# A RANDOMIZED, DOUBLE-BLINDED COMPARATIVE STUDY OF PRE-OPERATIVE NEBULIZED DEXAMETHASONE AND INTRAVENOUS KETOROLAC TROMETHAMINE FOR THE PREVENTION OF POST-OPERATIVE SORE THROAT FOLLOWING GENERAL ANESTHESIA

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## MASTER OF SCIENCE IN ALLIED HEALTH SCIENCES

**BY**

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No part of this thesis has been submitted anywhere else for any other degree. This thesis is submitted to the Faculty of Allied Health Sciences, The Superior University, Lahore, in partial fulfillment of the requirements for the degree of Master of Science in the field of "**Allied Health Sciences"** in the Faculty of Allied Health Sciences at The Superior University, Lahore.

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# DEDICATION

This thesis is dedicated to my parents, whose unwavering support, unconditional love, and constant encouragement have been the foundation of my journey. Your sacrifices and belief in me have been my greatest strength.

To my family, thank you for being my pillars of support, for celebrating my successes, and for standing by me in times of struggle. Your presence has made this achievement all the more meaningful.

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**Abdul Mabood**

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# LIST OF ABBREVIATIONS

| Abbreviation | Full Form |
|---|---|
| POST | Post-Operative Sore Throat |
| GA | General Anesthesia |
| IV | Intravenous |
| Neb. | Nebulized |
| ASA | American Society of Anesthesiologists |
| ETT | Endotracheal Tube |
| OR | Odds Ratio |
| CI | Confidence Interval |
| SD | Standard Deviation |
| SE | Standard Error |
| B | Beta Coefficient |
| $\chi^2$ | Chi-Square |
| Mm | Millimeter |
| Min | Minutes |
| N | Number of Patients |
| % | Percentage |
| ≥ | Greater Than or Equal To |
| ≤ | Less Than or Equal To |

# ABSTRACT

**Background:** Many pharmacological interventions have been proposed as a way of preventing or stopping its prevalence. This study was aimed to compare the efficacy of intravenous ketorolac tromethamine and preoperative nebulized dexamethasone in postoperative nausea and vomiting (POST) preventive treatment.

**Methods:** This was a randomized, double blinded study that recruited 100 patients who were scheduled to undergo elective surgery under general anesthesia into this study, randomizing them to either nebulized dexamethasone (Group D, n=50) or intravenous ketorolac (Group K, n=50). To assess the severity of POST at 2, 4, 6 and 12 hours after surgery, a standardised scoring was used. Secondary outcomes included perioperative complications, the need to administer rescue analgesia and demographic and procedure associations. To determine predictors of POST, the use of logistic regression was adopted.

**Results:** Baseline demographics, ASA status, surgery type, ETT size, and intubation attempts were comparable between groups. Mean POST scores were consistently lower in Group D across all time points (2 h: 20.8 ± 5.1 vs. 24.6 ± 6.3; 12 h: 13.8 ± 3.0 vs. 16.2 ± 3.6), and a greater proportion of patients in Group D reported no or mild sore throat. Overall complication rates were similar (36% vs. 40%), with hyperglycemia more frequent in Group D and gastrointestinal irritation more common in Group K. Logistic regression identified Group D (OR = 0.43, p = 0.043), higher cuff pressure (>24 cm $H_2O$, OR = 2.46, p = 0.024), and longer surgery duration (per 10 min, OR = 1.11, p = 0.046) as significant predictors of POST.

**Conclusions:** Preoperative nebulized dexamethasone significantly reduces the severity and incidence of postoperative sore throat compared with intravenous ketorolac, with an acceptable safety profile. Mechanical factors, particularly cuff pressure and longer surgery duration, remain important contributors to POST.



**Keywords:** Postoperative sore throat, Dexamethasone, Ketorolac, General anesthesia, Randomized controlled trial, Endotracheal intubation

# CHAPTER 1

## INTRODUCTION

Another common side effect of general anesthesia is sore throat in patients, which occurs after a procedure (1). It mainly occurs after the manipulation of the airways that are done to facilitate the airway in the patient as a transient of ensuring that the airway is available to the patient in order to achieve mechanical ventilation which is the most paramount in general anesthesia (2). Airway management is carried out with the help of different devices: an endotracheal tube (ETT) or laryngeal mask airway (LMA) to make sure that the patient has his or her airway secured. Breathing of the patient is supported either by the endotracheal tube (ETT) placed in the trachea or a laryngeal mask airway (LMA) which is blindly inserted into the upper airway (3,4). In spite of their apparent minor size, POST causes discomfort, hoarseness, cough, and dysphagia, therefore, affecting the postoperative comfort and satisfaction of patients (5-7).

Studies indicate that POST occurs in between 20 and 74 percent (1). The prevalence of postoperative sore throat (POST) is higher in a patient who is placed in general anesthesia with an endotracheal tube (ETT) than in patients who use a laryngeal mask airway (LMA) or facemask (1,3). The occurrence of POST depends on a number of factors such as positioning during surgery, surgical length, type of surgery and mechanical injury to the airway as a result of intubation (7). POST is also a common phenomenon; however, the clinical measures to alleviate it have not been universally adopted (7).

The exact pathophysiology of POST has not been fully demonstrated, but it has been assumed to relate to the change of the upper airway, which leads to mucosal inflammation (8). Damage or discomfort occurs during intubation, or mechanical stress due to pressure caused by the cuff of the tube (8). The POST risk factors can occur before, during or after surgery (8). The risk factors of POST include women gender, younger age, longer time of surgery, pulmonary conditions, and blood on the endotracheal tube, which is likely due to trauma to the upper airways (1,3,9). Postoperative sore throat (POST) can be increased by the application of a double-lumen tube (DLT), increased cuff pressure, and lack of neuromuscular blockade (1,3,9).

The severity of POST may range between mild discomfort to excruciating pain which makes swallowing difficult. Extubation also causes changes in voice in patients (10). These symptoms do not delay the discharge of the patient; however, they may negatively impact patient satisfaction and make the patient unable to perform his regular activities after the surgery (10). In some cases, recovery after POST can take a long period whereas in some cases it is irreversible (10). Such complications are common due to the trauma in the process of endotracheal tube insertion, foreign body exposure, or airway mucosal dehydration (10). Postoperative prevention (POST) is an important part of patient care because it determines patient satisfaction, comfort, and recovery (7).

The reduction of POST can be achieved by different approaches, including both drug and non-drug ones. Non-pharmacological interventions focus on the improvement and control of airway securing methods, including the use of a supralottic airway device or laryngeal mask airway (LMA) instead of endotracheal tube (ETT). It can also be helpful to choose a smaller size of an endotracheal tube instead of a regular one and reduce the pressure of the cuff to 20 cmH2O. Pre-extubation of the endotracheal tube cuff with gentle suctioning and full deflation is essential and intubation must be strictly performed by an experienced anesthesiologist. These non-pharmacological interventions reduce airway damage and POST (7,9).

The methods of pharmacology include the use of different medicines before, during, or after surgical procedures. Such drugs may be topically applied, injected into the bloodstream or delivered as a nebule. As a rule, medications that are used postoperatively include corticosteroids, non-steroidal anti-inflammatory medicines (NSAIDs), local anesthetics, and ketamine. Nebulization is the most effective of the numerous drug administration modalities as it imparts medications directly to the airway (7,9,11).

The pharmacological interventions of POST focus on the control, prevention and reduction of symptoms. Dexamethasone is a widely used corticosteroid due to its anti inflammatory properties. It has been revealed in many studies that dexamethasone significantly reduces the incidence and prevalence of POST. Benzydamine hydrochloride is an anti-inflammatory and analgesic, nonsteroidal anti-inflammatory drug (NSAID), which is effective in the management of postoperative pain. Ketamine and magnesium proved to be effective in the treatment

of postoperative pain and act on NMDA receptors, both of which have been used in the past (12,13).

Ketorolac tromethamine works by inhibiting enzymes known as cyclooxygenase (COX), thereby impeding the production of chemicals known as prostaglandins that cause pain and inflammation. Ketorolac is useful in the prevention of postoperative pain, and the analgesic effect is probably the reason of its effectiveness (14).

Nebulized dexamethasone has been found to be the most effective way of reducing the cases of POST compared with intravenous delivery or using it on the cuff (15). According to the previous studies, the nebulized drug delivery could be used to improve patient satisfaction and the result of the post-operative period. The proposed study will be aimed at examining and comparing the effectiveness of steroidal and non-steroidal anti-inflammatory drugs in alleviating the occurrence and progression of postoperative sore throat (POST) following general anesthesia with endotracheal intubation.

One of the recognized mild subjective effects and causes of discomfort is Postoperative Sore Throat (POST). Presence of POST has a significant impact on patient satisfaction in relation to anesthetic treatment that is given. The American anesthesiologist categorizes it the ninth most undesirable post general anesthesia outcome (1). The POST incidence rate is significantly different and dissimilar in numerous studies. The incidence is usually reported to be 14.4% (Christensen et al., 1994) to 59.6% (15), and the maximum incidence was recorded 2 to 4 hours after surgery (16).

Supplementary morbidities, including postoperative hoarseness, cough, and dryness, were reported at rates of 50.1, 18.5 and 70.5, respectively (18). Hoarseness was 29% prevalent in the future research. Augmented cough rates are essentially related to POST, particularly the coughing that happens due to rising. Cough occurred in 66.4 percent of the group with POST and 38.6 percent of the group without POST with hoarseness being an important factor strongly linked with POST in the Post-Anesthesia Care Unit (PACU). Patients described the cough as a fast and strong abdominal contraction and hoarseness as a harsh or hurt voice (19).

Another important mechanism in airway protection is coughing. The scattered sensory receptors are activated by a chemical or mechanical stimulus across the respiratory tract (20). The edema of vocal cords in endotracheal intubation causes

hoarseness as a result of mechanical contact, abrasion of the tube in the glottic region (21).

POST is an inevitable and unwanted complication of endotracheal intubation under general anesthesia. One of the nonpharmacological approaches of reducing POST occurrence and severity is the use of smaller endotracheal tube (ETT) diameters. The phenomenon of POST significantly reduced when smaller ETT was used (22). A methodical assessment conducted by El-Boghdadly et al. (2016) revealed that the application of smaller tube size, video laryngoscopes, and reduced endotracheal cuff pressure were all effective in reducing the postoperative sore throat (POST). In addition, intravenous, topical selections, or inhaled steroids, topical nonsteroidal anti-inflammatory medication (NSAIDs), topical selections, or inhalation N-methyl-D-aspartate (NMDA) receptor antagonists were identified as the effective pharmacological approaches to reduce the rate and severity of POST(11).

Numerous studies researched pharmacological treatments. Ketamine and magnesium sulfate that followed corticosteroids were the best nebulized agents in preventing and alleviating POST (22). In a study that was conducted several years ago using both animals and humans, the etiology of POST was studied and found that there was a morphological change in the tracheal cilia following the injury and lack of proper humidity created by the pressure the endotracheal cuff applied to the tracheal wall in its surroundings even at low pressures (18-25 mmHg) and during a procedure less than 2 hours (23). The recent study implied that the pathogenesis is associated with direct trauma of the tracheal mucosa brought about by an increase in tightness of the endotracheal tube cuff (24).

There are several risk factors linked to posttraumatic stress disorder and its severity. The female gender was among the most important risk factors in these researches. Postoperative rates were also found to be higher among females than males (25), and application of ETT was also identified as the most critical risk factor of POST (26).

Other risk factors include the use of large endotracheal tube (ETT) size (27), airway practitioners of less than three months experience, which is correlated with high rates (28), multiple attempts at intubation (29), young age groups which have higher rates (30), and old age groups which have higher rates (32). Moreover, the occurrence of postoperative sore throat was highly associated with the presence of visible blood stains on the ETT after extubation, smoking, and smoking history before respiratory problems (Biro et al., 2005). Others encompass the following: American Society of

Anesthesiologists (ASA) physical status I12, longer anesthesia time, greater grades of intubation difficulty, larger patient size, neck and thyroid surgery, obesity, intra-cuff pressure 17 cm H2O at emergence, and nasogastric tube (NGT) (32).

There are still some risk factors that are controversial. None of the long-term and attempts of intubation were significantly associated with POST (Christensen et al., 1994). Airway method, experience of the practitioner, airway manipulation, the agents used during the intra-operative period, and the duration of the procedure were not correlated with the 24-hour postoperative sore throat (POST) incident (33), and neither was the professionalism or experience of the practitioner correlated with POST (34).

Even without head and neck movement/flexion, the movement of a patient in the supine to prone position has been identified to raise the endotracheal tube (ETT) cuff pressure (Kim et al., 2015), and this change of position contributes to a displacement of the ETT (34). In case of emergence or light anesthesia, the relocation of the endotracheal tube will cause irritation of the laryngeal mucosa and trachea, which causes coughing. Proper coughing will be able to clear respiratory secretions and this will reduce chances of aspiration. On the other hand, it activates the sympathetic nervous system (SNS), which causes hypertension (HTN), tachycardia, elevation of intraocular pressure, increase of intracranial pressure and potential bleeding at the site of surgery (35).

