 years and those 12 years and older, the older group had a higher percentage of graft take rate both at 3 and 6 months post operative follow up. This is comparable with other studies^(38,39,43,51). This however, may be biased since the younger group had a relatively higher percentage with larger perforations prior to surgery. Also the difference between the two is not statistically significant.

The longer the duration of dry ear the better the graft take rate. This is comparable to another study³⁹. This was not statistically significant. The exact duration of dry ear and the type of ear

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discharge could not be objectively determined since this was patient self reported. The state of the middle ear at the time of surgery was not studied making it difficult to explain the exact reason for the pattern of surgical outcome in relations to the duration of last discharge.

The state of the contralateral ear appears to influence the surgical outcome, with those who have normal contralateral ear having better outcomes. This is similar to the findings of Boronat-Echeverria N E et al⁽³⁹⁾. This difference may be due to relatively smaller preoperative perforations size in the group with normal contralateral ear. This may also be due to an underlying eustachian tube dysfunction in those with in those with bilateral disease. Ears that had prior surgery for CSOM had better surgical outcomes. These ears also had smaller perforations size prior to surgery when compared to those that underwent primary surgery.

Type one tympanoplasty with or without mastoidectomy was the most common surgery. Postgraduate otorhinolaryngology students of UoN performed the majority of the surgeries. This finding differs from two studies done in Nigeria^(35,36) while being similar to a study in Ethiopia⁽⁴¹⁾. There was no significant difference in graft take rate between surgeries performed by qualified Otorhinolaryngologist and those performed by postgraduate otorhinolaryngology students of UoN. This differs from study by Mburu P N, where he found better outcomes where surgeries were done by qualified Otorhinolaryngologist⁽⁴²⁾. The finding is due to the fact that qualified Otorhinolaryngologist were more likely to do revision surgeries as well as more complex surgeries.

There was progressive improvement in the air conduction, bone conduction and air bone gap averages. This finding is consistent with other studies. The improvement in hearing is probably due to the protection of the round window by the graft. This applies in all cases with complete graft take as well as those with partial graft take. The improvement in bone conduction may be due to a similar phenomena to the reversibility of the 2 kHz bone conduction loss in otosclerosis after stapedectomy.

Mastoidectomy was effective in achieving a dry non-discharging ear in about 88.9% of the cases. This is better than reports by other authors^(35,36,48,49). Mastoidectomy did not significantly affect the graft take rate, which is similar to the findings of another study⁽⁵²⁾.

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CONCLUSION

Chronic suppurative otitis media surgery is beneficial not only in correcting the anatomical defect in the tympanic membrane, but also in achieving dry non-discharging ears as well as improve hearing threshold thereby reducing the burden of hearing loss. The size of the perforation, the state of contralateral ear and prior surgery seem to have a positive effect on the surgical outcome. However, this is not statistically significant. There is progressive improvement in both surgical and hearing outcomes postoperatively, with possible better outcomes at longer duration of follow up.

RECOMENDATIONS

We recommend that these patients be followed up at one year and two years postoperative period to further study the hearing and surgical outcomes and determine whether or not there will be change in the outcomes. It is recommended that surgeons should not rush to operate on an ear at 3 months postoperative period if the graft did not take, but should at least wait for 6 months postoperative period before operating on such an ear.

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APPENDIX

CONSENT EXPLANATION AND FORM

1. Consent explanation

Title

Outcome of chronic suppurative otitis media surgery in two Teaching Hospitals in Kenya

Introduction

My name is Dr. Abdifatah Ibrahim Sheikh, a postgraduate student at the section of ENT, School of Medicine, The University of Nairobi. I am carrying out a study to determine the outcome of chronic suppurative otitis media surgeries done in Kenyatta National Hospital (KNH) and Moi Teaching and Referral Hospital (MTRH) under the auspice of Operation Ear Drop (OED). This will be determined by data collection through filling a questionnaire, patient examination and hearing tests before and after ear operation. The findings may form a useful baseline to assess and improve care of patients undergoing these surgeries. I am inviting you to participate in my study at your free will. You will be given the opportunity to ask questions before you decide and you may talk to anyone you are comfortable with about the research before making a decision. You may seek further clarification from myself if there are words or details that you do not understand.

If you agree to participate, you will be asked to provide personal information and other details related to you/your child's condition. You/your child will then undergo ear examination and hearing tests before and at specific durations after the operation. All the information that you provide will be kept confidential and no one but the researchers will see it.

Your name will not appear in any document. The information about you will be identified by a number and only the researchers can relate the number to you as a person. Your information will not be shared with anyone else unless authorized by the Kenyatta National Hospital/University of Nairobi - Ethics and Research Committee (KNH/UoN-ERC) and the institutional research and ethics committee (IREC).

