PROPHYLACTIC USE OF INTRAVENOUS DEXAMETHASONE IN REDUCING THE INCIDENCE OF POSTOPERATIVE SORE THROAT FOLLOWING GENERAL ANAESTHESIA WITH ENDOTRACHEAL INTUBATION AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM

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By

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A Dissertation submitted in (partial) Fulfillment of the Requirements for the Degree of Master of Medicine (Anaesthesiology) of

Muhimbili University of Health and Allied Sciences
October 2017

CERTIFICATION

The undersigned certify that he has read and hereby recommend for acceptance for examination by the Muhimbili University of Health and Allied Sciences a dissertation entitled ***Prophylactic Use of Intravenous Dexamethasone in Reducing the Incidence of Postoperative Sore Throat Following General Anaesthesia with Endotracheal Intubation at Muhimbili National Hospital, Tanzania,*** in (Partial) fulfillment of the requirements for the Degree of Master of Medicine (Anesthesiology) of Muhimbili University of Health and Allied Sciences**.**

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Dr. Frederic Mbanga

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Date

DECLARATION AND COPYRIGHT

I, **Dr. Steven Sebastian Nandi**, declare that this **dissertation** is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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LIST OF ABBREVIATIONS

ASA AMERICAN SOCIETY OF ANAESTHESIOLOGISTS

PONV POSTOPERATIVE NAUSEA AND VOMITING

NPO NIL PER ORAL

ECG ELECTROCARDIOGRAM

POST POSTOPERATIVE SORE THROAT

GA GENERAL ANESTHESIA

ETT ENDOTRACHEAL TUBE

MNH MUHIMBILI NATIONAL HOSPITAL

BP BLOOD PRESSURE

SPSS STATISTICAL PACKAGE FOR SOCIAL SCIENCES

URTI UPPER RESPIRATORY TRACT INFECTION

NGT NASAL GASTRIC TUBE

I.V INTRAVENOUS

NF-ƙB NUCLEAR FACTOR- ƙB

DNA DEOXYRIBONUCLEIC ACID

ICU INTENSIVE CARE UNIT

NMDA N-METHYL-D-ASPARTATE

LMA LARYNGEAL MASK AIRWAY

ENT EAR, NOSE and THROAT

VAS VISUAL ANALOGUE SCALE

NSAIDs NON-STEROIDAL ANTI-INFLAMMATORY DRUGS

GI GASTROINTESTINAL

DEFINITION OF TERMS

Sore throat: a term used to simply describe experience of pain, dryness, scratchiness or irritation in the throat

Difficult intubation: refers to more than three attempts of intubation

Hoarseness: refers to change in the pitch or quality of voice leading to difficulties in making sounds

Inflammation: is a localized physical condition in which a body part becomes erythematous, edematous, hot and painful as a complex biological response to tissue injury or infection

Placebo: normal saline solution (0.9%)

Standard Induction drugs: Midazolam 0.05-0.1 mg/kg, onset 1.5-5 min, & duration 2-6hr. Morphine 0.1-1.0mg/kg, onset 15-30 min & duration 3-4hrs. Propofol 2-3mg/kg, onset approximately 30 seconds, Succinylcholine 0.5-1.0mg/kg, onset 30-60 seconds & duration 5-10min.

Standard Maintenance drugs: used of balanced anesthesia: 30-100% Oxygen, Atracurium 0.5mg/kg, onset 2-4min, & duration 20-30min. Isoflurane MAC 1.2%

ABSTRACT

Background: Postoperative sore throat is a common complication that develops after mucosal damage by the endotracheal tube. It may be very distressing to the patient and thus undermining patient satisfaction due to discomfort experienced in the postoperative period. The present study examined the effects of prophylactic dexamethasone on the incidence of sore throat and severity of sore throat after extubation.

Objective: To assess the effectiveness of prophylactic intravenous dexamethasone in reducing the incidence of postoperative sore throat in elective patients under general anesthesia with endotracheal intubation at Muhimbili National Hospital

Methodology: A prospective, randomized double-blind study of intravenous dexamethasone using a dose of 0.1 mg/kg was conducted. A total of 92 patients aged 18-60 years of age with American Society of Anaesthesiologists physical status class I or II undergoing elective surgery under general anesthesia were enrolled and randomly allocated into two separate groups. One group (D1) received I.V dexamethasone 0.1 mg/kg 60 minutes before endotracheal intubation and the other group (D2) received placebo (normal saline) at the same time. The incidence and severity of sore throat was then evaluated postoperatively at 1, 6 and 24 hours.

Results: The incidence of patients developing sore throat postoperatively at 1, 6 and 24 hours was statistically different between the two groups. The group of patients who received dexamethasone exhibited statistically significant lower incidences compared to the group of patients who received placebo (58.7% vs 95.6%; 21.7% vs 95.6%; 4.4% vs 69.6%) at 1, 6 and 24 hours respectively with the reduction of incidence sore throat by 36.9% during the first hour. In addition, the intensity of postoperative sore throat was less in the dexamethasone group than in the placebo group with statistically significant less proportion of patients experiencing moderate sore throat at 1 hour in the dexamethasone group.

Conclusion: This study has shown that prophylactic use of intravenous dexamethasone at a dose of 0.1 mg/kg has significantly lowered the incidence of postoperative sore throat by 36.9% at 1 hour post-extubation as well as its severity.

1.0 INTRODUCTION

1.1 BACKGROUND

Endotracheal intubation is an advanced technique of airway management which is carried out in an elective or emergent situation whereby a flexible plastic tube is placed into the trachea to maintain an open airway or serve as a conduit for passage of inhalational anesthetic agents. It is frequently performed in critically injured, ill or anesthetized patients to facilitate lung ventilation and prevent airway obstruction

Being an invasive and extremely uncomfortable procedure, tracheal intubation is usually performed under general anesthesia along with the administration of a muscle relaxant. However, it can be performed in awake patients with local or topical anesthesia.

For quite a long period of time, direct laryngoscopy and endotracheal intubation has been the mainstay of airway management. It is well known that tracheal intubation will achieve all three important objectives which are maintenance of adequate oxygenation, adequate ventilation and securing the airway from aspiration. However, there are other various techniques used as part of airway management such as the use of supraglottic devices, cricothyrotomy or tracheostomy.

Direct laryngoscopy and tracheal intubation carry quite a good number of complications ranging from sore throat to tracheal stenosis. Most of these complications result from the external pressures above 30 mmHg which compress important airway structures causing obstruction of blood vessels. This leads to limitation of mucosal blood flow which leads to an ischemic tissue propagating into inflammation, ulceration, granulation and eventually stenosis (1).

Sore throat has been the most common complication postoperatively following endotracheal intubation. This has led to increased morbidity and patient's dissatisfaction. According to literature, the incidence of sore throat has been found to vary from 14.4%-50% when endotracheal tube is used (2).

With the choice of airway management, tracheal intubation has the greatest incidence of sore throat which is followed by the incidence of 17.5% when using laryngeal mask airway. Facemask has been found to have the lowest incidence of sore throat (3).