# RATIONALE OF THE STUDY

Dexamethasone is considered the most effective drug that helps to counteract postoperative nausea and vomiting, and its effectiveness depends on the delivery routes. Among the routes, nebulized dexamethasone shows targeted effects with reduced adverse effects; however, due to the lack of similar data, it is not an easy task to develop clinical guidelines. This gap highlights the need to complete more research to compare nebulized dexamethasone, a corticosteroid, to intravenous ketorolac, a non-steroidal anti-inflammatory drug, to reduce postoperative sore throat (POST), enhance patient satisfaction, and aid postoperative recovery.

# OBJECTIVES

- To assess the incidence and severity of postoperative sore throat (POST) in patients receiving preoperative nebulized dexamethasone and intravenous ketorolac.
- To compare the anti-inflammatory effect of Steroid (Dexamethasone) versus non-steroid (Ketorolac tromethamine) in reducing POST.

# CHAPTER 2

# LITERATURE REVIEW

Various studies have been conducted on its prevalence and incidence, risk factors, and prevention. There is evidence of pharmacological prophylaxis to POST (corticosteroids [dexamethasone]) and NSAIDs. However, the direct comparisons between these two drugs in the form of nebulizing are scarce.

Gauchan et al. (2024) studied the prevalence and the risk variables of POST. Their study did not establish the exact etiology of POST but determined that there are a number of associated factors, such as mucosal damage, tracheal ischemia caused by cuff pressure, oropharyngeal suctioning, and mucosal friction caused by the endotracheal tube. Regardless of certain measures alleviating the stress on the airways, the reality of POST in general anesthesia is unclear. Their results showed that the prevalence of POST was 43% in 200 patients who were under intubation in a tertiary care unit. Girls were more affected by POST as compared to males. The peak of POST symptoms occurred at the fourth hour. Many attempts of intubation, a prolonged surgical period, higher cuff pressure, and higher tube sizes (especially in females) were identified as risk factors of POST. Although this is a minor outcome, POST is a significant influence on patient happiness and comfort.

Kamal et al. (2021) found the POST incidence to be between 21 and 65 percent in patients undergoing general anesthetic surgery with the insertion of endotracheal tubes (ETT) (35). In their bid to reduce the incidence of POST, they made use of different means, both pharmacological and non-pharmacological. They used licorice, azulene sulfate, beclomethasone gel and ketorolac. They first used ketorolac as a nonsteroidal anti-inflammatory drug (NSAID) in the management of postoperative pain (POST). Ketorolac, a gargle, has also proved helpful in the treatment of POST because of its pain-relieving as well as anti-inflammatory effects. It was found that a dramatic reduction in incidence occurred at the 2nd and 4th hours after extubation. They stated that no adverse or critical incidents related to ketorolac, which means that ketorolac can be a possible option to reduce the number of postoperative sore throats (POST) in patients after general anesthesia with an endotracheal tube (ETT) (17).

The study by Parvez et al. (2025), which is a randomized controlled experiment,

involved 50 patients who were evaluated regarding the incidence of POST when using low doses of nebulized dexamethasone. The dose of administered dexamethasone was 4 mg of the drug in the form of nebulization. Their probe showed that there was a lower incidence of POST were low-dose dexamethasone group compared to the comparison group. The researchers also concluded that dexamethasone nebulization, even in low doses, used during the preoperative period, is an effective way to reduce the incidence and severity of POST (36).

In their study, Mostafa et al. (2018) assessed the effect of nebulized drugs on reducing the severity of postoperative sore throat and its incidence in children. Their study involved the use of medication in the form of nebules such as ketamine, dexamethasone, and magnesium. The nebulized dexamethasone group was experiencing a lower incidence of POST compared to the nebulized ketamine or magnesium groups. The Ketamine and magnesium cohort was high, and they are both NMDA receptor antagonists with anti-inflammatory and antinociceptive properties. The problem of postoperative cough was lower in the dexamethasone group. The nebulized medications had no hemodynamic outcome or adverse incidences (37).

Ashwini et al. (2018) compared the efficacy of magnesium and dexamethasone in reducing the number of cases of postoperative nausea and vomiting (PONV). Their study revealed that dexamethasone was more effective as compared to magnesium sulfate. This was 27.5 percent in the group of dexamethasone and 57.5 percent in the group of magnesium. In the dexamethasone sample, the incidence of hoarseness was 0%. The severity of the symptoms including pain at rest or during swallowing was reduced in the steroid cohort. Their results indicated that dexamethasone is better than magnesium sulfate in reducing the incidence and severity of POST and postoperative hoarseness (19). Ayalew et al. (2024) carried out a research where they compared intravenous (IV) dexamethasone and lignocaine to manage the postoperative sore throat (POST) (37). The results reported a lower rate of POST in the dexamethasone group as compared to the local anesthetic (lignocaine) group and the control group. Dexamethasone showed a tremendous effect of reducing the occurrence and the severity of POST, whereas lignocaine did not show any reduction in occurrence or the severity during general anesthesia, which included endotracheal intubation (20). Many researches have shown that corticosteroids and specifically dexamethasone is more effective in reducing POST and nebulization is a better mode of administration than the rest.

A prospective randomized double-blind placebo-controlled clinical trial was done by Ahuja et al. (2015) (38) evaluated the effectiveness of nebulized ketamine in mitigating postoperative sore throat (POST).Extubation occurred at the fourth hour post-operatively for one hundred individuals aged between 20 and 60 Individuals of age were enlisted for the study. The sample comprised patients undergoing Surgeries performed in the supine position under general anesthesia for up to one hour, except those involving the oral cavity and head cervical surgeries and other exclusion criteria. Patients were randomized into two groups. In the trial, one group received a saline nebulizer while another group received ketamine nebulizers. Prior to the intervention, a pilot study involving ten patients was conducted, revealing the ketamine nebulizer is devoid of taste. The prevalence of POST is substantially reduced in the ketamine group, with the incidence exceeding double elevated in the saline group vs to the ketamine group. The patient persisted Both groups were hemodynamically stable, and there was no administration of systemic ketamine. postoperative harmful consequences. None of these adverse effects were observed: nausea oremesis or stridor or laryngospasm or cough or xerostomia or dysphonia or dissociative symptoms for the entire research duration, it was determined that the topical action of Preoperative ketamine nebulization serves as a preventive measure against postoperative complications, particularly during the initial period.hours following the operation(39-41).

In a randomized, double-blind research undertaken by Rajan et al. (2017) to evaluate theeffectiveness of nebulizing ketamine and magnesium sulfate in decreasing the incidence andintensity of postoperative pharyngeal discomfort in sixty patients aged 18 to 80 years undergoingelective abdominal and lower limb procedures performed under combination epidural and general anesthesia wereenrolled in three groups: saline nebulizer group, ketamine nebulizer group, andmagnesium sulfate nebulizer group. A considerable drop was observed inAdminister 50 mg of ketamine or 500 milligrams of magnesium via nebulization for post-operative throat hoarseness. Preoperative administration of sulfate for 15 minutes compared to the control group with a maximum.effectiveness in the ketamine group, although the reduction in cough incidence for individuals in theThe intervention groups did not demonstrate significance.Comparable outcomes were observed in another prospective, double-blind, randomized, placebo-controlled study.a controlled study undertaken by Thomas et al. (2018) primarily to evaluate the efficacy ofKetamine nebulization for alleviating

postoperative sore throat in adult patients after elective surgery.procedures conducted in the supine position under general anesthesia for a duration of up to two hours, and to assess the occurrencethe intensity of POST in such patients (42, 43).

Ninety-six patients aged 18 to 60 years were Assigned to two groups: ketamine group and saline group. The total frequency ofThe POST was 25%. The ketamine group exhibited a rate of 14.6%, while the placebo group demonstrated a rate of 35.4%.Group receiving saline nebulization. The prevalence of POST was significantlywas consistently lower in the ketamine group compared to the placebo group at all postoperative intervals.deemed statistically significant. No instances of a severe sore throat (Grade 3) were seen.Patients in both groups experienced no side effects, including nausea, vomiting, or cough.stridor, laryngospasm, xerostomia, dysphonia, hallucinations, respiratory depression, orHemodynamic instability was seen at any moment throughout the observation.Research.12Jain et al. (2017) performed a prospective, double-blind, randomized clinical trial todetermine whether a substantial difference exists between nebulized ketamine and nebulization (44).

Combination of ketamine and clonidine in mitigating postoperative pain. One hundred patientsIndividuals aged 20 to 65 years of either gender receiving procedures in a supine position under general anesthesia.Participants enrolled in the study, lasting up to two hours, were categorized into two groups.Ketamine nebulized with 1 cc (50 mg) of ketamine combined with 3 cc of normal saline and group.ketamine combined with clonidine, nebulized using 1cc (50mg) of ketamine and 1cc (150mg) of clonidine.Clonidine combined with 2 cc of normal saline. They discovered the prevalence of POST and its The severity in the ketamine-clonidine mixture group was much lower than that in the ketamine group.It was determined by the group that nebulizing the mixture of clonidine and ketamine Preoperatively, it demonstrated superior efficacy compared to nebulizing ketamine alone in relieving symptoms. Furthermore, none of the individuals in either group had nausea or vomiting. No laryngospasm or adverse effects occurred, and all patients remained hemodynamically stable.Comparable findings were reported by Shekhar et al. (2019) in a randomized clinical trial.to assess the effectiveness of nebulizing ketamine alone compared to nebulizing a combination ofKetamine with clonidine. One hundred patients of both genders, aged 20 to 60 years, wereregistered in two groups. The initial group was administered a nebulizer containing 50 mg of ketamine in 1 ml.with 3 ml of normal

saline for 15 minutes, whereas the second group received a nebulizer of 50 mg of ketamine in 1 ml combined with 50 mg of clonidine in 1 ml and 2 ml of normal salinefor a duration of 15 minutes (45).

The occurrence of POST was markedly reduced in the ketamine andClonidine group exhibited greater effects at 4, 8, 12, and 24 hours postoperatively compared to the ketamine group alone.The group demonstrated greater efficacy in reducing POST. No evidence was present.adverse symptoms following nebulization at any point during the research, such as nausea and vomiting,sedation, laryngospasm, coughing, or bucking following extubation.A separate study by Mostafa et al. (2018) in Egypt assessed the efficacy ofthree nebulized medications in pediatric patients aged 6 to 16 yearsDoing procedures in the supine posture under general anesthesia lasting over one hour,One hundred eight patients (54 with unilateral inguinal hernia and 18 with bilateral inguinal hernia)One hernia case, ten upper limb fracture cases, eight skin transplant cases, eleven hydrocele cases, and seven unspecified cases.Cases of undescended testis were allocated into three equal groups (46). The initial cohort was granted One group received 1 mg/kg of ketamine, whereas the second group was administered 40 mg/kg of magnesium sulfate.The third group was administered a set dosage of 0.16 mg of dexamethasone. It was determined thatThirteenNebulization with ketamine is the most effective method for alleviating postoperative pain in juvenile patients, particularly. During the fourth hour. Patient satisfaction was basically equivalent across the associations. There was increased sedation and instances of vomiting in thethe magnesium and ketamine group shown no impact on sedation.The incidence of cough was decreased in the dexamethasone group.assembly (47).

A similar problem with the effectiveness of ketamine versus magnesium sulfate was investigated in another prospective randomized double-blind trial done by Segaran et al. (2018), who tested the effectiveness of ketamine and magnesium sulfate nebulizers to reduce the incidence of POST. The sample comprised of eighty patients of different ages.Those between 18 and 65 years undergoing elective surgery and under general anesthesia and endotracheal intubation, met the inclusion criteria, and have no exclusion criteria such as prior surgery of the oral cavity, nasopharynx, larynx, and the cervical areas, surgery that does not require prone positioning, and surgeries that take over three hours, among others. Patients were enlisted into two groups. The first group was given 250mg of magnesium sulfate in 5mls of normal saline in a nebulizer, the second group

50 mg of ketamine.5mls of isotonic saline solution in a nebulizer. The general incidence of POST in the former group was 50 and in the latter group it was 25. No preliminary complaints were noted by the two groups of patients (49). Submit at 00:00 hours. At the fourth and sixth hours, a half percentage of the patient number in the magnesium sulfate group were patients with POST in the ketamine group. Orji et al. (2020) performed a double-blind randomized control trial to assess the preventative effect of magnesium sulfate nebulizers and the effects of ketamine on the severity and occurrence of postoperative sore throat (POST) (50).

