1. Title:

TRANSLATION AND VALIDATION OF A SWAHILI VERSION OF OBSTRUCTIVE SLEEP APNEA 18 (OSA 18) QUALITY OF LIFE INSTRUMENT IN CHILDREN WITH SLEEP DISORDERED BREATHING DUE TO ADENOID AND TONSILLAR HYPERTROPHY.

INVESTIGATOR: Dr Stephen WaruruWarui ;MBCHB,

Registrar, Ear,Nose and Throat Surgery,

University of Nairobi, College of Health Sciences.

Email: wandindi12@gmail.com

Registration Number: H58/68945/2011

SUPERVISORS: 1. Dr Joyce Aswani,

Consultant ENT, Head and Neck Surgeon,

Senior Lecturer, Department of Surgery,

University of Nairobi, College of Health Sciences.

2. Dr Musa Kipingor,

Consultant ENT Surgeon, Head and Neck Surgeon.

Kenyatta National Hospital, Nairobi.

A thesis submitted in partial fulfilment for the degree of Masters of Medicine in Ear, Nose and Throat Surgery at the University of Nairobi.

2. DECLARATION

I hereby certify that this thesis is my original work and has not been submitted for any degree at any other institution.

Dr Stephen Waruru Warui

Signed……

…. Date:……

This Thesis has been submitted for examination with our approval as supervisors:

1. Dr Joyce Aswani

   Signed……

   Date:……

2. Dr Musa Kipingor

   Signed……

   Date:…….

3. ACRONYMS AND ABBREVIATIONS

AHI - Apnea Hypopnea Index

AH -Adenoid Hypertrophy

TH - Tonsil Hypertrophy

AS - Adenoid Surgery

ASTS - Adenoid surgery, Tonsil Surgery

ANR -Adenoid Nasopharyngeal Ratio

ENT-HN - Ear Nose and Throat, Head and Neck

KNH - Kenyatta National Hospital

OSA - Obstructive Sleep Apnea

OSD 6 - Obstructive Sleep Disorders 6 Quality of Life Questionairre.

OSA 18 - Obstructive Sleep Apnea 18 Quality of life Questionnaire

PSG - Polysomnography

QOL - Quality of life

SDB - Sleep Disordered Breathing

SPSS - Statistical Package for the Social Sciences

TS - Tonsil surgery

UARS - Upper Airway Resistance Syndrome

URTI - Upper Respiratory Tract Infection

UON - University of Nairobi

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4. ABSTRACT

BACKGROUND: Sleep disordered breathing (SDB) is associated with numerous cardiac, respiratory and behavioural complications. Adenotonsillar hypertrophy is a common cause of SDB in children. Given limitations in accessing polysomnographs, OSA 18 quality of life questionnaire is used to assess quality of life in sleep disordered breathing.

OBJECTIVES: To translate and validate a Kiswahili version of OSA 18 in children with sleep disordered breathing due to adenoid and tonsil hypertrophy.

STUDY SETTING: ENT Clinic at the Kenyatta National Hospital Nairobi.

STUDY DESIGN: A prospective Cross Sectional Study.

STUDY DURATION: 2 months; November 2016 to December 2016 from the time of approval by the KNH/UON Ethics and Research Committee.

STUDY POPULATION: Children with adenotonsillar hypertrophy and clinical features of sleep disordered breathing attending the ENT Clinic at Kenyatta National Hospital (K.N.H.) scheduled for surgery.

MATERIALS AND METHODS: A translation and cross cultural adaptation of the OSA 18 was done using revised Brislin's method followed by testing and retesting of the Kiswahili version to 75 recruited patients/their guardians to assess reliability. The scores were tested against adenoid and tonsil size to determine the validity. Children underwent adenoid and tonsil surgery and QOL measured 4 weeks postoperatively.

RESULTS: Good test test-retest reliability and internal consistency achieved (Crombach's Alpha 0.70). Correlation between scores and Tonsil size was found to be r=0.21 which was similar to the original r = 0.29 against tonsil size but not against AHI r=0.10 against r=0.43. There average preoperative score was 79.17(+/-13.58). The sleep disturbance domain had the highest scores. There was significant improvement in QOL following adenoidectomy and tonsillectomy with the average post-op scores being 22.20(+/- 6.58). Sleep disturbance showed the greatest improvement.

CONCLUSION: The Kiswahili version has shown good test retest reliability, internal consistency and satisfactory validity. It has also shown significant improvement in QOL post adenoidectomy and tonsillectomy.

5. CHAPTER ONE: INTRODUCTION

1. INTRODUCTION TO THE STUDY

Sleep-disordered breathing (SDB) is a term that encompasses a spectrum of sleep-related upper airway obstruction that ranges from primary snoring and upper airway resistance syndrome (UARS) to OSAS and, at the extreme, obesity-hypoventilation syndrome (Pickwickian syndrome).

Snoring has been used as a marker of SDB and the prevalence of snoring in children has been reported as 7.45 per cent in a meta-analysis[1].Simple snoring is defined as snoring without obstructive apnoeas, frequent arousals or gas exchange abnormalities

Obstructive sleep apnea is defined as sleep characterized by prolonged partial upper airway obstruction, intermittent complete or partial obstruction (obstructive apnoea or hypopnoea) or both prolonged and intermittent obstruction that disrupt normal ventilation during sleep, normal sleep patterns or both[2,3].

Whilst thought to be benign,habitual snoring in children has been shown to lead toneurocognitive disorders and reduction in Growth hormone secretion[5] .With SDB, disturbed sleep patterns in children lead to behavioral changes and poor concentration thus reduced QOL [4,5]. In the extreme the rise in pulmonary blood pressure as a result of increased sympathetic activity leads to transient pulmonary hypertension. Long-standing sleep apnoea can result in irreversible pulmonary hypertension and if sustained this will lead to right heart failure and cor pulmonale. In Kenyan children with adenoid hypertrophy, 21.9% were shown by Marangu et al to have pulmonary hypertension[6]

In the paediatric population, adenotonsillar disease is the commonest cause of SDB.[7] 1-3% of children are thought to have OSA whilst 7% are habitual snorers.[1] There have been no outright studies on sleep disordered breathing done in our local setting. However, upper airway obstruction was found to form 58.9% of the indications for adenoidectomy and tonsillectomy in children in tertiary institutions in Nairobi.[8]

The gold standard for diagnosing SDB is in laboratory polysomnography (PSG). Given that PSG is expensive and often difficult to obtain, especially in low resource settings primary care physicians look to other alternatives for diagnosis of SDB. The OSA-18, developed by Franco is the most widely used QOL survey for pediatric SDB, and has been validated as an evaluative and discriminative instrument.[9] It has also been widely adapted into various languages for use in the clinical setting.[10,11,12]

2. EPIDEMIOLOGY

There is an absence of local data on SDB.A meta-analysis of articles in various continents showed snoring to have a prevalence of 7.45% in children[1]. SDB prevalence has been estimated between 1 and 4 per cent. AfricanAmerican children compared to Caucasian children have greater SDB.[13-16].

There has been no gender differences shown in pre-pubertal children[3]. Although SDB can occur at any age, it seems to present most commonly in 2 to 5 yr olds[3,17].Adenoid hypertrophy is a significant factor in SDB and in Nairobi, Professor Oburra found upper

airway obstruction to be a significant indication for adenoid and tonsil surgery in Kenyan children.[6,8]

3. PATHOPHYSIOLOGY

Clinical signs of SDB; loud snoring, nostril flaring, suprasternal and intercostals recession are caused by breathing against a partially or completely obstructed upper airway. Complete obstruction of the pharyngeal airway, as in OSA, leads to silent periods followed by choking or gasping as the child rouses from sleep to reestablish their airway.

The pharyngeal dilator, intrinsic and extrinsic tongue muscles are responsible for stiffening of the airway in an awake healthy subject[18,19,20]. During sleep, they relax resulting in collapsibility of the airway and thus increased airflow resistance. There is then a subsequent increase in PCO2 of about 3-5mmHg in healthy individuals.[18,21].

The pathophysiology of SDB is thought to have 3 main contributors: inflammation, neuromotor tone and anatomical structure. SDB patients, when awake have been shown to have a structurally narrow airway. This leads to increased resistance and increased collapsibility when asleep. [22,23]. There is subsequent hypopnea or apnea due to this reduced or absent airflow. The sites of this resistance may vary and may include solitary or multiple sites from the nasopharynx to the hypopharynx.

Three patterns of airway collapse have been described by Fujita. These are; Type 1 (retropalatal), Type 2 (retropalatal and retrolingual) and Type 3 (retrolingual). [24] In type 3, retrolingual obstruction includes both lateral pharyngeal wall collapse and base of

tongue collapse. Anatomical obstruction at one or more of these levels results in varying degrees of SDB by increasing both airway resistance and negative thoracic pressure. Adenotonsillar tissue is largest in the first few years of life involuting in adolescence into adulthood. This makes adenotonsillar disease the most significant contributor to paediatric SDB.[25] Adenoids develop by fusion of two lateral primordial in the midline in early fetal life. By the seventh month of gestation, they are fully formed. They continue growing till the fifth year of life. This may cause airway obstruction to varying degrees. Thereafter, the nasopharynx grows, adenoids atrophy and airway patency improves.[26,27] Adenotonsillar hypertrophy, obesity, craniofacial disproportion and familial disposition are the commonest risk factors for SDB in children. [28]

With hypopnea or apnea during sleep, hypoxia and hypercarbia develop. A rise in sympathetic output due to hypoxia leads to tachycardia and increased blood pressure Changes in the pulse and blood pressure reflect increased sympathetic activity and are markers of subcortical arousal.