There are a number of other factors implicated in the development of sore throat postoperatively which include the following;

Smaller tube sizes have lower incidence of POST as compared to the larger ones (4). Excessive ETT cuff pressure decreases markedly the flow of blood to the mucosa (with the cuff pressure of 30mmHg and above) causing postoperative sore throat and hoarseness. The latter being probably due to edema (5). In addition, the intracuff pressure appears to increase excessively with the use of nitrous oxide (N_2O) due to the fact that N_2O diffuses into endotracheal tube cuff leading to the damage of tracheal mucosa (6).

Also, endotracheal tube cuff design plays a major role in postoperative morbidity. The use of low-volume high pressure cuffed tubes has the highest incidence of sore throat due to its ability of causing the greater depth of tracheal erosions as compared to the use of high-volume low pressure cuffs (7,8). Lack of adequate relaxation during intubation may lead to traumatization of laryngeal mucosa when a muscle relaxant is not used (9). Furthermore, oropharyngeal airway and aggressive suctioning of the pharynx contribute to sore throat (10). Other factors such as patient positioning (prone and lithotomy), nasogastric tube and obesity are regarded as etiological causes of postoperative sore throat.

There are various non-pharmacological and pharmacological methods employed in reducing the incidence of POST with great efficacy. The non-pharmacological ways include the use of small-sized ETT, reducing the ETT cuff pressure, gentle pharyngeal suctioning, lubricating the tracheal tube with jelly, adequate relaxation before intubation, full deflation of the ETT cuff during extubation. Pharmacological methods include the use of ketamine or benzydamine hydrochloride gargles, IV steroids, local application of steroids like betamethasone (11).

As far as tracheal intubation is concerned during general anesthesia, sore throat has been regarded as the most common complication worldwide. Though it is found to be minor, the symptom has been so distressing to the patient. The incidence vary greatly in various literature and it has gone to as high as 90% but this depends on the interview method whereby the direct interview method has shown to have the most accurate results.

In Africa, there is limited information on the incidence of sore throat postoperatively. The study done on the incidence of postoperative sore throat was conducted at the University of Benin in Nigeria along with other throat complications like cough and hoarseness as well as factors related to sore throat. Postoperative sore throat incidence was found to be 49% which falls into the range of many studies done worldwide (12).

There is a great potential for tracheal injury when endotracheal intubation is considered since cuff pressure is implicated as one among the causes for trauma in the trachea. This is evidenced by the study done in Ghana which revealed the cuff pressures being way too high when palpation technique of the pilot balloon was employed for estimation. The proper recommended cuff pressure would be maintained only by regular measuring the pressure of the cuff to avoid tracheal injury (13), of which most of the anesthetists do not know or have little experience.

The problem of postoperative sore throat has also been reported in East Africa with subsequent development of the interest of ways in lessening the incidence of sore throat post-intubation. A study done in Aga Khan University, Nairobi which focused on the effect of intravenous diclofenac in reducing the incidence of postoperative sore throat revealed no significant reduction in postoperative sore throat despite the fact that diclofenac can be used in the treatment of pain postoperatively (14).

However, in Tanzania there is no study yet that has been done on the incidence of sore throat after tracheal intubation.

1.0.1 PHARMACOLOGY OF DEXAMETHASONE

Dexamethasone is a potent anti-inflammatory and immunosuppressant drug employed in the treatment of a variety of disorders including allergic, inflammatory, dermatologic, rheumatic, endocrine and autoimmune disorders.

1.0.2 MECHANISM OF ACTION

In the same way as all other glucocorticoids, dexamethasone acts by binding to a glucocorticoid receptor including the DNA receptor within the cell to form a complex which results in changes in gene transcription (15). Glucocorticoids inhibit inflammatory processes through the induction and activation of Annexin I which is an anti-inflammatory protein inhibiting cytosolic phospholipase $A_{2\alpha}$. Eventually, annexin I inhibits arachidonic acid release and the conversion to eicosanoids (i. e prostaglandins, thromboxanes, prostacyclines and leukotrienes). Also, the glucocorticoid-receptor complex blocks the transcriptional activity of NF-ƙB which initiates the transcription of cytokines, chemokines, cell adhesion molecules, complement factors and cyclooxygenase 2 enzymes, all of which are significantly involved in the inflammatory signaling mechanism (16).

1.0.3 Pharmacokinetics

With oral administration, dexamethasone becomes readily absorbed and the peak concentration in the plasma is attained after an hour. An injectable form of dexamethasone is of variable onset and duration of action depending on whether it is administered into intra-articular space, a muscle or the blood supply to the muscle. With I. V administration, it is readily and completely absorbed into the tissues. Compared to other corticosteroids, the binding of dexamethasone to plasma proteins (transcortin and albumin) is found to be less. Only the unbound portion is active.

Dexamethasone is metabolized in the liver to inactive glucuronide and sulfate metabolites. Both of the inactive metabolites and small quantities of un-metabolized drug undergo renal excretion.

The biological half-life (duration of action) is approximately 36-54 hours and it penetrates tissue and cerebrospinal fluid.

1.0.4 Clinical indications

Dexamethasone may be clinically indicated in the management of patients with secondary adrenal insufficiency as a replacement therapy despite having little or no mineralocorticoid activity in patients with secondary adrenal insufficiency resulting from insufficient corticotrophin secretion. However**,** it is not clinically indicated in patients with primary adrenal insufficiency disorder like in Addison's disease or after adrenalectomy since in these conditions there is no production of aldosterone hormone which has mineralocorticoid activity. (17)

Other clinical benefits of glucocorticoid use are seen in conditions such as indications allergic disorders such as asthma or allergic skin reactions, blood disorders such as thrombocytopenia, leukemia, hemolytic anemia, selected collagen and rheumatic disorders (only rarely in rheumatoid arthritis), gastrointestinal disorders such as crohn's disease and ulcerative colitis, connective tissue disorders such as arteritis, systemic lupus erythematosus (but not scleroderma), some skin disorders like pemphigus, some eye disorders such as optic neuritis, certain neoplastic disorders such as cerebral neoplasm or multiple myeloma and acute leukemia in children (18). Also, dexamethasone has been used in the prevention of neonatal respiratory distress syndrome in pre-term babies after being administered in pregnant women during the antenatal period whereby it has been shown to improve neonatal outcome because it speeds up fetal lung maturation (55).

1.0.5 Contra-indications

It is contra-indicated in patients who are hypersensitive to dexamethasone and its ingredients. The patients who have systemic infections or immunized with live or attenuated vaccine are contraindicated to use dexamethasone. (19)

1.0.6 Warning and Precautions

It has to be used cautiously in patients with diabetes mellitus since it is found to have insulin resistance effect leading to increased plasma sugar level. Also, the drug is thought to cause peripheral vascular resistance hence precaution is needed when given to hypertensive individuals as well as in patients with recent MI or congestive heart failure as it may exacerbate heart failure. Other conditions which require cautious administration of dexamethasone include hypothyroidism, impaired renal function, GI ulcer, renal disease, osteoporosis, cirrhosis, diverticulitis, nonspecific ulcerative colitis, seizure disorder, recent intestinal anastomoses, thrombotic disorders, tuberculosis, ocular herpes simplex, emotional instability and psychosis.

1.0.7 Adverse effects

The cardiovascular effects of dexamethasone include hypertension and congestive heart failure in susceptible patients.

