

An-Najah National University

Faculty of Graduate Studies

The effect of alkalized lidocaine, dexamethasone, and their combination versus air in the endotracheal tube cuff to evaluate post-extubation morbidity in smoker patients undergoing laparoscopic surgery. A double blind randomized control study

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Dedication

I dedicated this thesis to the sake of Allah, and my great teacher and messenger, Mohammed (May Allah bless and grant him), who taught us the purpose of life.

To my homeland Palestine, the intimate womb, and to the great martyrs and prisoners, the symbol of sacrifice.

My great parents, who have always loved me unconditionally and whose have taught me to work hard for the things that I aspire to achieve, my beloved brother and sisters. To all my family, and my friends who encourage and support me, all the people in my life who touch my heart, I dedicate this research.

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الاقرار

انا الموقع ادناه مقدم الرسالة التي تحمل العنوان

The effect of alkalized lidocaine, dexamethasone, and their combination versus air in the endotracheal tube cuff to evaluate post-extubation morbidity in smoker patients undergoing laparoscopic surgery. A double blind randomized control study

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Declaration

The work provided in this thesis, unless otherwise referenced, is the researcher's own work and has not been submitted elsewhere for any other degree or qualification.

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List of Abbreviations

ETT	Endo tracheal tube
ASA	American Society of Anesthesiologists
ICU	Intensive care unit
OR	Operation room
PACU	Post anesthesia care unit
PER	Post extubation reaction
LMA	Laryngeal mask airway
HR	Heart rate
BP	Blood pressure
MAP	Main arterial pressure

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Abstract

Background: Endotracheal intubation is the conclusive method of attaining the respiratory tract during standard anesthesia. Nonetheless, endotracheal intubation has been shown to cause post-operative coughing, hoarseness and sore throat after involvement of airway-related side effects. Smoking is one of the largest hazard factors that incline patients to perioperative difficulties. Previous studies have used Lidocaine and Dexamethasone through instillation into the ETT cuff and its diffusion to the basic of the mucosa of trachea there by decreasing regional excitability and airways inflammations.

Aim: The trial aims to compare between the effect of combination of [alkalinized 2% lidocaine plus dexamethason] , alkalinized 2% lidocaine alone, dexamethason alone, and air on decreasing the post extubation morbidity such as cough, sore throat and hoarsness when inflated in endotracheal tube cuff in patients undergoing laparoscopic surgery under general anesthesia.

Methods: A prospective, randomized double-blind study. 100 smoking patients, underwent laparoscopic operation under general anesthesia.. Participants are randomly allocated to receive a different intra-cuff endotracheal tube agents either [alkalinized 2% lidocaine (L group, n=25), dexamethazon, D group, n=25, alkalinized 2% lidocaine +dexamethason LD group, n=25, air, A group, n=25]. Their ETT cuffs were inflated regarding to the group in a volume adequate to create a cuff pressure that would protect from leakage during positive pressure ventilation, at an intra-airway pressure of 20-25cm H₂O. Incidence of coughing, sore throat, hoarseness, BP, heart rate, respiration, postoperative nausea and vomiting were analyzed. The period of anesthesia and operation, the time passed by to extubation after discontinuation of anesthesia were recorded.

Results: All 100 patients recruited in the trial, accomplished it. The groups were comparable in terms of patient characteristics, anesthetic and surgical data.

Cough

The results show that the incidence of cough at emergence in group A (12 (48%)) is significantly higher than group L (3 (12%)) $p = 0.004$, and the group D (1 (4%)), $p = 0.000$ and group LD (0 (0%)), $p = 0.000$. The results also show that the incidence of cough in group L (3 (12%)) is significantly higher than the group LD (0 (0%)), $p = 0.037$.

The results show that, the incidence of cough on 2 hr. in group A(22(88%)) is significantly higher than group L(10(40%))(P=<0.001) and group D(4(16%))(P=<0.001) and group LD(8(32%)) (P=<0.001), and there are no significant differences between groups(L, D, and LD).

The incidence of moderate cough on 2hr.in the L group 0(0%), in D group 0(0%), in LD group 1(4%) are significantly lower than A group, (p=0.000). A significant increase in the severity of cough at moderate levels in the air group compared with other three groups observed.

The results show also that, according to the incidence of cough on 8 hour, group A (21 (84%)) is significantly higher than group L (1 (4%)) (p = <0.0001) and group D (1(4%)) (p = <0.0001) and group LD (0 (0%)) (p = <0.0001), so the authors conclude that all groups are better than group (A).

The results show that there are statistically significant differences between the study groups according to the severity of 8-hour cough (Mild). n (%) of the patients in the L-group1 (4%), the D-group 1 (4%) and LD group 0 (0%), are significantly lower than A group 18 (72%), P = 0.000.

The results show that, according to the incidence of coughing on 24 hours, group A (3 (12%)) is significantly higher than group L (0 (0%)) (p = 0.037) and group D (0 (0%)) (p = 0.037) and group LD (0 (0%)) (p = 0.037), so all groups are significantly better than group (A).

Sore throat

The results show that, incidence of sore throat on 2 hours in group A (18 (72%)) is significantly higher than group L (2 (8%)) ($p = <0.001$) and group LD (5 (20%)) (<0.001). There is a significant difference in the number (percentage) of patients with severity of sore throat at moderate level on 2 hr. in L group 0(%), D group 5(20%) and LD group 0(0%) when compared to A group (14(56%)), $p=0.000$. The above results mean a significant increasing in a severity of sore throat in air group comparing with other three groups.

According to the incidence of sore throat on 8 hours, The results show that n(%) patients is significantly higher in group A 17(68%) compared to L group 0 (%), LD group 1 (4%) and D group 10(40%)) $p = 0.000$. Also n(%) of patients is significantly higher in the D group 10 (40%) compared to L group 0 (0%) and LD group 1 (4%)) $p = 0.000$. So the best group is group (L), then (LD), then (D) and the worst group is (A).

Analysis show that the incidence of sore throat on 24 hour in group A (8(32%)) is significantly higher than group L(0(0%)) ($p <0.000$) and group D (0(0%)) ($p <0.000$) and group LD (0(0%)) ($p <0.000$), so all groups are equally better than group (A). There are significant differences according to severity of sore throat at mild level between air group and other three groups, $p=0.000$.

Hoarseness

The incidence of hoarseness on 2 hr. in group A(21(84%)) is significantly higher than group L(13(52%))(p= 0.014) and group D(8(32%))(p= <0.001) and group LD(9(36%))(p= <0.001). All groups are equally better than group (A).

There are statistically significant differences between the study groups on 2 hour regarding hoarseness (noted only by the patient) $P = 0.015$. Hoarseness was (noted only by patients) of 11(44%) in A group that significantly higher than D group 4 (16%) and LD group 4 (16%), $P = 0.0325$. And there are significant differences between L group 12 (48%) and both D group 4 (16%) and LD group 4 (16%), $P = 0.0164$. So, the D group and LD group are better than the other two groups (A and L) in reducing hoarseness noted only by patients. The incidence of hoarseness (Easily noted)) was 10(40%) in A group that significantly higher than L group 1 (4%), $P = 0.0024$ and D group 4(16%), $P = 0.0614$ and LD group 5 (20%), $P = 0.1266$, $p=0.015$.

The incidence of hoarseness on 8 hours in group A (21 (84%)) is significantly higher than group L (6 (24%)) ($p = 0.009$) and group LD (7 (28%)) ($= 0.009$). No significant difference between group A (21 (84%)) and D (9 (36%)). So, the best groups are (L) and (LD).

There are statistically significant differences between the study groups according to the hoarseness on 8 hour (Noted By patient only) $P=0.033$. Further analysis show that there are statistically significant differences between the study groups according to hoarseness on 8 hour (Easily noted), $P=0.003$. The results indicate that all three groups are significantly better than the A group to reduce the severity of hoarseness.

Incidence of hoarseness on 24 hours in group A (10 (40%)) is significantly higher than group L (0 (0%)) ($p = <0.001$), group D (0 (0%)) ($p = 0.001$) and group LD (1 (4%)) ($p = 0.001$), so all groups are better than group (A).

There are significant differences in the severity of hoarseness on 24 hr. (noted by patient only) between L (0%), D (0 (0%)) and LD (1 (4%)) versus A group 10 (40%), $p=0.000$. The results indicate that all groups are better than group (A) in reducing the severity of hoarseness that can be noted by patients on 24 hr.

Conclusion

The combination of alkalized lidocaine and dexamethasone in ETT cuff or lidocaine alone had a superior effect in reducing incidence and the severity of post-extubation morbidities such as cough, sore throat and hoarseness and softening extubation and no risk of ETT cuff failure.

Nurse anesthetic implications

Lidocaine, Lidocaine plus Dexamethasone and Dexamethasone decrease the incidence of cough and decrease the severity of cough and sore throat. Lidocaine had a superior benefit to decrease the severity of hoarseness in patients undergoing general anesthesia.

Keywords: Smoking; Lidocaine; Dexamethasone, Cough; Hoarseness; Sore throat.

Chapter One

Introduction

Introduction

Endotracheal intubation is the conclusive manner of attaining the respiratory tract under standard anesthesia. It expedites positive pressure ventilation and provides respiratory reassurance from aspiration of stomach contents. On the other hand, endotracheal intubation has been acknowledged to source post-intubation airway-related after effect, including postoperative cough on the tube, nervousness, hoarseness and sore throat (Biro, Seifert, Pasch, 2005). Postoperative respiratory morbidities usually occur and interfere with endotracheal intubation in general anesthesia (Lam et al., 2015). A sore throat is reported in thirty percent to seventy percent of patients post endotracheal intubation. The occurrence of sore throat differs depending on the style, width and intra-cuff pressure of the used endotracheal tube (ETT). Providing drugs prophylactically to reduce postoperative pain in the throat is helpful (Tanaka et al., 2015).

Cough at evolution of standard anesthesia in the operating room and after anesthesia care is a serious complication with an percentage of fifteen percent to ninety four percent which might lead to probably serious issues such as increased blood pressure, ischemia of myocardial muscle, cardiac arrhythmia, spasm in the bronchus, surgical bleeding and raised intracranial pressure and pressure of the eye (Soltani &Aghadavoudi, 2002).

Sustainable smokers progress inflammation of laryngeal epithelial, and distortion of the tissues, that can affect laryngeal purity&function (Schwilk et al., 1997). Dodds (1995) assessed respiratory reactivity against synthetic and automatic stimulation. They noticed an increment in susceptibility in patients who are sustained smokers that was accompanied with raised frequency of spasm in the larynx, obstruction in the airway and fall in saturation of oxygen. It has been proposed that since smoking engenders these sustained developments in the upper respiratory epithelium, there is a large vulnerability of sub-epithelial airway receptors to stimuli. Intubation of trachea results in strain tension in the trachea generated by the tube and owned cuff.