Episodes of upper airway obstruction are terminated by these subcortical arousals. The child is unaware of these but they may occur several hundred times a night. Repeated arousals lead to behavioral changes and impaired concentration ability as well as having general effects on a child's quality of life by greatly disturbing the sleep pattern of the child[5]. Increased pulmonary blood pressure due to increased sympathetic activity leads to transient pulmonary hypertension. Should the sleep apnea be long standing, the pulmonary hypertension becomes irreversible leading to right heart failure and cor

pulmonale.[29] In Kenyan children with adenoid hypertrophy, 21.9% were shown by Marangu et al to have pulmonary hypertension[6].

4. INVESTIGATIONS

Overnight laboratory polysomnography (PSG) is considered to be the gold standard for diagnosing SDB.. Given its limitations; it is expensive and often difficult to obtain, primary care physicians look to other alternatives for diagnosis of SDB.

Questionnaires have subsequently been developed in an attempt to diagnose OSA in centres without access to polysomnographs or oximeters.OSD 6 developed by Serres et al[50] and OSA 18 developed by Franco et al[9] have been validated for use in children with clinically suspected sleep disordered breathing. The OSA-18 is the most widely used QOL survey for pediatric OSA, and has been validated as an evaluative and discriminative instrument.[9] It features 18 items organized into five domains: sleep disturbance, physical suffering, emotional distress, daytime problems, and caregiver concerns.

Constantin et al ,however showed that the OSA 18 could not be used to replace polysomnography in diagnosis of moderate to severe OSA. She assessed 334 children undergoing polysomnography and administered the OSA 18 as well. The OSA-18 was found to have a sensitivity of 40% and a negative predictive value of 73% for detecting an abnormal McGill Oximetry Score[52].

Home based audio and video taping have been used as alternatives with studies showing 75 and 83% predictive value for audio and video respectively.[30,31,32]

5. TREATMENT

1. MEDICAL

Children with OSA who present with mucopurulent nasal discharge should have this treated, as it will improve their nocturnal symptoms. Treatment should consist of a four to six-week course of systemic antibiotics combined with topical intranasal steroids. These children should be tested for sensitivity to airborne allergens that may be irritating the mucosal lining of the nose and paranasal Sinuses.

2. CONTINOUS POSITIVE AIRWAY PRESSURE

Continuous positive airway pressure (CPAP) entails splinting of the airway and maintaining of its patency by continous insufflations of the nasopharyngeal airway during sleep.. This is delivered via a nasal mask and has to be used every night on an indefinite basis .Long term CPAP may be considered to be of benefit to patients such as the obese child, syndromic children and children with cerebral palsy who may not be .considered surgical candidates.

3. SURGERY

Adenoidectomy and Tonsillectomy are considered the first line surgical treatment once SDB is diagnosed in children. Combined tonsillectomy and adenoidectomy have been shown to have superior results compared to either procedure alone.[33]

6. CROSS CULTURAL TRANSLATION AND ADAPTATION OF SURVEY INSTRUMENTS

Culturally appropriate translated survey instruments are defined as conceptually and technically equivalent to the source language, culturally competent, and linguistically appropriate for the target population. In translating, it is important to distinguish between technical and conceptual equivalence. Technical equivalence refers to equivalence in grammar and syntax, while conceptual equivalence refers to the absence of differences in meaning and content between two versions of an instrument.

Conceptual equivalence includes item and scalar equivalence of the source and translated surveys. Item equivalence signifies that each item has the same meaning for subjects in the target culture. Scalar equivalence is achieved when the construct is measured on the same metric in two cultures [34]. Cultural competence refers to the requirement that the translated instrument adequately reflect the cultural assumptions, norms, values, and expectations of the target population [35].

To ensure this, single translation is not acceptable. A variety of techniques are used to ensure the reliability and validity of the translated survey instrument. Brislin's translation model has been widely used[35]. This model recommends forward translation, back translation and review.

Forward translation involves Professional translators experienced in translating similar survey instruments, preferably native speakers of the target language, being retained to translate the survey instrument. Back translation back to English then follows and this is done by individuals who are blinded to the original document. Review by the forward

translator,back translators and the reviewer is then done to correct errors in grammar and syntax and to resolve problems of equivalence found among the versions.

A field test of the translated survey instrument is also recommended to assess the reliability and validity of the translated survey instruments. Reliability estimates, such as Cronbach's [36] alpha coefficients, to measure the internal consistency of the instrument. Cronbach's alpha is based on the number of items in the scale and the homogeneity of the items. There are different reports about the acceptable values of alpha, ranging from 0.70 to 0.95. Factor analysis to examine the internal structure of the instrument or construct validity of the scales.

Validity means assessing whether the instrument is measuring what it is intended to measure. In order to establish validity, one needs to examine the logical relationships that should exist between assessment measures. Content validity assesses evidence that the items and domains of an instrument are appropriate and comprehensive relative to its intended measurement concept(s), population and use. Construct validity assesses evidence that relationships among items, domains, and concepts conform to a prior hypotheses concerning logical relationships that should exist with other measures or characteristics of patients and patient groups. Criterion related validity is used when the instrument being validated is used as a diagnostic tool and checks the extent to which it assesses a criterion measure.

6. CHAPTER TWO: LITERATURE REVIEW

1. LITERATURE REVIEW

In children, obstructive sleep apnea (OSA) is a sleep-related breathing disorder that is usually caused by adenotonsillar hypertrophy and is characterized by upper-airway obstruction that disturbs sleep and normal respiratory gas exchange[38,,40] with subsequent cardiac and pulmonary complications[6].Snoring has been used as a marker of SDB and the prevalence of snoring in children has been reported as 7.45 per cent[1]. Childhood OSA has a prevalence of 1% to 3%[38-42].

Arens et al in an assessment of children with OSA found adenotonsillar hypertrophy to be the main cause of obstruction leading to the OSA[7].For children with OSA that is caused by adenotonsillar hypertrophy, adenotonsillectomy is the treatment of choice[7].

Laboratory polysomnography is considered to be the gold standard measure of OSA in children. However, polysomnography involves a detailed, laborious evaluation of cardiorespiratory and neurologic parameters in a sleep laboratory and, therefore, is not widely accessible. Polysomnography is time-consuming, costly, and usually entails long waiting times.[36-40]

The OSA 18 has however been extensively used as a quality of life instrument in children with sleep disordered breathing and has been shown to be effective in this regard more so pre and post adenoidectomy and tonsillectomy. This has been shown for both short term follow up (within 1 month to 3months post operatively)[55,56,58] and long term (6-24 months)[54,57]

Goldstein et al analysed the QOL in 64 children before and after adenotonsillectomy and found improvement in OSA 18 scores post operatively particularly sleep disturbance, physical symptoms and caregiver concerns.There was found to be no difference in scores between different genders and economic status[53].

Similar results were gotten by Sohn et al, Mitchelle et al and Tran et al . All these studies assessed children with adenotonsillar hypertrophy pre and post adenotonsillectomy using the OSA 18 pre operatively and post operatively within one to three months.[55,56,58]

Long term follow up studies were conducted by Mitchelle et al (34 subjects tested 6 months post operatively) and Flanary et al (54 subjects and a 18 month post operative test period) showed similarly good results in terms of improvement of QOL post adenotonsillectomy. with pre-op scores of76.7 and 74.8 respectively and post op score of 32.0 and 36.48 respectively.[54,57]

Christina et al[59] in a metanalysis found no significant difference between the two groups; the ones who took the OSA 18 at one to three months and those who took it at a longer duration post operatively. They both showed a clinically significant improvement in the QOL post adenotonsillectomy.

Cross cultural adaptation has been done for the OSA 18 with subsequent validation in the various languages.

Fausto et al in Brazil translated the OSA 18 into portugese and subsequently validated it in 51 children with a clinical history suggestive of OSAS. The tool in Portugese was found to be valid for use in their population. The test retest reliability was found to have

Crombach alpha of 0.821. In testing validity, the Pearson correlation coefficient as found to be 0.20 .[60]

George Mousalidis et al in 2014 translated the OSA 18 into Greek and tested and retested in 141 children undergoing PSG and also on children postoperatively at 3 months. The Greek version showed good test and retest consistency (Crombach Alpha test) of 0.951 . Total and subscale OSA-18 scores and AHI were significantly correlated (Spearman's correlation coefficients: 0.376-0.633; $P<0.01$), while children with OSA had higher total OSA-18 score than those without OSA [median (interquartile range): 61 (35) vs. 38 (22), respectively; $P<0.001$)]. Sensitivity was 53.4%, suggesting poor validity compared to polysomnography as a diagnostic tool for moderate to severe OSA.[61]

Kuptanon et al in 2015 cross culturally adapted the OSA 18 into Thai and tested it on 43 children who were undergoing polysomnography. He found good test retest reliability(Crombachs) of 0.77 and the comparisons with the English version viz AHI was comparable. The correlation coefficient was found to be $r= 0.43$.[62]

Kang et al in 2014 cross adapted the OSA 18 for the Taiwanese population by translating it to Chinese and testing it on 109 children aged 2-18 years with sleep problems who were undergoing PSG. Excellent test-retest reliability and good internal consistency were achieved (Crombachs alpha score of 0.84), and the validity of OSA-18 with overnight polysomnography was confirmed with correlation coeffecients ranging from 0.29 to 0.53. He also assessed tonsil size and adenoid size and found correlation coeffecients of 0.17 and 0.16 respectively. The domain of sleep disturbance, daytime function, caregiver concerns, and the OSA-18 total scores were significantly higher in sleep apnea patients.

The domain of caregiver concern had the highest score, while those of emotional distress had the lowest scores. The optimal cut-off point of the OSA-18 total scores for detecting obstructive sleep apnea was 67.[67]

7. CHAPTER THREE: STUDY METHODOLOGY

1. STUDY RATIONALE

Sleep disordered breathing and in particular Obstructive Sleep Apnea are associated with multiple cardiac, respiratory and behavioural complications. Adenoid and Tonsillar enlargement is one of the major causes of SDB and OSA forms an indication for adenotonsillar surgery.