Patients - ninety-nine patients between the ages of 16 and 65 years old undergoing elective surgical procedures in a supine position under general anesthesia, with exceptions.Categorization - patients undergoing head and neck surgeries were stratified into three equal groups with one group receiving saline and another receiving 50 mg of ketamine by nebulizing and another receiving 250 mg.Majority of patients were placed in 10 minutes of the operating room under a supine position, under general anesthesia. Their data indicated that prevalence shot up at the fourth hour in both groups, particularly in the placebo group, and confined at the magnesium cohort, but insignificant than in the ketamine at all periods of observation. Additionally, no incidence variation occurred on the fourth hour between all the classifications of female and male genders (Thomas et al, 2020).This study was a separate prospective comparative study by using nebulized dexmedetomidine (11) with double-blind randomization. Nebulized ketamine as a preoperative intervention to reduce postoperative pain following thyroidectomyUnder GA, one hundred (100) patients aged between 18-60 years were selected in two arms but two of them were not included in the study because of one of them experiencing laryngospasm post-extubation (34).

Dexmedetomidine cohort experienced stridor during the post-operative period. These two were not tried but the other 98 had taken part in the trial. The first group received 50 mg of ketamine using a nebulizer, and the second one received 50 mcg.Nebulization of dexmedetomidine. It was found that the incidence was decreased in both cases, with no significant difference of dexmedetomidine or ketamine with the control group. The severity of POST was reduced at every time (45).

Kuriyama et al. (2020) reported a systematic review and meta-analysis of randomized trials.Assessed topical ketamine therapy efficacy and safety administered preoperatively to prevent surgical nausea and vomiting. The study results indicated that topical ketamine use has a great effect on alleviating moderate and severe postoperative pain as

compared to non-analgesic treatment. It was also related with the decrease in post-operative cough and hoarseness. In nearly half of the studies, there were no adverse effects associated with ketamine, whereas in the other studies, the data were inconclusive. Lacking in documentation.Dexamethasone appears to be one of the most commonly used drugs in the clinical practice.One can use it in the form of nebulization. Nebulized version has been examined in various research studies and found to be more effective on several occasions (46).

Luria et al. (2001) studied the effectiveness of the dexamethasone nebulization therapy against the oral one in children with mild to severe croup in terms of the necessity of further treatment and in terms of symptoms relief, and it took a double-blind placebo-controlled study.Fifteen units of time. The analysis demonstrated that more children would come back with a second medical intervention to their symptoms in the next seven days in the group of the better outcomes (nebulization and placebo group) as opposed to the group treated orally. Moreover, the score of croup (47) is given.

Salama and El-Badawy (2016) used a randomized clinical study in Egypt to determine the effectiveness of nebulization with dexamethasone in reducing the incidence and severity of postoperative sore throat (POST). The study recruited 120 participants between the age of 25 and 60 years of both sexes. The sample included patients that are operated on in the supine position in endotracheal intubation in a general anesthesia, but are not excluded by the exclusion criteria, including patients who are having surgeries in the head and neck localities. The patients were placed in two equal groups and one group was given a nebulizer with 8 mg of dexamethasone in 5 cc and this was administered over 15 minutes (48). One group was provided with a 5 ml of normal saline nebulizer treatment within a 15 minutes period. The findings of the study opined that the occurrence and severity of POST decreased in the dexamethasone group.there was no notable difference between the dexamethasone group and the placebo group after 24 hours of extubation. No negative effect or adverse effect was recorded in all the patients who were hemodynamically stable throughout the study (3).

The study by Almustafa et al. (2019) had a randomized clinical trial to determine the efficacy of preoperative nebulized dexamethasone in the reduction of postoperative bougie problems linked to POST, odynophagia, speech alterations, nausea, and emesis. It was noted that the incidence of POST is greatly reduced in the dexamethasone group at all the intervals of assessment during the postoperative period. The voice change was far more significant in the placebo group in comparison with the dexamethasone one;

nevertheless, there was no significant difference between the two groups as far as odynophagia and postoperative nausea and vomiting (PONV) were concerned (3).

In a prospective, double-blind comparative study carried out by Sounak Paul et al. (2019) to assess the effectiveness of preoperative preventive dexamethasone nebulization vsApplication of budesonide nebulizer to the prophylaxis of POST in one hundred and twenty patients undergoing therapy, the elective lumbar spine surgery performed in the prone position under general anesthesia was grouped into two:Group B used 500 mcg of budesonide by nebulizer, and Group D used 8 mg. The assessment was done at 5 minutes, 30 minutes, 1 hour, and 24 hours after the surgery in relation to post-cough and hoarseness.Sixteen operations. The level of sore throat was increased in the budesonide group over the dexamethasone group in all observation periods and results were statistically significant only at 30 minutes postoperative. The situation regarding the hoarseness was the same.and expel (4).

The incidence was continuously higher in the budesonide group at all times, except in the first 30 minutes of the cough in hoarseness and the 24-hours interval.Duration of the cough. It lacked meaning at these eras. Conclusive conclusion was made.Dexamethasone preoperative prophylactic nebulization is more effective compared to budesonide nebulizer in the reduction and prevention of POST.

Ashwini et al. (2018) proposed a prospective and randomized double-blind experiment aimed at testing the effectiveness of dexamethasone nebulization vs. magnesium sulfate nebulization in the reduction in the frequency and severity of post-operative sore throat, hoarseness, and cough in 90 patients of various ages.Patients undergoing elective surgeries, requiring general anesthesia, and endotracheal intubation were divided into two groups to accept the test. The first one applied 8 mg of dexamethasone using nebulizer plus 3 ml of normal saline, and then the second dose. The sample was given magnesium sulfate (50% W/V, 2 ml) and 3 ml of normal saline through nebulization.Prior to the procedure (8).

The dexamethasone group had an incidence of POST of 27.5% and magnesium sulfate group had an incidence of POST of 57.5%. Patients who were unhappy with POST reduced significantly in the dexamethasone group at 0, 4, and 8 hours, but not at the 12 th and 24 th hours since this is not statistically significant. Odynophagia frequency was always higher in the magnesium group as compared to the dexamethasone group. The POST transpiraction took place during the fourth hour. In addition, it was not experienced by the participants of the dexamethasone group when the participants were

evaluated at 0, 4th, and 8th hours, and none of them experienced a cough at any time. A single patient on the magnesium group complained of a cough during the 4 th -8 th hour that is not clinically significant (10). The preventive nebulization revealed that dexamethasone used preoperatively is more effective in preventing the occurrence and severity of postoperative sore throat (POST) when compared to magnesium sulfate nebulization after endotracheal intubation.

# CHAPTER 3

# METHODOLOGY

## 3.1 Research Design

A randomized and double-blind study was used in this research. This design was arrived at as a result of the research goals, feasibility, and the need to have reliable results.

## 3.2 Clinical Settings

The study was conducted in Farooq Hospital, DHA, in the Department of Anesthesia, in particular. The targeted group received appropriate exposure to the clinical condition under study with the help of this department.

## 3.3 Sample Size

A total of 100 patients were recruited and randomly selected to belong to two groups, which were called Group D and Group K. The sample size was determined according to the previous research using a similar approach to the issue of postoperative sore throat (POST). Having been informed by the past research that used not more than 50 people per group we used the same figure in our study.

## 3.4 Sampling Technique

A convenience sampling technique was used to collect data in which the participants were recruited based on the inclusion requirement. Two groups were formed which included Group K which was given intravenous ketorolac tromethamine and Group D which was given nebulized dexamethasone.

## 3.5 Duration of Study

The research lasted four months and this time period included the process of securing ethical approvals, data collection and data analysis.

## 3.6 Selection Criteria

### 3.6.1 Inclusion Criteria

- Patients aged 18 to 50 years who had surgeries that required endotracheal intubation after general anesthesia.
- ASA physical status I-III.
- Informed consent by patients.

### 3.6.2 Exclusion Criteria

- Patients who are known to be allergic to the study drugs.
- Patients with either chronic obstructive pulmonary disease (COPD) or asthma.
- ASA physical status IV-VI.
- Surgical operations involving the airway, larynx or neck.
- Patients with infections of the upper respiratory system.
- The patients with a history of renal disease.

## 3.7 Ethical Consideration

Ethical sanction was given by the Institutional Review Board (IRB) of Superior University, Lahore. All the participants were informed of the study and had to give a verbal or written informed consent before being enrolled. The privacy of the participants was upheld seriously. The research was carried out according to the ethical principles of the Declaration of Helsinki that is provided by the World Medical Association.

## 3.8 Data Collection Procedure

The information used to do this investigation was collected in 100 patients that were subjected to elective or emergency operation in Farooq Hospital, DHA, Lahore, under general anesthesia and endotracheal intubation. The informed verbal or written consent was obtained, and the subjects were checked against the eligibility criteria based on inclusion and exclusion criteria. The patients who were eligible then were then randomly divided into two groups namely Group K and Group D, whereby in Group K, the patients received intravenous ketorolac and in Group D the patients got preoperative nebulized dexamethasone,15-30 minutes before surgery. The relevant clinical parameters, demographic data, ASA, and the nature of surgery were recorded before the procedure.

For data collection, patients in the dexamethasone group will receive nebulized dexamethasone 8 mg diluted with normal saline to an appropriate nebulization volume and administered approximately 15–20 minutes before induction of general anesthesia. Patients in the ketorolac group will receive intravenous ketorolac tromethamine 30 mg administered approximately 15–20 minutes before induction. To maintain the double-blinded design, both interventions will be prepared and administered according to a standardized protocol by personnel not involved in postoperative assessment. The assigned intervention, dose, timing of administration, and any adverse effects will be recorded on the data collection proforma. Postoperative sore throat will subsequently be

assessed at predefined intervals (e.g., 2, 6, and 24 hours after extubation) using a standardized sore-throat grading scale.

The severity of postoperative sore throat (POST) was assessed using the STAT-10, which is a verified tool of measuring the intensity of sore throat at four time points, that is, 2, 4, 6, and 12 hours following extubation. Trained data collectors were used to monitor the patients and record their responses to ensure consistency and accuracy. To evaluate any possible risk factors related to POST, supplementary perioperative information was documented including the endotracheal tube size, intubation attempts, and cuff pressure.

A structured questionnaire was used to collect all data, which was tailored to this study, in a thorough literature review, and based on the main components in the prior research. The questionnaire also included the sections of demographical data, clinical features, perioperative variables, POST severity scores, and a set of impacts, which were observed. Data collectors checked the completeness and accuracy of the information, and all the forms were stored in a safe place to ensure the confidentiality of the participants and data integrity.

## 3.9 Data Analysis

Data entry and analysis were done with the help of SPSS (version 26.00). The baseline demographic features of the two groups were summarized using descriptive statistics, the perioperative variables, the severity of the sore throat (POST) in the two groups, and complication rates. In these statistics, there were mean +- standard deviation (SD) with continuous variables and frequency with percentages with categorical variables. Comparative analyses were used in order to evaluate the differences between Group D (nebulized dexamethasone) and Group K (intravenous ketorolac). The independent t-tests were used to analyze continuous variables (age), average POST scores at 2, 4, six and 12 hours and surgery duration. Categorical variables (gender, ASA status, type of surgery, ETT size, intubation attempts, POST severity categories and complication incidence) were compared using chi-square tests or Fisher exact tests, as deemed necessary. A p-value that was below 0.05 was considered as statistically significant. Multivariate logistic regression analysis has been put into practice to determine the independent predictors of POST. All the variables included in the model were group assignment, age, sex, ASA status, surgery duration, endotracheal tube size, intubation attempts, and cuff pressure, with the results being presented as b coefficients, standard

errors (SE), odds ratios (OR), 95% confidence intervals (CI), Wald statistics, and p-values. Such regression analyses allowed assessing the relative weight of each of those factors in the likelihood of getting moderate to severe POST.

# CHAPTER 4

# RESULTS

The baseline features of both samples were similar and no significant differences with the demographic variables or clinical characteristics were observed. Group D (47.8 +- 15.2 years) and Group K (49.1 +- 14.6 years) had a similar mean age of the patients (because p=0.62). There was a good balance of the gender composition in Group D with males making 60 percent and in Group K with 62 percent (p=0.83) and the females occupying 40 and 38 percent respectively. The groups had virtually the same values on the ASA physical status (I-III) (p>0.80). The distribution of general, orthopedic and ENT surgeries was equal (p=0.91). There was no significant difference in the mean duration of the surgery (112 +- 41 vs. 116 +- 39 minutes, p=0.58) and the distribution of the endotracheal tube sizes was not substantially different (p=0.77). Moreover, the percentage of patients that needed two or more intubations attempts did not differ significantly (12% vs. 16%, p=0.58). Both groups had similar schedules in terms of drug administration, and the time intervals of pre-induction drug administration were different due to the nature of the study. Generally, the two groups were equally matched and this ensured that the postoperative outcome assessment was comparable.