Distribution of lidocaine to the mucosa in connection with the endotracheal tube (ETT) cuff can be utilized as a practice of reducing invigoration of trachea . When lidocaine is infused into the ETT cuff, it transmits (Tanaka et al. 2009) over the semipermeable membrane wall and convinces anesthesia in the trachea. This raises the tolerance of placement of the endotracheal tube. (Hirota et al., 2000). Hemodynamic changes after extubation of the trachea are thus diminished and the rate of cough is dwindled (Altıntaş et al., 2000; Estebe et al., 2002). Buffering lidocaine has a high rate of diffusion through an ETT cuff membrane, less mucosa irritation and less inadvertent cuff membrane damage. (Estebe, et al. 2005, 2014). Dexamethasone was used as a topical drug to reduce sore throat postoperatively and its effect was demonstrated in many studies. (Rafiei et al., 2012; Jarahzadeh et al., 2014; Banihashem et al., 2015)

1.1.1 Background

Post-extubation morbidity is an emerging phenomenon that is described as a collection of respiratory tract complications related to tracheal stricture that may occur after general anesthesia. Many symptoms are the result of mucosa membrane damage, irritation sourced by airway appliances (laryngoscopes, ETT, suction catheters). Interjection of Lidocaine alone or dexamethasone alone into the ET cuff was terminated in many studies as a prophylactic method for decreasing the intensity and frequency of after-extubation reaction. Nonetheless, a smaller number of studies indicated the combination of lidocaine and dexamethasone in ETT cuff.

1.1.2 Laparoscopy surgery

Laparoscopy surgery is a new surgical technique called minimally invasive surgery (MIS), carried out far from the outside through a small incision (usually 0.5-1.5 cm) elsewhere in the body using a fiber optic cable system. General anesthesia and ETT were used as anesthetic technique in this procedure. (Soper, Swanström and Eubanks 2008). Advantages of laparoscopic surgery include decreased bleeding which reduces the risk of blood transfusion, minor incisions that reduce pain and shorten recovery time, resulting in less postoperative scarring; which facilitates throat control, even less pain, leading to less pain-relieving medication that can mask the sore throat. The procedure time is usually slightly longer which increases the chance of drugs diffusion

through the cuff membrane to the tracheal mucosa. N₂O gas that induces cough and increases ETT cuff pressure is not used in this procedure. (Lorente et al., 2014).

Laparoscopic surgery is performed under general anesthesia with mechanical ventilation and a high volume low pressure endotracheal tube with a sealing cuff pressure about 20 to 30 cmH₂O is commonly used for a proper seal and avoidance of over-inflation (Dullenkopf, et al. 2004; Al-Metwalli, et al. 2011)

There are several significant changes in the airways during laparoscopic surgery. Abdominal CO₂ insufflation raises chest pressure (Rauh, et al. 2001; Sprung, et al. 2002) and adjustment of patient positions with up or down slope results in a change in pulmonary compliance (Nguyen & Wolfe, 2005). However, the effect of these physiological changes on endotracheal tube cuff pressure has not been carefully elucidated. In a study conducted by Yu Wu, et al. (2014) was shown that an unintentional increase in endotracheal tube cuff pressure can be found in some types of laparoscopic surgery, especially at the major site colorectal resection. The increase in cuff pressure cannot be associated with the usual range of intra-abdominal pressure (10-15 mmHg) during laparoscopic surgery.

1.1.3 General anesthesia

GA is the condition that is commenced when a patient gets medication for memory loss, pain relief, paralysis of muscles and being relaxed and sleepy. Patient under anesthesia may be considered in an

oversight, changeful state of unconsciousness. Anesthesia allows a patient to endure the procedures of surgery that could differently cause intolerable ache, increase physiological aggravation and product in nasty remembrance. The merger of anesthetic drugs used for standard anesthesia generally assents a patient with many clinical constellations; troublesome even subtract to painful stimulant, inability to remind what occurred, inability to manage satisfactory respiratory and / or voluntary ventilation correspondingly of paralysis of the muscles as well as changes in the heart and blood vessels that are as the result to the stimulus / depressive consequences of the drugs of anesthesia agents (Zuccaro, 2006). Frequencies of anesthetic manifestations during the first 24 hours post-surgery are emesis (10-20%), nausea (10-40%), pain in throat 25% and pain in incision 30% (Jenkins and Baker 2003).

1.1.4 Endotracheal Tube (ETT)

ETT is a catheter introduced into the trachea during intubation to ensure upper airway patency by permitting elimination of seepage and preservation of sufficient air pathway. Endotracheal intubation can be proficient orally by usage of an orotracheal tube or over the nose by usage of a nasotracheal tube. Many divergent endotracheal tubes are accessible. Adult tubes are about "cufflinks" to hinder air and aspiration leakage and acquiesce them to be used with a mechanical ventilator. The cuff is a balloon-like component that is adapted to the lower end of the tube and is attached to a narrow tube that extends beyond the body and allows manual distension of the cuff. When the cuff is extended there is no air flow

through the trachea than it goes through the endotracheal tube. Caution should be considered to prevent over extension the cuff. ETT cuff pressure accompanied with deficient tracheal capillary blood flow diverge between 30 and 50 cm H₂O. Sustainable over exposure of the ETT cuff raises the possibility of the injury of the trachea, subglottic narrowing or offend, hoarseness, nerve damage, fistula and tracheal injury (Sole, Klein and Moseley, 2013).

1.1.5 Lidocaine

Lidocaine is a local anesthetic used in intravenous regional anesthesia, infiltration anesthesia and nerve blocking. The ultimate dose for healthy adults should not outpace 200 mg. Contraindications for the use of lidocaine is a known hypersensitivity to amide type anesthetics, hypervolemia and complete heart block (Ltd., Mercury Pharma International, 2013). The acute systemic toxicity classified by hypoxia and hypercapnia occurs quickly ensuing seizure due to the increment of the activity of the muscles together with the distortion of regular breathing. In serious conditions loss of breathing may occur. Effects on the cardiovascular system can occur in severe cases. Hypotension, bradycardia, arrhythmias and cardiac arrest may occur as a result of high systemic concentrations. Lidocaine is metabolized in the liver and about ninety percent of a disposed dose goes through N-dealkylation to mode monoethylglycinexylidide and glycine xylidide, both of which can devote to the medial and noxious consequence of lidocaine. Other animation happens and metabolites are eliminated in urine by lower than ten percent

as unaffected lidocaine. The half-life of lidocaine after i.v. one shot injection is 1-2 hours, but this could be lengthened in patients with liver abnormalities. (Ltd., Mercury Pharma International. 2013).

1.1.6 Dexamethasone

Dexamethasone, a long-acting synthetic adrenocorticoid with intensive anti-inflammatory activity and mineral corticoid activity. It is prescribed topically and systemically in the treatment of inflammatory conditions. The contraindications for this medicine are systemic fungal infections or known hypersensitivity to this drug. Among the more serious side effects are GI, endocrine, neurological, fluid and electrolyte disturbances (Partner 2012).

1.2.1 Problem statement

Post-extubation morbidity following general anesthesia in the theatre area and in the anesthesia care assemblage are a serious problem with an incidence of 15% to 94%, which may lead to potentially dangerous problems such as increased blood pressure, myocardial ischemia, cardiac arrhythmias, bronchospasm, surgical bleeding and increased intracranial pressure and intraocular pressure (IOP). (Soltani and Aghadavoudi 2002).

Sustainable smokers evolve inflammation in the epithelial cells of the larynx, which may affect laryngeal purity and function (Schwilk, et al. 1997). Tracheal intubation results in pressure in the trachea caused by the tube and emerged cuff. Many applications of lidocaine and dexamethasone

were used to prevent Post-extubation morbidity such as cough, sore throat and hoarseness, but they did not study the combination of these two drugs or attempted to use their effects at the same time. The authors conducted a randomized double blind study to investigate whether tracheal tube intracuff 2% alkalized lidocaine plus dexamethasone was preferable to lidocaine, dexamethasone or air at the onset of cough formation and after operation pain in the throat and hoarseness in patients who smoke experience intubation of the trachea.

1.2.2 Significance of the clinical trial

Post-extubation morbidity in general anesthesia with ETT for airway fuse has been reported in as many as 15% -94% of patients. Only one study - in Iran - has evaluated the combination of lidocaine and dexamethasone in ETT cuff to prevent harmful effects after extubation. Though; In Palestine, anaesthesiologists use lidocaine jell or intravenous dexamethasone to prevent post-extubation phenomena. Although these methods were reported to be less effective than topical dexamethasone or intra-ETT cuff lidocaine in several studies. Therefore, the post-extubation reaction is still an unresolved issue in our attitude.

1.2.3 Aim of the study

Aim: The aim of the study is to compare the effect of combination of [alkalized 2% lidocaine plus dexamethasone], alkalized 2% lidocaine alone, dexamethasone alone and air to reduce post-extubation morbidities such as cough, sore throat and hoarseness when inflated in endotracheal

tube cuff under general anesthesia in smokers undergoing laparoscopic surgery.

1.2.4 Hypothesis

Inflation of the tracheal tube cuff with 2% alkalized lidocaine plus dexamethasone decreases significantly at a level of ≤ 0.05 incidence of cough, sore throat and hoarseness postoperatively compared to tracheal tube cuff inflation with 2% alkalized lidocaine, dexamethasone or air.

Inflation of the tracheal tube cuff with 2% alkalized lidocaine plus dexamethasone decreases significantly at a level of ≤ 0.05 incidence of cough, sore throat and hoarseness postoperatively compared to tracheal tube cuff inflation with 2% alkalized lidocaine

Inflation of the tracheal tube cuff with 2% alkalized lidocaine plus dexamethasone decreases significantly at a level of ≤ 0.05 incidence of cough, sore throat and hoarseness postoperatively compared to tracheal tube cuff inflation with dexamethasone.

Inflation of the tracheal tube cuff with 2% alkalized lidocaine plus dexamethasone decreases significantly at a level of ≤ 0.05 incidence of cough, sore throat and hoarseness postoperatively compared to tracheal tube cuff inflation with air

Inflation of the tracheal tube cuff with 2% alkalized lidocaine decreases significantly at a level of ≤ 0.05 incidence of cough, sore throat and

hoarseness postoperatively compared to tracheal tube cuff inflation with dexamethasone.

Inflation of the tracheal tube cuff with 2% alkalized lidocaine decreases significantly at a level of ≤ 0.05 incidence of cough, sore throat and hoarseness postoperatively compared to tracheal tube cuff inflation with air.

Inflation of the tracheal tube cuff with dexamethasone decreases significantly at a level of ≤ 0.05 incidence of cough, sore throat and hoarseness postoperatively compared to tracheal tube cuff inflation with air

Chapter Two

Literature Review

Literature Review

This chapter illustrates a synopsis of preceding trials of patients go through planned surgery during general anesthesia with administration of lidocaine or dexamethasone or both as a topical treatment [spray, lubricant, garment roll or intra-ETTT cuff] to assess its effect on post -extubation phenomena.

A study was conducted in Iran by Soltani & Aghadavoudi, (2002), in this clinical study, the authors compared divergent manners of lidocaine use and their performance in decreasing after operation cough and pain in the throat . Patients were randomized via the convenience sampling method into six groups (G1, G2, G3, G4, G5, and G6). In the G1 group, 10% lidocaine was sprayed (3 puffs containing approximately 30 mg of lidocaine hydrochloride) on the distal end of the ETT and its cuff, before intubation. In the G2 group, the same dose of 10% lidocaine was sprayed on the laryngopharyngeal structures near the inlet of the larynx through a nozzle connected to the spray device during laryngoscopy. In the G3 group, the distal end of the ETTs and their cuffs were lubricated with 2.5 g of 2% lidocaine jelly (containing approximately 50 mg of lidocaine hydrochloride). In the G4 group, 1.5 mg/kg of lidocaine IV was administered at the conclusion of surgery. In the G5 group, the ETT cuffs were prefilled with 7 to 8 mL of 2% lidocaine for 90 minutes before

intubation to enhance diffusion of lidocaine across the cuff. All cuffs were reevacuated before intubation. Following intubation, the ETT cuffs were inflated with enough lidocaine to prevent retrograde leak at a tidal volume of 10 mL/kg. In the G6 group, the distal end of ETTs and their cuffs were lubricated with normal saline. In each group (n = 34). All patients were observed in PACU for frequency of coughs and possible incidents of stridor or spasms of the larynx. After one hour and at twenty four hours, sore throat and hemodynamic parameters were recorded. Hemodynamic parameters recorded before induction, three and fifteen minutes after intubation and three minutes after taking out of the endotracheal tube. The incidence of sore throat was significantly divergent between the six groups at one hour and twenty four hours, with high incidence in the G3, G2 and G6 groups.