Given the unavailability of Polysomnography to our population, Quality of life instruments can be used to assess the quality of life in children with SDB due to adenoid hypertrophy. OSA 18 being the most widely used and studied is ideal.

Given the demographics of the Kenyan population regarding languages and multi ethnicity, and given that most of the population speak Kiswahili as the national language, cross cultural adaptation of OSA 18 into Kiswahili would be beneficial for monitoring outcomes of treatment viz adenoid and tonsillar disease related SDB and QOL.

2. RESEARCH QUESTION

i. How reliable and valid is a Kiswahili version of OSA 18 compared to the English version in assessing Quality of Life in children with Sleep disordered breathing due to adenotonsillar hypertrophy?

ii. Is there any change in the quality of life after adenoid and tonsil surgery?

3. STUDY OBJECTIVES

1. Main Objective

i. To translate to Kiswahili and validate the Swahili version of OSA18 Quality of Life instrument in children with Sleep Disordered Breathing due to adenotonsillar hypertrophy.

2. Specific Objectives

i. To translate the OSA 18 Quality of life instrument into Kiswahili.

ii. To test the Kiswahili OSA 18 version for consistency, reliability and validity to assess QOL in children with SDB due to adenotonsillar hypertrophy.

iii. To assess quality of life before and after adenoid and tonsillar surgery using the Kiswahili OSA 18.

4. STUDY DESIGN

Cross- sectional study

5. SETTING

The setting was the ENT Clinic at the Kenyatta National Hospital which is the largest referral hospital in Kenya.

6. STUDY POPULATION

The study population comprised children who were attending in the ENT Clinic for adenoid and tonsillar hypertrophy with clinical features of sleep disordered breathing and scheduled for adenoid and/or tonsil surgery.

1. Inclusion Criteria

1. Children under 12 years with adenoid and tonsillar hypertrophy and clinical features of Sleep disordered breathing scheduled for adenotonsillar surgery.
2. Children with ATH and SDB whose parents or guardians consented to taking part in the study.

2. Exclusion Criteria

1. Those who had prior adenoid and /or tonsillar surgery
2. Those with craniofacial malformations
3. Genetic disorders, cognitive disorder, mental retardation or neuromuscular disorders.
4. Guardians who were not able to understand Kiswahili.

7. SAMPLE SIZE

The desired sample size was calculated using the formula;

$$n = \frac{\{u\sqrt{\pi(1-\pi)} + v\sqrt{\pi_0(1-\pi_0)}}{(\pi - \pi_0)^2}$$

Where:

n= sample to be selected

u = One-sided percentage point of the normal distribution corresponding to power of 80%, therefore 0.84

v = Two-sided percentage point of the normal distribution corresponding to 95% level of significance, therefore 1.96

π_0 = The proportion of positives detected with the gold standard, thus 97%

π = The proportion hypothesized to be detected, given by 88%

The sample size obtained thus became 75 children. Including a 5% increase in the sample to account for drop outs, we got a sample to be selected of 79 children.

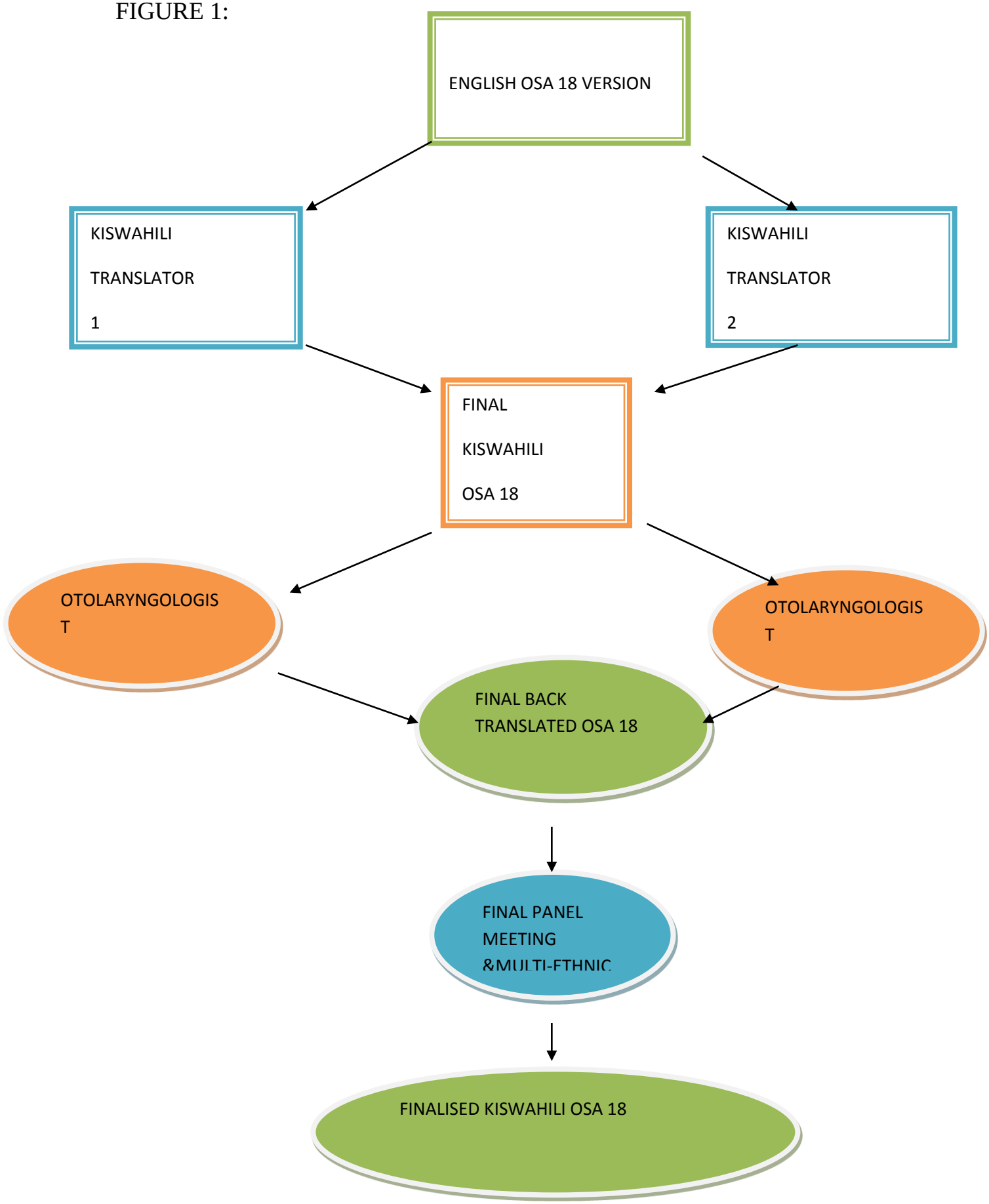
8. SAMPLING METHOD

Convenient consecutive sampling was used. All patients who fit the criteria and consent to taking part in the study were recruited into the study.

9. PROCEDURE

The study took place in three stages. **Stage** 1 will involve translating the OSA 18 questionnaire using the revised Brislin[35] model for cross cultural adaptation. This involved translation by 2 multi-lingual linguists into Kiswahili. They subsequently compared their versions to give the final Kiswahili version. Back translation to English was then done by 2 blinded multilingual(English and Kiswahili speaking) otolaryngologists. Through this the Kiswahili version was assessed for accuracy and for any material lost in translation. A final panel meeting of all translators and the researcher was held to give the final version. This version was then piloted on 18 children (not part of the study) from different ethnic backgrounds to further refine it.(FIGURE 1)

FIGURE 1:


ENGLISH OSA 18 VERSION
KISWAHILI TRANSLATOR 1
KISWAHILI TRANSLATOR 2
FINAL KISWAHILI OSA 18
OTOLARYNGOLOGIST
OTOLARYNGOLOGIST
FINAL BACK TRANSLATED OSA 18
FINAL PANEL MEETING &MULTI-ETHNIC
FINALISED KISWAHILI OSA 18

The caretakers of the 83 recruited children were then taken through the consent explanation elaborating the intricacies of the study. When satisfied by the explanation,the caretaker/guardian signed the consent form (Appendix 1).

A patient biodata form and questionnaire (Appendix 4) were then filled by the patient's guardian. The questionnaire asked about various symptoms related to SDB. A clinical examination was then done on the patients. Tonsil size was then graded based on size as first described by Brodsky[63] ie from grade 1 to grade 4 (FIGURE 2). Tonsillar hypertrophy was taken to be Grade 3 and Grade 4. A postnasal lateral soft tissue radiograph was then taken to diagnose adenoid hypertrophy (if patient did not have one) and to get the adenoid nasopharyngeal ratio; which was reviewed by a sole radiologist. Assessment as first described by Fujioka[64] was used; assessing the size of the adenoid tissue perpendicularly from the baso-occipital bone to the area of greatest convexity on the adenoid and comparing that to the nasopharynx; distance from the hard palate to the spheno-occipital synchondrosis (FIGURE 3). The level of significance for diagnosis of adenoid hypertrophy was taken to be an adenoid nasopharyngeal ratio of 0.80. These; adenoids and tonsils, formed the objective points of assessment to determine validity.