Long-term glucocorticoid effects on gastro-intestinal tract have been reported to be dyspepsia, peptic ulcers with perforation and gastrointestinal bleeding of which the risk increases with concomitant administration of NSAIDs. Other side effects include abdominal distension, abdominal pain to increased appetite resulting in weight gain, diarrhoea, esophageal ulceration, esophageal candidiasis, acute pancreatitis.

In musculoskeletal system, steroids may cause proximal myopathy, osteoporosis, vertebral and long bone fractures, avascular osteonecrosis, tendon rupture and myalgia.

It has also been found that glucocorticoids may result in sodium and water retention, hypokalemic alkalosis, potassium loss, negative nitrogen and calcium balance (20).

Furthermore, with the use of steroids impaired healing, hirsutism, skin atrophy, bruising, striae, telangiectasia, acne, increased sweating may occur.

Glucocorticoid use may result into derangement of the endocrine system such as suppression of the hypothalamo-pituitary adrenal axis with prolonged exposure to corticosteroids particularly during stress as seen in trauma surgery or illness. It may as well lead to growth suppression in infancy, childhood and adolescence, menstrual irregularities and amenorrhoea, cushingoid facies, weight gain, impaired carbohydrate tolerance with increased requirement for antidiabetic therapy, latent diabetes mellitus is manifested and increased appetite. (21)

In the nervous system, long-term administration of glucocorticoid may result into depression and psychosis especially in the elderly people, sleep disturbances, emotional instability, anxiety disorder, euphoria, psychological dependence and abuse in high doses. Also mania and delirium are reported to manifest as withdrawal symptoms after discontinuation from prolonged exposure. In children when given at high doses it is implicated in causing insomnia, hyperactivity and irritability. Other reported central nervous system adverse effects include dizziness, headache, vertigo, raised intracranial pressure with papilloedema usually after treatment withdrawal, aggravation of schizophrenia, aggravation of epilepsy, suicidal ideation, delusions, hallucinations and cognitive dysfunction. (22)

Glucocorticoids may as well lead to untoward side-effects involving the eyes including raised intra-ocular pressure, glaucoma, papilloedema, cataracts, exophthalmos, corneal or scleral thinning and exacerbation of ophthalmic viral or fungal disease. (23)

Owing to the anti-inflammatory and immunosuppressive effects of glucocorticoids, symptoms and signs of infection are markedly reduced due to reduced production of pro-inflammatory cytokines. Hence, drug-induced immunosuppression by the steroids propagates into severe infection. Also, opportunistic infections are noted with recurrence of dormant tuberculosis stemming from immunosuppression status.

It has been found that abrupt stopping of corticosteroids after prolonged treatment or exposure may lead to acute adrenal insufficiency, hypotension and death. A steroid withdrawal syndrome seemingly unrelated to adrenocortical insufficiency may also occur and include symptoms such as anorexia, nausea, vomiting, lethargy, headache, fever, weight loss, and/or hypotension. (24, 25)

1.0.8 Drug Interactions

Drugs that induce hepatic enzyme cytochrome P-450 isozyme 3A4 such as phenobarbital, phenytoin, rifampicin, rifabutin, carbamazepine, primidone and aminogluethimide may reduce the therapeutic efficacy of corticosteroids by increasing the rate of metabolism and thus reducing glucocorticoid plasma levels. (26)

Drugs such as ketoconazole, ciclosporin or ritonavir inhibit hepatic enzyme cytochrome P-450 isoenzyme 3A4 (hepatic microsomal enzyme inhibitors). This results into significant reduction in glucocorticoid clearance. Hence, the dose of glucocorticoid needs to be adjusted when hepatic microsomal enzyme inhibitors are co-administered in order to minimize the risk of adverse effects. (26)

Increased blood glucose levels have been found to be associated with corticosteroid use and this is thought to be due to induced insulin resistance by the steroids. Thus dose adjustment of oral hypoglycemic drugs or insulin needs to be considered in patients receiving glucocorticoids. (27)

Concomitant administration of NSAIDs and glucocorticoids may increase the risk of GI ulceration. Aspirin should be used cautiously in conjunction with corticosteroids in patients with hypothrombinaemia. The renal clearance of salicylates is increased by corticosteroids and steroid withdrawal may result in salicylate intoxication. Patients should be observed closely for adverse effects of either medicine. (28)

The effect of warfarin may be reduced or enhanced when co-administered with corticosteroid. The reason for change in effect of warfarin is interference with hepatic metabolism of warfarin by the corticosteroids. Thus, regular or close monitoring of INR is required.

It has been reported that concomitant use of amphotericin B and corticosteroids may result in an increased risk of hypokalemia. (26)

Following the anti-glucocorticoid activity of mifepristone, the administration of mifepristone results into reduced effect of glucocorticoid in 3-4 days of mifepristone administration, hence dose adjustment has to be considered. (29)

With the ability of corticosteroid to blunt the immune response, it is strictly contraindicated to immunize individuals with live-vaccines. Also, antibody response to other vaccines may be impaired. (30)

The effects of glucocorticoids are potentiated by estrogens. The dose adjustment of corticosteroid may be required, if oestrogen therapy is administered or stopped.

The growth promoting effect of somatotropin hormone may be inhibited by long-term use of corticosteroids.

When high doses of salbutamol, salmeterol, terbutaline or formoteral are administered concurrently with high doses of corticosteroids there is a greater potential for developing hypokalemia.

Moreover, when glucocorticoids are co-administered with potassium-depleting diuretics such as furosemide and thiazides or carbonic anhydrase there is an increased risk of potassium loss. (30)

It has been reported that antacids administration may decrease drug absorption in the gastrointestinal tract. Thus, its concurrent administration with corticosteroid may reduce absorption in the gut lumen. Dose adjustment of corticosteroid is needed in this situation. (31)

1.2 LITERATURE REVIEW

Sore throat has been the most common complication following endotracheal intubation either during the emergency or elective surgical procedure. It contributes a lot to patient dissatisfaction postoperatively along with patient's discomfort and bad experience of the surgical procedure.

In 2012, a study done by Bagchi D et al which involved 96 patients divided into two groups showed that there was a significant reduction in the incidence of postoperative sore throat by approximately 30% an hour after extubation when prophylactic intravenous dexamethasone was used. And the efficacy for postoperative sore throat reduction with I.V dexamethasone was calculated to be 61.2%. (32)`

Park et al as well conducted a study using two different doses of I.V dexamethasone prophylactically with double-lumen endobronchial tube which demonstrated that there was a significant reduction of sore throat incidence at 1 hour post-extubation by 22% and 44% of prophylactic I.V dexamethasone at a dose of 0.1mg/kg and 0.2mg/kg respectively with the reduction of 30% of sore throat incidence at 24 hours following extubation. (33)

Furthermore, the incidence and severity of postoperative sore throat and hoarseness can be reduced more effectively with a combination of drugs as evidenced in a study done by Safavi M et al in 2014 which demonstrated that the use of ketamine gargle combined with I.V dexamethasone was more effective and significant in reducing the incidence and severity of sore throat and hoarseness after tracheal extubation than using either of the drugs alone. (22)

Not only was the I.V prophylactic dexamethasone before intubation studied but also the effectiveness of the drug after tracheal intubation had been investigated as demonstrated by a study done by Sun-Young et al in 2010 which enrolled 70 patients who were randomly divided into two groups. Out of those patients, 10mg of I.V dexamethasone was administered 30 minutes before or after intubation in prophylactic and post-intubation groups respectively. It was found that the severity of sore throat at 1 hour and 6 hour was significantly lower in the prophylactic group as compared to the post-intubation group. (34)

