CLINICAL MANAGEMENT OF FOREIGN BODIES OF THE ESOPHAGUS AS SEEN AT THE KENYATTA NATIONAL HOSPITAL.

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A proposal for dissertation as partial fulfillment of requirements of the University of Nairobi, for the Award of the Degree of Masters in Medicine in Otorhinolaryngology, Head and Neck Surgery.

DECLARATION

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

DEDICATION

This dissertation is dedicated to my parents Mr and Mrs J. Ouyah, my siblings Dorothy, Frankline, Caroline and Vincent for their support. Many thanks to my wife Miriam Libutsi and my children Victor, Linda, Andrew and William for their encouragement and support throughout the study.

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APPROVAL

The proposal has been submitted in partial fulfillment of the degree of master of Medicine in Otorhinolaryngology, Head and Neck Surgery with our approval as supervisors.

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ABBREVIATIONS

A&E Accident and Emergency department

ANOVA Analysis Of Variance

CT Scan Computer tomography scan

EFB Esophageal Foreign Body

ENT Clinic Ear, Nose and Throat Clinic

FB Foreign body

FBI Foreign Body Impaction

GA General Anesthesia

GIT Gastrointestinal Tract

KNH Kenyatta National Hospital

MRI Magnetic Resonance Imaging

PACU Post Anesthesia Care Unit

SD Standard Deviation

SPSS Stastical Package for the Social Sciences

TEF Tracheoesophageal Fistula

U/S Scan Ultrasound Scan

ABSTRACT

Background:

Foreign bodies of the esophagus are common at the Kenyatta National Hospital with an increasing number of lithium disc batteries being seen. A local study showed two peak ages of patients with esophageal FBs, those below 6 years (59.3%) and adults at 23.7%.

In the United States, there are over 100 000 cases of esophageal FBs per year. In 80–90% of these cases, the FB passes spontaneously through the GIT while the remainders lodge in the esophagus and need to be removed.

Study objective: To determine the clinical presentation and management of FBs of the esophagus at the KNH.

Study design & setting: Hospital-based descriptive cross-sectional study, the setting being at the KNH A&E and ENT departments

Methodology: A total of 100 cases were recruited and a detailed history of the type of FB, presenting signs and symptoms, modes of management and complications were recorded.

Statistical Analysis:

Data analysis was conducted using SPSS (version 20). The bivariate analysis was based on calculation of Pearson's chi square test and statistical significance was based on a p value cut off of 0.05.

Significance of the study:

This study aimed at providing information on the local patterns of esophageal FBs, modes of management and complications.

Results

This study shows that the mean age of patients with FB esophagus is 6 years with a range of 9 months to 60 years. A large proportion of the patients are referrals (69%) and 31% of the patients presented directly to KNH. Coins form the largest proportion of FBs in the esophagus (77.2%), bones (9.9%), and lithium disc batteries (8.9%). A median duration of 24 hours is observed from ingestion to presentation with a higher proportion of the patients (32.7%) presenting after 2 days. Rigid esophagoscopy is used in 55% of the cases, Mackintosh laryngoscope and Magill forceps (44%) and flexible endoscopy (1%). Complications occur at a rate of 5% and lithium disc batteries are associated with the highest rates of complications (11.1%). Mortality occur at a rate of 1%.

Conclusion

This condition affects mainly the paediatric population with a mean age of 6 years. Coins and lithium disc batteries are common in the paediatric population, with bones being prevalent in adults. Lithium disc batteries cause the highest rates of complications and mortalities occur from the condition.

Recommendations

There should be proper disposal of the lithium disc batteries and a study on their long term complications is recommended.

1.0 BACKGROUND

1.1 INTRODUCTION

Globally FBs in the esophagus are a common occurrence affecting both children and adults. In the United States, more than 100,000 cases of foreign bodies in the esophagus are managed annually and 80 percent occur in children². Most of the foreign bodies that reach the gastrointestinal tract pass spontaneously and only 10 to 20 percent will require endoscopic removal, and less than 1 percent require surgical intervention². Although mortality from foreign body ingestion is extremely low, deaths have been reported⁴. Morbidity from foreign body ingestion is related to the various complications including weight loss or recurrent aspiration pneumonia ,mucosal damage leading to strictures, or erosion of the esophageal wall creating a fistula with the trachea or other nearby structures. Sharp objects may perforate the esophagus, and erosion into the aorta also has been reported, which can lead to mortalities⁹

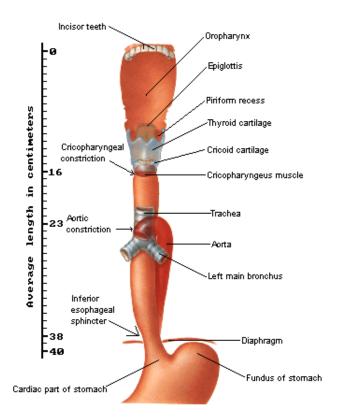
Locally and in the U.S, coins are the most common foreign bodies ingested by children. Other objects, including toy parts, magnets, batteries, safety pins, screws, marbles, bones and food boluses have been reported⁵

1.2 ANATOMY AND PHYSIOLOGY

The esophagus is a 25-cm long muscular tube that connects the pharynx to the stomach. The length of the esophagus at birth varies between 8 and 10 cm. At 5 years it measures 12cm and at 15 years it measures about 19 cm. It extends from the lower border of the cricoid cartilage (at the level of the sixth cervical vertebra) to the cardiac orifice of the stomach at the side of the body of the 11th thoracic vertebra. The upper limit in the newborn infant is found at the level of the fourth or fifth cervical vertebra, and the lower limit is at the level of the ninth thoracic vertebra.

The esophagus has been subdivided into 3 portions. These are the cervical portion, extending from the cricopharyngeus to the suprasternal notch, the thoracic portion extending from the suprasternal notch to the diaphragm and the abdominal portion extending from the diaphragm to the cardiac portion of the stomach. It's located in the posterior mediastinum and related to organs in this region. On the right side the esophagus is covered by the mediastinal part of the parietal pleura. Sharp objects may perforate this layer leading to mediastinitis. On the left side of the esophagus is the thoracic aorta. Erosion into the aorta caused by corrosive foreign bodies has been reported, causing life-threatening gastrointestinal bleeding⁹

Anterior to the esophagus, is the trachea and below the level of the tracheal bifurcation, are the right pulmonary artery and the left main bronchus. Longstanding foreign bodies may create a fistula with the trachea. The esophagus passes immediately posteriorly to the left atrium, separated from it only by pericardium. Other structures posterior to the esophagus include the thoracic duct, portions of the hemiazygos veins, the right posterior intercostal vessels, and, near the diaphragm, the thoracic aorta.



Courtesy of www.netterimages.com

Figure 1: Anatomy of the esophagus

The esophagus has 3 points of physiologic constrictions which are produced by the upper esophageal sphincter (cricopharyngeus muscle), the aortic arch and the left bronchus, and the lower esophageal sphincter. These can be seen in the diagram above. Esophageal foreign bodies tend to lodge in these areas of constrictions.

1.3 CLINICAL MANIFESTATIONS

Usually young children with esophageal foreign bodies are brought to medical attention by their parents because the ingestion was witnessed or reported to them⁷. Older children and adults may localize the sensation of something stuck to the neck or lower chest, suggesting irritation in the

upper or lower esophagus, respectively. Patients of any age may present with refusal of feeds or dysphagia, drooling, or respiratory symptoms including wheezing, stridor, or choking.

1.4 MANAGEMENT

A thorough history and physical examination are important in diagnosing an esophageal foreign body and to the prevention of complications¹⁰. The physical examination of the neck may reveal swelling, or crepitus, suggesting esophageal perforation has occurred. The chest examination may reveal inspiratory stridor or expiratory wheezing, suggesting a lodged esophageal foreign body with tracheal compression.

Imaging is important for all patients with suspected foreign body ingestion. The initial diagnostic test should be biplane radiographs (anteroposterior and lateral) of the neck, chest, and abdomen⁸. Flat objects (e.g., coins or disk batteries) usually orient in the coronal plane and appear as a circular object on an antero-posterior projection whereas objects lodged in the trachea tend to orient in the sagittal plane and are best seen in lateral projection. Plastic or wood, some thin metal objects, and many types of bones are not readily seen on plain films¹¹.

If the patient is symptomatic, or if the suspected foreign body has any dangerous characteristics (large >2 cm in width or long >5 cm in length, or sharp), or if the type of foreign body is not definitively known by the caretakers, then CT Scans with 3-dimensional reconstruction is done¹².MRI scans can be used for evaluation of radiolucent foreign bodies, but is contraindicated if any metallic foreign body is present.

Ultrasonography has been used to identify the location and nature of foreign bodies in the esophagus or stomach if appropriate expertise is available ¹³. Contrast studies e.g. barium contrast are avoided as they may obscure visualization of the FB on subsequent endoscopy. The contrast

may be aspirated if the esophagus is obstructed. Hence, endoscopy may be preferred over contrast even if radiographs are negative¹³.