All the information that you give us will be used for this research only.

This proposal has been reviewed and approved by the KNH/UoN-ERC and IREC, for the duration of one and half year. It was submitted to them through the Chairmen of the Departments of Surgery at the Schools of Medicine of the University of Nairobi and Moi University with the approval of the three university supervisors.

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Objectives of this study.

To determine the surgical and hearing outcomes of tympanoplasty and mastoidectomy for chronic suppurative otitis media, done at KNH and MTRH under the auspices of OED.

What benefits will I get if I participate?

You/your child may not get any immediate direct benefit by participating in this study. The results may be form a basis to improving care for patients undergoing these surgeries. It also may form the basis of improving postgraduate training programmes in The University of Nairobi.

What are the risks or cost involved?

You/Your child's involvement in this research will be through an interview and clinical evaluation and will not be exposed to any risks (other than those related to surgery which will be explained in the consent for surgery) if you consent to participate. The follow up periods selected are routine in our setting and hence you will not be incurring any extra cost as a result. There will be no extra cost incurred for participating in the study. The cost of the tests will be borne by the researcher.

What is the penalty if I decline to participate?

You/your child will not be denied medical care in case you refuse to participate in the study. All patients will receive the same attention and treatment whether they participate in the study or not. You may stop participating at any time with no consequences whatsoever.

Voluntarism

You/your child's participation in this study is out of your own free will. You may decline to participate without any consequences. You may stop participating at any time without any consequence.

Follow up schedule

You will be seen by at 3 and 6 months postoperative periods and video-otoscopy and PTA done. These tests will be paid for by OED. You will be reminded to attend the ENT clinic two weeks prior to the date of appointment via text message.

The contact information of these people is given below if you wish to contact any of them for whatever reason

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Email: uonknh_erc@uonbi.ac.ke

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Consent form

Ifreely give consent for me/my child

Name..... to take part in the study conducted by Dr. Abdifatah Ibrahim Sheikh, the nature of which has been explained to me by him. I have been informed and have understood that my/my child's participation is entirely voluntary and I understand that I am free to withdraw my consent at any time if I so wish and this will not in any way alter the care given to me/my child. The results of the study may directly be of benefit to me/my child or other patients and more significantly to the Medical professionals to better understand "OUTCOME OF CHRONIC SUPPURATIVE OTITIS MEDIA SURGERY IN TWO TEACHING HOSPITALS IN KENYA".

.....

Signature/left thumb print (Patient/Parent/Guardian)

Date..... Day/Month/Year

Thumb print of participant if Unable to sign due to illiteracy

□

Assent form

Ifreely assent to take part in the study conducted by Dr. Abdifatah Ibrahim Sheikh, the nature of which has been explained to my parents and me by him. I have been informed and have understood that my participation is entirely voluntary and I understand that I am free to withdraw my assent at any time if I so wish and this will not in any way alter the care given to me.

.....

Signature/left thumb print (Patient)

Date..... Day/Month/Year

Thumb print of participant if Unable to sign due to illiteracy

□

Statement by the witness if participant is illiterate

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness.....

Signature of witness.....

Date.....

Day/Month/Year

□

Part III: Statement by the researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands the following:

Refusal to participate or withdrawal from the study will not in any ways compromise the quality of care and treatment given to the patient.

All information given will be treated with confidentiality.

The results of this study might be published to enhance the knowledge of the "OUTCOME OF CHRONIC SUPPURATIVE OTITIS MEDIA SURGERY IN TWO TEACHING HOSPITALS IN KENYA". I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that there was no coercion of the participant into giving consent, and that the consent was given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher taking consent

.....

Signature of researcher taking the consent

.....

Date.....Day/Month/Year

□

KISWAHILI VERSION

MAELEZO YA UTAFITI NA KIBALI CHA KUSHIRIKI

1. Maelezo ya utafiti

Kichwa

“Outcome of chronic suppurative otitis media surgery in two Teaching Hospitals in Kenya”

Mwanzo

Jina langu ni Daktari Abdifatah Ibrahim Sheikh, kutoka chuo kikuu cha Nairobi, kitivo cha Utabibu, idara ya upasuaji. Ninafanya utafiti wa kuangalia matokeo ya upasuaji ya “chronic suppurative otitis media surgery” inayofanywa katika hospitali kuu ya Kenyatta na hospitali kuu ya Moi kwa udhamini wa “operation Ear drop (OED)”. Ningependa kukuchagua wewe ama mtoto wako katika utafiti huu wangu. Nitafanya hivyo kwa kukuuliza maswali fulani kuhusu afya yako/ya mtoto wako na kufanya vipimo vya afya pamoja na vile vya kusikia.