A prospective experiment was conducted in Japan, where patients go through planned surgery. Patients go through head, neck or oral operations. Patients in whom laryngoscopy attempted more than once were also ignored. In this study, the authors compared the incidence and severity of postoperative throat complications after laryngo- tracheal application of lidocaine spray (40 mg), lidocaine (40 mg) or normal saline as placebo during laryngoscopy with total intravenous anaesthesia in 122, in a double blinded, placebo controlled study. The incidence and severity of postoperative sore throat, hoarseness and dysphagia were evaluated on the day of and the day after surgery. Sore throat, hoarseness and difficulty in swallowing were evaluated based on severity; sore throat was graded as 0:

absent; 1: minimal; 2: moderate; and 3: difficult. Hoarseness was classified as 0: absent; 1: small; 2: difficult; Dysphasia was graded as 0: absent; 1: small; 2: moderate; and 3: cannot swallow because of pain. Data was shown that Sore throat and dysphagia were significantly more severe after lidocaine spray was used than after lidocaine or placebo was used. However, there was no significant difference in the incidence or severity of postoperative sore throat, hoarseness or dysphagia between the lidocaine group and the placebo group throughout the study(Hara & Maruyama, 2005).

A randomized double-blind study was conducted in Iran, in which the authors compared the efficacy of beclomethasone and lidocaine spray for the prevention and decrease of the frequency of post-operative sore throat and hoarseness after tracheal extubation. Ninety women of ASA physical status 1 or 2 and undergoing elective mastoidectomy were divided randomly into three groups, (n=30).The ETTs in each group were sprayed with 50% beclomethasone, 10% lidocaine hydrochloride, or normal saline. At 1 and 24 hours after extubation, patients were examined for sore throat, hoarseness, and cough. Other complaints, such as dysphonia, bucking, nausea and vomiting, and dysphagia were assessed as present or absent in the first 24 hours after surgery. Assessment of sore throat was done by a modified 4-point scale; (0= no sore throat, 1= mild: complains of sore throat only on asking, 2 = moderate: complains of sore throat spontaneously, and 3 = severe: change of voice or hoarseness, associated with throat pain). In the beclomethasone group, occurrence and severity of

post-extubation sore throat significantly decreased compared to the lidocaine and control groups. At 24 hours after extubation, occurrence and severity of sore throat and cough was significantly lower in the lidocaine group compared with the control group. While there was no significant difference of incidence of hoarseness among the three groups. (Banihashem et al., 2015)

An in-Vitro study conducted in India by Jaichandran, et al.(2008)to investigate the ideal pH to achieve ultimate dispersion of lidocaine through the ETT cuff membrane, three groups of 8.0 mm, large volume little pressure ETT with (n = 5) in every group, the cuffs were loaded with 6 ml 2% lidocaine shielded to a pH of 7.4 (Group one), 7.6 (Group two) and 7.8 (Group three). After that, They were buried in 20 ml of distilled water set at 38°C. Lidocaine which was diffused in water was then calculated using great prosecution solution chromatography each half hour interval for up to 5 hours. Authors found that the optimal pH of lidocaine diffusion over the membrane of endotracheal tube Cuff is (7.4). Then, this study suggested filling the ETT cuff with 6 ml of 2% lidocaine buffer to a pH of 7.4, which easily passed the cuff through dispersion to block the cough receptors in the mucosa of trachea. This can reduce or prevent ETT-induced cough in the appearance of general anesthesia.

In another vitro study conducted in France to evaluate the dispersion of lidocaine and alkalized lidocaine over (polyurethane) cuff for a lengthy time. ETT cuffs were bloated adopting diverse bicarbonate concentrations in lidocaine solving , Lidocaine from ETT cuffs was deliberated using a

disengagement model. Low diffusion rate through the cuff (<8% over 24 hours) was observed only in lidocaine while alkalized lidocaine had a high diffusion rate (> 90% over 24 hours). Authors also reported that a physiological pH (7.4) and a minimum dose of lidocaine (40 mg) will be secure in the event of inadvertent ETT cuff failure. (Estebe et al., 2014)

Navarro, et al., (2007) operated a trial of 50 female patients ASA one and Mallampatti two, planned considering gynecological surgery under general anesthesia. Every patient was randomly assigned to one of the two double-blind study groups. Air group, with ETcuff bloated with air to achieve a cuff pressure of 20 cmH₂O (n = 25); and Lidocaine group, with ETT cuff bloated with 2% lidocaine + 8.4% sodium bicarbonate to achieve the equivalent pressure (n = 25). Cough over 30 minutes after tracheal extubation, pain in throat and hoarseness when transferring out of PACU along with twenty four hours after extubation was recorded using a visual analogue scale: 0 [no discomfort] to 10 [the worst possible discomfort]. The study showed that ETT cuffs filled with alkalized lidocaine appear to be safer than classic air-filled ETT cuffs.

In a randomized prospective study in Bangladesh, patients received two percent lidocaine (Group L) as endotracheal cuff inflator and correlate to Distilled Water (Group D) and Air (Group A), in each group (n = 40). To protect patients from lidocaine toxicity in unexpected cuff damage, the volume of used lidocaine not ever exceeds 5 mg / kg. The prevalence and intensity of post-extubation pain in throat, dysphasia as well as hoarseness were checked for one to three hours and twenty two to twenty four hours

post-operatively. The outcomes was shown that pain in throat, hoarseness and dysphasia were extremely smaller in Group L, as opposed to the two groups A and D. The percentage was twenty eight percent in Group L in comparison to forty percent and sixty three percent in Groups D and A respectively. Dysphasia was present by 23 % in group L and 23% and 45% in groups D and A respectively after 1-3 hours. After 22-24 hr. dysphasia continued in 20% of cases in groups A as well as D and comprehensively clear up in group L. Hoarseness was referenced of twenty three percent of group L, 35% of group D and 55% of Group A after one to three hours(Ali et al., 2009)

A prospective randomized double-blind study was conducted in Brazil by Navarro,et al., (2012)50 individuals underwent planned gynecology, orthopedic or plastic operations were assigned into binary groups; The group (L) received intracuff lidocaine and group (S) got intracuff saline in a volume enough to create a cuff pressure that could avoid air from discharge all along positive pressure ventilation. Lidocaine used in the study was 6.9 ± 2.6 ml (138 ± 52 mg). This dose is subordinate than the systemic noxious level. The little dose used in the study (1 ml 8.4% bicarbonate in 20 ml solution) was adequate to increment the pH of lidocaine solution to 7.43 and expedite its dispersion without risk of tracheal injury if any cuff fracture occurred. Cough was evaluated at the start-up phase; Sore throat and hoarseness were reported at the end of (PACU) and twenty hours after extubation. Authors found that intracuff alkalized two percent lidocaine was preferable to saline in the instance of

emergence coughing ($p < 0.001$). Pain in throat was significantly lower in the L group at (PACU) ($p = 0.02$). Nonetheless, at twenty four hours post-operatively, the pain in throat was analogous in the two groups ($p = 0.07$). The incidence of hoarseness was similar in both groups (L) and (S). The intracuff pressure in the lidocaine group was constant, although increasing in time in the saline group.

A randomized double blind study from India conducted by Rao, et al., (2013), examined the effects of lidocaine (4%) instillation in the ETT cuff in surgical patients as compared to air on post-extubation morbidity. Eighty patients enrolled in this study were divided into two groups, air and lidocaine (4%) 5 ml each incorporated into ETTT cuff to study the emergence from general anesthesia. Cough was evaluated at extubation, 0-2, 2-4, 4-8, 8-15, 15-30 and 30-60 minutes after extubation. Heart rate and blood pressure are evaluated by extubation, 1 min, 2 min, 5 min, 10 min, 30 min and 1 h after extubation. The incidence of postoperative nausea, vomiting, dysphonia, hoarseness and sore throat was noted 24 hours after surgery. The sore throat was reported according to the patient's subjective evaluation and was scheduled as 1+, 2+ and 3+. The results reported a significant difference in the occurrence of sore throat after extubation in Group A (air) and group L (lidocaine). There was no significant change in heart rate first but it was changed in both study groups at later intervals. Similarly, there was a significant change in blood pressure in both study groups at 2, 5, 10, 30 and 60 min post-extubation. Authors concluded that lidocaine diffusion over the cuff membrane and the local anesthetic effect

resulted in a more stable blood pressure during the extubation period and during the following period.

A prospective controlled randomized blind study conducted in the Kingdom of Saudi Arabia (KSA) by Ahmady, et al., (2013b), participated in 50 children between six and twelve years and with ASA's physical status I or II and divided into two groups; lidocaine group and saline, in each group (n = 25). The single cuff aspirated as much as possible and was then blown up with a syringe filled with a mixed solution of 1.5 ml lidocaine 2% combined with 1.5 ml sodium bicarbonate 8.4% (lidocaine group) or 3 ml normal saline solution (saline). There after post-extubation coughing was reported based on the adjusted bird scale as follows; 0 = No cough, 1 = (Mild single frenzy of cough, 2 = Moderate) more than one episode of unsustained (≤ 5 sec) coughing and 3 = (Severe) sustained (> 5 sec) frenzy of coughing. The result of this study reported extension at the time of spontaneous ventilation prior to extubation in the lidocaine group compared to the control group with a p-value <0.0001 . Authors concluded that the incidence and severity of post-extubation cough decreased significantly in the lidocaine group.

A meta-analysis of RCTs was performed in the United States of America by Lam et al., (2015), to review control studies suggesting lidocaine as a ETT infusion solution to reduce post-extubation-related emergence reactions. Authors used a random model to make a meta-analysis to assess the relative risks (RR) and the mean difference (MD) of the incidence and intensity of relevant side effects. After reviewing 90

attempts, including 1566 patients, the results reported a significant decrease in early and late phase post-extubation sore throat, cough, agitation, hoarseness and dysphonia in lidocaine groups.

In a randomized double blind study conducted in Iran, one hundred patients scheduled for surgery under general anesthesia were divided into two groups; the experimental group of dexamethasone applied to the laryngeal mask's airway cuff (n = 50) and control group in which the laryngeal mask's airway band was introduced through distilled water (n = 50). The presence of sore throat, cough, hoarseness were reported before surgery at 1, 2 and 24 h after surgery. The results of this study reported that the incidence of sore throat for 24 hours after surgery was significantly reduced in the experimental group (8%) compared to the control group (22%). The local application of Dexamethasone on the LMA cuff was effective in reducing the incidence and severity of sore throat after surgery, so the authors concluded that the application of dexamethasone before surgery reduces the incidence of complications following the laryngeal mask's airway placement (Jarahzadeh et al., 2014)

In a randomized, double-blind controlled study, conducted in Iran by Tabari, et al., (2013) to investigate the effect of Betamethasone gel applied to the ETT cuff and IV dexamethasone on post-extubation sore throat. Seventy five patients with (ASA) values between I and II were registered in this study and randomly divided into three groups; Betametasone gel applied

over the ETT in the first group (n = 25), I.V dexamethasone is given in a second group (n = 25) and saline applied over ETT in the third group (n = 25). Evaluation of sore throat after extubation was done at 1, 6 and 24 hours after extubation. The result showed a significant decrease of occurrence of post-extubation sore throat and less bucking at extubation in the first group compared to the second and third group.