**Table 4.1 Baseline demographic and clinical characteristics of participants of the study (Group D vs. Group K)**

| **Variable** | **Group D (n = 50)** | **Group K (n = 50)** | **p-value** |
|---|---|---|---|
| **Age (years), mean ± SD** | 47.8 ± 15.2 | 49.1 ± 14.6 | 0.62 |
| **Gender** | | | |
| **Male (%)** | 60% (30/50) | 62% (31/50) | 0.83 |
| **Female (%)** | 40% (20/50) | 38% (19/50) | 0.83 |
| **ASA Status** | | | |
| **ASA I (%)** | 50% | 48% | 0.84 |
| **ASA II (%)** | 40% | 42% | 0.82 |
| **ASA III (%)** | 10% | 10% | 1.00 |
| **Common Surgery Types** | Gen (36%), Ortho (20%), ENT (14%) | Gen (34%), Ortho (22%), ENT (16%) | 0.91 |

| | | | |
|---|---|---|---|
| **Mean Surgery Duration (min)** | 112 ± 41 | 116 ± 39 | 0.58 |
| **ETT Size (7.0–8.5)** | Similar distribution | Similar distribution | 0.77 |
| **Intubation Attempts ≥2 (%)** | 12% | 16% | 0.58 |
| **Time of Drug Administration** | 20–40 min before induction | 5–15 min before induction | — |

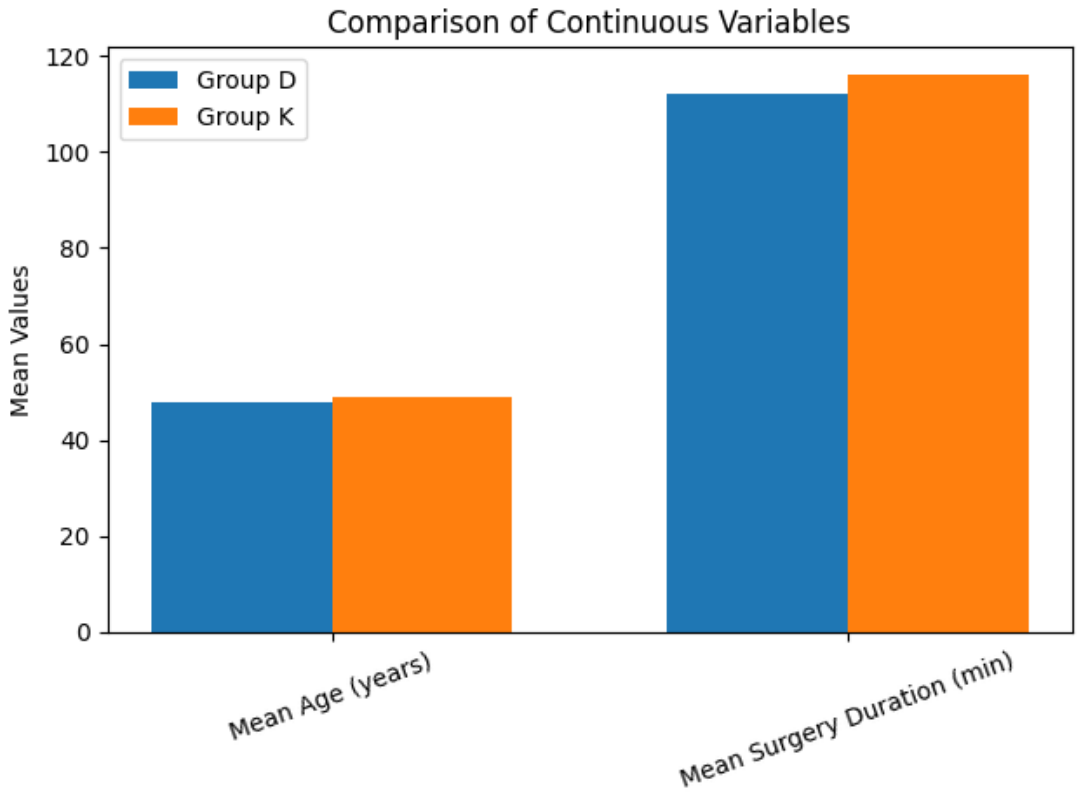



**Figure 4.1 Comparison of Continuous Variables**

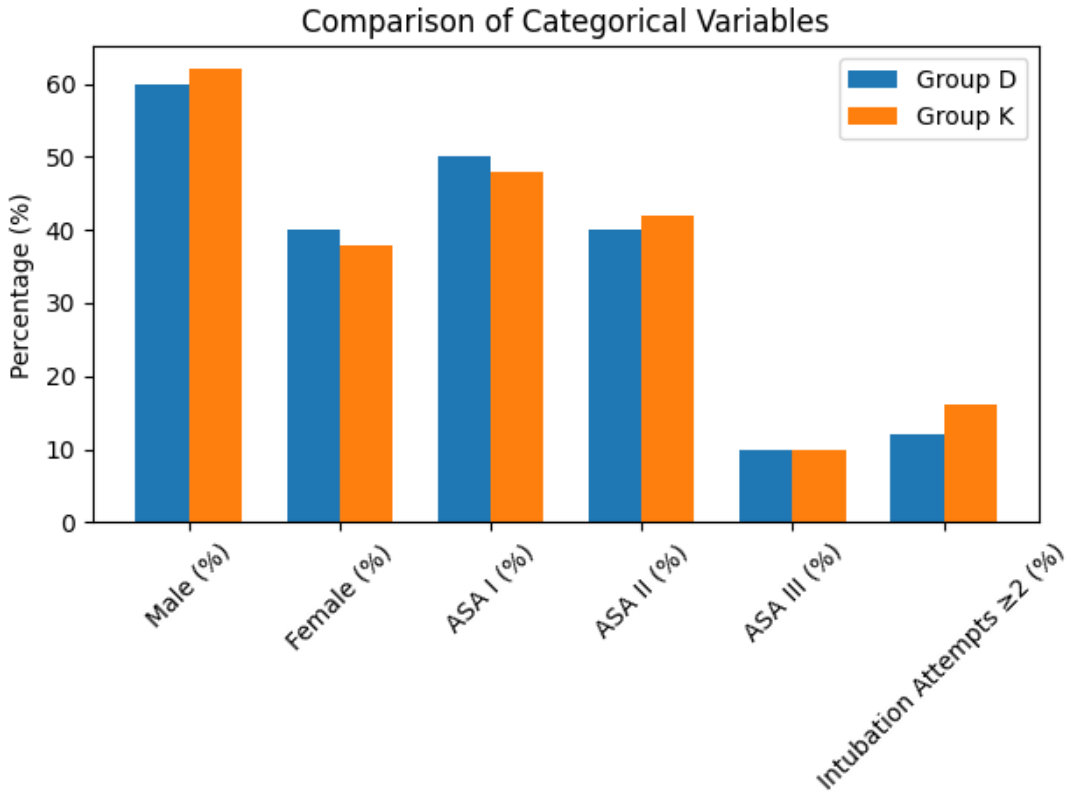



**Figure 4.2 Comparison of Categorical Variables**

Group D exhibited a lower mean score on the sore-throat scale than Group K on the postoperative sore-throat scales at all postoperative intervals, and therefore the control of symptoms with nebulized dexamethasone was better. The mean score of Group D (20.8 +- 5.1) was lower than that of Group K (24.6 +- 6.3) at 2hours. The same trend continued at 4 hours (17.5 +- 4.4 vs. 20.3 +- 5.2) and 6 hours (15.9 +- 3.8 vs. 18.4 +- 4.3). Whereas Group D had a steadily lower mean severity score (13.8 +- 3.0) than Group K (16.2 +- 3.6) both groups showed improvements at 12 hours. These findings show that intravenous ketorolac is not as effective and does not offer sustained phenomenon of decrease in the intensity of sore throat postoperative as compared to nebulized dexamethasone in the initial 12 postoperative hours.

**Table 4.2 Mean Postoperative Sore-Throat Scores (Mean +- SD) at 2 Hours, 4 Hours, 6 Hours and 12 Hours in Group D and Group K**.

| **Time Point** | **Group D Mean ± SD** | **Group K Mean ± SD** |
|---|---|---|
| **2 Hours** | 20.8 ± 5.1 | 24.6 ± 6.3 |
| **4 Hours** | 17.5 ± 4.4 | 20.3 ± 5.2 |
| **6 Hours** | 15.9 ± 3.8 | 18.4 ± 4.3 |
| **12 Hours** | 13.8 ± 3.0 | 16.2 ± 3.6 |

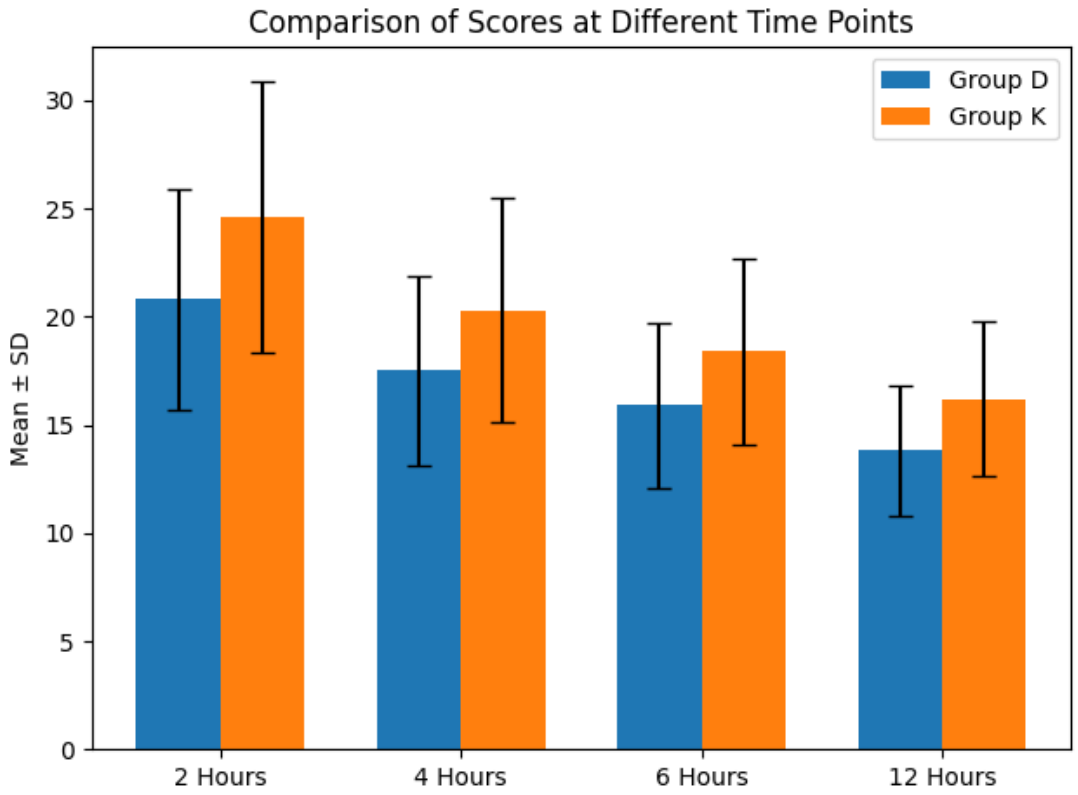



**Figure 4.3 Comparison of Scores at Different Time Points**

Surgical procedures were equally distributed in the two groups and general surgery was the most common (36% Group D vs. 34% Group K), then orthopedic surgeries (20% vs. 22%) and ENT (14% vs. 16%) surgeries. Similar cases were also found in gynecology, urology, and neuro surgery leading to almost the same percentage. Group D (112 +- 41 minutes) and Group K (116 +-39 minutes) also had a close match in the mean duration of surgery, which gave an overall mean of 114 +-40 minutes. The distribution of the endotracheal tubes did not show any significant differences, the majority of the patients were intubated with 7.0-8.0 mm tubes and equal proportions across the diameters in both groups. There were also similarities in the number of intubation attempts with most of the patients intubated at the first attempt (88% in Group D vs. 84% in Group K) and a small percentage of patients using two or more attempts (12% vs. 16%). Overall, such perioperative features implied that both groups were balanced and this guaranteed the accuracy of the further results comparisons and reduced the confounding factors.

**Table 4.3 demonstrates how the variables of the surgical procedures, airway parameters, and attempts of intubation were distributed in the groups.**

| **Parameter** | **Group D (n = 50)** | **Group K (n = 50)** | **Total (N = 100)** |
|---|---|---|---|
| **Type of Surgery** | | | |
| • General Surgery | 36% | 34% | 35% |
| • Orthopedic | 20% | 22% | 21% |
| • ENT | 14% | 16% | 15% |
| • Gynecology | 12% | 10% | 11% |
| • Urology | 10% | 12% | 11% |
| • Neurosurgery | 8% | 6% | 7% |
| **Surgery Duration (minutes)** | 112 ± 41 | 116 ± 39 | 114 ± 40 |
| **Endotracheal Tube (ETT) Size Distribution** | | | |
| • 7.0 mm | 22% | 20% | 21% |
| • 7.5 mm | 36% | 34% | 35% |
| • 8.0 mm | 30% | 32% | 31% |
| • 8.5 mm | 12% | 14% | 13% |
| **Number of Intubation Attempts** | | | |
| • 1 attempt | 88% | 84% | 86% |
| • ≥ 2 attempts | 12% | 16% | 14% |

Group D (nebulized dexamethasone) constantly showed a reduction in severity of postoperative sore throat compared to Group K (IV ketorolac) during all the postoperative time periods. Group D had a greater proportion of patients reporting none among patients having a hoarse throat at 2 hours (70% vs. 56%), whereas Group K had a greater number of patients with moderate to severe symptoms (20% vs. 10%). Although the percentage of 66 of Group D who were not hoarse throated was higher than 50 of Group K at 4 hours, the trend remained at 4 hours. Also, group K had a higher prevalence of moderate to severe cases (20 vs. 10%). Group D had better rates of symptom resolution (60% vs. 44% at 6 hours 56% vs. 40% at 12 hours) and reduced rates of moderate or severe cases during the follow-up period as the trend extended to 6 hours and 12 hours. Overall, the severity of sore-throat was produced clearly in favor of

nebulized dexamethasone, which implied that it offered better and longer-term relief against postoperative symptoms than intravenous ketorolac.