Urgent intervention is indicated if warning signs are present. These include when the foreign body is sharp, long (>5 cm), and is in the esophagus or stomach, or when a disk battery is in the esophagus, or when the patient shows signs of airway compromise and when there is evidence of near-complete esophageal obstruction seen when patient cannot swallow secretions. Objects lodged for more than 24 hours or for an unknown duration should be removed promptly¹⁴. After this period, complications such as transmural erosion, perforation, and fistulae are more likely to occur. Complications are more likely if the foreign body is a sharp or pointed object, disk battery, non-radio-opaque, or located below the upper third of the esophagus.

1.5 TECHNIQUES FOR ESOPHAGEAL FOREIGN BODY REMOVAL

Various methods are used to remove esophageal foreign bodies. One of the commonest method used in the West is flexible endoscopy. In this technique the foreign body can be visualized directly and manipulated, and the surrounding gastrointestinal tract can be examined for potential complications¹⁵. This procedure is performed under conscious sedation or general anesthesia. It is helpful to practice grasping a duplicate of the foreign body using the retrieval tools before beginning the procedure.

Rigid endoscopy is another technique which utilizes a non-flexible channeled device that is introduced into the esophagus under general anesthesia. It is most useful for impacted sharp objects that are located in the proximal esophagus, at the level of the hypopharynx and cricopharyngeus muscle.

A mackintosh laryngoscope and Magill forceps can be used to extract foreign bodies impacted in the oropharynx or upper esophagus. An endotracheal tube is placed to protect the airway, and a mackintosh laryngoscope is used to gently open the esophagus and visualize the foreign body which is grasped and removed using a Magill forceps.

Bougienage (passage of a dilator) has been used to push objects into the stomach and it does not permit visualization of the esophagus and does not retrieve the foreign body. Therefore, it is most appropriate for foreign bodies that are very likely to pass beyond the stomach without complications, and in situations where there is a low risk of esophageal injury¹⁸.

A Foley catheter has also been used. A deflated Foley catheter is passed beyond the foreign body. The balloon is then inflated using a radio-opaque contrast dye, and the catheter is slowly drawn back under fluoroscopic guidance, to remove the foreign body through the mouth. The technique can be successful with proximal esophageal foreign bodies but may cause aspiration of the foreign body if it is inadvertently dragged into the trachea¹⁴.

1.6 APPROACHES FOR SPECIFIC TYPES OF FOREIGN BODIES

Globally coins are the most common foreign body ingested by children¹⁹. If a coin is visualized in the esophagus and the patient is asymptomatic, he can be observed for up to 24 hours after ingestion of the coin. In such patients, 20 to 30 percent of coins will pass into the stomach spontaneously during the observation period. Spontaneous passage is more common in older children and when coins are located in the distal third of the esophagus. The esophageal coin should be removed promptly if the patient is symptomatic or if the time of ingestion is not known. If the child is asymptomatic and the coin does not pass spontaneously by 24 hours after ingestion, it should be removed.

Lithium disc batteries are associated with significant morbidity, when lodged in the esophagus and thus are a medical emergency. In addition to direct pressure necrosis, contact of the flat esophageal wall with both poles of the battery conducts electricity, resulting in liquefaction necrosis and perforation of the esophagus. Retained batteries also can cause problems through leakage of caustic material e.g. heavy metal like mercury, silver, lithium, and a strong hydroxide of sodium or potassium²⁰.

Sharp-pointed objects e.g. straight pins, needles, and fish bones lodged in the esophagus represent a medical emergency because of a high risk of perforation and should be removed immediately. When lodged in the hypopharynx, they can cause a retropharyngeal abscess⁸. The risk of mucosal injury during retrieval of a sharp object can be minimized by orienting the object with the sharpend trailing during extraction and using a protector hood on the end of the endoscope.

Esophageal food impaction commonly impacted meat is the most common esophageal foreign body in adults and relatively rare in children. It presents as dysphagia beginning acutely while eating. Patients who are unable to swallow oral secretions require immediate attention and removal of the impaction. If the patient is comfortable and able to handle oral secretions, endoscopic intervention can be delayed, as many food impactions will pass spontaneously. However, intervention should not be delayed beyond 24 hours. The food bolus can be removed en bloc or in a piecemeal fashion. Once reduced in size, the bolus may be gently pushed into the stomach using the tip of the endoscope²².

1.7 COMPLICATIONS OF ESOPHAGEAL FOREIGN BODIES

Longstanding esophageal foreign bodies may cause weight loss or recurrent aspiration pneumonia, due to decreased caloric intake and poor handling of oral secretions, respectively. They also can damage the mucosa and lead to strictures, or erosion of the esophageal wall, creating a fistula with the trachea or other nearby structures. Sharp objects may perforate the esophagus, resulting in neck swelling, crepitus, mediastinitis or pneumomediastinum. Erosion into the aorta also has been reported, causing life-threatening gastrointestinal bleeding⁹

2.0 LITERATURE REVIEW

Foreign bodies in the esophagus are a common condition locally and globally and studies have been done to ascertain the incidence, modes of management and complications arising from the condition.

The types of FBs found in the esophagus are quite varied and this was shown by Arana A, et al⁸ who conducted a retrospective and found FBs to be the following in decreasing order of frequency, coins, toy parts, jewels, batteries, sharp materials such as needles and pins, fish and chicken bones, and "large" amounts of food. He found that 9% of these FBs were removed with a Magill forceps, 20% were removed with a magnet probe and endoscopic removal was performed in 25% of the cases. Locally a retrospective study by Oduor P showed that majority of the FBs seen, were metallic objects including coins which made up 67% of the cases, followed by meat and bones which made 28.3%, vegetable material constituted 4.1% and plastics made up 1.6%.¹

The location of FBs in the esophagus, is determined by various factors including the natural esophageal constrictions, the size and shape of the FB. Athanassiadi K, et al⁵ in a retrospective study showed that 57% of the FBs were located in the cervical esophagus, 26% were in the thoracic esophagus and 17% were at the cardioesophageal junction. The location, type of FB, and availability of expertise and equipment determines the mode of management. In a randomized prospective study by Waltzman ML, et al²³, a comparison was made between immediate endoscopic removal of esophageal FBs and observing the patients for a period of 24hrs—then followed by removal of the FB when necessary. The results—showed that 23% of the patients taken for immediate endoscopic removal had spontaneous passage of the FB as compared to 30% in the observation group. Similar findings were made by Sharieff GQ, et al²⁴in a retrospective study in which healthy patients with acute (less than 24 h) coin ingestions, were observed at home

with next-day follow-up. He also found that patients with acute esophageal coin ingestions may experience spontaneous coin passage.

Another comparison of the modes of management was done by Gmeiner D,et al¹⁶ where use of a flexible endoscope was compared to the use of a rigid endoscope. The study showed the success rate for foreign body removal was at 93.4% using the flexible endoscope and 95.2% using the rigid endoscope. These results are similar to those shown by Katsinelos P. et al³⁰ who did a study on endoscopic management of foreign body and food bolus impaction in the upper gastrointestinal tract. He found that the overall success rate for endoscopic management was 98.6% and that surgical removal of a foreign body was required in only 1.4% of the cases.

Other modes of management of FBs in the esophagus have been studied and Little DC,et al²⁵ analyzed 468 cases in a retrospective study which were managed using balloon extraction with fluoroscopy, and 80% of the objects were successfully and 8% were advanced into the stomach.Similarly,Janik JE,et al¹⁷conducted a retrospective review of 36 children who had upper esophageal coins extracted using a Magill forceps and found that all coins were removed without complication which was observed in 33 cases on the first attempt and 3cases on the second attempt. Though the sample size was small the study showed that the use of a Magill forceps minimizes instrumentation of the esophagus and is highly successful at removing coins lodged at or immediately below the level of the cricopharyngeus muscle.

Complications caused by FBs in the esophagus are a major cause of morbidity in the affected patients. In a prospective study, Peters NJ, et al²⁸ analyzed 7 cases of esophageal perforations due to foreign body ingestion and found the sites affected to be the cervical and thoracic esophagus. Two of these patients presented with subcutaneous emphysema and one patient had trachea-

esophageal fistula (TEF) after disc battery ingestion. Similarly, Ngan JH,et al²⁹conducted a prospective study on injuries arising from fish bone ingestion. They found that 1% of the cases had mucosal tears from triangular bones lodged in the hypopharynx and also found that prediction of the presence of fish bones by symptoms and radiograph was poor. The study showed that location of symptoms was useful in guiding the endoscopist to the site of lodgment and concluded that rigid laryngoesophagoscopy was the appropriate means of removing triangular bones lodged in the hypopharynx.