A prospective, double blind, randomized, controlled study was conducted in India by Sumathi,et al.,(2008), to compare betametason gel and lidocain gel applied to ETT to reduce post-extubation reaction. One hundred fifty patients with ASA's physical status 1 and 2, aged between 18 and 50 years undergoing an elective surgical procedure continuing from 30 to 240 minutes under general anesthesia with ETT. Patients were randomly divided into three groups; betamethasone group, lidocaine group and control group. All patients were evaluated for sore throat, cough and hoarseness after 1, 6 , 12 and 24 hours after surgery. The results reported that post-extubation of the throat, cough and hoarseness was significantly lower in the betametason group compared with lidocaine gel and control group. Authors concluded that betametason gel used generally over ETT is more efficient in relieving sore throat, cough and hoarseness compared with lidocaine gel application.

In a double-blind clinical trial conducted in Iran by Rafiei et al., (2012), to assess the effect of intra-cuff dexamethasone on post-extubation phenomena. One hundred and eighty male patients with ASA physical status between 1 and II, who underwent optional inguinal surgery under

general anesthesia with ETT for ventilation, were recorded in this study. They were randomly divided into three groups according to the type of drug filled into ET cuff; L group filled with 2% lidocaine, D group filled with dexamethasone and S-group filled with normal saline. The presence of sore throat, cough, aphonia and laryngospasm were evaluated after surgery. The result of this study showed that the effects of dexamethasone in decreasing pain in the throat, hoarseness and laryngospasm after extubation are the same as in lidocaine and normal saline. While lidocaine is better for preventing coughing than dexamethasone and saline, dexamethasone is better for preventing coughing. On the other hand, the prolongation of spontaneous ventilation time prior to extubation was higher in the lidocaine group compared with the dexamethasone and saline groups.

To compare the effectiveness of the intra-cuff dexamethasone and alkaline lidocaine to reduce the incidence of post-extubation reaction, 90 patients between the eighteen and sixty years of age with ASA physical status 1 and 2 undergoing surgery continued for 30 and 360 minutes were enrolled in a prospective randomized , single-blind controlled study conducted in Malaysia by (Kee et al., 2013). Patients were randomly divided into three groups according to the drug filled into ETT cuff; lidocaine group (n = 30), dexamethasone group (n = 30), and air group (n = 30). Patients were evaluated for cough and restlessness prior to extubation, Like for hoarseness in the recovery area before discharge. The severity of postoperative sore throat was assessed by the visual analogue scale at 30 minutes, in the recovery room, and at the 2 and 24 hours in the surgical

ward. The authors reported that dexamethasone diffused through a cuff membrane, which affects the tracheal mucosa in contact with it, reduces the inflammatory process in the tracheal wall. The results also showed a significant difference in the occurrence of hoarseness, cough, restlessness and sore throat in the dexamethasone group compared with the air group. Both intra-cuff dexamethasone and alkalized lidocaine significantly reduced the incidence of hoarseness. On the other hand, the incidence of restlessness was significantly reduced in the lidocaine group.

A randomized, double-blind, clinical trial conducted in Iran to evaluate the effect of combining 2% lidocaine and dexamethasone into ETT cuff to reduce side effects after extubation. Two hundreds and seven participants with ASA physical status 1 or 2 scheduled for operation under general anesthesia were included in this study. They were randomly divided into four groups, based on the drug filled into the ETT cuff; (Group A) filled with air (n = 48), (group L) filled with 5cc lidocaine 2% (n = 52), group(LD) filled with 1cc dexamethasone 4 mg and 4cc lidocaine 2% and (Group D) filled with 1cc dexamethasone 4 mg (n = 54). Sore throat, laryngospasm, cough, nausea, vomiting and bucking were evaluated immediately after extubation for an hour in all patients. The results showed that sore throat was significantly lower in group L compared to the other groups. The authors have concluded that the combination of dexamethasone with lidocaine in ETT has no beneficial effect in reducing respiratory adverse events following general anesthesia(Cho et al., 2016).

Reflection over the literature review

In previous studies, we noted many variables and factors that we care about in our track; in Rao, et al (2013) Soltani, et al. (2002) studies, we noted that they ignored the type of surgery that is important in these types of trials.

There is no control over intracuff pressure during surgery in all studies except in Kee et al. (2013) study; and all studies exclude the use of nitrosoxide except (Ahmady, et al 2013a ; Banihashim, et al. 2015 ;Hara, et al. 2005 ; Rao, et al.2013 ; Soltani, et al. 2002)

Smoking of cigarettes is considered in all studies except in Banihashim, et al. 2015; Hara, et al,2005;Rao, et al. 2013 studies.

We noted that the experiments used lidocaine intracuff they buffered it except in Ali, et al (2009) and Rao, et al (2013) trials.

Hara, et al (2005), Navarro, et al. (2012), Ahmady, et al. (2013), Rafie, et al. (2012) and Kee, et al (2013) were used intracuff saline as a control group which is not usually used in our approach.

In Ahmady, et al. (2013 a); Navvaro, et al. (2012);Rao, et al (2013) and Soltani,et al. (2002) , they used intracuff lidocaine but they didn't compare it with intracuff dexamethason as alternative intracuff media.

Regarding the variables were examined, the cough was evaluated in all studies except in the Ali, et al. (2009) and Hara, et al. (2005)trials, even sore throat and hoarseness were not evaluated in the Rao, et al (2013) study.

Finally; the time from first spontaneous breathing to extubation time-reflecting ETT tolerance - was only measured in Ahmady, et al. (2013 a); Estebe, et al (2005);Kee, et al. (2013)and Rafie,et al. (2012) studies.

So; We conducted this study taking into account all of the above factors that mentioned in the literature review related to examined variables, methods and materials, sampling and limitations.

It is noted that the percentage used of lidocaine was 2% for injection into the ETT cuff in the most previous studies, can be explained that the appropriate volume of this solution for filling the tracheal tube cuff and delivering it to pressures 20-30cmH₂O is the recommended concentration to not exceeding to prevention of toxicity in the event of breakage.

Despite the many different ways to use Dexamethasone to prevent postextubation problems ; Dexamethasone has not been used sufficiently in previous studies to prove its effectiveness if injected into the tracheal tube cuff.

The mixing between dexamethason and lidocaine into ETT cuff was utilized in Cho, et al.(2016) study, and he didn't mention any interaction between the tow drugs.

Chapter Three

Methodology

Methodology

This chapter shows a compendium of the research methodology used in this study.

3.1 Trial Design

A prospective, randomized, double blind, controlled study

3.2 Study Population

Participants are adult smokers patients scheduled for optional laparoscopic surgery under general anesthesia, aging 18-60 years with the American Society of Anesthesiologists(ASA) allocation of one & two.

3.3 Trial Setting

The trial was oversight in the operation room and surgical ward at Rafidia Governmental Surgery Hospital in Nablus-Palestine.

3.4 Participants

Hundred smokers, ranging between the ages of eighteen and sixty, with ASA Physical Status two and Mallampati Points 1-2, which were planned for optional laparoscopic surgery under general anesthesia.

3.5 Sample and Sampling

To investigate the optimal sample magnitude for the trial that safeguard an adequate effect to identify statistical significance, the effect of the trial was estimated at eighty percent, with alpha levels as ($p < 0.05$). Sample magnitude was computed as 21 patients for each group.

To raise the potential of the current trial, we have recruited 25 patients in every group as it was also executed in early studies.

3.6 Sample size

A blueprint (i.e. Pocock's sample magnitude blueprint) that can be precisely tested for the correlation of proportions P_1 and P_2 in two uniformly sized groups:

$$n = \frac{[P_1(1-P_1) + P_2(1-P_2)]}{(P_1 - P_2)^2} (Z_{\alpha/2} + Z_{\beta})^2$$

$$(P_1 - P_2)$$

Where:

n: required sample size

P_1 : estimated proportion of study outcome in the exposed group (i.e. combination therapy) ($P_1 = 0.30$).

P_2 : estimated proportion of study outcome in the unexposed group (placebo therapy) ($P_2 = 0.70$).

α : level of statistical significance

$Z_{\alpha/2}$: Represents the desired level of statistical significance (typically 1.96 for $\alpha = 0.05$)

Z_{β} : Represents the desired power (typically 0.84 for 80% power)

$n \approx 21$ patients

Hence a comprehensive of 84 participants (21 for every group) should be recruited into the trial. According to the analysis of power, 21 patients were recommended. But, 25 will be recruited to account for the possibility of dropout.

3.7 Pre-enrollment assessment

The patients who were recruited in the study should have had an assessment of respiratory problems, smoking habits, and allergic to study medication by a nurse who was not involved in the patients' care postoperatively. Thus, excluded patients who have had recent or chronic respiratory problems, lidocaine allergy, or non-smokers.

3.8 Randomization

Patients were randomly divided in four groups of an individual who was not participated in the trial. Randomization was performed by using impenetrable and well-locked envelopes. The arrangement formation was performed with a computer. The number was engraved on envelopes and the group was drafted on the card in it with the sequential number. When the participant landed, the envelope unclosed to identify the group to obtain either:

Group (A) (n = 25), [A cuff filled with air until a cuff pressure becomes 25 ± 5 cmH₂O].

Group (D) (n = 25), [ETT cuff filled with 8 mg dexamethasone and then completed with distal water until the ETT cuff pressure becomes 25 ± 5 cmH₂O].

Group (L) (n = 25), [A cuff filled with alkalized 2% lidocaine until ETT cuff pressure becomes 25 ± 5 cmH₂O].

Group (LD) (n = 25), [ETT cuff filled with 8 mg dexamethasone and added alkalized 2% lidocaine until the ETT cuff pressure becomes 25 ± 5 cmH₂O] (Consort Flow Diagram, Figure 1).

3.9 Blindness

Patients, anesthesiologists and caregivers who participated in the operation and intra operative and postoperative care of the patients were unsighted to group assignments.

3.10 Preparation of drugs

A separate anesthesiologist who did not involve in the patients' care intra-operatively prepared the intra cuff medications. The agents were arranged in two syringes of 2 ml and 10 ml as the following:

Group (A); each of the two syringes were filled with air, ETT cuff was first filled with the 2ml syringe, and then completed by the 10ml syringe until the ETT cuff pressure became 25 ± 5 cmH₂O

Group (D); a 2ml syringe was filled with 8mg dexamethasone and the 10ml syringe filled with distal water. ETT cuff was inflated by 2ml dexamethason and completed by distal water until ETT cuff pressure became 25 ± 5 cmH₂O.

Group (L); each of the 2ml and 10ml syringes were filled with alkalinized 2% lidocaine in the ratio [10ml 2% lidocaine:0.52ml8.4% sodium bicarbonate]. ETT cuff was then filled by 2ml syringe and completed by the 10ml one, until ETT cuff pressure became 25 ± 5 cmH₂O.

Group (LD); 2ml syringe was filled with 8mg of dexamethasone and 10ml syringe with alkalinized 2% lidocaine, ETT cuff inflated by 2ml dexamethasone and completed by alkalinized 2% lidocaine until ETT cuff pressure became 25 ± 5 cmH₂O.

3.11 Study period

May 2017 to May 2018

3.12 Inclusion criteria

-ASA II.