FIGURE 2[63]:

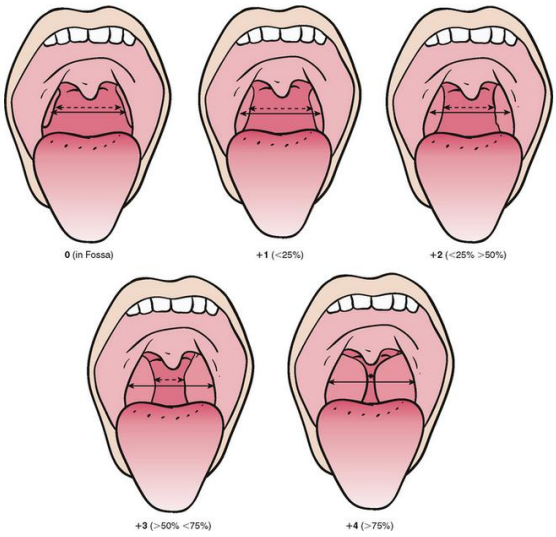
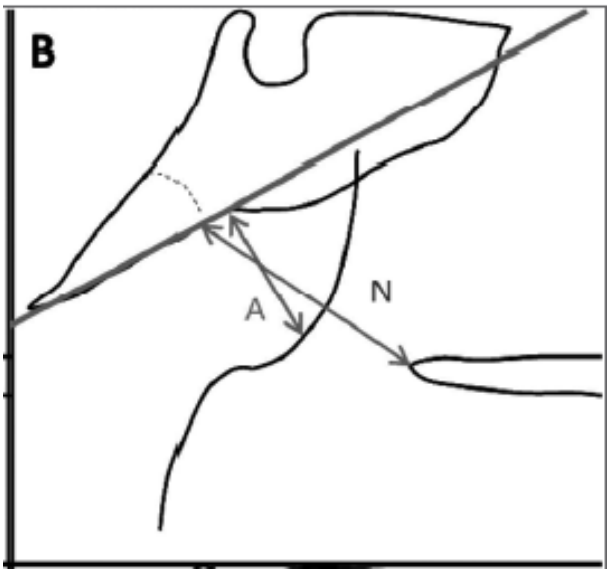


FIGURE 3[(64)]:



Stage 2 involved assisted filling of the Kiswahili version of OSA 18 (Appendix 3) by the caretakers of the children who fulfilled the inclusion criteria. A score of this was gotten. The caretakers were then asked to retake the questionnaire after 1week period just before their adenoid and tonsil surgery. The two results were then analysed for consistency, test – retest reliability and assessment for validity (using the tonsil size and the adenoid size as objective parameters).

Stage 3 involved filling the Kiswahili version of OSA 18 one month(4 weeks) after the adenoid and tonsil surgery. The result were then analysed to assess for any changes in the quality of life subject to intervention.

The study started after ethical approval by the Kenyatta National Hospital/University of Nairobi ethical committee.

10. STUDY DURATION

The study took approximately 2 months from the time of approval by the Ethical Committee.

11. DATA MANAGEMENT

All data on patient demographics, examination findings was entered into and analyzed using SPSS version 20.0. The data was cleaned of errors, inconsistent or conflicting answers, as well as missing or duplicate entries. Descriptive statistics were obtained. The correlation coefficient, positive predictive rates and other relevant statistical tests were obtained.

12. ETHICAL CONSIDERATIONS

1. Permission to undertake this study was sought from Kenyatta National Hospital Scientific and Ethics Committee. A letter of protocol approval was obtained prior to the commencement of the study.
2. Informed consent was obtained from the patients, parents or guardians after explaining to them the objective of the study and their role in the study and implications thereof. The consent explanation described the purpose of the study and the procedure to be followed. The investigator and/or research assistant conducted the consent discussion and checked that the patient/parent/guardian comprehended the information provided and answer any question about the study. Consent was voluntary and free from coercion.
3. No experimental treatments were employed in this study.
4. Participating patients received continued treatment through the course of the study.
5. Participating patients did not incur extra costs as a result of participating in the study.

6. Subject confidentiality was strictly held in trust by the investigator. The study protocol, documentation, data and all other information generated was held in strict confidence. No information concerning the study or the data was released to any unauthorized third party. All evaluation forms, reports and other records that leave the site will be identified only by the Subject Identification Number (SIN) to maintain subject confidentiality. All raw data was, at the conclusion of the study, destroyed. Clinical information will not be released without written permission of the subject, except as necessary for monitoring by Ethics, Research and Standards Committee. Study results will be availed to the medical fraternity through presentation in scientific conferences and publication in medical journals.

13. TIMELINES

ACTIVITY	**FROM**	**TO**
Completion of Research Proposal	January 2016	July 2016
Presentation to ENT Department	July 2016	July 2016
KNH/UON Ethics & Research Committee approval	July 2016	November 2016
Data collection	November 2016	December 2016
Data Analysis	December 2016	February 2017

Submission, revisions and defence	March 2017	March 2017

14. BUDGET

ITEM/ACTIVITY	**COST(KENYA SHILLINGS)**
STATIONERY	10,000
BIOSTATISTICIAN	30,000
TRANSPORT	15,000
TELEPHONE CHARGES	5,000
CONTINGENCY	20,000
ETHICS COMMITTEE FEE	5,000
TOTAL	95,000

8. RESULTS

1. Introduction

The aim of this study is to measure the validity is a Kiswahili version of OSA 18 compared to the English version in assessing Quality of Life in children with Sleep disordered breathing due to adenotonsillar hypertrophy. The data used in this study is from a cross-sectional study at Kenyatta National Hospital ENT Clinic. This sample consisted of 83 initial participants but 8 were lost to follow up or decided to drop

outleaving a sample of 75 participants aged 9 – 138 months. In addition to age, other factors considered in this study included gender, demographic data and clinical data such as tonsil enlargement and grade.

2. Methods of analysis.

The variables that were analysed were the patient responses to the OSA-18 quality of life questionnaire (this contains 18 items divided into subscales sleep disturbance, physical symptoms, emotional symptoms, daytime functions and caregiver concerns); gender; age; other factors including demographic data and clinical data such as tonsil enlargement and grade. The outcome measures were the responses on the OSA-18 items. Each item on the OSA-18 is scored on a seven-point ordinal scale. The continuous variables (age of child in months and age of caretaker in years) will be converted to categorical variables for simplicity during univariate analysis. All the other variables were categorical or binary (gender). The dataset had 4 missing values in the adenoid nasopharyngeal ratio (adenoid size) variable. A 95% level of confidence was assumed. Paired t test was used to compare the average total scores from the OSA – 18 questionnaire at the test and the post operation phase of the study while the validity was assessed by comparing the OSA – 18 sores to the clinical measures using a Spearman's rank correlation. Test-retest reliability was measured using the Spearman correlation of the test and retest scores of the study. A coefficient of at least 0.70 was regarded as acceptable. Spearman's rank correlation was used since the scores are ordinal.

3. RESULTS

1. Gender and age characteristics of the child and caretaker

The sample had 53.33% (n=40) male children and 46.67% (n=35) female children. The study sample had a mean age of 50.84 months with a standard deviation of 25.83 and ranging from 9 to 138 months (see figure 1).

The average age of the caretakers was 32.53 years with a standard deviation of 6.55 and ranging from 20 to 60 years. A majority of the caretakers attained the level of secondary education (40.00%, n=30) with most being mothers to the children (90.67%, n=68). Table one shows the demographic breakdown of the caretakers.

Table 1: Demographic distribution of the caretakers

Level of Education	**Frequency (Percentage)**
Primary level	17 (22.67%)
Secondary level	30 (40.00%)
College (Certificate) level	14 (18.67%)
Diploma level	8 (10.67%)
University level	6 (8.00%)
Relationship with the child	
Mother	68 (90.67%)
Father	6 (8.00%)
Grand parent	1 (1.33%)

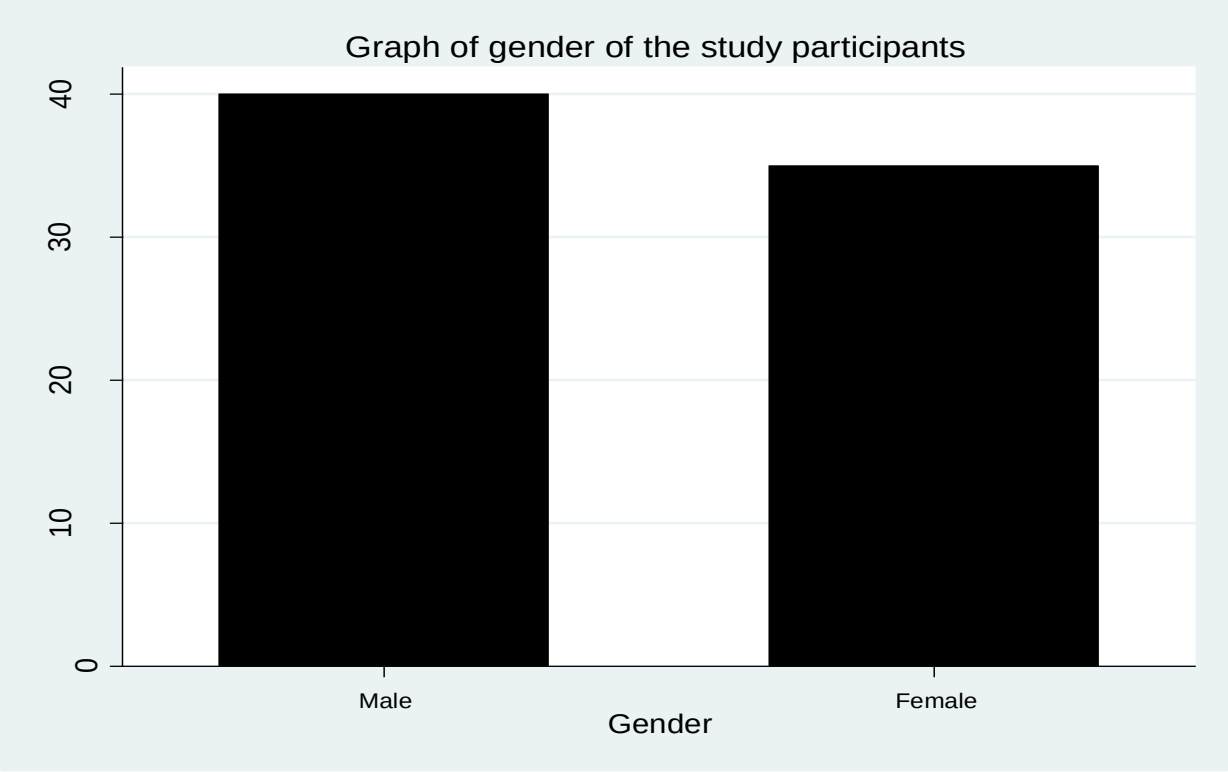


Figure 1: Graph of gender distribution in the children participants in the study

1. The Reliability and validity of OSA – 18

1. Reliability

Test- retest item correlations ranged from 0.64 to 0.99.(Table 3) All 18 items had excellent test-retest reliability, indicating good stability. The consistency coefficient (Cronbach's alpha) ranged from 0.70 to 0.76 thus >0.70, indicating acceptable internal consistency.