In addition, Shivakumar AM, et al²⁶ analyzed a total number of 104 cases and found that coins were the most frequent offending agents in children making 87.5% of the cases and retropharyngeal abscess as a complication was seen in 1.92% which was associated with ingestion of sharp FBs. Denney W, et al²⁷ did a 10-year retrospective analysis of foreign body and caustic ingestions showing that mucosal ulceration, seen in 30% of the cases, was related to a complaint of substernal pain and was related to duration of impaction and the unexpected finding of FB during chest radiograph. The study also found that esophageal FBs unexpectedly found on chest radiograph or known to be present greater than 72 hours were more likely to have esophageal ulceration.

Lithium disc batteries in the esophagus are an important cause of complications and Kimball SJ,et al²⁰ conducted a retrospective review of esophageal disc battery ingestions over a 10 year period. He analyzed 10 pediatric patients who had ingested disc battery which were lodged in the esophagus and found that 3 patients had minimal esophageal damage and 7 sustained severe esophageal damage which involved the muscularis layer. One patient in the latter group had an extensive injury that extended into the trachea resulting in a tracheoesophageal fistula and though

the sample size was small they concluded due to rapid and severe injury that occur following disc battery ingestion emergency endoscopic removal is necessary.

2.1 STUDY JUSTIFICATION

Foreign body impaction in the esophagus is common in the ENT department at KNH with an average of 25 cases seen and admitted on a monthly basis with a large proportion of these being referrals from other hospitals. In the recent years, new foreign bodies like lithium disc batteries have emerged. These are associated with certain complications including tracheosophageal fistulae, mediastinitis and esophageal strictures, which cause considerable morbidity to the affected patients. There was no current data available locally on these types of FBs.

This study aimed at providing insight into the types of FBs in the esophagus seen in KNH and the demographics of the patients involved. This information can be utilized in educating the public on the most appropriate preventive measures. In addition, the type of interventions can be adjusted according to the types of foreign bodies to minimize complications.

2.2 RESEARCH QUESTION

What are the types of foreign bodies and how are patients presenting with foreign body esophagus managed at The Kenyatta National Hospital?

2.3 OBJECTIVES

2.3.1 Broad objective

To determine the types, clinical presentation, and management of foreign bodies in the esophagus at the KNH

2.3.2 Specific objectives

1. To determine the demographic pattern including region of origin of pediatric and adult patients presenting with foreign bodies in the esophagus at the KNH A&E.

- 2. To determine the types of foreign bodies in the esophagus of pediatric and adult patients as seen at the KNH.
- 3. To determine the clinical presentation of the cases with esophageal FB in pediatric and adult patients as seen at the KNH.
- 4. To determine modes of management and outcomes of esophageal FB in patients during admission and inpatient stay at the KNH.
- 5. To determine complications caused by the FBs and the predisposing risk factors in patients admitted at the KNH.

3.0 METHODOLOGY

3.1 Study designs

This was a hospital based descriptive cross-sectional study, as all patients diagnosed or suspected to suffer from FB impaction in the esophagus and fulfill the inclusion criteria—were recruited at the A&E and followed up from—admission to the day of discharge. Any form of subsequent management provided to the patient while admitted at the KNH and complications arising from the FB were captured.

3.2 Study site

This study was undertaken at the KNH A&E department, ENT clinic, ENT wards and operating theatres. Patients were initially assessed at A&E and ENT clinic and radiological tests were requested for at this point and the patients were admitted for specific management. Patients were initially admitted to the ENT ward after being diagnosed with FB in the esophagus from where they were taken to theatre for removal of the FB under general anesthesia. Patients were then

returned to the ward postoperatively for monitoring and observation for any complication and were retained there until they fully recovered after which they were discharged home.

3.3 Study population

All patients both children and adults presenting with foreign bodies in the esophagus presenting at A&E and ENT department in KNH during the period of the study were recruited into the study.

3.4 Inclusion criteria

All patients both children and adults presenting with a history of suspected foreign body ingestion presenting at A&E and ENT department in KNH who or their parents /guardians consented or assented, were included in the study.

3.5 Exclusion criteria

Patients who declined to give consent for the study or whose parent/guardian declined to consent or assent to their participation in the study.

3.6 Sample size

Cochran's formula³¹ for calculating the sample was used.

$$n = \frac{NZ^2P(1-P)}{d^2(N-1) + Z^2P(1-P)}$$

N = population of patients attending KNH with FB in the esophagus is estimated at 25 to 30 per month. Based on this assumption and the projected duration of data collection for the current project a population size of 135 FB patients was used in this calculation.

P = Prevalence of FB in the esophagus was estimated at 50% to allow for the most conservative estimate of sample size

1-P = 1 minus the prevalence various patterns of FB in the esophagus

Z = Z statistic representing 95% level of confidence (1.96)

d = desired level of precision set to 5%

$$n = \frac{135 \times 1.96^2 \cdot 0.5(1 - 0.5)}{0.05^2 \cdot (135 - 1) + 1.96^2 \times 0.5(1 - 0.5)}$$

n = 100

3.7 Sampling procedure

Patients, both children and adults who presented to A&E and ENT departments at the KNH with a history of suspected foreign body in the esophagus or those observed to have swallowed a FB were informed about the study by the principal investigator. Parents or guardians of the affected children were informed about the study. Once the patient and the parent/guardian were agreeable to the study they were requested to consent or give assent to the study.

The study employed consecutive sampling involving recruiting each eligible patient until the desired sample size was achieved.

3.8 Data Collection

The patients and parents/guardians who consented to the study underwent a physical examination by the principal investigator and the findings were recorded in a preformed structured questionnaire. This was done in three stages:

Stage 1, Preoperative stage: the patient or the parent/guardian was taken through the consent explanation elaborating details of the study. If satisfied by the explanation and are agreeable, the patient or guardian signed the consent and the patient was recruited to participate in the study

Demographic data of the patient were taken and details about the type of FB taken and time of ingestion was recorded. The period from ingestion of the FB to presentation to A&E or ENT clinic at the KNH was recorded. The signs and symptoms which occurred after ingestion of the FB were recorded. Mode of investigation for the FB was recorded. Details of any initial management like forced feeding and subsequent referral was recorded.

Patients who were not taken to theatre and passed the FB spontaneously were captured at this stage.

Stage 2, Preoperative stage: an operative record questionnaire was provided for the surgeon to indicate the type of FB removed and the method used for removal intraoperatively. Details of the level at which the FB was found, any injuries to the esophagus observed intraoperatively and if a nasogastric tube (NGT) was placed were recorded in the questionnaire.

Stage 3, Postoperative stage: the number of days the patient was admitted in the ENT ward was recorded i.e. from the date of FB removal to the discharge date. Any complications arising from the FB in the esophagus was also captured in this stage.

3.9 Standard Operating Procedure

The Standard Operating Procedure for removal of esophageal FBs at KNH was observed for all the patients undergoing removal of the FB under general anesthesia(GA). All the patients were starved prior to the procedure and GA was given following the laid down protocol in KNH.

Reversal from the GA followed the protocol and all patients were observed in Post anesthesia Care Unit(PACU) before being transferred to the ENT ward.

3.10 Quality control

Patient selection, history taking, examination and assessment of the imaging modalities were done by the principal researcher to prevent observer bias. Data collection was conducted using procedures outlined in a standard operating procedure (SOP). The SOP contained details on codes to be used during data collection and standardization of medical and surgical terms that are commonly used in the study setting

The questionnaires were pretested before use and appropriate adjustments implemented. At the end of each interview or data abstraction the investigator inspected all the fields in the questionnaire to ensure data completeness and minimize missing data. A specific code (999) was used to identify truly missing information. A database for data was designed during the pilot phase and tested to ensure filters for minimizing data entry errors work as desired.

3.11 Data management and analysis

Data was collected using paper questionnaires and entered into Microsoft Excel worksheets before being transferred to SPSS (version 20) for analysis. Data cleaning was conducted in SPSS using functions for univariable analysis to produce frequency tables and summaries. The main outcome in the analysis was the percentage of patients with the leading clinical presentations of FB and the frequencies (percentages) reported for each of the main modalities of FB management. The demographics of patients presenting with foreign bodies were determined by calculating descriptive statistics including mean (SD) for continuous variables e.g. age and counts and percentages for categorical characteristics e.g. sex. Methods for univariate analysis of categorical

factors were used to calculate frequency (counts) and relative frequency (percentage) for objectives related to: types of FB in the esophagus seen at KNH, clinical presentation of cases, early indicators of complications and modes of management. The next stage of analysis used statistical inference to conduct bivariate analysis of association between (i) specific FBs and patient demographics, (ii) regional variation in types of esophageal FB, and (iii) both clinician and patient predisposing risk factors for FB complications. The bivariate analysis was based on cross tabulations and calculation of Pearson's chi square test for independence. The level of statistical significance was based on a p value cut off of 0.05.

Results are presented using frequencies and frequency distributions, cross-tabulations, pie charts and graphs.