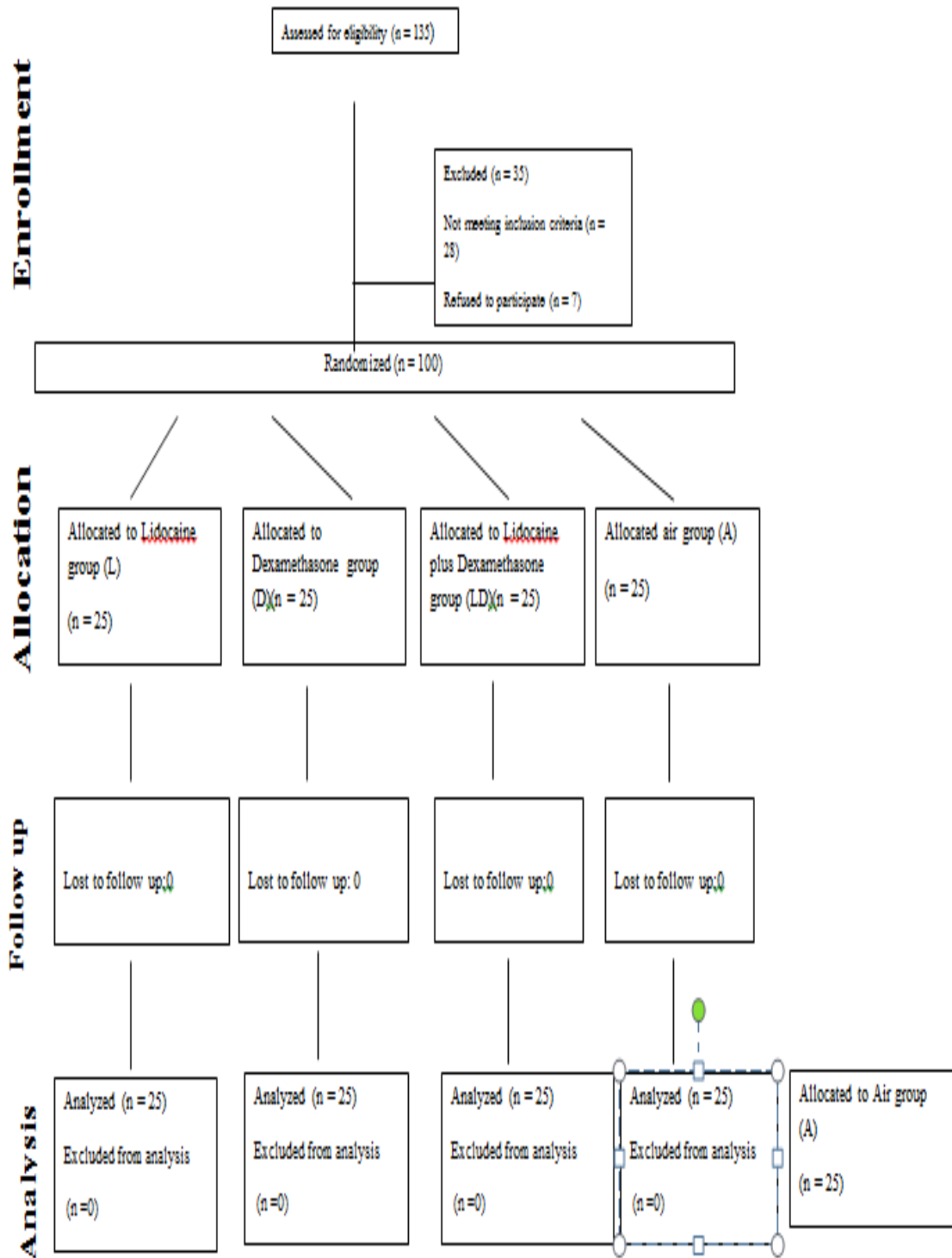
-Laparoscopy surgery under general anesthesia with ETT to secure airway.

-Isoflorane inhalation agent.

- Patients who have been smokers for a longer period than 5 years and did not finish before surgery.
- Age between (18-60) years.
- Both sex.
- Elective indication for laparoscopic surgery.

3.13 Exclusion criteria

- Patients with any chronic or acute respiratory disease and any laryngeal surgery or disease.
- Use of any inhalant with the exception of isofluran (N₂O, Sevoflurane, Enflurane, ect).
- Patients who have taken any corticosteroid or lidocaine in the last 4 hours or in the operating room.
- Non-smoking patients.
- A less than 18 or more than 60 years.
- More than one attempt for intubation.
- Anticipated difficult intubation [Mallampathy scores more than 2].
- ASA status more than II.

CONSORT FLOW DIAGRAM

3.14 Study Variables

- Dependent variables: Cough sore throat, hoarseness and hemodynamic status.
- Independent variables: alkalinized 2% lidocaine, dexamethasone, air, and combined alkalinized 2% lidocaine with dexamethasone.

3.15 Follow up with patients

Every participant in the four groups involved in the study obtained follow-up intra-operatively and post-anesthetic in PACU, and two, eight and twenty four hours after surgery. Participants were assessed for cough, sore throat and hoarseness. Vital signs were also recorded.

3.16 Procedure

After accessing the trial endorsement from the Institutional Review Board (IRB) of An-Najah National University, written consent form was gathered from all participating patients after explanation of the objectives and process of the trial. One hundred participant patients with ASA one or two who were anticipated for planned laparoscopic surgery under general anesthesia were enlisted.

A data blanket encompassing the consecutive material was round out for every participant: hospital file number, age, height, weight, gender, brief medical and surgical history, smoking history, blood pressure, heart rate, respiratory rate, ECG rhythm, and SpO₂. A physical assessment was complete for all participants. Participants were evaluated for weight

measurements; non-invasive blood pressure, pulse and respiration, and the particular were guarded and documented .I.V cannula 16 Fr G was infused. Ringer's lactate (RL) (20 ml/kg) was given 30 minutes before anesthesia induction for the all patients.

The anesthetic apparatus was controlled and anesthesia accompaniments were also processed for any necessity. Material for standard anesthesia and anesthetic medications were processed. Basic control that includes continuous ECG, non-invasive blood pressure, and pulse oximetry was pursued.

All patients received a standardized anesthetic consisting of 100% preoxygenation. GA was introduced with Fentanyl (2 μ g / kg) and Propofol (3 mg / kg). Atracurium was given (0.5 mg / kg) to ease intubation of the trachea. Anesthesia consists of one MAC isoflurane, 50% air in O₂. The mechanical ventilation was used and adapted to keep the end tidal of carbon dioxide (ETCO₂) between 35 and 40 mmHg deliberated by capnography. After the induction of anesthesia, forthright laryngoscopy was executed using either a Macintosh 3 or 4 laryngoscope blade ensued by intubation. The ETT cuff was filled with the experimental solution (lidocaine, Dexamethasone, Lidocaine plus Dexamethasone or Air) directly after ETT inclusion and the cuff volume was adapted to maintain a tape at an airway pressure of 25 cmH₂O.

If the cuff pressure decreased or air leak was detected during surgery, additional distilled water could be injected into the cuff of dexamethason group, additional alkalized lidocaine in lidocaine group and lidocain+dexamethason group, and additional air in the Air Group. So the pressure returns to 20-30 cmH₂O.

At the boundary of the surgery, the remaining neuromuscular blockade was conversed with neostigmine and atropine, and pharyngeal secretion was carefully removed before the isoflurane evaporator was switched off. Extubation of the trachea was accomplishing when patients reacted to simple mandates.

Intubation of the trachea was implemented employing tracheal tube (Murphy TM high volume, low pressure, PVC cuff) 7.0-7.5 mm inner diameter for female and 8.0-8.5 mm inner diameter for male). Greasing of ETT was out righted with water soluble gel. ETT cuffs (low volume and high pressure) amplified conferring to the randomized obligation of the experiment. ETT cuffs are blown up at the smallest occlusive volume (ie no escape was identified under controlled ventilation). In the control group, the cuff or merly developed slowly with air. For dexamethason group 2 ml/8mg was primitively injected into a cuff and then extension of distilled water was combined. Cuff pressure was documented at initial pressure 20-30 cm H₂O. The anesthesiologist, unconcerned of the trial guideline. Maintenance of anesthesia is consisted of: air / O₂ (50% / 50%), and isoflurane MAC=1-1.2% was practiced to manage anesthesia. until surgical

termination (time T0). At the end of surgery, Atropine was given 0.01 mg / kg and Neostigmine 0.05 mg / kg IV for departure of muscle relaxation.

After repeal of neuromuscular block, isoflurane was terminated and 100% oxygen disposed. Mechanical ventilation was continued until swallowing or spontaneous respiration commenced, and after that, transformed to assisted manual ventilation. When all airway criteria were faced with extubation (spontaneous ventilation, ability to follow verbal commands (eye opening or hand grip) and ability to indicate appropriate movements, extubation of the trachea was hanged directly after suction at the responsibility of the physician. Time for spontaneous ventilation time (Time between the occurrence of spontaneous breathing and extubation) was documented.

The patients were then given 6L oxygen via face mask and transferred into the recovery room. An unaware nurse to the group assignment evaluated pain in the throat (At 2, 8 and 24 h, systematically evaluated other problems of throat, such as cough, hoarseness, and dysphonia. Hemodynamic parameters and postoperative nausea and vomiting were also documented for 2, 8 and 24 hr.

3.17 Data Collection

Routine monitoring including vital signs (BP, Pulse, SpO₂, EtCO₂, ECG rhythm, and RR) were documented each 5 minutes during operation and every 3 minutes in emergence phase, in addition to tidal volume, and cough. Vital signs observation (BP, Pulse, Spo₂, ECG rhythm, and RR),

cough were recorded in the PACU two times. Cough, laryngospasm, PONV, aphonia and head tilt support were observed after extubation and in PACU. On 2, 8, 24 hours, vital signs, cough, sore throat, hoarseness and PONV were recorded. All drugs given during surgery, in PACU, and post-surgery were recorded. The intracuff pressure, the duration of anesthesia and surgery were recorded. Postoperative nausea and vomiting (PONV) were also recorded. The following variables were noted in addition to socio-demographic data: ASA status, operating time, anesthetic time, tobacco use and laryngospasm were noted.

3.18 Assessment tool

The coughing was evaluated as present or absent in all participants. Coughing was contemplated absent when no coughing or coughing only while taking out the ETT. It was contemplated present when the patient coughed while breathing regularly or irregularly with the ETT in place. An anesthesiologist who did not aware to which group the participant belonged assessed the frequency of emergence coughing and PACU coughing. Sore throat and hoarseness were assessed after participant discharged from PACU at 2, 8, and 24 hours after extubation by nurses who were blinded for the patient's type of groups

The patients were assessed for sore throat, cough and hoarseness at 2, 8 and 24 hrs. postoperatively using assessment scales given by Harding CJ & McVey FK (1987). Cough, sore throat, hoarseness were scored conferred to severity.

Sore throat

0 No sore throat at any time since the operation

1 Minimal sore throat

2 Moderate sore throat

3 Severe sore throat

Cough

0 No cough at any time since the operation

1 Minimal cough or scratchy throat

2 Moderate cough

3 Severe cough

Hoarseness

0 No evidence of hoarseness at any time since the operation

1 No evidence of hoarseness at the time of interview

2 Hoarseness at the time of interview noted by patient only

3 Hoarseness that is easily noted at the time of interview

3.19 Data Analysis Plan

1. Frequencies and Percentages to describe personal and demographic variables.
2. Chi Square test for testing the differences between the four study groups among the Qualitative or Categorical variables and its chi square tests for Pairwise Post Hoc tests.
3. Means and Standard Deviations with One Way ANOVA test(One Way Analysis of Variance) to study the differences between the four study groups among the Quantitative or Scale variables, with LCD Post Hoc Pairwise test.