Habari zote zitakazo kusanywa zitashughulikiwa kwa siri na hazitasambazwa ila kwa ruhusa kutoka kwa kamiti ya utafiti ya chuo kikuu cha Nairobi na hospitali kuu ya Kenyatta (KNH-UoN ERC) na ile ya chuo kikuu cha Moi na hospitali kuu ya Moi (IREC).

Utafiti huu utawasaidia madaktari kuelewa ni faida gani wagonjwa wanaweza kupata kutokana na upasuaji wa maskio katika hospitali yanayo husika na masomo ya afya.

Naomba uniruhusu nikuulize maswali ambayo yatajibiwa kwa fomu maalum. Habari yote ambayo utatuarifu ni ya siri kati yako nasi watafiti na haitaenezwa kwa watu wengine. Jina lako halitaandikwa kwenye fomu yoyote.

Unaweza kuuliza maswali yoyote kuhusu utafiti huu na ukiridhika tafadhali ijaze fomu ya idhini iliyopo hapa chini. Unaweza pia kuuliza swali lolote baadaye kwa kupiga simu ama kwa kutuma barua ya mtafiti mkuu ama mkuu

Lengo la utafiti huu.

Kuangalia matokeo ya upasuaji ya “tympanoplasty” na “mastoidectomy” inayofanywa kutibu ugonjwa wa “chronic suppurative otitis media” katika hospitali kuu ya Kenyatta na hospitali kuu ya moi, kwa udhamini wa OED.

Ni faida gani nitapata kwa kushiriki?

Wewe/mtoto wako hu/hawezi kupata faida ya fedha kwa kushiriki. Lakini matokeo ya utafiti huu inaweza kutumika kuboresha matibabu ya wagojwa wanaofanyiwa upareshoni huu. Pia inaweza tumika kuboresha masomo ya udaktari katika chuo kikuu cha Nairobi.

□

Kuna hatari ama gharama ya kushiriki?

Kushiriki kwako/kwa mtoto wako ni kupitia kukuuliza maswali fulani kuhusu afya yako/ya mtoto wako na kufanya vipimo vya afya pamoja na vile vya kusikia. Hakuna hatari kwako / kwa mtoto wako (ila ile inayotokana na upasuaji, ambao utaelezwa katika fomu ya kibali ya upasuaji). Muda wa kurudi ambao umechagulia katika utafiti huu ni muda ambao kwa kawaida wagonjwa wa upasuaji huu wanafaa kurudi kuonekana, kwa hivyo hakuna gharama itaongezeka kwako. Kuhusika kwako kwenye utafiti huu hakuna gharama yoyote kwako. vipimo vya afya vitagharamiwa na Mtafiti.

Kuna adhabu gani nikikataa kushiriki?

Wewe/mtoto wako hu/hatanyimwa matibabu utakapokataa kushiriki. Wagonjwa wote watahudumiwa sawa bila kujali kushiriki/kutoshiriki kwao katika utafiti huu. Unaweza kujiondoa kwa utafiti huu wakati wowote bila kuhatarisha matibabu yako/ya motto wako.

Hiyari

Kuhusika kwako kwenye utafiti huu ni kwa hiari yako mwenyewe. Unaweza kukataa kushiriki katika utafiti huu. Na pia unaweza kujiondoa kwa utafiti huu wakati wowote bila kuhatarisha matibabu yako/ya motto wako

Muda wa kurudi hospitali

Utarudi hospitali kuonekana na kufanyiwa vipimo vya afya na vya kusikia baada ya muda wa miezi mitatu na pia miezi sita. Vipimo vita gharamiwa na OED. Utakumbushwa kufika kiliniki ya ENT wiki mbili kabla ya terehe uliyopewa, kupita njia ya ujumbe wa simu.

Unaweza wasiliana na watu wafuatao kuulizo jambo lolote

Mtafiti mkuu

Daktari. Abdifatah Ibrahim Sheikh

Idhara ya upasuaji, kitivo cha Utabibu, Chuo kikuu cha Nairobi

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Mwenyekiti,

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Hospitali kuu ya Kenyatta

Tel 726300-9,

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Email: uonknh_erc@uonbi.ac.ke

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(ii) Idhini ya mgonjwa.

Mimi(Jina)..... Mgonjwa/mzazi/ mchungaji wa (Jina la Mgonjwa)kwa hiari yangu nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Abdifatah Ibrahim Sheikh kutokana na hali ambazo nimeelezwa na sio kwa malipo ama shurutisho lolote.

Nimeelewa kwamba ninaweza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu ninayopata/anayoyapata mgonjwa wangu. Matokeo ya utafiti yaweza kuwa ya manufaa kwangu ama kwa wagonjwa wengine kwa jumla na hata madaktari wenyewe.