3.12 Ethical consideration

The study was carried out only after approval by the KNH/UON ethics and research committee. The ethical committee approval number is P712/10/2016. Those recruited in the study were required to give informed consent or assent. The study was carried out after permission from the KNH administration. Confidentiality was maintained at all times and the results will be published in medical journals and presented in medical conferences. They may also be published in print or electronic media where applicable. There is no monetary gain by the researcher. The patient or parent/guardian reserved the right to withdraw from the research without victimization and the participant (patient) incurred no extra financial costs and the investigator has no conflict of interest.

4.0 RESULTS

Demographic patterns

This study shows that the mean age of patients presenting with FB esophagus is 6 years (SD±10.8) with a range of 9 months to 60 years. The most frequent age group affected is 2 to 4 years (43.6%). There is a slight peak in patients above 40 years (4%). The SD is +/- 10 years due to the skewed age distribution with a large proportion being below 6 years.

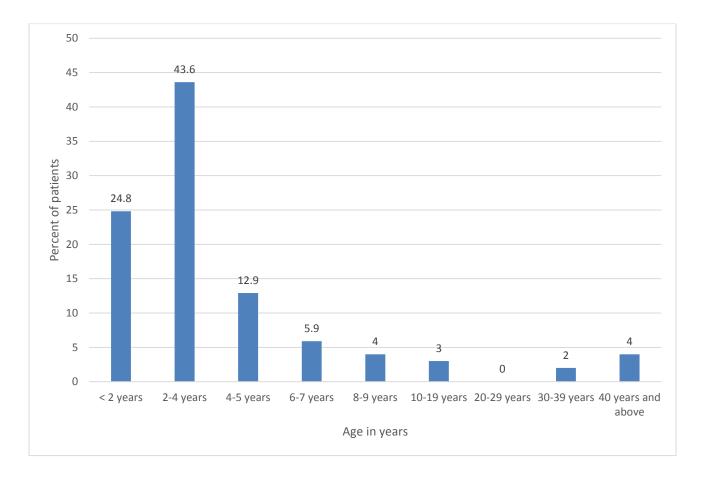


Figure 2: Age distribution of patients presenting with FBs of the esophagus in KNH

The numbers of the patients with esophageal FBs reduced with an increase in age hence the change in the age clusters for the patients above 10 years.

Sex distribution

The study shows that proportion of male patients presenting with FB esophagus is higher (61.4%) than that of female patients (38.6%) with a male to female ratio of 1.6:1.

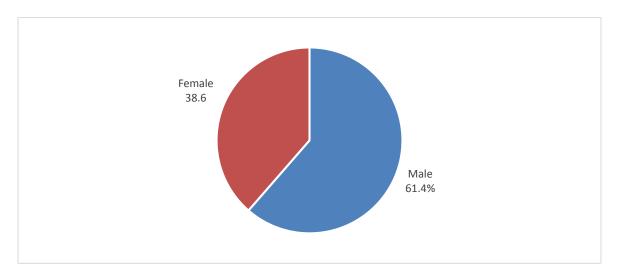


Figure 3: Sex distribution of patients with foreign bodies of the esophagus

Referrals

A higher proportion of the patients with foreign bodies in the esophagus present as referrals from other counties (69%) and 31% of the patients presented directly to KNH without going through another medical facility.

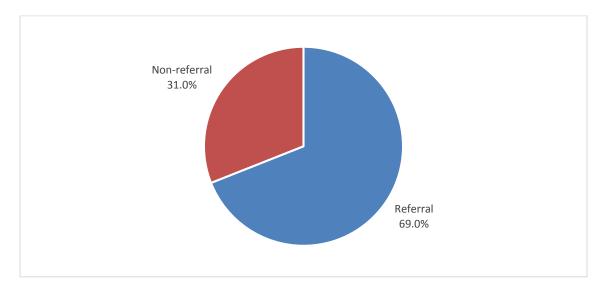


Figure 4: Referral and non-referral cases with foreign bodies of the esophagus

Majority of the patients are referred from facilities within Nairobi county (58.8%), followed by Kiambu county (14.4%), Kajiado, Machakos and Murang'a refer 6.2% of the cases each respectively. Makueni county refers 5.2% and others (Nakuru, Kitui counties) refer 3.1%.

Table 1: Referrals from other medical facilities

Region	N	%
Nairobi	57	58.8
Kiambu	14	14.4
Kajiado	6	6.2
Machakos	6	6.2
Makueni	5	5.2
Muranga	6	6.2
Others	3	3.1

Types of foreign bodies in esophagus

This study shows that coins form the largest proportion of foreign bodies in the esophagus (77.2%), followed by bone pieces (9.9%), lithium battery(8.9%) and other assorted FBs e.g wire, razor, tooth picks, plastic pieces(4%).

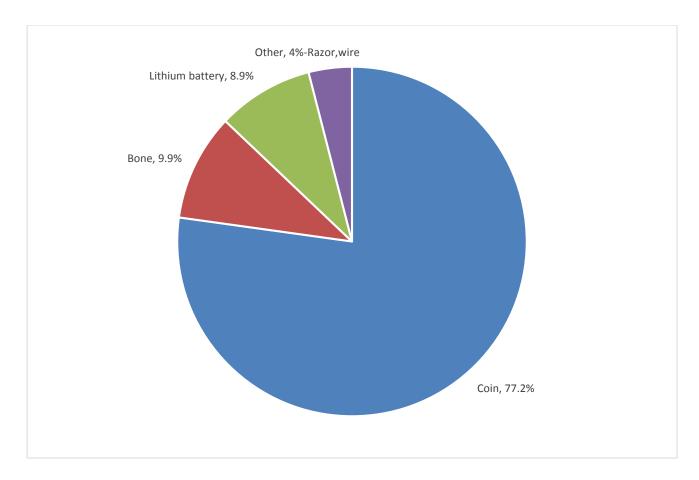


Figure 5: Proportion of foreign bodies of the esophagus seen at KNH.

The study also shows an association between the age of the patients and the type of foreign body as a significant proportion of the patients below 2 years had swallowed coins (68%) and lithium batteries (20%). In the 2 to 4 years age group 90.9% had swallowed coins and lithium (9.1%). The patients above 19yrs had pieces bones (100%) lodged in the esophagus.

Table 2: Relationship between patients' age, sex and referral to KNH with the type of FB

	Type of foreign body				
	Coin, n (%)	Bone, n (%)	Lithium battery, n (%)	Other, n (%)	P
Age		, ,	, ,		
< 2 years	17(68.0)	0(0.0)	5(20.0)	3(12.0)	<0.001
2-4 years	40(90.9)	0(0.0)	4(9.1)	0(0.0)	
4-5 years	12(92.3)	0(0.0)	0(0.0)	1(7.7)	
6-19 years	9(69.2)	4(30.8)	0(0.0)	0(0.0)	
Above 19 years	0(0.0)	6(100.0)	0(0.0)	0(0.0)	
Sex					
Male	50(80.6)	8(12.9)	3(4.8)	1(1.6)	0.074
Female	28(71.8)	2(5.1)	6(15.4)	3(7.7)	
Patient referred to KNH					
Yes	54(78.3)	4(5.8)	8(11.6)	3(4.3)	0.234
No	24(77.4)	5(16.1)	1(3.2)	1(3.2)	

The study shows no significance in the association between sex distribution and referral of these patients to KNH with the type of foreign body found as shown in table 2 above.

Presentation of the patients at KNH

This study shows that the median duration between ingestion of foreign body and presentation to KNH is 24 hours (interquartile range 8 to 48 hrs). A higher proportion of the patients present to KNH after 2 days (32.7%) from the time of ingesting the foreign body. This was attributed to the fact the parents and clinicians observed the patients for the FB to descend, and then referred to KNH after this failed.

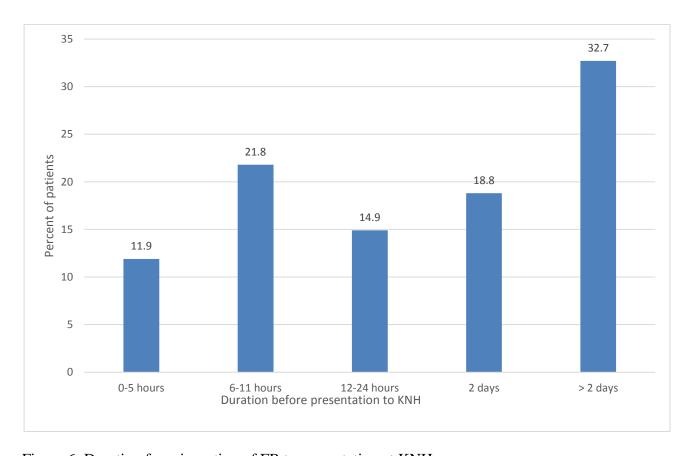


Figure 6: Duration from ingestion of FB to presentation at KNH

The study shows no significant association between the patients' residence and the duration from ingestion of the FB to presentation at KNH as shown in table 3.