SPSS Version 20 was performed for data analysis.. A $p < 0.05$ was contemplated significant.

3.20 Ethical Considerations

The current study was operated in conformance with the Helsinki Declaration and was endorsed by the IRB at An-Najah National University and the Ministry of Health of Palestine. Participants are asked to give their consent. Approval was obtained from the Ethics Committee of the hospital where the study was executed. The participants were insured about their right to privacy and anonymity. Anonymity was obtained by coding the participants. Privacy is insured by handle the contrary to unauthorized access to data. All participants were fully informed about the aim of the study and guaranteed that their anonymity should be obtained during

analysis and reporting of the outcomes. It was made that the participation was voluntary and could be terminated at any time.

Chapter Four

Results

4.1 Data Analysis

One hundred patients were randomly assigned to

Group (A): ETT cuff was filled with air.

Group (D): ETT cuff was filled with dexamethasone.

Group (L): ETT cuff was filled with alkalized 2% lidocaine.

Group (LD): ETT cuff inflated by dexamethasone and alkalized 2% lidocaine

4.2 Patients Characteristics and Operative Information

Demographic data

Table (1): Demographic data of the patients in the four groups of study. Data shown as F(ANOVA) test with Mean \pm Standard Deviations and Chi Square test with Percentages and Frequencies*

Variable	(A) n=25 Mean \pm S.D	(L) n=25 Mean \pm S.D	(D) n=25 Mean \pm S.D	(LD) n=25 Mean \pm S.D	F Or Chi Square	P-Value
Age	46.56 \pm 13.93	45.04 \pm 13.14	44.56 \pm 12.31	44.08 \pm 13.6	0.164	0.920
Gender						
Male n (%)	3(12%)	7(28%)	7(28%)	6(24%)	2.428	0.488
Female n(%)	22(88%)	18(72%)	18(72%)	19(76%)		
BMI	26.32 \pm 3.05	25.3 \pm 3.38	25.94 \pm 3.54	27.0 \pm 2.14	1.35	0.263

Cigarettes per day (n)	11.48 ± 9.63	12.4 ± 10.22	10.6 ± 7.26	13.08 ± 9.84	0.337	0.798
Years of smoking	19.28 ± 11.58	18.72 ± 11.96	16.56 ± 11.55	18.44 ± 11.24	0.337	0.798

* Chi Square test with Frequencies and Percentages used for Gender, the differences were not significant between the groups

All 100 patients included in the study completed it. In terms of gender, 77% of patients were female and 23% male, without statistical differences between groups ($p = 0.488$). The groups were similar to the patient's demographic data that are (age, gender, BMI, number of cigarettes per day and Years of smoking) (Table 1).

Anesthetic and surgical data

Table (2):Anesthetic and surgical data of the patients in the four groups of study. Data shown as F(ANOVA) test with Mean \pm Standard Deviations and Chi Square test with Percentages and Frequencies*

Variable	A Air (n=25) Mean \pm S.D	L Lidocaine (n=25) Mean \pm S.D	D Dexamethason (n=25) Mean \pm S.D	LD Lidocaine&Dexamethason (n=25) Mean \pm S.D	Chi Square Or F	P- Value
ASA						
II n (%)	25(100%)	25(100%)	25(100%)	25(100%)	0.000	1.000
Mallampati score						
1n (%)	17(68%)	15(60%)	17(68%)	22(88%)	5.197	0.158
2n (%)	8(32%)	10(40%)	8(32%)	3(12%)		
Total Propofol (mg)	188 \pm 43.97	184.4 \pm 50.17	211.6 \pm 53.9	200.4 \pm 20.51	1.977	0.123
Total fentanyl (μ g)	200 \pm 40.82	208 \pm 40	204 \pm 47.7	204 \pm 53.85	0.126	0.944
Total atracurium (mg)	50.8 \pm 14.19	50.4 \pm 11.36	51.8 \pm 9.01	52.4 \pm 18.77	0.111	0.953

Total dormicum (mg)	2.56 ± 0.77	2.48 ± 0.51	2.52 ± 0.51	2.56 ± 0.51	0.107	0.956
Duration of anesthesia time (min)	70 ± 16.46	73.4 ± 14.77	76.16 ± 15.98	77.8 ± 21.41	0.970	0.410
Duration of surgical time (min)	60.48 ± 14.82	62 ± 21.7	66.4 ± 20.69	65.4 ± 19.94	0.514	0.674
Time from first spontaneous breathing until extubation (min)	4.88 ± 2.39	10.12 ± 3.35	6 ± 2.66	9.08 ± 4.01	15.377	0.000

* Chi Square test with Frequencies and Percentages used for mallampati score and ASA.

The results in the table (2) show that there are no significant differences between the four study groups in total Propofol, total Fentanyl, total Atracurium, total dormicum, duration of anesthesia and duration of surgical time.

There is a significant time difference from first spontaneous breathing until extubation between study groups (Table 1). The post-hoc tests in Table 3 show that the differences were in L (Lidocaine) group Mean \pm SD (10.12 ± 3.35) and the LD (Lidocaine + Dexamethasone) group (9.08 ± 4.01) which is significantly higher than the A (Air) group (4.88 ± 2.39) and the D (Dexamethasone) group (6 ± 2.66), $p = 0.000$, while the differences were not significant between the other groups (Table 3).

Table(3): Post Hoc tests according to time from first spontaneous breathing until extubation (LSD)

Dependent variables	I group	J group	Mean Difference I-J	Sig.
Time from first spontaneous breathing until extubation	A	L	-5.240*	.000
		D	-1.120	.596
		LD	-4.200*	.000
	L	A	5.240*	.000
		D	4.120*	.000
		LD	1.040	.652
	D	A	1.120	.596
		L	-4.120*	.000
		LD	-3.080*	.005
	LD	A	4.200*	.000
		L	-1.040	.652
		D	3.080*	.005

*. The mean difference is significant at the 0.05 level.

** Based on LSD post hoc test.

Hemodynamic parameters

Table (4): Hemodynamic parameters of the patients in the four groups of study. Data shown as F (ANOVA) test with Mean \pm Standard Deviations

	A Air (n=25) Mean \pm S.D	L Lidocaine (n=25) Mean \pm S.D	D Dexamethason (n=25) Mean \pm S.D	LD Lidocaine&Dexamethason (n=25) Mean \pm S.D	F	P- Value
MAP during OP	87.76 \pm 10.58	88.32 \pm 14.91	85.01 \pm 6.83	88.11 \pm 10.75	0.480	0.697
MAP during emergence phase	102.85 \pm 11.39	103.06 \pm 20.11	101.82 \pm 16.94	97.53 \pm 13.29	0.667	0.575
MAP in PACU	96.25 \pm 12.29	96.96 \pm 14.37	97.42 \pm 15.22	95.12 \pm 14.1	0.127	0.944
HR during OP	79.43 \pm 9.73	75.17 \pm 9.76	80.22 \pm 10.16	79.59 \pm 9.56	1.389	0.251
HR during emergence phase	90.05 \pm 13.46	85.86 \pm 13.21	93.32 \pm 21.95	84.41 \pm 11.53	1.695	0.173
RR during emergence	20.25 \pm 7.91	18.33 \pm 6.3	15.87 \pm 4.83	16.89 \pm 7.07	2.063	0.110

The results in table (4) show that there are no statistically significant differences between the four study groups in the following variables: MAP during OP, MAP during development phase, MAP in PACU, HR during OP, HR during development phase and RR during emergence (all P-values > 0.05).

4.4 PONV in PACU

Table (7): PONV in PACU in the four study groups. Data displayed as n (%).

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square (n=25)	P-value
PONV in PACU	0(0%)	1(4%)	4(16%)	0(0%)	9.322	0.053

The results of the chi square test show that there are no statistically significant differences regarding the percentage of patients with PONV between study groups in PACU since $p = 0.053$ (Table 7). But the result is approximately significant.

Table (8): Post Hoc Pairwise Comparisons of PONV in PACU in the four study groups.

	Group(i)	Group(j)	chi-square	P-value
PONV in PACU	A(0(0%))	L(1(4%))	1.407	0.236
	A(0(0%))	D(4(16%))	5.893	0.015
	A(0(0%))	LD(0(0%))	----	----
	L(1(4%))	D(4(16%))	2.128	0.145
	L(1(4%))	LD(0(0%))	1.407	0.236
	D(4(16%))	LD(0(0%))	5.893	0.015

The results of pairwise comparisons show that the incidence of PONV in Group D (4 (16%)) in PACU is significantly higher than Group A (0 (0%)), $p = 0.015$ and group LD (0 (0%)) (Table 8).

4.5 Cough

Cough after extubation directly (at emergence)

Table (9): incidence of Cough after extubation directly in the four study groups. Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
Cough after extubation directly	12(48%)	3(12%)	1(4%)	0(0%)	26.573	0.000

The results of chi-square test show that there are statistically significant differences between the study groups according to the incidence of coughing after extubation directly, $p = 0.000$ (Table 9).

Table (10): Post Hoc Pairwise Comparisons of incidence of cough after extubation directly at emergence in the four study groups

	Group(i)	Group(j)	chi-square	P-value
Cough after extubation directly	A(12(48%))	L(3(12%))	8.123	0.004
	A(12(48%))	D(1(4%))	14.291	0.000
	A(12(48%))	LD(0(0%))	20.491	0.000
	L(3(12%))	D(1(4%))	1.133	0.287
	L(3(12%))	LD(0(0%))	4.351	0.037
	D(1(4%))	LD(0(0%))	1.407	0.236

The results of pairwise comparisons show that the incidence of cough at emergence in group A (12 (48%)) is significantly higher than group L (3 (12%)) $p = 0.004$, and the group D (1 (4%)), $p = 0.000$ and group LD (0 (0%)), $p = 0.000$. The results indicate that the incidence of cough at emergence of general anesthesia was significantly lower in groups LD, L and D than group A (Table 10).

The results also show that the incidence of cough in group L (3 (12%)) is significantly higher than the group LD (0 (0%)). This result indicates that LD therapy is significantly better than L $p = 0.037$ (Table 10).

There are no significant differences between group L (3 (12%)) and D (1 (4%)), there are no significant differences between group D (1 (4%)) and LD (0 (0%)). So the best group about cough after extubation is (LD), then (D), then (L) and the worst group is (A) (Table 10).

Cough in PACU

Table (11): Incidence of Cough in PACU in the four study groups.

Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
Incidence of cough in PACU	7(28%)	2(8%)	1(4%)	0(0%)	13.033	0.009

The results of chi-square test show that there are statistically significant differences between the study groups according to the incidence of cough in PACU ($P = 0.009$) (Table 11).

Table (12): Post Hoc Pairwise Comparisons of incidence of Cough in PACU in the four study groups.

	Group(i)	Group(j)	chi-square	P-value
Incidence of Cough in PACU	A(7(28%))	L(2(8%))	3.553	0.059
	A(7(28%))	D(1(4%))	5.922	0.015
	A(7(28%))	LD(0(0%))	10.849	0.001
	L(2(8%))	D(1(4%))	0.361	0.548
	L(2(8%))	LD(0(0%))	2.856	0.091
	D(1(4%))	LD(0(0%))	1.407	0.236

The results of pairwise comparisons show that the incidence of cough in PACU in group A (7 (28%)) is significantly higher than group D (1 (4%)), $p = 0.015$ and group LD (0 (0%)), $p = 0.001$. There is no significant difference between the incidence of cough in PACU in group L (2 (8%)) and group LD (0 (0%)), $p = 0.091$. (Table 12).