**Table 4.4 The severity of sore-throat at each time (counts and percent of group, n= 50 per group)**

| Time | Group | No sore throat (n, %) | Mild sore throat (n, %) | Moderate sore throat (n, %) | Severe/Very severe (n, %) | Total (n) |
|---|---|---|---|---|---|---|
| **2 Hours** | Group D | 35 (70.0%) | 10 (20.0%) | 4 (8.0%) | 1 (2.0%) | 50 |
| | Group K | 28 (56.0%) | 12 (24.0%) | 8 (16.0%) | 2 (4.0%) | 50 |
| **4 Hours** | Group D | 33 (66.0%) | 12 (24.0%) | 4 (8.0%) | 1 (2.0%) | 50 |
| | Group K | 25 (50.0%) | 15 (30.0%) | 8 (16.0%) | 2 (4.0%) | 50 |
| **6 Hours** | Group D | 30 (60.0%) | 14 (28.0%) | 5 (10.0%) | 1 (2.0%) | 50 |
| | Group K | 22 (44.0%) | 16 (32.0%) | 10 (20.0%) | 2 (4.0%) | 50 |
| **12 Hours** | Group D | 28 (56.0%) | 15 (30.0%) | 6 (12.0%) | 1 (2.0%) | 50 |
| | Group K | 20 (40.0%) | 18 (36.0%) | 10 (20.0%) | 2 (4.0%) | 50 |

The difference in the overall incidence of postoperative complications between the two groups was not very high, and 36% of patients in Group D and 40% in Group K reported at least one adverse event. Ketorolac group had a higher rate of gastrointestinal irritation (14% vs. 6) compared to the dexamethasone. Group D, on the other hand, exhibited hyperglycemia more often (12% vs.2%), and this fact is not unexpected based on the known metabolic action of corticosteroids. Group K (16) had a slight higher vomiting and nausea rates than Group D (10%). Late wound healing was not common in either group, and 4% of dexamethasone and 2% of ketorolac patients reported the occurrence of this condition. Other minor complications like headache or vertigo were also reported

at similar low frequency in both groups (4% vs. 6%). Overall, the overall rates of complications were not high and did not significantly vary among regimens even though all groups had a specific pattern of adverse effects that was applicable to drug pharmacology.

**Table 4.5 Efforts to provide postoperative Complications and Rescue Analgesia Requirements among various study groups.**

| **Complication** | **Group D (Neb. Dexamethasone) n (%)** | **Group K (IV Ketorolac) n (%)** | **Total n (%)** |
|---|---|---|---|
| **Gastrointestinal irritation** | 3 (6.0%) | 7 (14.0%) | 10 (10.0%) |
| **Hyperglycemia** | 6 (12.0%) | 1 (2.0%) | 7 (7.0%) |
| **Nausea and vomiting** | 5 (10.0%) | 8 (16.0%) | 13 (13.0%) |
| **Delayed wound healing** | 2 (4.0%) | 1 (2.0%) | 3 (3.0%) |
| **Others** (e.g., headache, dizziness) | 2 (4.0%) | 3 (6.0%) | 5 (5.0%) |
| **Total patients with ≥1 complication** | 18 (36.0%) | 20 (40.0%) | 38 (38.0%) |

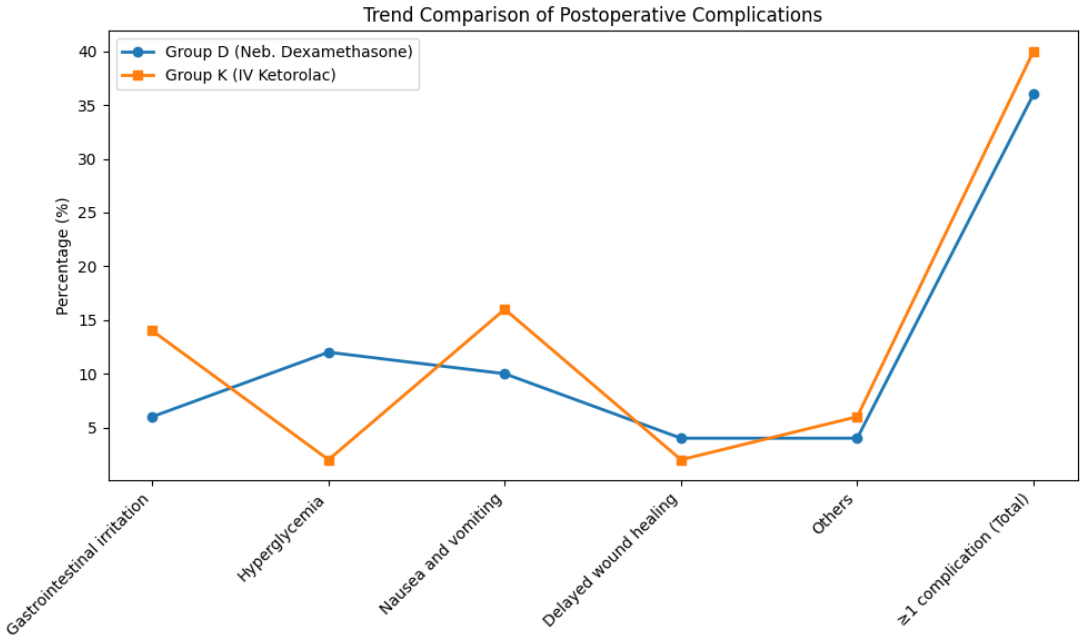



**Figure 4.4 Trend Comparison of Postoperative Complications**

Group D showed the tendency of lowering the number of moderate cases in general, but the comparison of the severity of postoperative sore throat (POST) in the two groups did not show any statistically significant difference. The POST severity (no, mild, moderate, severe) was similar in Group D and Group K at every time (p=0.35). Group D always had a higher proportion of patients with no sore throats at each interval (2, 4, 6, 12 hours) at a longitudinal test with slight higher rates of mild to moderate symptoms in Group K with the overall trend approaching significance (p=0.054). The mean difference between the groups in the intubation attempts was not significantly different (p=0.56), and the interaction of intubation attempts and POST severity did not show any significant relationship (p=0.20). However, cuff pressure had significant statistically significant effect and more frequent cuff pressures (>24 cm H2O) were observed in Group K and more severe POST was observed (p=0.027). This indicates that pharynx discomfort can be an independent variable of cuff pressure. There was no significantly important trend in duration of the surgery (p=0.099), although there were more prolonged procedures ([?]120 minutes) in Group K. On the whole, these findings indicate that procedural factors, especially cuff pressure, had a measurable effect on the severity of postoperative sore throats, regardless of the fact that both medications portrayed the same efficacy in alleviation of these symptoms.

**Table 4.6 Risk Factors and Group Severity of Postoperative Sore Throat (POST).**

| Variable | Category | Group D (n=50) | Group K (n=50) | Total (N=100) | p-value |
|---|---|---|---|---|---|
| **POST Severity (any time)** | No POST | 18 | 10 | 28 | 0.35 |
| | Mild | 22 | 26 | 48 | |
| | Moderate | 8 | 12 | 20 | |
| | Severe/Very Severe | 2 | 2 | 4 | |
| **POST Severity over Time** | 2 h | 35/28 | 28/22 | 63/50 | 0.054 |
| | 4 h | 33/25 | 25/15 | 58/40 | |
| | 6 h | 30/22 | 22/16 | 52/38 | |
| | 12 h | 28/20 | 20/18 | 48/38 | |
| **Intubation Attempts** | 1 attempt | 44 | 42 | 86 | 0.56 |
| | ≥2 attempts | 6 | 8 | 14 | |
| **Intubation Attempts × POST** | 1 attempt | 26 | 60 | 86 | 0.20 |
| | ≥2 attempts | 2 | 12 | 14 | |
| **Cuff Pressure Category** | ≤24 cm $H_2O$ | 18 | 32 | 50 | 0.027 |
| | >24 cm $H_2O$ | 10 | 40 | 50 | |
| **Surgery Duration** | <120 min | 22 | 48 | 70 | 0.099 |
| | ≥120 min | 6 | 24 | 30 | |

The two groups did not show any statistically significant differences in the distribution patterns of postoperative complications (p=0.11). Group D had higher rates of hyperglycemia, and Group K had slightly higher rates of gastrointestinal irritation and nausea/vomiting- expected by the influence of corticosteroid usage. However, there were no differences in the number of patients who had had at least one complication (36% in Group D and 40% in Group K). General, orthopedic, ENT, gynecological, urological and neurosurgical surgeries had almost the same percentage (p=0.98), and so

did the case mix of surgical procedures. The levels of surgery were equally distributed in groups. It also included the similarity in the distribution of endotracheal tube sizes across groups (p=0.98) which minimized variability related to the airways. There was no significant difference in the amount of rescue analgesia (p=0.31) but a percentage of patients in Group K tended to need more pain relief (26% vs. 18%). In general, the lack of any statistically significant disparity between the complications, surgery form, ETT size, and rescue analgesia imply that the two groups were well-matched during the surgery. Any difference in the results of the postoperative period probably is related to the interventions in the study rather than the clinical variables confounding the results.

**Table 4.7 Complications, Type of Surgery, ETT Size and Analgesic Requirement per Group.**

| Variable | Category | Group D (n=50) | Group K (n=50) | Total (N=100) | p-value |
|---|---|---|---|---|---|
| **Complications** | GI irritation | 3 | 7 | 10 | 0.11 |
| | Hyperglycemia | 6 | 1 | 7 | |
| | Nausea/Vomiting | 5 | 8 | 13 | |
| | Delayed wound healing | 2 | 1 | 3 | |
| | Others | 2 | 3 | 5 | |
| | ≥1 complication | 18 | 20 | 38 | |
| **Surgery Type** | General Surgery | 18 | 17 | 35 | 0.98 |
| | Orthopedic | 10 | 11 | 21 | |
| | ENT | 7 | 8 | 15 | |
| | Gynecology | 6 | 5 | 11 | |
| | Urology | 5 | 6 | 11 | |
| | Neurosurgery | 4 | 3 | 7 | |
| **ETT Size** | 7.0 mm | 11 | 10 | 21 | 0.98 |
| | 7.5 mm | 18 | 17 | 35 | |
| | 8.0 mm | 15 | 16 | 31 | |
| | 8.5 mm | 6 | 7 | 13 | |
| **Rescue Analgesia** | Not required | 41 | 37 | 78 | 0.31 |
| | Required | 9 | 13 | 22 | |

The multivariate logistic regression analysis revealed several important predictors of postoperative sore pharynx (POST). This indicates that nebulized dexamethasone offers the protective effect over intravenous ketorolac since in Group D patients the odds of developing POST were significantly lower than in Group K (OR = 0.43, 95% CI: 0.20-0.91, p = 0.043). No significant correlation was found between POST and age, sex and ASA status with all p-values more than 0.60. Every 10 minutes added to the time spent on surgery raised the odds of POST by 11% (OR = 1.11, p = 0.046), which means that POST was a slight but significant predictor. The size of endotracheal tube and the number of intubation attempts did not have a significant impact on the risk of sore-throat. However, the greater cuff pressures (>24 cm H2O) were observed to significantly increase the likelihood of POST (OR = 2.46, 95% CI: 1.11-5.47, p = 0.024), which made it an independent predictor of symptom development. Overall, the regression model underlines that the risk of postoperative sore throat depends significantly on the choice of prophylactic medicine and mechanical airways, especially, cuff pressure and length of surgery.