Table 3: Relationship between patients' residence and the duration before presentation to KNH

	0-5 hours n (%)	6-11 hours n (%)	12-24 hours n (%)	1 day n (%)	>2 days n (%)	P value
Nairobi	8(14.0)	13(22.8)	11(19.3)	8(14.0)	17(29.8)	0.279
Kiambu	0(0.0)	5(35.7)	2(14.3)	0(0.0)	7(50.0)	
Kajiado	1(16.7)	1(16.7)	0(0.0)	2(33.3)	2(33.3)	
Machakos	0(0.0)	1(16.7)	0(0.0)	4(66.7)	1(16.7)	
Muranga	0(0.0)	1(16.7)	1(16.7)	2(33.3)	2(33.3)	
Other	1(33.3)	1(33.3)	0(0.0)	0(0.0)	1(33.3)	

Clinical presentation of the patients.

In the clinical presentation, the study shows that drooling forms the largest proportion of symptoms (88.1%), followed by vomiting (66.3%), dysphagia (32.7%) and odynophagia (28.7%).

Table 4: Clinical presentation of patients with FB of the esophagus

	Frequency	Percent
Drooling	89	88.1%
Vomiting	67	66.3%
Dysphagia	33	32.7%
Odynophagia	29	28.7%
Choking	4	4%
Difficulty in breathing	4	4%

This study shows an association between clinical presentations of the patients with the type of foreign body. Drooling was seen in 88.5% with coins, 90% in patients with bone and 77.8% with lithium battery.

Table 5: Association between clinical presentation and type of foreign body.

			Type of f	oreign bod	y	
		Coin, n (%)	Bone, n (%)	Lithium battery, n (%)	Other, n (%)	P
Drooling	Yes	69(88.5)	9(90.0)	7(77.8)	4(100.0)	0.682
	No	9(11.5)	1(10.0)	2(22.2)	0(0.0)	
Choking	Yes	1(1.3)	2(20.0)	1(11.1)	0(0.0)	0.022
	No	77(98.7)	8(80.0)	8(88.9)	4(100.0)	
Vomiting	Yes	56(71.8)	1(10.0)	6(66.7)	4(100.0)	0.001
	No	22(28.2)	9(90.0)	3(33.3)	0(0.0)	
Odynophagia	Yes	23(29.5)	5(50.0)	0(0.0)	1(25.0)	0.117
	No	55(70.5)	5(50.0)	9(100.0)	3(75.0)	
Dysphagia	Yes	26(33.3)	3(30.0)	3(33.3)	1(25.0)	0.984
	No	52(66.7)	7(70.0)	6(66.7)	3(75.0)	
Difficulty in breathing	Yes	1(1.3)	1(10.0)	2(22.2)	0(0.0)	0.015
	No	77(98.7)	9(90.0)	7(77.8)	4(100.0)	

Examination findings

The study shows that on examination of the patients, dehydration is seen in 63.4% of the cases, lethargy in 9.9% and respiratory distress at 1%.

Table 6: Examination findings

	Frequency	Percent
Dehydrated	64	63.4%
Lethargic	10	9.9%
Respiratory distress	1	1%

Table 7: Relationship between examination findings and type of FB

			Type of foreign body			
		Coin, n (%)	Bone, n (%)	Lithium battery, n (%)	Other, n (%)	P
Dehydrated	Yes	51(65.4)	1(10.0)	9(100.0)	3(75.0)	< 0.001
	No	27(34.6)	9(90.0)	0(0.0)	1(25.0)	
Lethargic	Yes	7(9.0)	0(0.0)	2(22.2)	1(25.0)	0.292
	No	71(91.0)	10(100.0)	7(77.8)	3(75.0)	

The study also shows a relationship between the examination findings and the type of FB with lithium disc battery causing dehydration in 100% of the cases, coin (65.4%), other FBs-wire, razor, tooth pick, plastic (75%) and bone (10%) as seen table 7 above.

Modes of Management

The study has shown that all patients with FB esophagus have done x-rays (100%) as part of preoperative work-up.

Intraoperatively rigid esophagoscopy is the commonest method used by otorhinolaryngologists in removal of the FB (55%), mackintosh laryngoscope and magill forcep(44%) which was done by the anesthetist during the process of intubation and flexible endoscopy(1%).

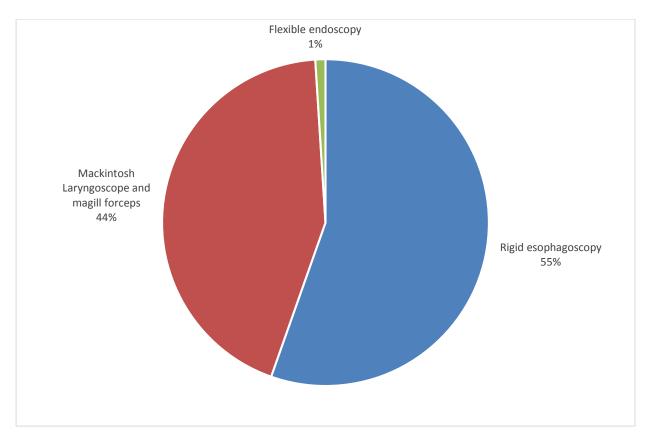


Figure 7: Methods used in removal of the FB

The study shows that esophageal injuries e.g laceration were seen more frequently in patients who underwent rigid esophagoscopy (55%) as compared to patients who had FBs removed during the intubation process using a mackintosh laryngoscope and a magill forceps (1.6%). Abrasions were noted in 32.5% of patients who underwent rigid esophagoscopy, and in 3.3% of patients whose FB was removed using a mackintosh laryngoscope and magill forcep.

Table 8: Relationship between methods used to remove the esophageal FB and injuries seen in the esophageal

			Mackintosh	
		Rigid esophagoscopy	Laryngoscopy	P
Laceration	Yes	22(55.0)	1(1.6)	<0.001
	No	18(45.0)	60(98.4)	
Abrasion	Yes	13(32.5)	2(3.3)	< 0.001
	No	27(67.5)	59(96.7)	
Necrosis	Yes	8(20.0)	0(0.0)	< 0.001
	No	32(80.0)	61(100.0)	
Strictures	Yes	1(2.5)	0(0.0)	0.215
	No	39(97.5)	61(100.0)	
Stenosis	Yes	1(2.5)	0(0.0)	0.215
	No	39(97.5)	61(100.0)	
	1			

The above table 8 shows the advantages of using a rigid esophagoscope in FB removal as the esophagus can be inspected after the FB has been removed and any injuries are clearly described.

Hence lacerations, abrasions, necrosis or strictures can be noted as compared to the use of Mackintosh laryngoscope and magill forceps where the injuries may not be seen.

The study also shows an association between esophageal injury and the type of FB, with lithium disc batteries causing injuries in 100% of the cases, bone (90%) and coins 25.6%.

Table 9: Association between esophageal injury and type of foreign body

	Esophageal injury caused by FB		
	Yes	No	P
Coin	20(25.6)	58(74.4)	<0.001
Bone	9(90.0)	1(10.0)	
Lithium battery	9(100.0)	0(0.0)	
Other	2(50.0)	2(50.0)	

The study found that 11.9% of the patients require an NGT for feeding postoperatively after suffering esophageal injuries.

Complications

The study shows complications caused by FB occur at a rate of 5%. The types of complications seen include esophageal strictures, cricopharyngeal stenosis, tracheoesophageal fistulae and bronchiectasis with lung collapse.

Table 10: Types of FB and postoperative complications

	Cor	mplications	
	Yes	No	P
Type of foreign body			
Coin	4(5.1)	74(94.9)	0.68
Bone	0(0.0)	10(100.0)	
Lithium battery	1(11.1)	8(88.9)	
Other	0(0.0)	4(100.0)	
Duration before presentation			
0-5 hours	1(8.3)	11(91.7)	0.313
6-11 hours	1(4.5)	21(95.5)	
12-24 hours	0(0.0)	15(100.0)	
1 day	2(10.5)	17(89.5)	
2 days	0(0.0)	33(100.0)	

An association between the complications and the type of FB shows that lithium disc batteries are associated with higher rates of complications 11.1% as seen in table 10 above. The complicated cases were referred to the cardiothoracic surgeons for specific management. The study showed a mortality rate of 1% caused by complications from esophageal FBs.

The study shows that the mean duration of inpatient stay is 2.2 days (SD 3), with a range of 1 to 14 days. The SD is at +/- 3days due to the skewed distribution with majority of the patients being admitted for 1 day.

DISCUSSION

Foreign bodies of the esophagus are common at the Kenyatta National Hospital affecting both children and adults and this study has shown the current trend and burden of this condition. In this study a total of 100 patients with FBs of the esophagus were recruited. The mean age of the patients is found to be 6 years with a range of 9 months to 60 years.