Cough on 2 hour

Table (13): Incidence of cough on 2 hour in the four study groups.

Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
incidence of Cough on 2 hour	22(88%)	10(40%)	4(16%)	8(32%)	31.862	0.000

The results of chi square test show that there are statistically significant differences between the study groups according to cough on 2, $p=0.000$ (Table 13).

Table (14): Post Hoc Pairwise Comparisons of incidence of cough on 2 hour in the four study groups

	Group(i)	Group(j)	chi-square	P-value
incidence of Cough on 2 hour	A(22(88%))	L(10(40%))	13.345	0.000
	A(22(88%))	D(4(16%))	28.905	0.000
	A(22(88%))	LD(8(32%))	17.611	0.000
	L(10(40%))	D(4(16%))	3.661	0.056
	L(10(40%))	LD(8(32%))	0.348	0.555
	D(4(16%))	LD(8(32%))	1.781	0.182

The results of pairwise comparisons show that according to cough on 2 hour, the incidence of cough in group A(22(88%))is significantly higher than group L(10(40%))(P=<0.001) and group D(4(16%))(P=<0.001) and group LD(8(32%)) (P=<0.001), and there are no significant differences between groups(L, D, and LD), but it is clear that the highest percentage is for group (L), then group (LD) then group (D), so we can say that group(D) is the best here (Table14).

Table (15): Severity of Cough on 2 hour in the four study groups. Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
cough on 2 hour (Mild)	10(40%)	10(40%)	4(16%)	7(28%)	4.888	0.188
Cough on 2 hour (Moderat)	11(44%)	0(0%)	0(0%)	1(4%)	30.691	0.000
Cough on 2 hour (sever)	1(4%)	0(0%)	0(0%)	0(0%)	2.803	1.000

In Table 15, The results of chi-square test show that there are no statistically significant differences between the 2-hour study groups in the cough (Mild) since the P-value = (0.188).

According to the 2-hour cough (Moderate), there are statistically significant differences between the study groups since the P-value = (<0.000). The percentage of patients with moderate cough in the L group 0(%), in D group 0(0%), in LD group 1(4%) are significantly lower than the number of patients in the A group, (p=0.000). A significant increase in the severity of cough at moderate levels in the air group compared with other three groups (Table 15).

According to the 2-hour cough (severe), there are no statistically significant differences between the study groups since the P-value = (1,000)

Cough on 8 hour

Table (16): Incidence of Cough on 8 hour in the four study groups.

Data displayed as n (%).

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
incidence of Cough on 8 hour	21(84%)	1(4%)	1(4%)	0(0%)	69.077	0.000

The results of the chi-square test showed that there are statistically significant differences between the study groups according to the incidence of cough on 8 hours, $P = 0.0001$) (Table 16).

Table (17): Post Hoc Pairwise Comparisons of the incidence of Cough on 8 hour in the four study groups.

	Group(i)	Group(j)	chi-square	P-value
incidence of Cough on 8 hour	A(21(84%))	L(1(4%))	28.362	0.000
	A(21(84%))	D(1(4%))	28.362	0.000
	A(21(84%))	LD(0(0%))	35.694	0.000
	L(1(4%))	D(1(4%))	0.000	1.000
	L(1(4%))	LD(0(0%))	1.407	0.236
	D(1(4%))	LD(0(0%))	1.407	0.236

The results of pairwise comparisons show that, according to the incidence of cough on 8 hour , group A (21 (84%)) is significantly higher than group L (1 (4%)) ($p = <0.0001$) and group D 4%)) ($p = <0.0001$) and group LD

(0 (0%)) ($p = <0.0001$), so we can say that all groups are better than group (A) (Table 17).

Severity of cough on 8 hour

Table (18): The severity of cough on 8 hour in the four study groups.

Data displayed as n (%).

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
cough on 8 hour(Mild)	18(72%)	1(4%)	1(4%)	0(0%)	53.638	0.000
Cough on 8 hour (Moderate)	3(12%)	0(0%)	0(0%)	0(0%)	8.602	0.057

The results of chi-square test show that there are statistically significant differences between the study groups according to the severity of 8-hour cough (Mild). n (%) of the patients in the L-group1 (4%), the D-group 1 (4%) and LD group 0 (0%), are significantly lower than A group 18 (72%), $P = 0.000$ (Table 18). According to the 8-hour cough (moderate), there are no statistically significant differences between the study groups = 0.057. (Table 18)

Cough on 24 hour

Table (19): incidence of cough on 24 hour in the four study groups.

Data displayed as n (%).

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
incidence of cough on 24 hour	3(12%)	0(0%)	0(0%)	0(0%)	8.602	0.057

The results of chi square test show that there are no statistically significant differences between the study groups according to incidence of cough on 24 hour P =0.057 (Table 19).

Table (20): Post Hoc Pairwise Comparisons of the incidence of cough on 24 hour in the four study groups

	Group(i)	Group(j)	chi-square	P-value
incidence of Cough on 24 hour	A(3(12%))	L(0(0%))	4.351	0.037
	A(3(12%))	D(0(0%))	4.351	0.037
	A(3(12%))	LD(0(0%))	4.351	0.037
	L(0(0%))	D(0(0%))	----	----
	L(0(0%))	LD(0(0%))	----	----
	D(0(0%))	LD(0(0%))	----	----

The results of pairwise comparisons show that, according to the incidence of coughing on 24 hours, group A (3 (12%)) is significantly higher than group L (0 (0%)) (p = 0.037) and group D (0 (0%)) (p = 0.037) and group LD (0 (0%)) (p = 0.037), so all groups are significantly better than group (A) (Table 20).

Severity of cough on 24 hour

Table (21): Severity of cough on 24 hour in the four study groups. Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
cough on 24 hour(Mild)	3 (12%)	0(0%)	0(0%)	0(0%)	8.602	0.057
cough on 24 hour (Moderat)	0(0%)	0(0%)	0(0%)	0(0%)	-----	-----

No significant differences due to the severity of coughing neither mild nor moderate between the four groups of the study on 24 hr. (Table 21).

4.6 Sore throat

Incidence of Sorethroat on 2 hour

Table (22): incidence of Sore throat on 2 hour in the four study groups. Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
incidence of Sore throat on 2 hour	18(72%)	2(8%)	14(56%)	5(20%)	30.847	0.000

The results of the chi-square test show that there are statistically significant differences between the study groups according to the incidence of sore throat of 2 hours, $p = 0.001$ (Table 22).

Table (23): Post Hoc Pairwise Comparisons for incidence of Sore throat on 2 hour in the four study groups

	Group(i)	Group(j)	chi-square	P-value
incidence of Sore throat on 2 hour	A(18(72%))	L(2(8%))	23.715	0.000
	A(18(72%))	D(14(56%))	1.398	0.237
	A(18(72%))	LD(5(20%))	14.327	0.000
	L(2(8%))	D(14(56%))	14.452	0.000
	L(2(8%))	LD(5(20%))	1.538	0.215
	D(14(56%))	LD(5(20%))	7.090	0.008

The results of pairwise comparisons show that, incidence of sore throat on 2 hours in group A (18 (72%)) is significantly higher than group L (2 (8%)) ($p = <0.001$) and group LD (5 (20%)) (<0.001). there was no significant differences between group A (18 (72%)) and group D (14 (56%)) ($p=0.237$), so the best group is (L) then (LD) then (D) and the worst group is(A) (Table 23)

Severity of sorethroat on 2 hour

Table (24): Severity of Sore throat on 2 hour in the four study groups. Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
Sore throat on 2 hour (Mild)	4(16%)	2(8%)	9(36%)	5(20%)	6.467	0.126
Sore throat on 2 hour (Moderate)	14(56%)	0(0%)	5(20%)	0(0%)	37.928	0.000

The results of chi square test show that there are no statistically significant differences between the study groups according to the severity of sore throat (Mild) on 2 hours, $P = 0.126$.

There is a significant difference in the number (percentage) of patients with severity of sore throat at moderate level on 2 hr in L group 0(%), D group 5(20%) and LD group 0(0%) when compared to A group (14(56%)), $p=0.000$ (Table 24).

The above results mean a significant increasing in a severity of sore throat in air group comparing with other three groups (Table 24).

Incidence of Sorethroat on 8 hour

Table (25): Incidence of Sore throat on 8 hour in the four study groups. Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
incidence of Sore throat on 8 hour	18(72%)	0(0%)	10(40%)	1(4%)	48.735	0.000

The results of the chi-square test show that there are statistically significant differences between the study groups in the incidence of sore throat on 8 hours, $P = 0.001$ (Table 25).

Table (26): Post Hoc Pairwise Comparisons of the incidence of Sore throat on 8 hour in the four study groups

	Group(i)	Group(j)	chi-square	P-value
incidence of Sore throat on 8 hour	A(18(72%))	L(0(0%))	35.694	0.000
	A(18(72%))	D(10(40%))	5.295	0.021
	A(18(72%))	LD(1(4%))	28.362	0.000
	L(0(0%))	D(10(40%))	16.390	0.000
	L(0(0%))	LD(1(4%))	1.407	0.236
	D(10(40%))	LD(1(4%))	10.643	0.001

The results of pairwise comparisons show that, on the 8-hour the incidence of sore throat in group A (18 (72%)) is significantly higher than group L (0 (0%)) ($p = <0.000$) and group LD (1(4%)) ($p = <0.000$). Also the results show that the incidence of sore throat in group D (10 (40%)) is significantly higher than group L (0 (0%)) ($p = <0.001$) and group LD (1(4%)) (0.001), so the best group is group (L), then (LD), then (D) and the worst group is (A) (Table 26).

Severity of sorethroat on 8 hour

Table (27): Severity of sore throat on 8 hour of the incidence of Sore throat in the four study groups. Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
Sore throat on 2 hour(Mild)	17(68%)	0(0%)	10(40%)	1(4%)	45.199	0.000
Soret hroat on 2 hour (Moderat)	1(4%)	0(0%)	0(0%)	0(0%)	2.803	1.000

The results of the chi-square test show that the number of (percent) patients is significantly higher in group A (68%) compared to L group 0 (%), LD group 1 (4%) and D group (10(40%)) $p = 0.000$. The number of (percentage) patients is significantly higher in the D group 10 (40%) compared to L group 0 (0%) and LD group 1 (4%)) $p = 0.000$. So the best group is group (L), then (LD), then (D) and the worst group is (A). According to the sore throat of 8 hours (moderate), there are no statistically significant differences between the study groups, $p = 1,000$ (Table 27).

Incidence of Sorethroat on 24 hour

Table (28): Incidence of Sore throat on 24 hour in the four study groups. Data displayed as n (%)

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi-square	P-value
incidence of Sore throat on 24 hour	8(32%)	0(0%)	0(0%)	0(0%)	24.410	0.000

The results of chi square test show that there are statistically significant differences between the study groups according to incidence of Sore throat on 24 hour, $P = 0.000$ (Table 28).