Tabari et al did a comparative study on the effectiveness of betamethasone gel applied on an endotracheal tube and I.V dexamethasone on postoperative sore throat. The results showed a significant lower incidence of sore throat in the betamethasone gel group as compared to I.V dexamethasone group and control group at 1, 6 and 24 hours postoperatively. (35)

Also, a study was done to evaluate the combined effect of intravenous dexamethasone and lidocaine in minimizing postoperative sore throat as opposed to the use of dexamethasone alone. A total number of 70 female patients who underwent breast mass excision were enrolled and divided into two groups. One group (DL) received dexamethasone 8mg and lidocaine 1.5mg/kg 5 minutes prior to induction, with repetition of lidocaine injection at the end of surgery while group D received only dexamethasone 8 mg with normal saline. Results showed that there was significant lower incidence of sore throat post-extubation in group DL than in D (62.9% vs. 85.7%, respectively; P = 0.029). The assessed severity of sore throat and hoarseness was as well found to be significantly reduced in group DL as compared to group D. (36)

Being an anti-inflammatory agent, dexamethasone profoundly reduces laryngeal edema by inhibiting the release of cytokines and reducing membrane permeability of the blood vessels. This has been shown in a study that enrolled 60 children who were ventilated for more than 24 hours. They were divided into two groups whereby group 1 patients were administered with 0.5mg/kg of dexamethasone 4 hours prior to extubation, at extubation, at 6 and 12 hours after extubation while the other group received placebo (normal saline). The results showed that the difference between two groups was statistically significant (P value=0.004) since stridor and laryngeal edema in group 1 was observed to be 26.67% while in placebo group was 63.33%. (37)

The above observation has been consistent with the findings of the study done on rabbits which investigated the role of dexamethasone in reducing laryngeal edema after short-term intubation. A total of 33 rabbits were divided into 3 groups whereby high-dose dexamethasone (1mg/kg) was administered to group 1 just after intubation and group 2 just before extubation while group 3 was given normal saline. The subglottic excursion pressure was measured and

found to be less increased in group 1 and 2 as compared to group 3 ($P<0.05$). Also, histologic sections of the larynges taken from the rabbits revealed less edema of the submucosa in group 1 and 2 compared to group 3 ($P<0.05$). (38)

Also, the local effect of dexamethasone has been found to minimize the incidence of postoperative sore throat and hoarseness. A study that involved 100 patients who were randomly divided into two groups of 50 patients in each was carried out. They were operated under general anesthesia with the airway secured using an LMA. Dexamethasone was applied on the LMA cuffs of the study group while the other group (control) received placebo (distilled water applied on LMA cuff). Results showed that the mean score of sore throat at 1, 2 and 24 hours were significantly lower in the study group as compared to control group. On the contrary, the incidence of hoarseness was reduced at 1, 2 and 24 hours after LMA removal as compared to the control group ($P=0.112$, 2% vs 12%; $P=0.269$, 4% vs 12%; $P=1$, 2% vs 4% respectively) but the difference in the incidence of hoarseness were not statistically significant. (39)

2.0 PROBLEMSTATEMENT

It is well known that direct laryngoscopy and tracheal intubation has been a traditional method of keeping airway patent in anesthetized patient during a surgical procedure or when admitted in the ICU. With the knowledge imparted from the literature reviews, the endotracheal tube once placed and cuffed it causes mechanical irritation and trauma to the pharyngo-laryngeal mucosa triggering an inflammatory process which has the propensity of causing early complications after extubation including sore throat, cough, hoarseness and laryngeal edema which manifests as stridor. These become troublesome at large to the patient in terms of satisfaction as well as to the anesthetist in terms of airway management.

In Nigeria, the incidence of POST was 49% posing a great deal of discomfort (12). It is difficult to control even when pain from a surgical wound is successfully controlled by systemic administration of analgesics. From the observation point of view, postoperative sore throat in our setting is experienced in our daily practice contributing largely to patient's dissatisfaction.

Dexamethasone has been widely and safely used in Tanzania for the treatment of different medical conditions such as neck swelling following neck or oropharyngeal surgeries, reducing peri-tumoral oedema in neurocritical care ICU. Also, dexamethasone had been found to have the effect in reducing postoperative nausea and vomiting following adenotonsillectomy in a study done at MNH (54). However, there is lack of knowledge on its use in prevention of postoperative sore throat following mechanical irritation by the endotracheal tube in our clinical setting.

2.1 RATIONALE

This study has not been done in our setting. Sore throat being the most common complaint reported by the patients following laryngoscopy and tracheal intubation imposes a great discomfort making the patients reluctant on the choice of anesthetic technique next time they present for surgery.

The provision of quality care and satisfaction to our patients is of great importance. Hence, the study will add up to the possible ways of reducing throat complications in our setting.

In addition, this research will be conducted as a partial fulfillment of my Masters Degree Program in Anesthesiology.

2.2 RESEARCH QUESTION

Does the prophylactic use of dexamethasone effectively reduce the incidence of postoperative sore throat?

3.0 OBJECTIVES

3.1 Broad objective:

To assess the effectiveness of prophylactic intravenous dexamethasone in reducing the incidence of sore throat postoperatively in elective patients under general anesthesia with endotracheal intubation from September 2016 to February 2017 at MNH

3.2 Specific objectives

a) To determine the proportion of patients developing sore throat postoperatively at MNH
b) To determine the effect of dexamethasone in preventing postoperative sore throat in patients operated under general anesthesia with orotracheal intubation

4.0 METHODOLOGY

4.1 Study design

It was a prospective randomized double-blind study of intravenous dexamethasone using the dose of 0.1mg/kg

4.2 Study Area

The study was conducted in Muhimbili National Hospital (MNH) found in Ilala municipal council in Dar-es-salaam, Tanzania. MNH is a tertiary hospital (referral center) which provides health services to residents of Dar-Es-Salaam as well as people from different regions of the country at large. Also, it is a teaching hospital through which students get the opportunity to participate in the clinical aspect of their learning process. It has a directorate of surgical services composed of 6 surgical departments namely Surgery, Otorhinolaryngology (ENT), Anesthesia, Ophthalmology, Obstetrics and Gynecology and Dental Departments. In addition, it has about 17 operating theatres

4.3 Study duration

The study was conducted in a 6 months period beginning from September, 2016 to February 2017

4.4 Study population

A study population included the patients aged 18-60 years who were scheduled for elective surgical procedures under general anesthesia (GA) and intubated with an endotracheal tube (ETT). Both male and female patients who met the inclusion criteria and signed the consent form were enrolled in the study.