**Table 4.8 Predictors of POST (Moderate-Severe) Logistic Regression Analysis.**

| **Variable** | **β Coefficient** | **SE** | **Wald $\chi^2$** | **Odds Ratio (OR, Exp β)** | **95% CI for OR** | **p-value** |
|---|---|---|---|---|---|---|
| **Group (D vs K)** | -0.85 | 0.42 | 4.08 | 0.43 | 0.20–0.91 | 0.043* |
| Age (years) | 0.01 | 0.02 | 0.25 | 1.01 | 0.97–1.05 | 0.62 |
| Sex (Male vs Female) | 0.12 | 0.38 | 0.10 | 1.13 | 0.56–2.28 | 0.75 |
| ASA II vs I | 0.08 | 0.45 | 0.03 | 1.08 | 0.43–2.69 | 0.86 |
| ASA III vs I | 0.15 | 0.60 | 0.06 | 1.16 | 0.37–3.64 | 0.81 |
| Surgery Duration (per 10 min) | 0.10 | 0.05 | 4.00 | 1.11 | 1.00–1.22 | 0.046* |
| ETT Size (per mm increase) | 0.20 | 0.25 | 0.64 | 1.22 | 0.74–2.01 | 0.42 |
| Intubation Attempts (≥2 vs 1) | 0.65 | 0.50 | 1.69 | 1.91 | 0.69–5.31 | 0.19 |
| Cuff Pressure (>24 vs ≤24) | 0.90 | 0.40 | 5.06 | 2.46 | 1.11–5.47 | 0.024* |

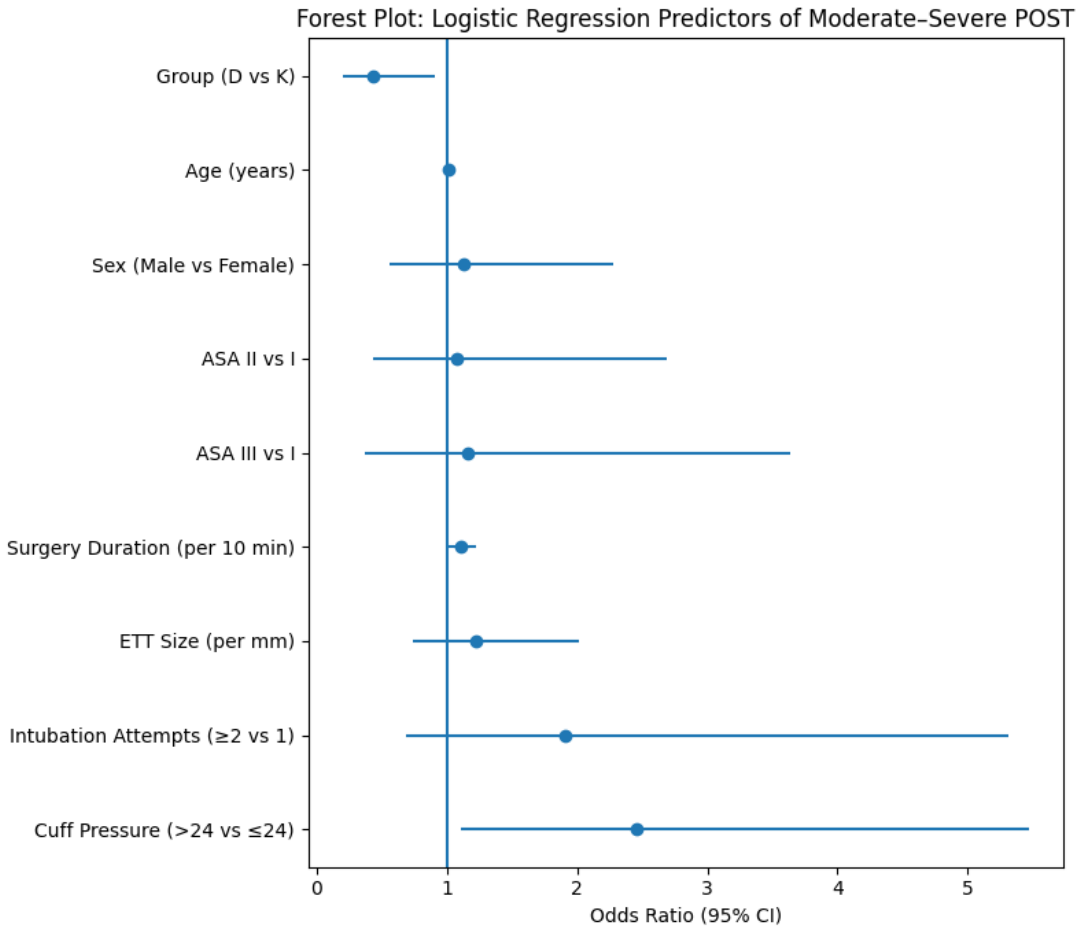



**Figure 4.5 Forest Plot: Logistic Regression Predictors of Moderate–Severe POST**

# CHAPTER 5

# DISCUSSION

Postsurgical sore pharynx (POST) is the most prevalent side effect of endotracheal intubation. It exists in both sexes and may be uncomfortable, such that the affected person develops discomfort. By employing both the pharmacological and non-pharmacological approaches, various studies have been adopted to fix this problem. In Group 1, betamethasone gel was administered to the tracheal tube whereas in another group, he used intravenous dexamethasone. He has concluded that betamethasone gel is superior in treating sore pharynx post operative (POST) compared to intravenous dexamethasone(3).Pharmacological methods are the use of steroids, lignocaine jelly to endotracheal tube as well as steroids nebulization. The non-pharmacological options entail the use of smaller-sized endotracheal tubes in minimizing the occurrence of postoperative sore throat (POST).(5,6)

Tabari et al. (8) carried out a study to determine the effectiveness of dexamethasone and topical steroid in the treatment of skin. Dexamethasone is a man-made glucocorticoid which can be categorized into steroid and is a powerful anti-inflammatory agent. Many studies have proposed that dexamethasone intravenously is useful in the treatment of postoperative sore throat (POST). On the other hand, studies carried by other researchers have indicated that preoperative nebulization using 8 mg of dexamethasone has significant effects in reducing the occurrence of sore throat. Due to the aim of assessing the effectiveness of dexamethasone in the treatment of postoperative nausea and vomiting (POST), we used a low dosage. There were 50 participants (20-60 years old) in the study. They randomly selected 25 patients to each group as part of a random selection of patients of this kind. Group D consisted of 25 patients, where 4 mg of dexamethasone in 4 mL of saline was used to nebulize the patients and administer the treatment, lasted between 10-15 minutes, and then the patients underwent endotracheal intubation. The saline nebulization (5 mL) was used in 25 patients undergoing surgery under general anesthesia with 10-15 minutes intubation (Group S) (50).

The evaluation of the postoperative sore throat was performed after the stated intervals with the help of the 4-point scale (0-3), and the result was that group D had much lower rate of sore throat than group S. It was concluded that the result was statistically significant as long as the instance of extubation ($P = 0.024$). Here, the POST values were

given at 0, 2, 4, 8, 12 and 24 hours. It was decided to be statistically significant after 2 hours following the extubation (P = 0.004). The final result was calculated as statistically significant (P = 0.000) four hours after the extubation. This was statistically significant (P = 0.000) eight hours following the extubation. Significance was found 12 hours after the extubation (P = 0.002). There was no significant change in incidence of POST at the 24 hours (P = 0.513) (14).

No statistically significant difference was found in the characteristics of the patients, including age, weight, sex, Mallampati classification, and ASA status as well as length of operation and type of surgery, in the two groups. Group D showed a considerable reduction in the occurrence and severity of POST when compared to Group S. This paper suggests that postoperative sequelae, cough, vertigo, and vomiting, show no significant differences in the two groups. There are reported similar findings that indicate a reduced rate of surgical sore pharynx due to perioperative nebulization using dexamethasone. Gihan Nasr et al. (9) established that the prevalence of postoperative sore throat was 2 implying that a single dosage of nebulized dexamethasone was effective to reduce the prevalence and severity of POST among patients undergoing general anesthesia with endotracheal intubation. It was discovered by Bagchi et al. (3) that a dosage of 0.2 mg/kg dexamethasone was able to lower the rate of occurrence of postoperative sore throat (POST) by approximately 30 percent an hour post-extubation, and thus, there was an efficacy of about 60 percent.

Saladi Aruna Kumari et al. (10) observed that postoperative nausea and vomiting (POST) was low in people that received nebulized dexamethasone as compared to people that received nebulized ketamine. Salama et al. (1) established that one dose of nebulized dexamethasone at 0, 2, 4, 6 and 12 hours respectively decreased the incidence and severity of POST. According to Park et al. (18), intravenous dexamethasone at 0.1 mg/kg and 0.2 mg/kg reduced the prevalence of POST by 22% and 42% respectively one hour after extubation. Further, POST is reduced by about 30 percent following 0.2 mg/kg dexamethasone IV at 24 hours of extubation. Thomas et al. (11) found out that the use of 8 mg IV dexamethasone preoperative reduced the overall incidence of POST 24 hours after extubation by 36.3%.

Ashwini et al.(12) reported that the incidence of POST was 27.5% in Group D (dexamethasone) as compared to 27.5% in Group M (magnesium sulfate) in the prevention of POST. Group D was characterized by 27.5 percent incidence of POST and group M by 57.5 percent incidence. In a comparative study, Sharma et al. (13) aimed at

establishing the effectiveness of dexamethasone of equal concentration that is applied in three different routes, namely intravenous (IV), topical, and nebulization, before surgery to prevent postoperative sore throat (POST). Their findings were that topical dexamethasone is as effective as IV dexamethasone in POST reduction; but neither route is very effective in minimizing hoarseness of voice. On the contrary, nebulization can successfully address both POST and hoarseness of voice. This study revealed that the rate of postoperative sore pharynx in Group D was extremely lower than that of Group S. The side effects in this study were minimal and unimportant in both groups (2).

The main result of this study after general anesthesia and laryngoscopy, as well as orotracheal intubation is that 8 mg of intravenous dexamethasone is effective in the prevention and treatment of hoarse throat. In the previous studies that were done to ascertain the effectiveness of dexamethasone in preventing the occurrence of sore throat postoperative endotracheal intubation; the confounding factors that lead to the occurrence of painful throat were not taken into consideration (13)... The amount of dexamethasone that was used during our trial and the time it was administered were similar to that in a specific study that indicated the patient receiving extractions on the molar dental area experienced reduced postoperative surgical pain (10).

Wang et al.13 carried out a study to determine the influence of dexamethasone on the onset of postoperative sore throat in patients who had undergone thyroidectomy. They have discovered that dexamethasone reduces postoperative sore throat. Nevertheless, the research failed to consider the presence of confounding factors that might have contributed to the occurrence of postoperative sore throats, including the nature of endotracheal tube, nature of cuff and intracuff pressure, oral suctioning, coughing or buckling on the endotracheal tube, blood staining on the endotracheal tube after extubation, and the history of smoking and lung disease, because its main aim was to test the impact of dexamethasone on the occurrence of postoperative nausea and vomiting (4

The majority of patients in this study were considered to have ASA physical status I, and more than two-thirds (69.7) of the patients had Mallampati score of I. The average time taken was 56.66 minutes of anesthesia and 48.48 minutes of surgery. Before the operation, all of them had normal sinus rhythm (NSR). The average age of the patients was 38.06 years, a range of 18 to 60 years.The average intra-cuff pressure was maintained at normal range experienced by all patients with mean of 22 mmHg to 25 mmHg and a duration of 0 to 60 min. Most of the patients were above 45 years (34.3%). There was equal distribution between male (51.5) and female (48.5) patients, and an

approximate half of the patients were of normal weight (45.5%). ETTs of size 8-8.5 were offered to men, whereas ETTs of size 7-7.5 were offered to women (24, 29). All patients were intubated with a laryngoscope blade of size three with about 1/3 of the patients intubated with a blade of 7.0 mm (36.4%), 7.5 mm (30.3%), 8.0 mm (30.3%). That is, our groups were similar with regard to the age, gender, body weight, ASA PS, Mallampati score, intra-cuff pressure, and the length of surgery (23,27).

According to Biro et al. (2005) and Christensen et al. (1994) (13, 43), the incidence rate in lower age groups was more and in the older age group, the rate was more than in lower age groups. In our case though, age of the patient was not significantly correlated with POST, cough, or hoarseness at the ward. Nonetheless, the age of the patient was found to have a moderate negative relationship with the incidence of PONV in our research, which showed that the incidence of PONV is significantly low in the case of older patients compared to younger ones. An experienced performer with 2-5 years of experience (63.6%), and in the first attempt (100%), was used to perform the intubation, as the less experienced airway performer is a risk factor with increased rates (Jaensson et al., 2012) (16). Contrary to Biro et al. (2005), our study proved that there existed no significant difference in all ward events (POST and other morbidities) in smoker and non-smoker patients. Also, the exclusion criterion included the presence of visible bloodstains on the ETT post extubation and prior respiratory illnesses and no visible blood stain was found in the NGT or in the ETT in any patient (23).

The laryngoscopic sight was evaluated in all the patients according to the Modified CormackLehane score which produced a percentage of 39.4, 154.5, 3 and 3 in class 1, 2a, 2b, and 3 respectively. Further, 42.4 percent of the patients had an excellent intubation condition, 57.6 percent had a good intubation condition and no patient experienced a poor intubation condition according to the 1994 Copenhagen Consensus Conference recommended score. Excellent conditions of intubation were greater in the ketamine group (72.7) compared to saline and dexamethasone groups (63.6 and 81.8, respectively). It is important to note that we cannot ascertain whether such differences between the study groups are linked to nebulizers especially since no previous studies have been conducted on effects of nebulizers on the conditions of intubation. Nevertheless, the conditions of intubation were the least in the saline group (45).