2. Validity

The criterion validity between each test item and the tonsil grade and Adenoid nasopharyngeal were examined. The total OSA-18 score, the emotional symptoms and caregiver concerns were significantly correlated with tonsil grade while the emotional symptoms and daytime functions were significantly correlated with the adenoid

nasopharyngeal ratio (adenoid size). These results confirm the internal validity of OSA-18 with the proxy of tonsil grade (in place of a polysomnography). Spearman correlation coeffecients were considered significant when r= > 0.20 (p <0.05) with a p value of less than 0.05 considered significant.

Table 3 contains all the correlation values and test retest reliability and internal consistency values (Crombach alpha). The Tonsil Grade and ANR show the Spearman correlation coefficient.

Table 2: Reliability and validity of each OSA-18 item

OSA-18	**Consistency**	**Test-Retest (p-value)**	**Tonsils grade**	**Adenoid nasopharyngeal ratio (adenoid size)**
OSA – 18 total scores.	0.70	0.99 (<0.001)	0.21*	0.10
Sleep disturbance				
Loud snoring	0.74	0.79 (<0.001)	0.03	-0.02
Breath holding/pauses	0.75	0.78 (<0.001)	0.01	-0.10
Choking or gasping	0.75	0.69 (<0.001)	0.10	0.13
Fragmented sleep	0.74	0.64 (<0.001)	0.05	0.13

Physical symptoms				
Mouth Breathing	0.74	0.76 (<0.001)	0.08	0.11
Frequent colds or upper respiratory infections	0.76	0.76 (<0.001)	-0.06	0.06
Nasal discharge or runny nose	0.76	0.72 (<0.001)	0.03	0.10
Difficulty swallowing	0.74	0.74 (<0.001)	0.07	-0.06
Emotional symptoms				
Mood swings or tantrums	0.75	0.79 (<0.001)	0.18	0.10
Aggression/hyperactivity	0.74	0.76 (<0.001)	0.20 *	0.06
Discipline problems	0.76	0.83 (<0.001)	0.22*	0.21*
Daytime function				
Daytime sleepiness	0.75	0.80 (<0.001)	0.07	0.32*
Poor attention span or concentration	0.76	0.84 (<0.001)	0.05	0.19
Difficulty getting up in the morning	0.76	0.77 (<0.001)	0.06	0.09

Caregiver concerns				
Caregiver worried over child health	0.73	0.78 (<0.001)	0.09	-0.11
Caregiver concerned not enough air	0.74	0.72 (<0.001)	0.19	-0.13
Caregiver missed daily activities	0.74	0.83 (<0.001)	-0.03	-0.20*
Caregiver frustrated	0.73	0.87 (<0.001)	0.24*	-0.22*

KEY: *- segments that show a significant correlation (> r=0.20) coefficient when compared to Tonsil Size and Adenoid size.

2. The OSA-scores measurements

The average total OSA – 18 score in the patients at first test was 79.35 (standard deviation of 13.75; ranging from, 47 to 112), during retest it was 79.17 (standard deviation of 13.58) and after the operation it dropped to 22.20 (standard deviation of 6.58). The OSA-18 scores were distributed as follows during the pre-operative phase of the study: 9.33% (n=7) had a small impact in health related quality of life, 44.00% (n=33) had a medium impact on health related quality of life while 46.67% (n=35) had a severe impact on health related quality of life. In the post-operative phase of the study, all the 75 patients were graded as experiencing small impact on health related quality of life due to adenotonsillar hypertrophy.

There is very little evidence (p=0.5091) against the hypothesis that there is a difference in average scores during the test and the retest phase. However, there was very strong evidence against the hypothesis that the test and the post-operative scores have a similar mean scores (p<0.0001). This therefore means that there was a significant difference in OSA scores pre and post operation. Table 2 shows the mean scores (standard deviation in brackets) and a p value of the paired t test between the test and the post-operative scores.

Table 3: The quality of life questionnaire mean scores and respective comparison.

OSA-18	**Test scores**	**Retest scores**	**Post-operative scores**	**p-value**
OSA – 18 total scores.	79.35 (13.75)	79.17 (13.58)	22.20 (6.58)	<0.0001
Sleep disturbance	21.87 (4.26)	22.04 (4.38)	4.91 (2.52)	<0.0001
Loud snoring	5.90 (1.24)	5.85 (1.25)	1.36 (0.85)	<0.0001
Breath holding/pauses	5.49 (1.52)	5.59 (1.48)	1.19 (0.67)	<0.0001
Choking or gasping	4.88 (1.87)	5.09 (1.78)	1.15 (0.59)	<0.0001
Fragmented sleep	5.59 (1.56)	5.51 (1.60)	1.21 (0.72)	<0.0001
Physical symptoms	20.75 (3.93)	21.15 (3.60)	5.12 (2.18)	<0.0001
Mouth Breathing	6.04 (1.28)	5.96 (1.39)	1.21 (0.55)	<0.0001
Frequent colds or upper respiratory infections	5.64 (1.24)	5.80 (1.05)	1.36 (0.82)	<0.0001
Nasal discharge or runny nose	4.91 (1.80)	5.19 (1.52)	1.41 (1.03)	<0.0001

Difficulty swallowing	4.16 (2.11)	4.20 (2.11)	1.13 (0.53)	<0.0001
Emotional symptoms	8.67 (5.06)	8.25 (5.28)	4.04 (2.13)	<0.0001
Mood swings or tantrums	3.43 (2.17)	3.20 (2.15)	1.52 (0.99)	<0.0001
Aggression/hyperactivity	3.25 (2.29)	3.05 (2.22)	1.35 (1.01)	<0.0001
Discipline problems	1.99 (1.61)	2.00 (1.71)	1.17 (0.60)	<0.0001
Daytime function	8.67 (4.21)	8.50 (4.71)	3.64 (1.36)	<0.0001
Daytime sleepiness	2.71 (2.02)	2.81 (2.20)	1.07 (0.38)	<0.0001
Poor attention span or concentration	2.39 (1.82)	2.37 (1.89)	1.33 (0.86)	<0.0001
Difficulty getting up in the morning	3.57 (2.46)	3.32 (2.39)	1.24 (0.84)	<0.0001
Caregiver concerns	19.40 (7.18)	19.23 (7.38)	4.49 (1.59)	<0.0001
Caregiver worried over child health	4.97 (2.06)	4.93 (2.15)	1.24 (0.88)	<0.0001
Caregiver concerned not enough air	5.35 (1.94)	5.09 (1.98)	1.12 (0.68)	<0.0001
Caregiver missed daily activities	4.64 (2.23)	4.61 (2.12)	1.09 (0.44)	<0.0001
Caregiver frustrated	4.44 (2.30)	4.59 (2.28)	1.04 (0.26)	<0.0001

3. The diagnostic outcome measures

The adenoid nasopharyngeal ratio (adenoid size) had a mean value of 0.90 with a standard deviation of 0.05 and ranging from 0.64 to 0.98. Only three patents had an adenoid nasopharyngeal ratio of less than 0.80.

The most common diagnosis was ATH with 77.33% (n=58) being diagnosed as having ATH. Consequently, the most common operation was ASTS having the same proportion (77.33%, n=58). A majority of the patients had a tonsil grade of 3 (62.67%, n= 47) while a minority had grade 4 tonsils (6.67%, n=5). It is important to note that there was very little evidence of difference in scores between those diagnosed with ATH compared to those diagnosed with AH and CRT (p-value = 0.1341). This could probably be as a result of the small sample of patients who were diagnosed with AH and CRT (a total of 17) as compared to those diagnosed with ATH. Similar results were found with regards to operation. Table 3 shows the distribution of the operation, diagnosis and tonsil grade.