4.5.1 INCLUSION CRITERIA

Patients aged 18-60 years

Patients in ASA I and II

Patients scheduled for surgeries with an estimated duration of 45 minutes-3 hours

Patients who have signed a written consent form

Patients needing GA with an ETT

4.5.2 EXCLUSION CRITERIA:

Patients with upper respiratory tract infection (URTI)

Anticipated difficult airway

Use of NGT and throat packs

Patients on steroids

Patients with diabetes mellitus or hypertension

Patients with hypersensitivity reaction to dexamethasone

Patients undergoing surgeries of the oral cavity or oropharynx

Unpredicted or long duration surgeries (>3 hours)

4.5.3 SAMPLE SIZE (*Note: formula for calculation cited as 56 in reference page*)

$$N= (z_{1-\alpha/2}+ z_{1-\beta})^2 \frac{[(1+RR)/(1-RR)]^2}{(\pi_c + \pi_t)}$$

$RR = \ln (1-\pi_c)/\ln (1-\pi_t)$

RR=Relative risk

Π_c= incidence rate for control group 49% (32)

Π_t= incidence rate for dexamethasone group 19% (32)

N = sample size per group

α = type I error, ß = type II error

Power of study= 80%; $\alpha = 0.05$

$Z_{1-\alpha/2} = 1.96$; $z_{1-ß} = 0.84$

RR = 3.19543

$$N = (1.96+0.84)^2 \frac{[(1+3.19543)/(1-3.19543)]^2}{(0.49+0.19)}$$

N = 42 plus 10% missing data, N=46 patients per group

Hence, 92 patients in total were enrolled for the study

4.5.4 Sampling method

A simple random sampling method was employed to both in-patients and outpatients who were scheduled for elective surgery and enrolled into the study after meeting the inclusion criteria. During a recruitment process, the patients were assigned into two groups based on the order of recruitment number whereby those patients falling in odd numbers were assigned into a study group (dexamethasone group) and those with even numbers were assigned into a placebo group (placebo group). All patients were explained and provided with all necessary and detailed information on what the study was all about and screened for eligibility to be part of the study. Upon reaching the agreement of participating in the study, they were requested to sign a written consent form.

4.6 Data collection and management

The data was collected by the principal investigator through the use of a well-structured questionnaire at 1 hour, 6 hour and 24 hour after extubation whereby the patients were directly asked questions on sore throat with the incidence and severity being assessed by the use of a 4-point scale adopted from a study done by Bagchi et al (32).

4.6.1 Preoperative assessment

Pre-anesthetic evaluation was done thoroughly which included the following

A detailed history encompassing chief complaint, review of other systems aiming at unmasking symptoms the patient is unaware of, past medical conditions, history of allergy, anesthetic history, current medications, family & social history and physical examination

Airway assessment including Mallampati classification

Nutritional status and weight of the patient

A detailed examination of the respiratory system

Blood workup and radiological investigations were done based on the history and physical findings

Information was also delivered to the patients about staying nil per oral (NPO) over midnight, premedication, choice of anesthetic technique, risks of anesthesia, possible side-effects and postoperative pain management. Then, a consent form was signed. The investigator who was not blinded in the study gave numbers to the enrolled patients after each individual interview during the recruitment process. The participants (patients) in the study who had odd numbers were placed into dexamethasone group and those with even numbers were placed into placebo group. The principal investigator who was not blinded to the two groups of patients prepared the drugs in different syringes with codes which were D1 and D2 representing dexamethasone (0.1mg/kg) and placebo (normal saline) respectively.

The drugs were distributed to the anesthetists working in respective theatres where the enrolled patients were to be operated. The timing of administration of dexamethasone was considered in such a way that dexamethasone was intravenously administered 60 minutes in a waiting area by the anesthetist before induction of anesthesia following insertion of a cannula gauge 16-18.

4.6.2 Intraoperative Phase

In the operating room as routinely done, the patient was connected to the standard monitoring equipment (ECG, Cuff for Non-invasive BP monitoring, Pulse oximetry) and baseline parameters recorded which included Non-invasive blood pressure, heart rate and oxygen saturation. Pre-oxygenation with 100% oxygen was done for 3-5 minutes. Induction phase was carried out using standard induction drugs followed by smooth and gentle orotracheal intubation using cuffed endotracheal tube size 7.0 mm of internal diameter for females and size 7.5 mm of internal diameter for male patients. ETT cuff was inflated using a cuff pressure manometer with the intracuff pressure being kept in the range of 20-30 cmH2O to attain adequate seal in order to prevent leakage. And the cuff pressure was recorded for each individual patient.

The patients were maintained with standard maintenance drugs. Also, the patient’s movement was largely minimized.

During the end of anesthesia, gentle oropharyngeal suctioning was done with the purpose of minimizing trauma and clearing the airway of secretions. Extubation was done to the patient with full deflation of the tracheal cuff after fulfilling the criteria for extubation (respond to command, sustained head lift and hand grip for 5 seconds).

4.6.3 Postoperative Phase

The patient postoperatively was directly questioned using a specially designed questionnaire by the investigator on sore throat which was graded on a 4-point scale (*Appendix II*) at 1 hour, 6 hour and 24 hour after extubation.

4.7 Data Analysis

Every questionnaire was rechecked for completeness and clarity by the investigator.The data collected was coded and entered into the Statistical Package for Social Sciences (SPSS) Program, version 11.0. Data cleaning was done by doing preliminary frequencies to identify missing variables and then the data was analyzed using the same software.

The presence and differences in severity of sore throat were analyzed using chi square test and Fischer's exact test. The significance level of 0.05 (P value < 0.05) was considered.

4.8 Ethical considerations

The investigator briefly introduced himself to each patient and explained about the study and its significance. The interview was conducted in a secluded room. The patients who freely consented were enrolled into the study. All information obtained was kept confidential by identifying the patients using numbers in the questionnaire.

4.9 Ethical Clearance

The proposal was presented in the department of Anesthesiology of Muhimbili University of Health and Allied Sciences (MUHAS). This was followed by seeking ethical clearance from the Research and Publications Committee of the Muhimbili University of Health and Allied sciences.

5.0 RESULTS

Ninety two patients were allocated into two groups (dexamethasone group and control group) of 46 patients each and followed up within a period of 24 hours. No patient was lost to follow-up, thereby all recruited patients were available for data collection and analysis. Patient characteristics were comparable with respect to the mean age, sex ratio and body mass index (BMI) in both groups. Other variables regarding the number of intubation attempts and duration of surgery were as well comparable in both groups.**Table1**

Table 1: Distribution of patient characteristics

Patient characteristics	**Dexamethasone group =46**	**Placebo group=46**	**P value**
Age (years)	41.17±14.13	37.89±12.97	0.249
Sex	22:24	23:23	0.835
BMI (kg/m^2)	24.11±3.71	25.19±4.09	0.189
Intubation attempts	1.17±0.38	1.13±0.341	0.567
Duration of surgery (minutes)	81.28±34.35	83.02±26.39	0.786

The incidence of sore throat at 1 hour in group D1 and D2 was 27 (58.7%) and 44 (95.6%) respectively [D1 vs D2, p<0.001]. The reduction of sore throat incidence at 1 hour was 36.9%. At 6 hour post-extubation the incidence of sore throat in group D1 and D2 was 10 (21.7%) and 44 (95.6%) respectively [D1 vs D2, p<0.001]. At 24 hour after extubation, the incidence of sore throat in group D1 and D2 was 2 (4.4%) and 32 (69.6%) respectively [D1 vs D2, p < 0.001]. The incidences in the dexamethasone group have been comparably lower than the incidences in the control group. In both groups the difference of the incidences is statistically significant (p value<0.001). The frequency of patients who developed sore throat in the dexamethasone group had been progressively decreasing with time. On the contrary, the frequency of patients who developed sore throat after extubation had been increasing in the control group with the maximum incidence being at 24 hour post extubation during follow-up. **(Table** 2)

Table 2: Incidence of sore throat at 1, 6, 24 hours post-extubation

	Dexamethasone(D1) group =46	**Placebo (D2) group=46**	**P value**
Incidence of sore throat at 1hr	27(58.7%)	44(95.7%)	<0.001
Incidence of sore throat at 6hrs	10(21.7%)	44(95.7%)	<0.001
Incidence of sore throat at 24hrs	2(4.4%)	32(69.5%)	<0.001

In overall, less proportion of patients developed mild, moderate and severe sore throat in the dexamethasone group as compared to the control group except for the first hour post-extubation where larger proportion of patients developed mild sore throat in the dexamethasone group. At 1 hour post-extubation, less number of patients in the dexamethasone group 5(10.9%) had moderate sore throat as compared to control group 27(58.7%). No patient in the dexamethasone group developed severe sore throat as compared to 13(28.3%) in the control group. The difference is statistically significant.