.....

Sahihi/ama alama ya kidole cha gumba katika sanduku →

Tarehe.....

Siku/Mwezi/Mwaka

Jina la shahidi.....

Sahihi.....

Tarehe.....

(Siku/Mwezi/Mwaka)



□

kibali cha motto

Mimi(Jina)..... kwa hiari yangu nimekubali kushiriki katika utafiti huu unaofanywa na Daktari Abdifatah Ibrahim Sheikh.Nimeelewa kwamba ninaweza kujiondoa wakati wowote nitakapo na hatua hii haita hatarisha matibabu ninayopata.

.....

Sahihi/ama alama ya kidole cha gumba katika sanduku →

Tarehe.....

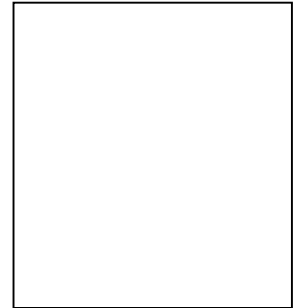
Siku/Mwezi/Mwaka

Jina la shahidi.....

Sahihi.....

Tarehe.....

(Siku/Mwezi/Mwaka)



□

(iii) Sehemu ya tatu - Dhibitisho la mtafiti

Hii nikuidhinisha ya kwamba nimemueleza mgonjwa/mzazi/mchungaji kuhusu utafiti huu na pia nimempa nafasi yakuuliza maswali. Nimemueleza yafuatayo;

Kwamba kushiriki ni kwa hiari yake mwenyewe bila malipo.

Kushiriki hakutasababisha madhara ama kuhatarisha maisha kamwe.

Anaweza kujiondoa kutoka kwa utafiti huu wakati wowote bila kuhatarisha matibabu anayoyapata.

Habari ambazo atapeana hazita tangazwa hadharani bila ruhusa kutoka kwake (mshiriki) na pia kutoka kwa mwenyekiti wa idara kuu ya utafiti wa hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi.

Jina la mtafiti ama msimamizi wake.....

Sahihi.....

Tarehe.....

(Siku/Mwezi/Mwaka)

□

STUDY PROFORMA

STUDY NUMBER_____

BIODATA

Age		Sex	MALE		MALE	
-----	--	-----	------	--	------	--

CLINICAL SYMPTOMS

Duration since last otorrhea						
Affected ear:	Left		Right		Both	
Prior adenoidectomy:	Yes		No			
Craniofacial dysmorphism:	Present		Absent			
State of contralateral ear:	Normal		Abnormal			

CLINICAL EXAMINATION

EAR: (Include Videotoscopy)	Normal		Abnormal	
Postauricular region	Normal		Abnormal	
Pinna	Normal		Abnormal	
EAC	Normal		Abnormal	

VIDEO-OTOSCOPY (preoperative)

TM perforation							
Site	AS		AI		PS		PI
Size	<25%		25-50%		50-90%		Total

VIDEO-OTOSCOPY (postoperative 3months)

TM perforation							
Site	AS		AI		PS		PI
Size	<25%		25-50%		50-90%		Total

□

VIDEO-OTOSCOPY (postoperative 6 months)

TM perforation							
Site	AS		AI		PS		PI
Size	<25%		25-50%		50-90%		Total

TUNING FORK (preoperative)

RINNE'S:	LEFT	POSITIVE		NEGATIVE	
	RIGHT	POSITIVE		NEGATIVE	
WEBER'S	CENTRAL		LEFT		RIGHT

TUNING FORK (postoperative 3 months)

RINNE'S:	LEFT	POSITIVE		NEGATIVE	
	RIGHT	POSITIVE		NEGATIVE	
WEBER'S	CENTRAL		LEFT		RIGHT

TUNING FORK (postoperative 6 months)

RINNE'S:	LEFT	POSITIVE		NEGATIVE	
	RIGHT	POSITIVE		NEGATIVE	
WEBER'S	CENTRAL		LEFT		RIGHT

PTA

TIME	Preoperative		Postoperative 3 months		Postoperative 6 months
Bone conduction (dB)					
Air conduction (dB)					
ABG (dB)					

□

SURGERY

mastoidectomy	Simple		Canal wall up		Canal wall down		Modified radical		Radical	
Tympanoplasty	Type 1		Type 2		Type 3		Type 4		Type 5	
Surgeon	Consultant		Registrar 5		Registrar 4		Registrar 3			
Place of surgery	KNH				MTRH					

KNH= Kenyatta National Hospital, MTRH = Moi Teaching and Referral Hospital, Consultant = qualified Otorhinolaryngologist, Registrar 3,4,5 = year 3, 4 and 5 postgraduate otorhinolaryngology students of UoN respectively

Complications. (List)