It is important to note that a majority of the patients had enlarged tonsils (69.33%, n=52) while 30.67% (n=23) did not have them. (See figure 2)

Table 2: Distribution of diagnosis, operation and tonsil grade

Diagnosis	**Frequency (Percentage)**
ATH	58 (77.33%)
AH	16 (21.33%)
TH	1 (1.33%)
Operation	
ASTS	58 (77.33%)
AS	16 (21.33%)

TS	1 (1.33%)
Tonsil Grade	
Grade 1	14 (18.67%)
Grade 2	9 (12.00%)
Grade 3	47 (62.67%)
Grade 4	5 (6.67%)

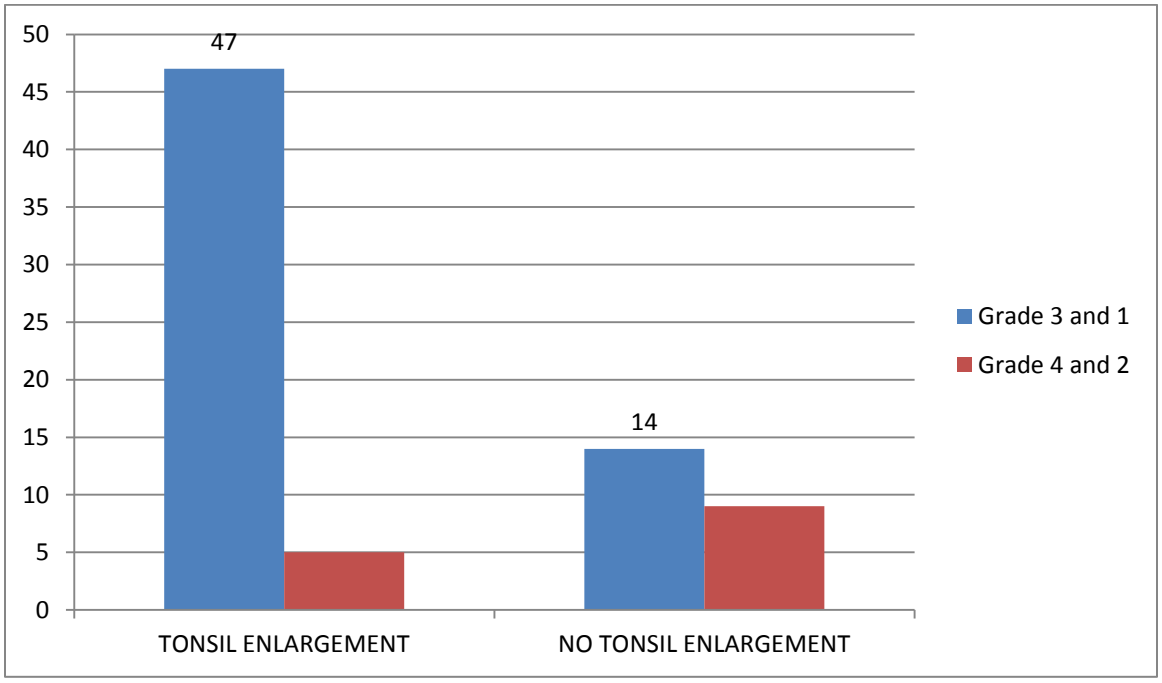


Figure 2: Proportion distribution of the patients by tonsil enlargement

9. DISCUSSION

According to the World Health Organisation, health is described as the state of complete physical, mental, and social well being and not merely the absence of disease or

infirmity.[65] Quality of life is therefore recognized as an important component of an individuals and in particular, a child's well being.

Sleep disturbed breathing due to various reasons contributes significantly towards the detriment of quality of life.[1] In children, adenoid and tonsillar hypertrophy have been found to be significant causes of SDB[7] and in our local set up, it has been found to be a significant indication for adenoidectomy and tonsillectomy.[8]

There have been several general and specific quality of life instruments that have been developed to assess the impact of SDB and to assess the response to treatment vis a vis quality of life. The Gold standard for diagnosing SDB remains the full night polysomnography. This is however largely expensive, time consuming and largely unavailable to most patients. Questionnaires have subsequently been developed for the purpose of assessing quality of life; OSD 6[50], Tonsil and Adenoid health instrument and the OSA 18[51]. The OSA 18 is the most widely studied.

In this study, we set out to translate and cross culturally adapt OSA 18 to the Kiswahili language and to assess impact of treatment, in this case adenoidectomy and tonsillectomy.

Cross cultural adaptation, reliability and validity analysis is important to ensure that validated English language instruments are found specific to a particular social and cultural structure. For this study, the Brislin method of cross cultural adaptation was

used.[35] The English OSA 18 was translated to Kiswahili by two independent translators. There was subsequently a refining of the translated version by the two translators to produce a uniform Kiswahili version. This was subsequently given to two independent Otolaryngologist for a back translation back to English. There was a meeting to finalise the back translated version. This was subsequently piloted on 18 patients from various ethnic backgrounds who were not part of the study to finalise the usable Kiswahili version of OSA 18. This was the standard that was used by the other cross adaptation studies.

The caretakers of our study subjects filled in a questionnaire that assessed for symptoms of sleep disordered breathing. The caretakers of the study subjects; children with adenoid and tonsillar enlargement were then taken through a researcher administered answering of the Kiswahili OSA 18 at the point of contact in the clinic. The retest was then done 5-7 days later just before their surgeries to assess the test- retest and total reliability factor for our study. Our subject scores were then assessed against objective parameters; adenoid size as per the adenoid nasopharyngeal ratio on a lateral soft tissue radiograph of the post nasal space and tonsil size on the basis of clinical assessment. Given the absence of polysomnography in our set up, these were used to assess consruct validity of our questionnaire. Franco et al and Kang et al in their studies in the original OSA 18 and in the Chinese versions respectively assessed the correlation coeffecients of Tonsil grade and adenoid size in addition to AHI from polysomnography to assess validity.

The OSA 18 was then filled in again 4 weeks after adenoidectomy and tonsillectomy. This was to assess the variation in scores given the intervention and thus the impact on the quality of life.

The internal consistency coefficient for our study; Crombachs alpha ranged from 0.70 to 0.76 showing good test – retest reliability and good internal consistency. This was in line with other studies: Portugese[59] (0.821), Greek[60] (0.85 – 0.946), Chinese/Taiwanese (0.70)[67], Thai[61] (0.77). With an acceptable range of o.70 to 0.95[36] the reliability was found to be sufficient.

Construct validity for our study was assessed using the adenoid nasopharyngeal ratio as a measure of adenoid size and tonsil size as adjucts for polysomnography (which still remains the gold standard) given its unavailability. These were also used in the original study by Franco et al[43] and also by Kang[67] for the validation of the Chinese version of OSA 18. They also assessed the correlation coefficient using overnight polysomnography. The correlation coefficient vis a vis the polysomnograph was noted to be at Spearmon rank correlation r = 0.43 for the original study[43] ,r =0.48 for the Thai version[54] , r=0.40 for the Chinese version[67] . this showed a moderate correlation . Concerning the relation with tonsil grade, the original study found a rank correlation coefficient factor r=0.29 . Kang found a correlation coefficient of 0.17 for the tonsil grade. This related to the total correlation coefficient for tonsil grading in our study of r = 0.21. With a coefficient factor of > 0.20 considered satisfactory. Adenoid correlation was

found to be at r = 0.45 for the original OSA 18 version and r = 0.16 for the Chinese version. Our study had a coefficient of r = 0.10.

Important to note is that Franco et al in their original study assessed adenoid size using fibre optic nasopharyngeal endoscopy assigning a grade on the basis of the percentage of choanal obstruction; 1+(0-25%), 2+ (26 -50%), 3+(51-75%), 4+ (76- 100%)[50]. Our study utilized adenoid nasophayngeal ratio based on lateral soft tissue post nasal space radiograph. As shown by Fujioka[64], the significant level was taken to be an adenoid nasopharyngeal ratio of > 0.80. In our study ,only 4% of our study subjects had an ANR of less than 0.80. The mean value was found to be 0.90. It was unclear whether the method of adenoid size assessment had a significant determinable effect on the eventual correlation coeffecients as seen in our study compared with the original. Certain studies have indicated a preference for fibre optic nasoendoscopy compared with radiography[66] citing an underestimation when using radiographs. In our study, 69% of our study subjects were found to have enlarged tonsils ;grade 3 and 4 (47 and 5 respectively). There is very little evidence (p=0.5091) against the hypothesis that there is a difference in average scores during the test and the retest phase. However, there was very strong evidence against the hypothesis that the test and the post-operative scores have a similar mean scores (p<0.0001). This therefore means that there was a significant difference in OSA scores pre and post operation.

Concerning the scores seen on the OSA 18 preoperative scores, of the five subsections the section on Sleep disturbance had the highest scores followed by physical symptoms and caregiver concerns. Emotional symptoms and daytime function were noted to have

the lowest scores. This was similar to the findings in the Greek[60] and Portugese[59] versions. In the Thai[61] and Chinese[67] populations, however, it was noted that the section on caregiver concerns had the highest scores followed by sleep disturbance and physical symptoms. According to Kang (Chinese) , this reflected the way culture of parenting in the Taiwanese population. He also indicated a selection bias as being a clinic based study,those bringing their children showed heightened concern .[66]Emotional symptoms and daytime function still formed the least scores. . In our study most parents admitted that due to their children being at school or them at work, this did not allow for truly accurate scoring of daytime functionality.

In terms of impact of quality of life, 9.33%(n=7) had a small impact on the quality of life. 44.00% (n=33) had a moderate impact on the quality of life and 46.67% (n=37) had a severe impact on the Quality of Life. The mean preoperative score in our study was noted to be 79.17 (+/- 13.58). The Chinese had a mean of 71.05 +/-16.77. The Thai had a mean score of 66.7 whilst the Greek OSA 18 had a mean of 67.13 +/- 15.27.

It was noted that whilst the Chinese OSA 18 showed higher scores in patients with severe OSA compared to mild, the values were not noted to be statistically significant. In the study by Mitchell, it was found that some children with severe OSA actually had better score compared to some with mild ones. These findings confirm the findings by Conatantin that whilst the OSA 18 is good at assessing the quality of life, its OSAS diagnostic capabilities are limited.[51,55,64]

In assessing quality of life following adenoid and tonsilar surgery, the greatest changes were seen in sections of sleep disturbance, physical symptoms, caregiver concern, daytime function then emotional symptoms respectively. There was no noted significant difference noted between patients with adenotonsilar enlargement and those with adenoid hypertrophy alone. This may be due to the discrepancy in the sample size of the adenotonsilar patients (n= 58) and the adenoid hypertrophy patients (n=16). This may thus lend itself to further studies with a larger and more comparative sample size. The mean postoperative score was found to be 22.20 (+/- 6.58). The changes noted were seen to be significant and was found to relate to previous QOL assessment studies by Sohn, Mitchell and Tran for the short term [55,56,58] (1 to 3 months postoperatively) and Mitchel and Flanary for the long term[54,57] (6 and 18 months). Whilst there was noted to be a comparatively slight difference in short term post operative measures (1- 3 months); 20-36, with long term (6-18 months); 32- 40.9, this was not found to be statistically significant in a meta analysis by Christina et al[59].