At 6 hour after extubation, less proportion 3(6.5%) of patients in the dexamethasone group had moderate sore throat as compared to control group 21(45.7%). None of the patients in the dexamethasone group was shown to have severe sore throat when compared to patients in the control group.

At 24 hour after surgery, none of the patients was found to have severe sore throat in both groups. But a larger proportion of patients had mild (47.8%) and moderate (21.7%) sore throat in the control group compared to patients who received dexamethasone. (**Table 3**)

Table 3: Postoperative sore throat severity among patients who were given dexamethasone and those who were given placebo at 1 hour, 6 hours and 24 hours after surgery

Postoperative sore throat	Patients group		Total	P value
	Dexamethasone n (%)	Placebo n (%)		
Sore throat 1hr after surgery				
Mild	22 (47.8)	4 (8.7)	26	
Moderate	5 (10.9)	27 (58.7)	32	< 0.001
Severe	0 (0)	13 (28.3)	13	
Total	**27(58.7)**	**44(95.7)**	**71**	
Sore throat 6hrs after surgery				
Mild	7(15.2)	17(37.0)	24	
Moderate	3(6.5)	21(45.7)	23	0.087
Severe	0(0)	6(13.0)	6	
Total	**10(21.7)**	**44(95.7)**	**53**	
Sore throat 24hrs after surgery				
Mild	1(2.2)	22(47.8)	23	
Moderate	1(2.2)	10(21.7)	11	0.582
Severe	0(0)	0(0)	0(0	
Total	**2(4.4)**	**32(69.5)**	**34**	

6.0 DISCUSSION

Postoperative sore throat as mentioned earlier is a common presenting complication following general anesthesia with endotracheal intubation. It leads to patient dissatisfaction after a surgical procedure carried out under general anesthesia. Postoperative sore throat develops after traumatization of pharyngolaryngeal mucosa and is influenced by many factors such as endotracheal tube size, laryngoscopy, placement of a nasal gastric tube, cuff design, oral suctioning and pressure affecting capillary perfusion of tracheal mucosa resulting in edema formation and mucosal lesion (40).

This study demonstrates that the use of prophylactic intravenous dexamethasone using a dose of 0.1mg/kg results in reduction of the incidence of postoperative sore throat as evidenced by the lower incidence of sore throat in the study group than a control group at 1, 6 and 24 hours post extubation

At 1 hour, the incidence of postoperative sore throat was lower (58.7%) in the dexamethasone group than in the control group (95.7%) and this finding was statistically significant. Thus, it shows a reduction in the incidence by 37%. At 24 hour post extubation, the reduction in the incidence of sore throat by 65.1% was observed. This finding has been consistent with previous studies. In a study conducted by park et al in patients intubated with a double lumen tube and intravenous dexamethasone was administered prophylactically at two different doses (0.1mg/kg and 0.2mg/kg) demonstrated a significant reduction in postoperative sore throat at 1 hour post-extubation by 22% and 44% respectively (33).

Furthermore, a study done by Thomas S et al to evaluate the role 8 mg of intravenous dexamethasone in preventing postoperative sore throat involved 110 subjects who underwent abdominal and lower limb surgeries showed lower incidence in the dexamethasone group 11(20%) than in the placebo group 31(56.3%) with the reduction in the overall incidence by 36.6%. Similar results of the previous study have been reflected in this current study. (41)

Also, in a study done by Park J. H et al which involved 146 patients who were randomly allocated to receive intravenously dexamethasone or magnesium sulfate showed none of them to be inferior over the other in terms of reducing incidence of sore throat. It was reported that the incidence of sore in the dexamethasone group at 1 hour, 6 hour and 24 hour were 58.9%, 35.6% and 17.8% respectively. When comparing with the incidences of this current study at 1, 6 and 24 hours (58.7%, 21.7% and 4.4% respectively) it is found that the incidence of sore throat in the previous study was higher. The main reason for that higher incidence is due to the fact that the patients in the previous study underwent lumbar spine surgery in a prone position which is one among the factors contributing to development of postoperative sore throat. (42)

Of note, administration of dexamethasone before intubation offers more benefit than when administered post-intubation. This stems from the fact that laryngoscopy and tracheal intubation trigger an inflammatory process which is prevented by dexamethasone. This is proved by the findings from this current study showing that there was a significant reduction in the incidence and severity of sore throat at different time intervals. A similar study was done by Sun-Young et al which evaluated the effect of dexamethasone prior to intubation and after intubation which showed that it was more effective to administer dexamethasone before intubation than after tracheal intubation as evidenced by the significant reduction in the incidence of postoperative sore throat and severity in the group that received the drug prior to intubation compared to the other group that showed insignificant reduction in sore throat incidence (34).

In this present study, the dose of 0.1 mg/kg of dexamethasone was chosen for safety purposes yielding far better results in reducing incidences of sore throat for the first 6 hours (58.7%) and at 24 hours (4.4%) in dexamethasone group. A similar finding was revealed in a study conducted by Oliveira De et al which evaluated the dose-dependent effects of dexamethasone using 0.1mg/kg and 0.05mg/kg with the former dose showing positive effects on lessening airway morbidity such as sore throat incidence and severity, thus promoting postoperative recovery (43). Also, the dose-dependent effects exhibited by dexamethasone has been revealed in a study done by Park et al showing that the dose of dexamethasone 0.2 mg/kg was more

effective in reducing the incidence of sore throat post extubation than when dexamethasone was administered at a dose of 0.1 mg/kg (33).

On the contrary, the dose of dexamethasone 0.2mg/kg used in a study carried out by Bagchi et al showed comparably higher incidences of sore throat in an experimental group than what has been found in our study. The increased incidence despite higher dose of dexamethasone can be resulting from the use of larger sizes of endotracheal tubes (8-8.5mm and 7-7.5 mm in diameter for male and female respectively) and failure to measure the cuff pressure, all of which increase the risk of postoperative sore throat. (32)

Also, our finding from this study has shown that there is significant reduction in the severity of sore throat with the administration of intravenous dexamethasone before intubation. No single patient presented with severe sore throat during follow-up at 1 hour, 6 hour and 24 hour post-extubation in the dexamethasone group as compared to the control group. Comparing the two groups in the first hour, greater proportion of patients developed mild sore throat (47.8%) in the dexamethasone group while in the control group most of the patients had moderate sore throat (58.7%). Less proportion of patients (6.5%) developed moderate sore throat in the dexamethasone group at 6 hour compared to the control group (45.7%). Similar findings have been observed in studies conducted by Park et al (33) and Bagchi et al (32). However, in a systematic review and meta-analysis conducted by Hayward G et al which included 8 trials consisting of 743 patients showed that one study did not support the effect of dexamethasone on milder symptoms of sore throat (44).