On the other hand, females had the highest incidence of POST that aligns with the observation that the level of intubation difficulty is a risk factor of POST.In addition, they had a significantly higher incidence of cough, hoarseness, and PONV inward in

comparison to males. Nonetheless, gender did not show any significant difference in POST in our study. This corresponds to the results of Orji et al. (2020) (26) at POST at the fourth hour since the incidence of the two sexes (female and male) did not differ in all groups.

Although females had more POST than males, the studies did not mention the difference between the two genders in terms of other morbidities, and that is why our findings are consistent with the information presented by Green and Krauss (2004) about laryngospasm, which was not experienced by any of our patients: during nebulization, before induction, or after extubation. It is uncommon to the point of being mentioned as a side effect of ketamine though it does exist. Based on the aggregated data, the risk of the occurrence of laryngospasm, requiring intubation during ketamine anesthesia is 1 per 5,000 people (0.02%). This is almost 100 times less risky than the risk posed by other anesthetic drugs.In this article, the dexamethasone group recorded a decrease in the occurrence and intensity of sore throats compared with the control group. This finding is in line with the topical application of corticosteroids to the upper airway before endotracheal intubation (8, 9).

Conversely, studies that demonstrated the inconsistencies between studies, include Hamelberg (16), where the application of the 1% hydrocortisone ointment to the endotracheal tube before intubation led to an insignificant reduction in the rate of postoperative sore throat.Anesthesia and interview methodologies are the possible causes of the differences between research.Stride18 concluded, in late 1991, that 1% hydrocortisone ointment use to endotracheal tube before intubation did not lead to The synthesis of inflammatory mediators, including prostaglandins and leukotrienes, is inhibited by corticosteroids by blocking phospholipase A2 by production of calcium-dependent phospholipid-binding proteins known as annexins, which in turn requires several hours, as per Hamelberg methodology. Also, they are capable of suppressing cyclooxygenase-2. Our investigation revealed only one patient who had vertigo and vomiting in the control group. More likely, there was a significant low incidence of nausea and vomiting because of a complex of circumstances. Other contributory factors might be ondansetron at the first six hours, dexamethasone-ondansetron mixture in the dexamethasone group and enhanced non-opioid analgesia (24, 25). Despite the fact that a single dose of dexamethasone is believed to be secure, the prolonged use of corticosteroids is linked to negative aspects, including glucose intolerance, heightened infection probability, poor healing of wounds, adrenal insufficiency and avascular

necrosis of the joints. The amount of dexamethasone necessary to prophylaxis the postoperative sore throat, when the dexamethasone should be given and when the entire sore throat will be healed remain unknown.

# CONCLUSION

IVK was inferior to preoperative nebulized dexamethasone in terms of preventing and minimizing postoperative sore throat of general anesthesia patients. Patients that were given dexamethasone always had lower scores on sore-throat at all postoperative times and a higher proportion of them experienced no or few symptoms. The general rates of complications were also low and similar in the two groups, with both drugs having a unique but controllable safety profile. The multivariate analysis indicated that group allocation, increased cuff pressure, and longer duration of surgery were serious predictors of postoperative sore throat. These findings suggest that nebulized dexamethasone is a safe and effective prophylactic treatment of POST. Nevertheless, to reduce the patient distress, it is required that the airway management and procedural factors are carefully observed.

# RECOMMENDATION

To prevent the incidence of postoperative sore throats in endotracheal intubation patients undergoing general anesthesia, preoperative nebulized dexamethasone must be introduced as a prophylaxis. In order to further prevent the postoperative sore-pharynx, it is recommended that cuff pressure should be monitored and the period of intubation should be minimized. Future research should be done on an extensive multicenter study to confirm such findings and determine the best dose and timing of the dexamethasone administration. The comparison of the results with other anti-inflammatory or analgesic drugs can provide additional information about the best approaches to POST prevention. Before surgery, patients need to know that they may experience postoperative sore throats and the available preventive interventions to improve their satisfaction and recovery.

# LIMITATION

- The sample 100 patients is rather limited in terms of generalizing the findings, as the data were gathered on a relatively small sample.
- The findings of the study might not be universal to other clinical environments and could be open to institutional practices.
- A maximum of 12 hours of the postoperative period (POST) was observed; no evaluation of the long-term effects was conducted.
- It is also possible that with the introduction of selection bias using convenience sampling, the representativeness of the study population could be affected.
- It was not controlled by other things which may affect POST incidence: intraoperative fluid management, difference in anesthetic technique, or differences in postoperative care.

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# APPENDICES

## APPENDIX-1

## ETHICAL APPROVAL LETTER

OFFICE OF THE DEAN-FAHS

SUPERIOR UNIVERSITY

Ref.: IRB /FAHS/Allied/10/25/MS/AHS-3836

Date: 10th October 2025

Name: Abdul Mabood

Registration: SU91-MSAHW-S24-034

**Subject: Ethical Approval Letter**

The Research Ethical Committee convened on Dated: **3rd October, 2025** to discuss your protocol titled "**A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia.**"

No further corrections and recommendations were suggested. The above-mentioned protocol has been approved after considering various research issues including ethical concerns with condition that the researcher will submit completion report at the end of his/her research.

**Prof. Dr. Muhammad Naveed Babur**
**Dean/Convener REC**
**Faculty of Allied Health Sciences**
**Superior University, Lahore**

# APPENDIX-2

## RCT REGISTRATION

**Clinical Trial Protocol**
**Iranian Registry of Clinical Trials**

08 Sep 2026

## A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia

### Protocol summary

**Study aim**
• To assess the incidence and severity of postoperative sore throat (POST) in patients receiving preoperative nebulized dexamethasone and intravenous ketorolac. • To compare the anti-inflammatory effect of Steroid (Dexamethasone) versus non-steroid (Ketorolac tromethamine) in reducing POST.

**Design**
This study employed a randomized, double-blinded research design.

**Settings and conduct**
The study was be conducted at Farooq Hospital, DHA, specifically within the Department of Anesthesia.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: • Patients aged 18 – 50 undergoing surgeries that require endotracheal intubation after general anesthesia • ASA Physical status of I–III. • Patient giving informed consent. Exclusion criteria. • Patient known to be allergic to study drugs. • Asthmatic or COPD patients. • ASA physical status IV – VI • The Patient has a pre-existing sore throat or pain • Surgeries involving the neck, throat, or airway. • Upper respiratory tract infection. • Patients with a history of renal disease

**Intervention groups**
Interventions: Group K (Ketorolac group): Participants in this group will receive intravenous ketorolac tromethamine preoperatively, 15–30 minutes before induction of general anesthesia. Group D (Dexamethasone group): Participants in this group will receive nebulized dexamethasone preoperatively, 15–30 minutes before induction of general anesthesia.

**Main outcome variables**
Main Outcome Variables: Incidence of Postoperative Sore Throat (POST): Presence or absence of sore throat at 2, 4, 6, and 12 hours after extubation. Severity of Postoperative Sore Throat: Measured using the STAT-10 scale at 2, 4, 6, and 12 hours post-extubation. Anti-inflammatory Effect of Intervention: Assessed indirectly through reduction in sore throat severity scores between the two groups.

### General information

**Reason for update**

**Acronym**
POST: Postoperative Sore Throat

**IRCT registration information**
IRCT registration number: **IRCT20260222068917N1**
Registration date: **2026-02-25, 1404/12/06**
Registration timing: **retrospective**

Last update: **2026-02-25, 1404/12/06**
Update count: **0**

**Registration date**
2026-02-25, 1404/12/06

**Registrant information**

**Name**
Abdul Mabood

**Name of organization / entity**
Superior University, Lahore

**Country**
Pakistan

**Phone**
+92 345 8561831

**Email address**
abdulmabood856@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-07-16, 1404/04/25

**Expected recruitment end date**
2026-01-12, 1404/10/22

**Actual recruitment start date**
2025-07-16, 1404/04/25

**Actual recruitment end date**
2026-01-12, 1404/10/22

**Trial completion date**
2026-01-12, 1404/10/22

**Scientific title**
A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia

**Public title**
A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients aged 18 – 50 undergoing surgeries that require endotracheal intubation after general anesthesia ASA Physical status of I-III Patient giving informed consent.

**Exclusion criteria:**
Patient known to be allergic to study drugs Asthmatic or COPD patients ASA physical status IV – VI The Patient has a pre-existing sore throat or pain Surgeries involving the neck, throat, or airway Upper respiratory tract infection Patients with a history of renal disease

**Age**
From **18 years** old to **50 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **100**
Actual sample size reached: **100**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Participants in this study were allocated to either the pre-operative nebulized dexamethasone group or the intravenous ketorolac tromethamine group using simple randomization at the level of the individual participant. No stratified randomization was applied, as the study population was homogeneous regarding age, gender, and type of surgery. The random sequence was prepared manually using a table of random numbers, and each participant was assigned a unique sequential number upon enrollment, which was then matched to the pre-prepared random allocation list to determine group assignment. Allocation concealment was maintained using sealed opaque envelopes, which were opened only at the time of intervention to prevent selection bias. No pseudorandomization methods, such as odd/even days, birthdays, or physician choice, were used.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
In this study, participants are blinded to the type of intervention they receive, as both nebulized dexamethasone and intravenous ketorolac tromethamine are administered in a manner that conceals group allocation. The principal investigator and outcome assessors are also blinded to group assignments to prevent assessment bias when recording postoperative sore throat outcomes. Healthcare providers administering the interventions are aware of the treatment for practical reasons but do not participate in outcome assessment. Data collectors and individuals entering and analyzing the data are blinded to group allocation to maintain objectivity. A sealed opaque envelope system ensures that group allocation remains concealed until the intervention is given. The Data Safety and Monitoring Board (DSMB) and manuscript writers are not involved in treatment administration or outcome assessment and remain unaware of group assignments until study completion. This blinding strategy minimizes bias at multiple levels of the study while maintaining safety and practical feasibility.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
The Research Ethical Committee, Superior University, Lahore

**Street address**
17 Km Raiwind Road, Lahore, Pakistan

**City**
Lahore

**Postal code**
54000

**Approval date**
2025-10-16, 1404/07/24

**Ethics committee reference number**
IRB /FAHS/Allied/10/25/MS/AHS-3836

## Health conditions studied

# APPENDIX-3

## INFORMED CONSENT FORM

**Study Title**

**A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia**

**Introduction**

You are being invited to participate in a research study. Before you decide whether to participate, you need to understand why the research is being conducted and what it will involve. Please read the following information carefully. You may ask questions at any time.

Participation in this study is completely voluntary.

**Purpose of the Study**

Post-operative sore throat (POST) is a common complaint after general anesthesia with endotracheal intubation. This study aims to compare the effectiveness of:

- Nebulized Dexamethasone
- Intravenous Ketorolac Tromethamine

in preventing post-operative sore throat.

**Study Procedures**

If you agree to participate:

1. You will be randomly assigned (like flipping a coin) to receive either:
    - Nebulized Dexamethasone before anesthesia, or
    - Intravenous Ketorolac before anesthesia.
2. Neither you nor the doctors assessing your sore throat will know which medication you received (double-blinded study).
3. The medication will be administered before induction of general anesthesia.
4. After surgery, you will be assessed for sore throat and other related symptoms at specific time intervals (e.g., 2, 4, 6, and 12 hours postoperatively).

No additional invasive procedures will be performed beyond standard anesthesia care.

**Duration of Participation**

Your participation will last from the time of drug administration until 12–24 hours after surgery.

**Possible Benefits**

You may benefit from a reduced chance or severity of post-operative sore throat. However, there is no guarantee of direct benefit.

The results of this study may help improve patient comfort in future surgical procedures.

**Possible Risks and Discomforts**

Both medications are commonly used and generally safe. However, possible side effects include:

**Nebulized Dexamethasone:**

- Mild throat irritation
- Rarely, increased blood sugar (especially in diabetic patients)

**Intravenous Ketorolac:**

- Nausea or vomiting
- Gastric irritation
- Rarely, bleeding tendency

All medications will be administered under medical supervision.

**Confidentiality**

All information collected during this study will remain confidential. Your identity will not be disclosed in any publication or presentation resulting from this study. Data will be coded and stored securely.

**Voluntary Participation**

Your participation is voluntary. You are free to refuse participation or withdraw at any time without affecting your medical care.

**Compensation and Treatment for Injury**

If you experience any injury directly related to the study, appropriate medical care will be provided according to institutional policy.

**Contact Information**

If you have any questions regarding the study or your rights as a participant, you may contact:

Principal Investigator: _____
Department: _____
Contact Number: _____
Institution: _____

**Consent Statement**

I have read and understood the information provided above. I have had the opportunity to ask questions, and my questions have been answered satisfactorily. I voluntarily agree to participate in this study.