The most frequent age group affected is 2 to 4 years (43.6%) while the adults comprise 6% of the cases with a peak in patients above 40 years. These results compare to a local study by P.Oduor¹ for the period between 1981 and 1986, which showed two peak ages for FBs in the esophagus of patients below 6 years comprising 59.3% of the patients and adults comprising 23.7% of the cases, a much higher percentage than what this study has shown. This study has shown that the proportion of male patients was higher (61.4%) than that of female patients (38.6%) with a male to female ratio of 1.6:1.

This study shows that a higher proportion of the patients with foreign bodies in the esophagus presented as referrals from counties neighbouring Nairobi county (69%) and 31% of the patients presented directly to KNH without going through another medical facility. Majority of the patients (58.8%) were referred from facilities within Nairobi county, followed by Kiambu county (14.4%), Kajiado, Machakos and Murang'a refer 6.2% of the cases each. Makueni refers 5.2% and other counties (Nakuru, Nyeri) refer 1% of the cases.

This study shows that coins form the largest proportion of foreign bodies in the esophagus (77.2%),followed by bone pieces(9.9%),lithium disc battery(8.9%) and other assorted FBs e.g wire, razor, tooth picks, plastics(4%). This compares with a study done by Arana A, et al⁸ who found FBs to be the following in decreasing order of frequency, coins, toy parts, jewels, batteries,

sharp materials such as needles and pins, fish and chicken bones, and "large" amounts of food. Locally, Oduor P showed that majority of the FBs seen, were metallic objects including coins which made up 67% of the cases, followed by meat and bones which made 28.3%, vegetable material constituted 4.1% and plastics made up 1.6%.

This study also shows an association between age of the patients and the type of foreign body with a significant proportion of the patients below 2 years shown to have swallowed coins(68%) and lithium batteries(20%). In the 2 to 4 years age group, 90.9% had swallowed coins and lithium(9.1%). Patients above 19yrs had bones(100%).

The study also analyzed the duration from ingestion to presentation at KNH and shows a median duration of 24 hours (interquartile range 8 to 48 hrs). It shows that a higher proportion of the patients present to KNH after 2 days (32.7%) from the time of ingesting the foreign body. This is attributed to the fact the parents and clinicians observe the patients at home or in the hospital, waiting for the FB to descend, and were referred to KNH when this failed. Sharieff GQ,et al²⁴ studied healthy patients with acute (less than 24 h) coin ingestions, they were observed at home with next-day follow-up and he found that patients with acute esophageal coin ingestions may experience spontaneous coin passage.

In the clinical presentation of these cases, this study shows that drooling forms the largest proportion of the symptoms (88.1%), followed by vomiting (66.3%), dysphagia (32.7%) and odynophagia (28.7%). An association is made between clinical presentations of the patients with the type of foreign body and drooling is seen in 88.5% of cases with coins, 90% in patients with bone and 77.8% with lithium battery. On general examination of the patients dehydration is seen in 63.4% of the cases, lethargy in 9.9% and respiratory distress was seen in 1% of the cases. This study shows an association between the clinical signs and the type of FB, with lithium disc battery

causing dehydration in 100% of the cases, coin (65.4%), other FBs-wire, razor, tooth pick, plastics (75%) and bone (10%).

On management, this study shows that all the patients have x-ray (100%) done as part of preoperative work-up. Intraoperatively, this study shows that rigid esophagoscopy is used in 55% of the cases, mackintosh laryngoscope and magill forcep(44%) which was used during the process of intubation by the anesthetist and flexible endoscopy (1%). The modes of management were all successful in removing the FB, similar to results shown by Gmeiner D, et al¹⁶ who compared use of a flexible endoscope and a rigid endoscope. He showed the success rate for foreign body removal was at 93.4% using the flexible endoscope and 95.2% using the rigid endoscope. Our results are also comparable to those that Janik JE, et al¹⁷got in a retrospective review of 36 children who had upper esophageal coins extracted using a Magill forceps. All coins were removed without any complication.

This study also shows that injuries to the esophagus are seen in 55% of patients who undergo rigid esophagoscopy as compared to laryngoscopy (1.6%). This was a setback in the study as a reexamination of the esophagus was not done in all cases after the FB was removed using a mackintosh and magill forcep. The study also shows an association between esophageal injury and the type of FB with lithium disc battery causing injuries in 100% of the cases, bone (90%) and coins 25.6%. It also shows that postoperatively 11.9% of the patients require an NGT for feeding due to the severity of the esophageal injuries caused by the FB.

The study shows that the mean duration of inpatient stay is 2.2 days (SD+/- 3), with a range of 1 to 14 days. The SD is at +/- 3days due to the skewed distribution with majority of the patients being admitted for 1 day. Another setback of the study was that the patients were not followed up after discharge to monitor their progress and any complications which may arise thereafter. The study shows that complications caused by FB are at 5%. These were esophageal strictures, cricopharyngeal stenosis, tracheoesophageal fistulae and bronchiectasis with lung collapse. An association between the complications and the type of FB is made and lithium disc battery is shown to be associated with the highest rates of complications 11.1%. Kimball SJ, et al²⁰ also concluded that lithium battery are a major cause of complications in the esophagus. These complicated cases were referred to the cardiothoracic department who managed them until they

The study showed a mortality rate of 1% caused by complications from esophageal FBs.

CONCLUSION

recovered.

Foreign bodies of the esophagus are a common condition affecting mainly the paediatric population with a mean age of 6 years and the age group between 2-4 years being the most affected. Most of these cases are referred from primary health care facilities to KNH. Coins and lithium batteries are common in the paediatric population with pieces of bones being prevalent in the adult population. Esophageal injuries are best assessed using a rigid esophagoscope and Lithium disc batteries cause the highest rates of complications which can eventually lead to mortalities.

RECOMMENDATIONS

In line with the findings of this study, lithium disc batteries should be disposed off safely away from children and public education on the effect of swallowing the batteries should be done to reduce the incidence of these cases. This can be done through posters, radio programs, newspapers, MCH clinics and in schools.

A study should be done on the long term effects of the lithium disc batteries on the patients who did not develop immediate complications. Long-term follow-up of these patients is recommended.

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APPENDICES

APPENDIX 1: GENERAL PATIENT INFORMATION

1. Introduction

I am a senior house officer in ENT-Head&Neck Surgery department. I am requesting for your consent to participate in a study on the clinical management of foreign bodies of the esophagus as seen in Kenyatta National Hospital.

2. How you will participate

- a) I will ask you questions regarding the foreign body swallowed and any symptoms which occurred soon after swallowing it.
- b) I will carry out a complete Ear, Nose, Throat, Head and Neck examination.
- c) I will record the imaging modality that was done.
- d) I will record the method used to remove the foreign body any injuries caused by the foreign body and the post-operative management if any.
- e) I will record the number of days you will spend in hospital after the FB has been removed.
- f) There will be no monetary benefits for participating in the study and it will be purely on voluntary basis.
- g) You will incur no extra financial costs and confidentiality will be maintained at all times.
- h) You will reserve the right to withdraw from the study at any time without any penalty.
- i) You will be informed about investigations and importance of the results.

3. How will participation affect you?

The study does not affect you negatively in any way because

- a) All the information you give will be confidential.
- b) The conclusions drawn from the study shall be useful to improve the management of foreign bodies in the esophagus.

4. What do we do with the information we get?

The information we get will help us understand the pattern of foreign bodies in the esophagus and in the management of these cases.

We may publish our findings in scientific journals or present them in scientific meetings.

5. Are you satisfied with the information given?

If you are satisfied with our explanation and you are willing to participate in the study, then please sign the consent form below.

If you have any questions or need further clarification about the study, kindly contact the following:

Principal investigator:

Dr.Ouyah W.Libutsi,

Department of Surgery, College of Health Sciences,

University of Nairobi, P.O. Box 2134-00100, Nairobi.

Phone number:0723541968, Email:wlibz@yahoo.com

2. Supervisors:

Prof.Isaac Muthure Macharia,

Professor and Consultant ENT-Head and Neck Surgeon,

Department of Surgery,

University of Nairobi.

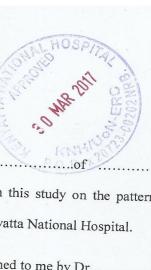
Dr.Peter Masinde

Head of ENT Department and Consultant ENT-Head and Neck Surgeon,

Kenyatta National Hospital.

The Chairman KNH-UON Ethics and Research Committee,

Kenyatta National Hospital, Nairobi



Department of Surgery, University of Nairobi.