Nevertheless, the data obtained from this current study has shown that severity of sore throat had been progressively decreasing with time with the lower intensity being observed in the dexamethasone group than in the control group. The difference in severity was significant during the first hour. But at 6 and 24 hours the difference was not significant even though reduction in severity was appreciated in the dexamethasone group compared to the control group. A similar finding has been reflected in a study done by Singh G et al on the effect of a single dose of dexamethasone in reducing postoperative sore throat, nausea and vomiting consisting of 60 patients who underwent caesarian section. In all time intervals, the intensity

of sore throat scored using visual analogue scale was lower in the study group than in the control group. (45)

Studies on sore throat rely on subjective endpoints by self-reporting the intensity of sore throat. The perception of sore throat tends to differ from one patient to another (46). Objective measures which can be employed to assess the degree of injury to the airway include fiberoptic laryngoscopy and histological examination of the tissue, both of which are quite invasive. The patients with mild sore throat appear to be not in so much distress making them not to report and seek for medical attention. On the other hand, moderate to severe sore throat has been documented to cause patient dissatisfaction and delayed discharge (47).

Postoperative sore throat is hypothesized to be mediated by an aseptic inflammatory process resulting from leucocyte migration to the site of irritation. The activated macrophages lead to initiation and modulation of pro-inflammatory cytokine/chemokine gene stimulated by NF-kB. Cytokines particularly TNF-α and IL-1 are found to be key mediators which induce expression of cell surface adhesion molecules and thus increasing the adhesion of polymorphonuclear neutrophils. Also, dexamethasone inhibits the metabolism of Arachidonic acid thus preventing the release of prostaglandins and leukotriene with subsequent modulation of inflammatory process (48). Having an anti-inflammatory property, corticosteroids act generally by suppressing the expression of pro-inflammatory cytokines (49).

Pharmacological intervention using topical steroid has also been employed in reducing the incidence and severity of postoperative sore throat by exerting its anti-nociceptive and anti-inflammatory effects locally (11). There are several studies done aiming at studying the effectiveness of dexamethasone in lessening the incidence and severity of sore throat with promising results (50) (39). The findings obtained in the study done by Tabari et al comparing betamethasone gel locally applied over the entire tracheal tube and intravenous administration of dexamethasone showed that when corticosteroid is applied topically it has more beneficial effects than when administered intravenously hence supporting the evidence that betamethasone gel topically applied resulted in lower incidence of sore throat than patients

receiving intravenous dexamethasone (35). In this present study, similar findings have been observed.

However, Stride P. C showed that topical 1% hydrocortisone as a corticosteroid was ineffective in reducing the incidence of postoperative sore throat. The reason was found to be that hydrocortisone cream was only applied from the tip of an endotracheal tube to 5cm above the cuff (51).

Lastly, the overall proportion of patients who developed sore throat in the control group which is basically the group with no intervention was 86.9% based on the finding of the current study. In one study done in Ethiopia, it was documented that the patients who complained of sore throat was 56.6% (52) and others reported the incidence of 64% (2). The incidence obtained from the current study is higher than the previous studies. However, others have documented to have the incidence of postoperative sore throat varying from 20-80% (53).

During a 24 hour follow up, no patient was found to have developed adverse effects of dexamethasone since a single-dose of dexamethasone has been observed to be safe when administered.

6.1 Study Limitations

This study is subject to several limitations. One of them being the small sample size of the patients recruited in the study. The objective way of assessing damage to the mucosal tissue using fiberoptic bronchoscope was not employed. Thus, assessment of sore throat was based on subjective descriptions with severity expressed differently depending on patient's experience.

Also, follow up of the patient was only limited to 24 hours post extubation. Furthermore, this study only examined clinical outcomes in patients who underwent surgery with the exclusion of those surgeries involving the airway, neck, head and prone positioning of which in several studies have found to highly increase the risk of developing postoperative sore throat after extubation. Thus, the study could not establish whether prophylactic administration of dexamethasone will also be effective in decreasing the incidence and severity of postoperative

sore throat in those surgeries involving airway and neck with greater degrees of patient's movements.

6.2 Conclusion

With this present study, it is concluded that the prophylactic administration of dexamethasone before surgery offers beneficial effects in terms of lowering the incidence and severity of postoperative sore throat in patients emerging from general anesthesia with endotracheal intubation.

6.3 Recommendations

Owing to the findings of the current study which reveal the good clinical outcome of dexamethasone in lowering the incidence and severity of sore throat, it is recommended that a single prophylactic dose of intravenous dexamethasone should be routinely administered before surgery as a prophylaxis against developing sore throat after extubation in order to increase patient satisfaction in anesthesia clinical practice.

Also, it is recommended that a multi-center study with larger sample size is needed for proper representation of the general population since a small sample size was used in the current study with similar findings obtained from previous studies.

Lastly, the recommendation is made on carrying out a study which focuses on determining the effectiveness of prophylactic dexamethasone in surgeries with high risk of developing sore throat due to greater degrees of movement and airway manipulation.

6.4 Dissemination of results

The findings from this study will be presented as dissertation (in Partial fulfillment of Masters Degree in Anesthesiology of MUHAS), and in scientific seminars/conferences (abstract) and scientific reports (manuscripts) submitted to an appropriate journal for the purpose of sharing knowledge and improve on clinical management in the line of conduction of safe anesthesia and patient satisfaction. Another copy will be kept in the library archive.

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APPENDIX I: <u>Questionnaire</u>

ASSESSMENT OF THE PROPHYLACTIC USE OF INTRAVENOUS DEXAMETHASONE IN REDUCING THE INCIDENCE OF POSTOPERATIVE SORE THROAT

1. Hospital File Number……..
2. Code number of the patient (indicates the group into which he/she is placed-Dexamethasone or placebo group)……
3. Age ……. Years
4. Sex …….. (a)Male (b)Female
5. Weight ……. (kg)
6. Height ……...(cm)
7. Duration of surgery …….. minutes
8. Duration of intubation……. minutes
9. Endotracheal tube size……... mm I.D
10. Endotracheal tube Cuff pressure …… cm H_2O
11. Was external laryngeal pressure applied during intubation? ..... (*indicate YES/NO*)
12. Number of intubation attempts …….
13. Is there blood on the endotracheal tube during extubation (indicate YES/NO)……
14. Is there blood noted on a suction catheter (indicate YES/NO) ……..

POSTOPERATIVE

At 1 hour post-extubation

15. Do you experience sore throat after surgery? (Indicate YES=1 or NO=0)…….
16. If ***Yes*** please grade its severity (1=mild; 2=moderate; 3=severe)……..