Participant Name: _____

Signature: _____

Date: _____

Researcher Name: _____

Signature: _____

Date: _____

# APPENDIX-4

# URDU VERSION

**کا مکمل اردو ورژن، جو (Informed Consent Form)** یہ رہا آپ کے مطالعے کے لیے **رضامندی نامہ**
:ایتھکس کمیٹی اور تحقیقی استعمال کے لیے موزوں ہے

**رضامندی نامہ**

**مطالعے کا عنوان**

**جنرل اینستھیزیا کے بعد ہونے والی پوسٹ آپریٹو گلے کی سوزش کی روک تھام کے لیے پری آپریٹو نیبولائزڈ ڈیکسا میتھازون اور وریدی کیٹوروولاک ٹرومیتھامین کا تقابلی، بے ترتیب اور ڈبل بلائنڈ مطالعہ**

تعارف

آپ کو ایک تحقیقی مطالعے میں شرکت کی دعوت دی جا رہی ہے۔ شرکت کرنے کا فیصلہ کرنے سے پہلے ضروری ہے کہ آپ اس تحقیق کے مقصد اور طریقہ کار کو اچھی طرح سمجھ لیں۔ براہِ کرم درج ذیل معلومات کو غور سے پڑھیں۔ آپ کسی بھی وقت سوال پوچھ سکتے ہیں۔

اس تحقیق میں شرکت مکمل طور پر رضاکارانہ ہے۔

مطالعے کا مقصد

جنرل اینستھیزیا کے دوران سانس کی نالی میں ٹیوب ڈالنے (انٹیوبیشن) کے بعد گلے کی تکلیف یا خراش (Post-Operative Sore Throat) ایک عام شکایت ہے۔

:اس تحقیق کا مقصد دو ادویات کا موازنہ کرنا ہے

نیبولائزڈ ڈیکسا میتھازون

وریدی کیٹوروولاک ٹرومیتھامین

تاکہ معلوم کیا جا سکے کہ کون سی دوا آپریشن کے بعد گلے کی سوزش کو زیادہ مؤثر طریقے سے کم کرتی ہے۔

طریقہ کار

:اگر آپ اس تحقیق میں شرکت پر رضامند ہوتے ہیں تو

:آپ کو بے ترتیب طریقے سے (قرعہ اندازی کی طرح) دو گروپوں میں سے کسی ایک میں شامل کیا جائے گا

آپریشن سے پہلے نیبولائزڈ ڈیکسا میتھازون دیا جائے گا، یا

آپریشن سے پہلے وریدی کیٹوروولاک دیا جائے گا۔

نہ آپ کو اور نہ ہی بعد میں معائنہ کرنے والے ڈاکٹر کو معلوم ہوگا کہ آپ کو کون سی دوا دی گئی ہے (ڈبل بلائنڈ مطالعہ)۔

دوا جنرل اینستھیزیا شروع کرنے سے پہلے دی جائے گی۔

آپریشن کے بعد 2، 4، 6 اور 12 گھنٹے پر گلے کی تکلیف کا جائزہ لیا جائے گا۔

معمول کے اینستھیزیا کے علاوہ کوئی اضافی تکلیف دہ عمل نہیں کیا جائے گا۔

شرکت کا دورانیہ

آپ کی شرکت دوا دینے کے وقت سے لے کر آپریشن کے بعد تقریباً 12 سے 24 گھنٹے تک ہوگی۔

ممکنہ فوائد

ممکن ہے کہ آپ کو گلے کی تکلیف میں کمی محسوس ہو، لیکن اس کی ضمانت نہیں دی جا سکتی۔

اس تحقیق کے نتائج مستقبل میں مریضوں کی سہولت کے لیے مددگار ثابت ہو سکتے ہیں۔

ممکنہ خطرات یا مضر اثرات

:دونوں ادویات عام طور پر محفوظ سمجھی جاتی ہیں، تاہم ممکنہ مضر اثرات درج ذیل ہو سکتے ہیں

:نیبولائزڈ ڈیکسا میتھازون

گلے میں ہلکی جلن

(بعض اوقات خون میں شوگر کی سطح میں اضافہ (خاص طور پر ذیابیطس کے مریضوں میں

:وریدی کیٹوروولاک

متلی یا قے

معدے میں جلن

شاذ و نادر خون بہنے کا رجحان

تمام ادویات طبی نگرانی میں دی جائیں گی۔

رازداری

آپ کی تمام معلومات کو خفیہ رکھا جائے گا۔ آپ کا نام یا شناخت کسی اشاعت یا رپورٹ میں ظاہر نہیں کی جائے گی۔ تمام معلومات کو کوڈ کر کے محفوظ رکھا جائے گا۔

رضاکارانہ شرکت
اس تحقیق میں شرکت مکمل طور پر رضاکارانہ ہے۔ آپ کسی بھی وقت بغیر کسی وجہ کے شرکت سے انکار یا علیحدگی اختیار کر سکتے ہیں، اور اس سے آپ کے علاج پر کوئی اثر نہیں پڑے گا۔

کسی نقصان کی صورت میں
اگر اس تحقیق کی وجہ سے آپ کو کوئی نقصان پہنچتا ہے تو ادارے کی پالیسی کے مطابق مناسب طبی سہولت فراہم کی جائے گی۔

رابطہ کی معلومات
:اگر آپ کو اس تحقیق کے بارے میں کوئی سوال ہو تو آپ درج ذیل سے رابطہ کر سکتے ہیں
پرنسپل انویسٹی گیٹر:_____
شعبہ :_____
ادارہ :_____
رابطہ نمبر :_____

رضامندی کا بیان
میں نے اوپر دی گئی تمام معلومات کو پڑھ لیا ہے اور سمجھ لیا ہے۔ مجھے سوال پوچھنے کا موقع دیا گیا اور میرے سوالات کے تسلی بخش جوابات دیے گئے۔ میں اپنی مرضی سے اس تحقیق میں شرکت پر رضامند ہوں۔

شرکاء کا نام :_____
دستخط :_____
تاریخ :_____
محقق کا نام :_____
دستخط:_____
تاریخ :_____

# APPENDIX-5

## RESEARCH QUESTIONNAIRE

*A Randomized, Double-Blinded Comparative Study of Pre-Operative Nebulized Dexamethasone and Intravenous Ketorolac Tromethamine for the Prevention of Post-Operative Sore Throat Following General Anesthesia*

---

**Demographic Information**

Patient ID: _____ Age/Sex: _____

ASA Status: _____ Time drug administration: _____

Drug Given: **Dexamethasone Nebs** ☐ **Intravenous Ketorolac** ☐

Contact: _____

**Anesthesia and Surgery Details**

**Parameter Details:**

Surgery: _____ Duration: _____

Size of ETT: _____ Number of Intubation Attempts: _____

**Section 2: Sore Throat Assessment Tool – 10 (STAT-10)**

Please assess the patient based on the following symptom descriptions. Rate each item on a scale of 1 to 5 at each time point.

Scoring Scale:
1 – Not at all, 2 – Mild, 3 – Moderate, 4 – Severe, 5 – Very Severe.

| S. No | Description | 2 Hours | 4 Hours | 6 Hours | 12 Hours |
|---|---|---|---|---|---|
| 1 | The patient reports throat soreness. | | | | |
| 2 | The patient has difficulty swallowing. | | | | |
| 3 | The patient complains of dryness in the throat. | | | | |
| 4 | The patient feels irritation or scratchiness in the throat. | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 5 | The patient's voice is hoarse or altered. | | | | |
| 6 | The patient feels a lump or tightness in the throat. | | | | |
| 7 | Throat pain is interfering with eating. | | | | |
| 8 | Throat pain is interfering with speaking. | | | | |
| 9 | A sore throat disturbs sleep. | | | | |
| 10 | The patient is experiencing overall throat discomfort. | | | | |
| **Total Score** | | | | | |

**Rescue Medication Used:** Yes ☐ No ☐
If yes, specify: _____

**Complications Occurred:** ☐ Gastrointestinal irritation ☐ Hyperglycemia ☐ Nausea and vomiting ☐ Delayed wound healing ☐ Others: _____

By participating in this study, I voluntarily give my consent and understand that my information will be kept confidential and used solely for research purposes.

_____
Sign or Thumb impression

# APPENDIX-6

## PLAGIARISM REPORT

**Abdul Mabood**

ORIGINALITY REPORT

| 12% | 8% | 6% | 1% |
|---|---|---|---|
| SIMILARITY INDEX | INTERNET SOURCES | PUBLICATIONS | STUDENT PAPERS |

PRIMARY SOURCES

| | | |
|---|---|---|
| 1 | www.researchgate.net<br>Internet Source | 2% |
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| 3 | Siji Thomas, Suhara Beevi. "La dexaméthasone réduit la sévérité du mal de gorge postopératoire", Canadian Journal of Anesthesia/Journal canadien d'anesthésie, 2007<br>Publication | 1% |
| 4 | journals.lww.com<br>Internet Source | 1% |
| 5 | Sun Young Park, Sang Hyun Kim, Se Jin Lee, Won Seok Chae, Hee Cheol Jin, Jeong Seok Lee, Soon Im Kim, Kyung Ho Hwang. "L'application d'une pâte d'acétonide de triamcinolone à la sonde endotrachéale réduit les maux de gorge postopératoires: une étude randomisée contrôlée", Canadian Journal of Anesthesia/Journal canadien d'anesthésie, 2011<br>Publication | <1% |
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| | | |
|---|---|---|
| | Study of Three Nebulized Medications for the Prevention of Postoperative Sore Throat in the Pediatric Population", The Open Anesthesia Journal, 2018<br>Publication | |
| 8 | www.vitals.com<br>Internet Source | <1 % |
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| 10 | Sang-Hyun Park. "Prophylactic Dexamethasone Decreases the Incidence of Sore Throat and Hoarseness After Tracheal Extubation with a Double-Lumen Endobronchial Tube", Anesthesia & Analgesia, 12/2008<br>Publication | <1 % |
| 11 | Sun Young Park. "The effect of intravenous low dose ketamine for reducing postoperative sore throat", Korean Journal of Anesthesiology, 2010<br>Publication | <1 % |
| 12 | Avi A. Gajjar, Rashad Jabarkheel, Oleg Shekhtman, Mohamed M. Salem et al. "Regional Variations in the Management of Cerebral Arteriovenous Malformations: A Nationwide Inpatient Sample Analysis of Surgical Excision and Endovascular Embolization", Journal of Clinical Neuroscience, 2025<br>Publication | <1 % |
| 13 | Submitted to Florida International University<br>Student Paper | <1 % |

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| 14 | Submitted to Maharishi Markandeshwar University Mullana<br>Student Paper | <1 % |
| 15 | www.omicsdi.org<br>Internet Source | <1 % |
| 16 | Zheping Chen, Yanwu Jin, Guodong Lu, Yuelong Jin, Chang Feng, Xin Zhao. "Preoperative Ultrasound-Guided Internal Branch Block of Superior Laryngeal Nerve Reduces Postoperative Sore Throat Caused by Double Lumen Endotracheal Intubation: A Randomized Trial", Anesthesia & Analgesia, 2023<br>Publication | <1 % |
| 17 | "Abstracts", European Journal of Nuclear Medicine, 12/2001<br>Publication | <1 % |
| 18 | www.mdpi.com<br>Internet Source | <1 % |
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| 20 | ipindexing.com<br>Internet Source | <1 % |
| 21 | clinicaltrials.gov<br>Internet Source | <1 % |
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| 26 | Gustavsson, Linda, Irene Vikman, Cecilia Nyström, and Åsa Engström. "Sore throat in women after intubation with 6.5 or 7.0mm endotracheal tube: A quantitative study", Intensive and Critical Care Nursing, 2014.<br>Publication | <1 % |
| 27 | Jianhui Liu, Xiaoqing Zhang, Wei Gong, Shitong Li, Fen Wang, Shukun Fu, Mazhong Zhang, Yannan Hang. "Correlations Between Controlled Endotracheal Tube Cuff Pressure and Postprocedural Complications", Anesthesia & Analgesia, 2010<br>Publication | <1 % |
| 28 | elsa.ecancer.org<br>Internet Source | <1 % |
| 29 | Jiwon Lee, Hee-Pyoung Park, Mu-Hui Jeong, Hyun-Chang Kim. "Combined intraoperative paracetamol and preoperative dexamethasone reduces postoperative sore throat: a prospective randomized study", Journal of Anesthesia, 2017<br>Publication | <1 % |
| 30 | Submitted to University of Iowa<br>Student Paper | <1 % |
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| 38 | Anil Agarwal. "An Evaluation of the Efficacy of Licorice Gargle for Attenuating Postoperative Sore Throat: A Prospective, Randomized, Single-Blind Study", Anesthesia & Analgesia, 07/2009<br>Publication | <1 % |
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| 44 | Anupam Kundu, Priti Rooj, Nikhilesh Joardar, Ashok Kumar Sinha, Animesh Sen. "Clinical trials unveiling the potential of phytochemicals across different diseases", Elsevier BV, 2026 | <1 % |

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|---|---|---|
| | Publication | |
| 45 | U. Aypar. "Ketamine gargle for attenuating postoperative sore throat", British Journal of Anaesthesia, 02/27/2008<br>Publication | <1 % |
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