In terms of demographics, all the caregivers in our study spoke 3 languages; English, Kiswahili and their mother tongue. This proved to be advantageous. It was noted that they were more comfortable in Kiswahili compared to English. Majority of our caregivers; 40%(n=30) had a secondary level education followed by primary; 22.67%(n=17), college ,18.67%(n=14), university 8%(n=6). Mothers formed 90.67% of the caretakers interviewed.

10. LIMITATIONS

There were several limitations noted in our study. In the domain of daytime function, it was noted that most parents did not spend time with their children throughout the day due to either the children being in school or the parents being at work . This may have led to some discrepancy in the scores of this domain. Kiswahili like most ethnic African languages is limited in its description of emotional disturbance disorders and hence there was noted limitation in answering the emotional disturbance segment. This may have led to the low change in scores.

The absence of a polysomnograph posed some problems as pointed above; an inability to compare scores with severity of OSA. It also did not allow for assessment of cutoffs for OSA as demonstrated in other studies. The discrepancy in the number of patients with adenoid hypertrophy alone compared to those with adenotonsillar disease did not allow for comparisons in score between the two subgroups.

11. CONCLUSION

The Kiswahili version of OSA 18 was found to good reliability, internal consistency . The validity was found to be satisfactory. There was significant impact on quality of life in the children with adenoid and tonsillar hypertrophy with the largest percentage exhibiting severe impact on Quality of life preoperatively. Tonsillectomy and

adenoidectomy resulted in a significant improvement in the quality of life with all the patients showing drastically reduced scores. The segment on Sleep Disturbance was affected the most preoperatively by adenoid and tonsil hypertrophy. This same segment had the greatest improvement following adenoid and tonsillar surgery. The Kiswahili OSA 18 can be used for assessing impact on Quality of life in children with sleep disturbed breathing due to adenoid and tonsil disease in our clinical set up.

12. RECOMMENDATIONS

A study with a larger sample size and equal subject to compare the impact on quality of life in patients with adenoid hypertrophy and in patients with both adenoid and tonsillar hypertrophy.

Despite Kiswahili being a language used in East Africa, it varies in accents (Lafudhi) among various regions and cultural differences exist from one country to another hence cross cultural adaptation may be necessary in other countries.

13. CONFLICT OF INTEREST

None to declare. The study was self funded.

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15. FINAL KISWAHILI OSA 18

UCHUNGUZI KUHUSU UBORA WA MAISHA (OSA-18)

	Hakuna wakati hata mmoja	Nadra kwa wakati huo	Kiasi kidogo sana cha wakati huo.	Sehemu ndogo ya wakati huo.	Angalau sehemu kubwa kiasi ya wakati huo .	Mara nyingi	Kila wakati .
<u>Usumbufu wakati wa kulala</u>: **Katika muda wa majuma manne yaliyopita ni mara ngapi mwanao amekuwa :**							
Anakoroma kwa sauti ya juu?	1	2	3	4	5	6	7
Anazuilia pumzi, ama anakatiza katiza pumzi anapopumua usiku?	1	2	3	4	5	6	7
Anasakamwa ama kutoa sauti za ishara ya kukosa hewa anapo lala?	1	2	3	4	5	6	7
Ana usumbufu anapo lala ama kuamka amka kila wakati?	1	2	3	4	5	6	7
<u>Dalili mwilini</u>: Katika muda wa majuma manne yaliyopita ni mara ngapi mwanao amekuwa na:							
Visa vya kupumua kutumia mdomo kutokana na kufungika kwa mapua?	1	2	3	4	5	6	7

Homa ya mafua, ama maambukizi katika sehemu ya mapua na koo?	1	2	3	4	5	6	7
Tatizo la kutokwa na makamasi?	1	2	3	4	5	6	7
Ugumu wa kumeza?	1	2	3	4	5	6	7
Dalili za kihisia: Katika muda wa majuma manne yaliyopita, ni mara ngapi mwanao amekuwa na:							
Mabadiliko ya mara kwa mara ya kihisia au vipindi vya hasira?	1	2	3	4	5	6	7
Tabia ya kukasirika kupita kiasi bila sababu au tabia ya kutotulia?	1	2	3	4	5	6	7
Amekuwa na tatizo la ukosefu wa nidhamu?	1	2	3	4	5	6	7
Utendakazi nyakati za mchana: Katika muda wa majuma manne yaliyopita, ni mara ngapi mwanao amekuwa na:							
Shida ya kulala kupita kiasi nyakati za mchana?	1	2	3	4	5	6	7
Tatizo la kufuatilia jambo kwa umakini ama kutekeleza jambo kikamilfu?	1	2	3	4	5	6	7
Shida ya kuamka kutoka usingizini asubuhi?	1	2	3	4	5	6	7
Wasiwasi wa mlezi: Katika muda wa majuma manne yaliyopita ni mara ngapi mwanao:							
Amekufanya kuhofia hali yake ya kiafya kwa jumla?	1	2	3	4	5	6	7
Amekufanya uwe na wasiwasi kuwa hapati hewa ya kutosha?	1	2	3	4	5	6	7
Ametatiza uwezo wako wa kutekeleza majukumu yako ya kila siku ?	1	2	3	4	5	6	7
Amekuweka katika hali ya kutojua cha kufanya?	1	2	3	4	5	6	7

Jumulisha alama: ____

0-60 = Madhara madogo kwa ubora wa maisha kiafya

60-80 = Madhara ya kadri kwa ubora wa maisha kiafya

80+ = Madhara makubwa kwa ubora wa maisha kiafya

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16. APPENDIX 1: CONSENT EXPLANATION AND FORM

1. CONSENT EXPLANATION:

My name is Dr Stephen Warui. I am the principal researcher in this study. The study has been approved by the KNH/UON Ethics and Research Committee.

I am conducting a study amongst patients with adenoid and tonsillar hypertrophy to determine their quality of life using a Kiswahili version of OSA 18. This is a validated questionnaire used to assess the quality of life of patients who have sleep disordered breathing due to various conditions, adenoid and tosil hypertrophy being one of them.

OSA 18 is used to assess quality of life in children with adenotonsillar hypertrophy and to determine improvements in quality of life following various intervention measures.

The OSA 18 questionnaire is currently in use in the English version. Kiswahili is our national language and understood by a majority of the population.

The aim of this study is to develop a Kiswahili version for the same and validate its usefulness in determining the Quality of Life in children with sleep disorders brought about by adenoid and tonsil hypertrophy.

The Study will entail you; the child's caretaker to respond to the Kiswahili version of OSA 18 questionnaire at the point of recruitment into the study.(One week before your assigned booking for surgery) Your biodata and social data will be taken at the same sitting. The principal researcher will then do a physical examination.

You will then be requested to respond to the Kiswahili version again after one week. This will be just before your adenoid and/or tonsil surgery. You will again be required to respond to the Kiswahili OSA 18 one month after surgery.

The first two sets of responses will then be analysed to determine the validity of the instrument. The third post operative response will be used to assess and compare quality of life before and after adenoid and tonsil surgery.

Are there any risks involved?

There are no known risks anticipated in the participation of you and your child in this study.

Is there any penalty for refusing to participate in the study?

No, there are no penalties and the patient will receive the same treatment expected for adenotonsillar disease.

What benefits will I get for participating in the study?

There will be no immediate direct benefits to you and your child. The study will however help doctors monitor their patients and their response to treatment modalities in a more accessible manner and language.

What about confidentiality?

All the information that we obtain will be kept confidential.

Are there any extra costs involved?

There are no extra costs involved in the participation in this study. The patient will however be subject to any standard fees charged by the Kenyatta National Hospital as part of their management.

Are you satisfied with the information provided?

In case of any questions or inquiries, contact the following:

A. **Principal Investigator:**

Dr. Stephen Warui,
Department of Surgery,
College of Health Sciences,
University of Nairobi.
P.O. BOX 2134-00100 Nairobi.
Phone number:0727173493
Email: wandindi12@gmail.com.

B. **Supervisors:**

1. Dr. Joyce Aswani,
Consultant ENT- Head and Neck Surgeon,
Senior Lecturer, Department of Surgery,
College of Health Sciences,
University of Nairobi.

2. Dr. Musa Kipingor,
Consultant ENT Surgeon,
Kenyatta National Hospital,
Nairobi.

C. The Chairman, KNH-UON Ethics and Research Committee,
Kenyatta National Hospital, Nairobi

If you are satisfied with the explanation, kindly complete and sign the attached consent form.

2. CONSENT FORM

I…….……..……IDNo……

……of…… do hereby consent Mr/Mrs/Master/Miss/Self ……. to be included in this study on "Validation of a Kiswahili version of OSA 18 Quality of Life questionnaire in children with adenotonsillar hypertrophy related sleep disordered breathing". The nature of the study has been fully explained to me by Dr……. I have not been promised any material gain to participate.

Signed (Patient/parent/guardian) …….

Date…….

Signed (Doctor) …….

Date ……...

For any further clarification, contact any of the following:

Principal Investigator:

Dr. Stephen Warui

Department of Surgery,

College of Health Sciences,

P.O. Box 2134-00100 Nairobi.

Tel: 0727173493

Email: wandindi12@gmail.com

Supervisor:

Dr. Joyce Aswani

Department of Surgery,

College of Health Sciences,

P.O. Box 19676 – 00202, Nairobi.