At 6 hour post-extubation

17. Do you still experience sore throat after surgery? (Indicate YES=1 or NO=0)…….
18. If ***Yes*** please grade its severity (1=mild; 2=moderate; 3=severe)……

At 24 hour post-extubation

19. Is there still the complaint of sore throat since surgery was ended? (Indicate YES=1 or NO=0)
20. If ***Yes*** please grade its severity (1=mild; 2=moderate; 3=severe)……..

Appendix II FOUR-POINT SCALE SCORING SYSTEM (*Adopted from Bagchi D, et al. Efficacy of intravenous dexamethasone to reduce incidence of postoperative sore throat: A prospective randomized controlled trial. J AnaesthesiolClinPharmacol. 2012; 28(4):477–80).*

SORE THROAT

0 – No sore throat at any time after the operation

1 – Mild (scratchy throat following operation). Less severe than a cold (patient answers in the affirmative when asked about)

2 –Moderate (similar to that noted with cold)

3 –Severe –more severe than noted with cold (the patient is in obvious distress)

Appendix III: CONSENT FORM
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS, MUHAS

INFORMED CONSENT FORM

Consent to Participate in a Study

Greetings! My name is Dr. Steven Sebastian Nandi, a resident in the department of Anesthesia (MUHAS).

I am working on my research in determining the use of intravenous dexamethasone in reducing the incidence of postoperative sore throat in elective patients under general anesthesia with endotracheal intubation.

Purpose of the study

The aim of this study is to determine the effect of intravenous dexamethasone in reducing the incidence of postoperative sore throat in patients who have been intubated under general anesthesia with an endotracheal tube.

How to participate

If you agree to participate in the study, you will sign a written consent form to approve your willingness of being enrolled in the study. At the end of the operation when you are awake, you will be asked a series of specified questions in accordance with the structured questionnaire at different time intervals.

Confidentiality

I would like to assure you that the information collected about you will remain confidential since your name will not be linked to any research information. The information will be entered into the computer and any unauthorized person will not be able to access the information.

Costs

I guarantee you that you will not pay anything for your participation in the study.

Risks

We do not expect that your participation in the study will do you any harm with the fact that only a single-dose of the study drug will be used.

Benefits

The information gathered from you during the study will serve the purpose of knowing the magnitude of the problem and possible ways of minimizing it. In addition, this will make way for developing appropriate protocols, hence providing quality care, safety and satisfaction to our patients presenting for surgery.

Right to withdraw

Taking part in this research is completely voluntary. You can decide to stop participating in this study at any time even though you have given already your consent. Refusal to participate or withdraw from the study will not involve any penalty or strip you the right to receive surgical treatment.

Who to contact

If you ever have questions on this study, please do not hesitate to contact

Dr. Steven Sebastian Nandi

The Principle investigator

Muhimbili University of Health and Allied Sciences (MUHAS)

P. O. Box 65001, Dar-Es-Salaam

Mobile number: (+255) 652 460352

OR In case of any inquiries about your rights as a participant in the study please contact

Prof. Said Aboud

The Director,

Research and Publication Committee,

Muhimbili University of Health and Allied Sciences (MUHAS),

P. O. Box 65001 Dar-Es-salaam,

Tel: 2150302-6

AND Dr. Frederic Mbanga, who is the supervisor of this study (Tel: +255 754 288171) and Dr. Asha Abdulla who is the co-supervisor of my study (Tel: +255 713 244 032)

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI CHA MUHIMBILI

KURUGENZI YA TAFITI NA UCHAPISHAJI

FOMU YA RIDHAA YA RIDHAA YA KUSHIRIKI KWENYE UTAFITI

Habari! Mimi ni Dkt. Steven Sebastian Nandi, ninayesomea shahada ya uzamili katika chuo kikuu cha Sayansi za Tiba cha Muhimbili. Ninashughulika na utafiti unaohusisha dawa ya dexamethasone itakayotolewa kwa mgonjwa kupitia njia ya mshipa wa damu yenye lengo la kupunguza matukio ya dondakoo baada ya upasuaji kwa wagonjwa waliolazwa mwili mzima kwa kutumia nusu kaputi na kuwekewa mpira wa kupumulia kwenye koo.

Nia ya utafiti

Dhumuni la tafiti hii ni kujua na kuamua ufanisi wa dawa ya dexamethasone katika kupunguza dondakoo baada ya upasuaji kwa wagonjwa waliopewa nusu kaputi na kuwekewa mpira wa kupumulia kwenye koo.

Jinsi ya kushiriki

Ukikubali shiriki katika tafiti hii utaweka sahii ya kokuonyesha utayari wako wa kushiriki. Mwisho wa upasuaji utakapo amka toka kwenye dawa za usingizi utaulizwa maswali machache toka kwenye dodoso lililoandaliwa kwa ajili ya utafiti huu katika nyakati tofauti.

Usiri

Ninapenda kukuhakikishia kua taarifa zitakazo patikana kupitia njia ya dodoso zitakua na usiri na hakuna mtu yeyote asiyehusika ataweza pata taarifa zilizo kusanywa na kuingizwa katika ngamizi (kompyuta) kwa kutumia namba za utambulisho.

Gharama

Hautotakiwa kulipa gharama zozote zinazo husiana na utafiti huu.

Hatari

Hatutegemei madhara yoyote kutokea kutokana na kwamba ni dozi ndogo ya dawa itatumika na itatolewa mara moja tu.

Faida

Ushiriki wako kwenye utafiti huu na taarifa utakazo zitoa zitatuwezesha kujua kiwango

Au ukubwa wa tatizo ambao ni muhimu katika uamuzi wa kuzuia au kupunguza tatizo la dondakoo litokanalo na vifaa vinavyo tumika katika njia ya upumuaji mathalani mpira wa kupumulia kwenye njia ya hewa. Kwa maana hiyo itasaidia kutoa huduma sahihi na yenye kuridhisha kwa mgonjwa.

Uhuru wa kushiriki na haki ya kujitoa

Uamuzi wa kushiriki kwenye utafiti huu ni wa hiari. Unaweza kujitoa kwenye utafiti huu wakati wowote hata kama umeshajaza fomu ya ridhaa ya kushiriki utafiti huu. Kukataa kushiriki au kujitoa kwenye utafiti huu hakutaambatana na masharti yoyote au kukuondolea haki yako ya matibabu ya upasuaji.

Nani wa kuwasiliana naye

Kama una maswali kuhusiana na utafiti huu, wasiliana na Mtafiti mkuu, Dkt.
Steven Nandi, Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili, S. L. P. 65001, Dar es Salaam.
Kama una swali kuhusu stahili zako kama mshiriki unaweza kumpigia simu
Prof. Said Aboud
Mwenyekiti wa kamati ya Utafiti na Uchapishaji,
Chuo kikuu cha Afya na Sayansi Shirikishi Muhimbili
S.L.P 65001, Dar-Es-Salaam
Simu: 2150302-6
Au msimamizi wa utafiti huu Dkt. Frederic Mbanga (Simu: +255 754 288171) au msimamizi msaidizi Dkt. Asha Abdulla (Simu: +255 713 244 032)

Mimi……..... nimeelezwa/nimesoma maelezo ya fomu hii na kuyaelewa. Kwa akili zangu timamu nimekubali kushiriki katika utafiti huu.

Sahihi…….. (Mshiriki)

Sahihi…….. (Mtafiti)

Tarehe ya kutia sahihi ya idhini ya kushiriki……..