I
hereby give consent to be included in this study on the patterns and management of foreign
bodies in the esophagus as seen in Kenyatta National Hospital.
The nature of the study has been explained to me by Dr.
DateSigned
I Dr
the nature of the study.
DateSigned
For any further clarifications, contact any of the following:
1.Principal investigator:
Dr. Ouyah W. Libutsi, Resident in ENT-Head & Neck Surgery, Department of surgery,
University of Nairobi, P.O Box 2134-00100 Nairobi.
Phone number:0723541968
Email:wlibz@yahoo.com
2.Supervisors:
Prof. Isaac Muthure Macharia,
Professor and Consultant ENT-Head and Neck Surgeon,

Dr.Peter Masinde

Head of ENT Department and Consultant ENT-Head and Neck Surgeon,

Kenyatta National Hospital.

The Chairman KNH-UON Ethics and Research Committee,

Kenyatta National Hospital, Nairobi

Tel.2726300 Ext.44355





APPENDIX 3: ASSENT INFORMATION DOCUMENT

1. Introduction

I am a senior house officer in ENT-Head & Neck Surgery department. I am requesting for your assent for the patient under your care to participate in a study on the clinical management of foreign bodies of the esophagus as seen in Kenyatta National Hospital.

2. How you will participate

- j) I will ask you questions regarding the foreign body swallowed and any symptoms which occurred soon after swallowing it.
- k) I will carry out a complete Ear, Nose, Throat, Head and Neck examination on the patient.
- l) I will record the imaging modality that was done.
- m) I will record the method used to remove the foreign body any injuries caused by the foreign body and the post-operative management if any.
- n) I will record the number of days your patient will spend in hospital after the FB has been removed.
- o) There will be no monetary benefits for participating in the study and it will be purely on voluntary basis.
- p) You will incur no extra financial costs and confidentiality will be maintained at all times.
- q) You will reserve the right to withdraw from the study at any time without any penalty.
- r) You will be informed about investigations and importance of the results.

3. How will participation affect you?

The study does not affect the patient under your care negatively in any way because:

- c) All the information you give will be confidential.
- d) The conclusions drawn from the study shall be useful to improve the management of foreign bodies in the esophagus.

4. What do we do with the information we get?

The information we get will help us understand the pattern of foreign bodies in the esophagus any complications and the management of these cases.

We may publish our findings in scientific journals or present them in scientific meetings.

5. Are you satisfied with the information given?

If you are satisfied with our explanation and you are willing to participate in the study, then please sign the assent form below.

If you have any questions or need further clarification about the study, kindly contact the following:

Principal investigator:

Dr.Ouyah W.Libutsi,

Department of Surgery, College of Health Sciences,

University of Nairobi, P.O. Box 2134-00100, Nairobi.

Phone number: 0723541968, Email:wlibz@yahoo.com

2. Supervisors:

Prof. Isaac Muthure Macharia,

Professor and Consultant ENT-Head and Neck Surgeon,

Department of Surgery,

University of Nairobi.

Dr.Peter Masinde

Head of ENT Department and Consultant ENT-Head and Neck Surgeon,

50 MAR 2017

Kenyatta National Hospital.

The Chairman KNH-UON Ethics and Research Committee,

Kenyatta National Hospital, Nairobi

APPENDIX 4: ASSENT FORM

APPENDIX 4: ASSENT FORM	EO WHE SOLL
Ipare	ent/guardian to.
do hereby give assent for the patient to be inc	cluded in this study on the patterns and management
of foreign bodies in the esophagus as seen in	
The nature of the study Dr	has been explained to me by
	Signed
I Dr	
parent/guardian the nature of the study.	
Date	Signed
For any further clarifications, contact any of the	e following:
1.Principal investigator:	
Dr.Ouyah W.Libutsi, Resident in ENT-Head &	k Neck Surgery, Department of surgery,
University of Nairobi,	
P.O Box 2134-00100 Nairobi.	
Phone number:0723541968	
Email:wlibz@yahoo.com	

2. Supervisors:

Prof. Isaac Muthure Macharia,

Professor and Consultant ENT-Head and Neck Surgeon,

Department of Surgery, University of Nairobi.

Dr.Peter Masinde

Head of ENT Department and Consultant ENT-Head and Neck Surgeon,

Kenyatta National Hospital.

The Chairman KNH-UON Ethics and Research Committee,

Kenyatta National Hospital, Nairobi

Tel.2726300 Ext.44355

APPENDIX 5: KIAMBATISHO

KIAMBATISHO 1:

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MAELEZO KUHUSUIDHINI YA MGONJWA

1. Kitangulizi

Mimi ni daktari ninaye endelea na masomo ya juu kwa kitengo cha upasuaji wa masikio,mapua,koo na shingo katika Chuo Kikuu cha Nairobi.Ningependa kuomba idhini yako ya kushiriki katika utafiti wenye lengo la kujua mwenendo wa vitu visivyo faa kuwa kwenye koromeo na vile ya kuviondoa kwenye koromeo katika hosipitali kuu ya Kenyatta.

2. Jinsi ya kushiriki

- a) Nitakuuliza maswali kuhusu kitu ulichomeza na mambo yaliyofanyika baadaye kama kutapika,kushindwa kumeza au kupumua, ama uchungu.
- b) Nitafanya uchunguzi wa kikamilifu wa masikio,pua na koo.
- c) Nitaandika njia iliyotumika kuondoa kitu ulichomeza kutoka kwenye koromeo, majeraha yaliyotokana na kitu ulichomeza na njia iliyotumika kukutibu baada ya kuondoa kitu ulichomeza.
- d) Utafiti huu utafanywa kwa hiari ya mgonjwa na hakutakuwepo na faida ya fedha au fidia kwa kushiriki.
- e) Hakutakua na malipo yoyote ya ziada au gharama utakayo hitajika kulipa na siri za mgonjwa zitaendelezwa wakati wowote.
- f) Una haki ya kujiondoa kutoka kwa utafiti huu wakati wowote bila adhabu yoyote.
- g) Utapewa taarifa au habari kuhusu uchunguzi utakaofanywa na umuhimu wa matokeo.

3. Jinsi gani kushiriki kwako kunaweza kuleta madhara

Utafiti hautakudhuru kwa njia yoyote kwa vile:

- a) Taarifa yote kuhusu mgonjwa itakuwa ni ya siri
- b) Utambulisho hautatangazwa.
- c) Baada ya kuhitimisha utafiti huu maarifa yatakayopatikana yatakuwa ya manufaa na yanaweza kutumika kusaidia kuboresha matibabu ya hali hii.

4.Je,kuna hatari ya kushiriki au kutoshiriki?

- a) Hakuna hatari yoyote itakayo jiri kwa kushiriki au kutoshiriki.
- b) Kujiondoa wakati wowote au kupinga sehemu ya utafiti hakutaathiri matibabu au ubora wa huduma ya afya utakayopokea.

5.Je,tutafanyia nini matokeo ya utafiti huu?

Habari itakayotokana na utafiti huu pengine haitakifaidi binafsi lakini itatupa maarifa ambayo yataboresha matibabu ya vitu vilivy katalia kwenye koromeo.

Kuna uwezekano wa kuchapishwa kwa matokeo ya utafiti huu katika majarida ya kisayansi au kuwekwa katika mikutano ya kisayansi.

6. Je,umeridhika?

Ukiridhika na maelezo yangu na uko tayari kushiriki,tafadhali weka sahihi yako kwenye fomu ya idhini.

KIAMBATISHO 2:Fomu ya Kukubali kwa mgonjwa Mimi....kutoka....ninakubali kushirikishwa katika utafiti huu wenye lengo la kujua mienendo na matibabu vitu visivyo faa kuwa kwenye koromeo katika hosipitali kuu ya Kenyatta. Nimeelezewa na daktari.... Tarehe.....Sahihi..... Mimi daktari.....nahakikisha ya kwamba nimeelezea mgonjwa juu ya utafiti huu Mawasiliano: Mtafiti mkuu Daktari Ouyah Wilson Libutsi, mwanafunzi wa upasuaji wa masikio, mapua na koo, Chuo kikuu cha Nairobi,anwani 2134-00100, Nairobi Simu 0723541968 Barua pepe:wlibz@yahoo.com Wasimamizi Profesa Isaac Muthure Macharia Idara ya upasuaji,kitengo cha upasuaji wa Masikio,Mapua na Koo Chuo kikuu cha Nairobi, anwani 2134-00100, Nairobi, Daktari Peter Masinde,

Mkuu wa kitengo cha upasuaji wa Masikio, mapua na koo, Hosipitali kuu ya Kenyatta

Mwenyekiti

KNH/UON Ethical and Research Committee

Hosipitali kuu ya Kenyatta,

Simu 2726300-9 Ext.44355



KIAMBATISHO 3 : MAELEZO KUHUSU IDHINI YA MZAZI WA MGONJWA

1. Kitangulizi

Mimi ni daktari ninaye endelea na masomo ya juu kwa kitengo cha upasuaji wa masikio,mapua,koo na shingo katika Chuo Kikuu cha Nairobi.Ningependa kuomba idhini yako ya kushirikisha mtoto wako katika utafiti wenye lengo la kujua mwenendo wa vitu visivyo faa kuwa kwenye koromeo na vile ya kuviondoa kwenye koromeo katika hosipitali kuu ya Kenyatta.