Tel: 0722814483

The Chairman,

KNH/UON Ethical and Research Committee,

Kenyatta National Hospital

Tel: 2726300 – 9 Ext. 44355

17. KIAMBATISHO: MAELEZO YA UTAFITI NA KIBALI CHA KUSHIRIKI

1. MAELEZO YA UTAFITI:

Jina langu ni Dk Stephen Warui. Mimi ndiye mtafiti mkuu wa utafiti huu.Utafiti wenyewe umeithinishwa na hospitali kuu ya Kenyatta na kamati ya madili na utafiti katika chuo kikuu cha Nairobi.Ninaendesha utafiti miongoni mwa wagonjwa wa findo la kooni kubaini dhamana yao ya maisha kutumia toleo la Kiswahili la OSA 18. Hili ni dodoso la maswali lililoidhinishwa kutumiwa katika kubaini dhamana ya maisha kwa wagonjwa walio na matatizo ya kutopata uzingizi na kupumua kutokana na hali mbalimbali findo la kooni iki wa moja wapo. Kigezo cha OSA 18 kinatumiwa kubaini dhamana ya maisha kwa watoto walio na matatizo ya kutopata uzingizi na mauzi ili kubaini jisni ya kuimarisha maisha yao kwa kutumia mbinu mbali mbali.Toleo la OSA 18 la maswali kwa sasa linatumiwa kwenye lugha ya kingereza . Kiswahili ndio lugha yetu ya kitaiafa na inaeleweka na watu wengi miongoni mwa jamii.

Somo hili linalenga kukuza toleo la Kiswahili la OSA 18 kwa minajili ya hilo na kuidhinisha matumizi yake katika kubaini kiwango cha hali ya maisha miongoni mwa watoto walio na mattaizo ya uzingizi yanayo letwa na findo na maumivu ya mwilini.

Utaifiti huu utakuhitaji wewe unayemuhudumia motto kulijaza toleo la Kiswahili la OSA 18 la maswali wakati utakapokuwa ukijiunga na somo (mwezi,wiki au siku mmoja kabla ya tarehe uliyopewa ya upasuaji) linalohusu utafiti huu . Maelezo yako ya kuzaliwa na yale ya kijamii yanayo kuhusu yatachukuliwa wakati wa kikao hicho.

Utahitajika kujibu maswali yanayohusu toleo hilo la Kiswahili. Tena baada ya mwezi,wiki au siku moja kabla ya upasuaji wako wa findo.Utahitajika kulijaza toleo la OSA 18 kwa mara ya tatu mwezi mmoja baada ya upasuaji.

Aina mbili za kwanza za majibu zitachunguzwa kubaini uhakika wa kifaa hicho.Majibu ya tatu yatatumika kubaini tofauti ya dhamana ya maisha kabla na baada ya upasuaji.

Je kuna hatari zinazohusiana na utafiti huo?

Hadi kufikia sasa hakuna hatari zozote ambazo huenda zikakukumba wewe ama mwanao unaposhiriki kwenye utafiti huu.

Je kuna hatua yoyote ya kinidhamu itakayo chukuliwa iwapo utakosa kushiriki?

La, hakuna adhabu yoyote na mgonjwa, atapokea matibabu yale yanayohitajika iwapo mmoja ana ugua ugonjwa wa findo na maumivu mengine.

Je ni faida ipi nitakayopata kwa kushiriki kwenye utafiti huu ?

Hakuna faida za haraka ama zile za moja kwa moja utakayopata ama mwanao.

. Hata hivyo utafiti huu utasaidia madakitari kufuatilia wagonjwa wao na jinsi wanavyopokea matibabu katika njia na lugha wanayofahamu vyema zaidi.

Je, kuhusu usiri?

Maelezo yote yatakayopatikana yatawekwa kama siri .

Je kuna gharama zaidi zinazohitajika?

Hakuna gharama inayohusishwa katika kushiriki kwenye utafiti huu. Mgonjwa hata hivyo atahitajika kulipa ada zozote ambazo zinalipwa na wagonjwa katika hoospitali kuu ya Kenyatta kama sehemu ya kufuatilia kwao.

Je umeridhika na maelezo yaliyotolewa?

Iwapo una swali ama dukuduku wasiliana na wafuatao:

A. Mchunguzi mkuu:

Dr Stephen Warui,
Idara ya Upasuaji,
Chuo cha Sayansi ya Afya,
Chuo kikuu cha Nairobi.
P.O. Box 2134-00100 Nairobi.
Nambariya simu:0727173493
Baruapepe: wandindi12@gmail.com.

B. Wasimamizi:

1. Dr Joyce Aswani,
Mshauri ENT- Head and Neck Surgeon,
Mhadhiri mkuu ,Idara ya upasuaji,
Chuo cha Sayansi yaAfya ,
Chuo kikuu cha Nairobi.
Anwani: 19676-00202 Nairobi
Simu:0722814483

2. Dk Musa Kipingor,

Mshauri ENT-Head and Neck Surgeon,

Hospitali kuu ya Kenyatta,

Nairobi.

Simu:0722749196

C. **Mwenyekiti ,**

Kamati ya utafiti na maadili katika hospitali kuu ya Kenyatta na chuo kikuu cha Nairobi.

Hospitali kuu ya Kenyatta,

Nairobi.

Simu:020-2726300

Iwapo umeridhika na maelezo yaliyotolewa ,tafadhili kamilisha na utie saini fomu ya kukubali hilo.

2. KIBALI CHA UTAFITI

Mimi……..……..……..Kitambulisho Nambari…….kutoka……n akubalimimi/mwanangu/ninayemsimamia…… ……. Kuhusishwa katika utafiti wa "kubaini dhamana ya maisha katika watoto wenye shida za usingizi kwa sababu ya findo ya koo kupitia toleo la Kiswahili la OSA 18" ambao nimeelezewa kwa makini na Daktari…….

. Mimi sijaahidiwa chochote cha kunifaidi kwa kushiriki.

SahihiyaMgonjwa/Mzazi/Msimamizi…….

Tarehe……..…….

Sahihi ya Daktari …….

Tarehe ……...

Ikiwa unahitaji maelezo zaidi kuhusu huu utafiti, unaweza kuwasiliana na wafuatao:

Mtafiti Mkuu:

Daktari Stephen Warui

Anwani: 2134-00100, Nairobi

Simu:0727173493

Barua pepe: wandindi12@gmail.com

MsimamiziMkuu

Daktari. Joyce Aswani,

Idara ya upasuaji,

Chuo Kikuu cha Nairobi.

Sanduku la Posta 19676 – 00202, Nairobi.

Simu: 0722814483

Baruapepe: joyceaswani@hotmail.com

Mwenyekiti

KNH/UON Ethical and Research Committee,

Hospitali ya kitaifa ya Kenyatta.

Simu: 2726300 – 9 Ext. 44355.

18. APPENDIX 2: QUALITY OF LIFE SURVEY (OSA-18)

	None of the time	Hardly any of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	A lot of the time
SleepDisturbance: During the past 4 weeks, how often has your child had:							
Loud snoring?	1	2	3	4	5	6	7
Breath holding spells or pauses in breathing at night?	1	2	3	4	5	6	7
Choking or making gasping sounds while asleep?	1	2	3	4	5	6	7
Restless sleep or frequent awakening?	1	2	3	4	5	6	7
PhysicalSymptoms: During the past 4 weeks, how often has your child had:							
Mouth breathing because of nasal obstruction?	1	2	3	4	5	6	7
Frequent colds or upper respiratory infections?	1	2	3	4	5	6	7
Nasal discharge or runny nose?	1	2	3	4	5	6	7
Difficultyswallowing?	1	2	3	4	5	6	7
Emotional Symptoms: During the past 4weeks,how often has your child had:							
Mood swings or temper tantrums?	1	2	3	4	5	6	7
Aggressive or hyperactive behavior?	1	2	3	4	5	6	7
Discipline problems?	1	2	3	4	5	6	7
Daytime Function: During the past 4 weeks, how often has your child had:							

Excessive daytime sleepiness?	1	2	3	4	5	6	7
Poor attention span or concentration?	1	2	3	4	5	6	7
Difficulty getting up in the morning?	1	2	3	4	5	6	7
Caregiver Concerns: During the past 4 weeks, how often has your child :							
Caused you to worry about your child's general health?	1	2	3	4	5	6	7
Created concern that your child is not getting enough air?	1	2	3	4	5	6	7
Interfered with your ability to perform daily activities?	1	2	3	4	5	6	7
Made you frustrated?	1	2	3	4	5	6	7

Total Score: _____

0-60=Small impact on health-related quality of life

60-80=Moderate impact on health-related quality of life

80+=Severe impact on health-related quality of life

19. APPENDIX 4: PATIENT DEMOGRAPHIC DATA

STUDY IDENTIFICATION NUMBER:……

IP NUMBER…….

AGE OF CHILD……SEX……

WEIGHT OF CHILD…… HEIGHT……

AGE OF CARETAKER……SEX……..

RELATIONSHIP WITH CHILD……

COUNTY OF RESIDENCE……

CARETAKER'S LEVEL OF EDUCATION……

LANGUAGES SPOKEN……

DATE OF ASSESSMENT……

SYMPTOMS

SYMPTOM	YES	NO
SNORING		
FREQUENT AROUSAL		
MOUTH BREATHING		
NOCTURNAL SWEATING		
DAYTIME SLEEPINESS		
RESTLESS SLEEP		

NASAL CONGESTION		

SIGNS

SIGN	YES	NO
TONSIL ENLARGEMENT		
TONSIL GRADE		
ENLARGED TURBINATES		

INVESTIGATIONS

ADENOID ENLARGEMENT ON RADIOGRAPH: YES…….. NO…….

ADENOID- NASOPHARYNGEAL RATIO:……