2. Jinsi ya kushiriki

- a) Nitakuuliza maswali kuhusu kitu mtoto alichomeza na mambo yaliyofanyika baadaye kama kutapika, kushindwa kumeza au kupumua ,ama uchungu.
- b) Nitafanya uchunguzi wa kikamilifu wa masikio,pua na koo ya mtoto.
- c) Nitaandika njia iliyotumika kuondoa kitu mgonjwa alichomeza kutoka kwenye koromeo,majeraha yaliyotokana na kitu alichomeza na njia iliyotumika kumtibu baada ya kuondoa kitu alichomeza.
- d) Utafiti huu utafanywa kwa hiari ya mzazi wa mgonjwa na hakutakuwepo na faida ya fedha au fidia kwa kushiriki.
- e) Hakutakua na malipo yoyote ya ziada au gharama utakayohitajika kulipa na siri za mgonjwa zitaendelezwa wakati wowote.
- f) Una haki ya kujiondoa kutoka kwa utafiti huu wakati wowote bila adhabu yoyote.
- g) Utapewa taarifa au habari kuhusu uchunguzi utakaofanywa na umuhimu wa matokeo.



3. Jinsi gani kushiriki kwa mtoto wako kunaweza kuleta madhara

Utafiti hautamdhuru mgonjwa kwa njia yoyote kwa vile:

- a. Taarifa yote kuhusu mgonjwa itakuwa ni ya siri
- b. Utambulisho hautatangazwa.
- c. Baada ya kuhitimisha utafiti huu maarifa yatakayopatikana yatakuwa ya manufaa na yanaweza kutumika kusaidia kuboresha matibabu ya hali hii.

4.Je, kuna hatari ya kushiriki au kutoshiriki?

- a. Hakuna hatari yoyote itakayo jiri kwa mgonjwa kwa kushiriki au kutoshiriki.
- b. Kujiondoa wakati wowote au kupinga sehemu ya utafiti hakutaathiri matibabu au ubora wa huduma ya afya utakayopokea.

5. Je, tutafanyia nini matokeo ya utafiti huu?

Habari itakayotokana na utafiti huu pengine haitakufaidi binafsi lakini itatupa maarifa ambayo yataboresha matibabu ya vitu vilivyo katalia kwenye koromeo na namna ya kuvitibu.

Kuna uwezekano wa kuchapishwa kwa matokeo ya utafiti huu katika majarida ya kisayansi au kuwekwa katika mikutano ya kisayansi.

6.Je, umeridhika?

Ukiridhika na maelezo yangu na uko tayari kwa mtoto wako kushiriki,tafadhali weka sahihi yako kwenye fomu ya idhini.Kama uko na maswali yoyote tafadhali wasiliana nasi kupitia njia zifwatazo:

Mtafiti mkuu

Daktari Ouyah Wilson Libutsi, mwanafunzi wa upasuaji wa masikio, mapua na koo,

Chuo kikuu cha Nairobi, anwani 2134-00100, Nairobi

Simu 0723541968

Barua pepe:wlibz@yahoo.com

Wasimamizi

Profesa Isaac Muthure Macharia

Idara ya upasuaji,kitengo cha upasuaji wa Masikio, Mapua na Koo

Chuo kikuu cha Nairobi, anwani 2134-00100, Nairobi,

Daktari Peter Masinde,

Mkuu wa kitengo cha upasuaji wa Masikio, mapua na koo

Hosipitali kuu ya Kenyatta

Mwenyekiti

KNH/UON Ethical and Research Committee

Hosipitali kuu ya Kenyatta,

Simu 2726300-9 Ext.44355

KIAMBATISHO 4:Fomu ya Kukubali kwa mzazi wa mgonjwa
Mimininakubali mtoto
wangu kushirikishwa katika utafiti huu wenye lengo la kujua mienendo na matibabu ya vitu
visivyofaa kuwa kwenye koromeo katika hosipitali kuu ya Kenyatta.
Nimeelezewa na daktari
TareheSahihi
Mimi daktarinahakikisha ya kwamba nimeelezea mzazi wa
mgonjwa kuhusu utafiti huu
TareheSahihi
Mawasiliano:
Mtafiti mkuu
Daktari Ouyah Wilson Libutsi, mwanafunzi wa upasuaji wa masikio,mapua na koo,
Chuo kikuu cha Nairobi,anwani 2134-00100,Nairobi
Simu 0723541968
Simu 0723541968 Barua pepe:wlibz@yahoo.com Wasimamiri
Wasimamizi
Profesa Isaac Muthure Macharia
Idara ya upasuaji,kitengo cha upasuaji wa Masikio,Mapua na Koo
Chuo kikuu cha Nairobi,anwani 2134-00100,Nairobi,
Daktari Peter Masinde,
Mkuu wa kitengo cha upasuaji wa Masikio,mapua na koo
Hosipitali kuu va Kenyatta

Mwenyekiti KNH/UON Ethical and Research Committee Hosipitali kuu ya Kenyatta, Simu 2726300-9 Ext.44355

APPENDIX 6:QUESTIONNAL	RE	
Study number	Date	
Section A:		
Patient Biodata		
I.P NoAge		
Section B:	THOSPITAL CE	
History	io man	
1. What foreign body did you or t	the patient swallow	?
2. What is the period between	n swallowing the foreign body and presentation to	A& E
department in KNH		?
3. Did you seek medical assistance	ce elsewhere prior to presenting at the A&E in KNH?	
a)YES	b)NO	
If YES,where		?
Was there any form of managen	ment given before being referred	?
4. Did you or the patient have an	y of the following symptoms soon after swallowing the	foreign
body?		
a) Drooling		
b) Choking		

c) Vomiting	6	
d) Odynophagia		
e) Dysphagia		
f) Difficulties in breathing		
Others		
Management:		
★5. What are the findings on examination of the patient?		
a) Dehydrated	•	
b) Lethargic c) Respiratory distress		
c) Respiratory distress		
d) Emaciated		
Other findings		
6. What the vital signs on examination of the patient?		
a)Temperature b)Pulse rate c) Respiratory rate	te	
7. Has the patient undergone any radiological investigations?		
a) X-ray		
b) CT Scan		
		*

c) MRI	
d) U/S Scan	
Operative Record	
8. What method was used to remove the foreign	gn body intraoperatively?
a) Rigid Esophagoscopy	
b) Direct hypopharyngoscopy	HOSPITAL EST
c) Laryngoscopy and Macgill forceps	4R 2017
d) Flexible endoscopy	30 W
e) Foleys catheter	The state of the s
9. How far is the Foreign Body located from the	he frontal incisors in centimeters?cm
10. What type of foreign body was found during	ng esophagoscopy?
11. Are there any injuries to the esophagus cau	used by the foreign body?
a) YES	b)NO
If YES, what injuries were observed?	
a) Lacerations	
b) Abrasion	
c) Perferations	

d) Necrosis	EPITAL '8			
e) Strictures	MAR 2017			
f) Adhesions	S D MA			
g) Stenosis	A Thomas			
Others		- ·····		
12. Does the patient require N	NGT postoperatively?			
a)YES		b)NO		
Postoperative management:				
13. Did the patient suffer any	postoperative complication	ation?		
a)YES		b)NO		
If YES, please specify				
14. How many days was the p	patient admitted for in the	ne ward postoper	atively?	

APPENDIX 7: RESEARCH APPROVAL



UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES P O BOX 19676 Code 00202 Telegrams: varsity Tel:(254-020) 2726300 Ext 44355

Ref: KNH-ERC/A/113

Dr. Wilson Libutsi Ouyah Reg. No.H58/63689/2010 Dept.of Surgery School of Medicine College of Health Sciences University of Nairobi

Dear Dr. Libutsi



KNH-UON ERC

Email: uonknh_erc@uonbi.ac.ke Website: http://www.erc.uonbi.ac.ke Facebook: https://wwx.facebook.com/uonknh.erc Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC



KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202 Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi

30th March 2017

REVISED RESEARCH PROPOSAL – CLINICAL MANAGEMENT OF FOREIGN BODIES OF THE ESOPHAGUS AS SEÊN AT THE KENYATTA NATIONAL HOSPITAL (P712/10/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above revised proposal. The approval period is from 30th March 2017 – 29th March 2018.

This approval is subject to compliance with the following requirements:

- a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
- c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
- e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period.
 (Attach a comprehensive progress report to support the renewal).
 f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of
- f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch or shipment.
- g) Submission of an <u>executive summary</u> report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

"Protect to Discover"

Yours sincerely,

PROF M. L. CHINDIA SECRETARY, KNH-UoN ERC

C.C.

The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH-UoN ERC
The Dean,School of Medicine,UoN
The Chair, Dept.of Surgery, UoN
Supervisors: Prof. Isaac Muthure Macharia, Dr. Peter Masinde

"Protect to Discover"