Table (29): Post Hoc Pairwise Comparisons of the incidence of sore throat on 24 hour in the four study groups

	Group(i)	Group(j)	chi-square	P-value
incidence of Sorethroat on 24 hour	A(8(32%))	L(0(0%))	12.624	0.000
	A(8(32%))	D(0(0%))	12.624	0.000
	A(8(32%))	LD(0(0%))	12.624	0.000
	L(0(0%))	D(0(0%))	----	----
	L(0(0%))	LD(0(0%))	----	----
	D(0(0%))	LD(0(0%))	----	----

The results of pairwise comparisons show that the incidence of sore throat on 24 hour in group A(8(32%)) is significantly higher than group L(0(0%)) ($p < 0.000$) and group D(0(0%)) ($p < 0.000$) and group LD(0(0%)) ($p < 0.000$), so all groups are equally better than group(A) (Table 29).

Severity of sorethroat on 24 hour

Table (30): Severity of Sore throat on 24 hour in the four study groups

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi- square	P-value
Sore throat on 2 hour (Mild)	8(32%)	0(0%)	0(0%)	(0%)	6.467	0.000
Soret hroat on 2 hour (Moderat)	0(0%)	0(0%)	0(0%)	0(0%)	-----	-----

There are significant differences according to severity of sore throat at mild level between air group and other three groups, $p=0.000$ (Table 30).

4.7 Hoarseness

Hoarseness on 2 hour

Table (31): Incidence of hoarseness on 2 hour in the four study groups

	A (n=25)	L (n=25)	D (n=25)	LD (n=25)	chi- square	P- value
hoarseness on 2 hour	21(84%)	13(52%)	8(32%)	9(36%)	17.974	0.001

The results of chi square test show that there are statistically significant differences between the study groups according to hoarseness on 2 hour, $P = 0.001$ (Table 31).

Table (32): Post Hoc Pairwise Comparisons of the Incidence of hoarseness on 2 hour in the four study groups

	Group(i)	Group(j)	chi- square	P-value
hoarseness on 2 hour	A(21(84%))	L(13(52%))	6.086	0.014
	A(21(84%))	D(8(32%))	14.702	0.000
	A(21(84%))	LD(9(36%))	12.647	0.000
	L(13(52%))	D(8(32%))	2.068	0.150
	L(13(52%))	LD(9(36%))	1.305	0.253
	D(8(32%))	LD(9(36%))	0.089	0.765

The results of pairwise comparisons show that the incidence of hoarseness on 2 hour in group A(21(84%)) is significantly higher than group L(13(52%))(p= 0.014) and group D(8(32%))(p= <0.001) and group LD(9(36%))(p= <0.001), (Table 32). The authors concluded that all groups are equally better than group (A).

Severity of hoarseness on 2 hour

Table (33): hoarseness noted by patient only and easily noted by others on 2 hour in the four study groups

	A	L	D	LD	chi-square	P-value
hoarseness on 2 hour (Noted By patient only)	11(44%)	12(48%)	4(16%)	4(16%)	10.939	0.015
hoarseness on 2 hour (Easily noted)	10(40%)	1(4%)	4(16%)	5(20%)	11.029	0.015

The results of the chi-square test show that there are statistically significant differences between the study groups on 2 hour regarding hoarseness (noted only by the patient) P = 0.015 (Table 32).

Hoarseness was (noted only by patients) of 44% in A group 11(44%) that significantly higher than D group 4 (16%) and LD group 4 (16%), P = 0.0325. And there are significant differences between L group 12 (48%) and both D group 4 (16%) and LD group 4 (16%), P = 0.0164. So, the D group and LD group are better than the other two groups (A and L) in reducing hoarseness noted only by patients (Table 33).

The incidence of hoarseness (Easily noted)) was 10(40%) in A group that significantly higher than L group 1 (4%), $P = 0.0024$ and D group 4(16%), $P = 0.0614$ and LD group 5 (20%), $P = 0.1266$, $p=0.015$ (Table 32).

Hoarseness on 8 hour

Table (34): Incidence of hoarseness on 8 hour in the four study groups

	A	L	D	LD	chi-square	P-value
hoarseness on 8 hour	21(84%)	6(24%)	9(36%)	7(28%)	24.807	0.000

The results of chi-square test show that there are statistically significant differences between the study groups according to the incidence of hoarseness on 8 hours $p = 0.001$ (Table 34).

Table (35): Post Hoc Pairwise Comparisons of the incidence of hoarseness on 8 hour in the four study groups

	Group(i)	Group(j)	chi-square	P-value
hoarseness on 8 hour	A(21(84%))	L(6(24%))	6.825	0.009
	A(21(84%))	D(9(36%))	2.913	0.088
	A(21(84%))	LD(7(28%))	6.825	0.009
	L(6(24%))	D(9(36%))	0.862	0.353
	L(6(24%))	LD(7(28%))	0.000	1.000
	D(9(36%))	LD(7(28%))	0.862	0.353

The results of pairwise comparisons show that, the incidence of hoarseness on 8 hours in group A (21 (84%)) is significantly higher than group L (6 (24%)) ($p = 0.009$) and group LD (7 (28%)) ($p = 0.009$). No significant difference between group A (21 (84%)) and D (9 (36%)) (Table

35). So, according to hoarseness of 8 hours, the best groups are (L) and (LD) .

Severity of hoarseness on 8 hour

Table (36): hoarseness noted by patient only and easily noted by others on 8 hour in the four study groups

	A	L	D	LD	chi-square	P-value
hoarseness on 8 hour(Noted By patient only)	15(60%)	6(24%)	9(36%)	6(24%)	9.254	0.033
hoarseness on 8 hour(Easily noted)	6(24%)	0(0%)	0(0%)	1(4%)	14.777	0.003

The results of chi square test show that there are statistically significant differences between the study groups according to the hoarseness on 8 hour(Noted By patient only) $P=0.033$ (Table 36).

The results of chi square test show also that there are statistically significant differences between the study groups according to hoarseness on 8 hour(Easily noted), $P=0.003$ (Table 36). The results indicate that all three groups are significantly better than the A group to reduce the severity of hoarseness.

hoarseness on 24 hour**Table (37): Incidence of hoarseness on 24 hour in the four study groups**

	A	L	D	LD	chi-square	P-value
hoarseness on 24 hour	10(40%)	0(0%)	0(0%)	1(4%)	27.255	0.000

The results of the chi-square test show that there are statistically significant differences between the study groups for incidence of hoarseness on 24 hours $P = 0.001$ (Table 37).

Table (38): Post Hoc Pairwise comparisons of the incidence of hoarseness on 24 hour in the four study groups

	Group(i)	Group(j)	chi-square	P-value
hoarseness on 24 hour	A(10(40%))	L(0(0%))	16.390	0.000
	A(10(40%))	D(0(0%))	16.390	0.000
	A(10(40%))	LD(1(4%))	10.643	0.001
	L(0(0%))	D(0(0%))	----	----
	L(0(0%))	LD(1(4%))	1.407	0.236
	D(0(0%))	LD(1(4%))	1.407	0.236

The results of pairwise comparisons show that according to the incidence of hoarseness on 24 hr. in group A (10 (40%)) is significantly higher than group L (0 (0%)) ($p = <0.001$), group D (0.001) and group LD (1 (4%)) ($p = 0.001$), so all groups are better than group (A) (Table 38).

Severity of hoarseness on 24 hour

Table (39): Hoarseness noted by patient only and easily noted by others on 24 hour in the four study groups

	A	L	D	LD	chi-square	P-value
hoarseness on 24 hour(Noted By patient only)	10(40%)	0(0%)	0(0%)	1(4%)	27.255	0.000
hoarseness on 24 hour(Easily noted)	0(0%)	0(0%)	0(0%)	0(0%)	-----	-----

There are significant differences in the severity hoarseness on 24 hr. (noted by patient only) between L (0%), D (0 (0%)) and LD (1 (4%)) versus A group 10 (40%), $p=0.000$. The results indicate that all groups are better than group (A) in reducing the severity of hoarseness that can be noted by patients on 24 hr. (Table 39).

There are no significant differences regarding the severity of hoarseness on 24 hours (easily noted by others) between L (0%), D (0 (0%)) and LD 0 (0%) versus A group 0 (0%).

Chapter Five

Discussion

Discussion

In this study, all patients in four groups were comparable with regard to ASA status, age, BMI, Mallampati score and smoking habits. The variables and data observed in the baseline parameters were anesthetic data (time for anesthesia and surgery, time from first spontaneous breathing to extubation, hemodynamic data and laryngo-tracheal morbidity data (Cough, sore throat and hoarseness)).

5.1 Features of the sample

In this study, all participants underwent laparoscopic surgery, all of which were not exposed to N₂O gas, as N₂O gas induces laryngo-tracheal morbidity by increasing ETT cuff pressure as completed and reported by many authors(Karasawa et al., 2000, 2002).

In the current study, anesthesia managed with an oxygen-air blend, while in the aforementioned trials an oxygen and nitrous oxide blend was operated. The spread of nitrous oxide in the cuff is expedited by the blood /gas solubility coefficient 0.444 / 0.013 for nitrous oxide / nitrogen. Cuff pressure is elevated, as nitrous oxide engenders into air fill cuff faster than leaving the cuff.

Jiménez-Rodríguez et al., (2016) and Estebe et al., (2005) studies showed that intra-cuff alkalinized lignocaine and saline significantly diminished the

incidence of airway-related side effects in comparison with air.. Blowing the ETT cuffs with fluids removes air pockets in the ETT cuffs and provides extra help by impeding extravagant intra-cuff pressure (Estebe et al., 2005).

Grant, et al.(2013) studied the effect of N₂O on endotracheal air-filled cuff pressure. They found that N₂O diffused through the thin-walled cuff and caused the increase in cuff pressure than the initial pressure, which then worsened the mucous membrane's blood flow. This tracheal mucosal blood flow is an important factor in tracheal morbidity associated with intubation. They also found that some damage to the tracheal mucous membrane due to the contact between the cuff material and the tracheal wall were inevitable. This cuff over expansion under anesthesia can be significant cause of tracheal or laryngeal trauma and possibly even postoperative pain in the throat of intubated patients. Patel, et al, (1984) found that the pressure in the cuff inflated with room air increased faster and to a higher level than pressure in the cuffs inflated with saline.

On the other hand, in a study conducted by Navarro, et al, 2012, the authors evaluated whether endotracheal tube (ETT) intracuff alkalized lidocaine was superior to saline in the onset of emergence, postoperative sore throat and hoarseness in smokers. It was a prospective double-blind study, enrolled 50 smoking patients undergoing surgery under general anesthesia including nitric oxide (N₂O). The patients were randomly released to receive either intracuff 2% lidocaine plus 8.4% sodium bicarbonate (L group) or ETT intracuff 0.9% saline (S group). The ETT

cuff was inflated to achieve a cuff pressure that prevented air leakage during positive pressure ventilation. The incidence of cough emergence, sore throat and hoarseness was analyzed. The volume of infusion solution, intracavity pressure, duration of anesthesia, time of extubation and the volume of the infusion solution and the air taken from the ETT cuff were also recorded. Their results showed that intracuff alkalized 2% lidocaine was superior to saline in blunting emergence coughing n ($p < 0.001$). The presence of sore throat was significantly lower in the L group at the post-anesthesia unit (PACU) ($p = 0.02$). However, at 24 hours after extubation, the sore throat was similar in both groups ($p = 0.07$). The incidence of hoarseness was similar in both groups. The intracuff pressure of the saline group increased with time, while the intracuff pressure in the lidocaine group was constant. The study showed that intracuff alkylized 2% lidocaine was superior to saline to reduce the incidence of cough and sore throat during the postoperative period in smokers. The authors did not mention any negative effect of using nitrous oxide in their study.

Therefore, the current study was evaluated where the ET cuff filled with either alkalized lidocaine alone, dexamethasone alone, alkalized lidocaine plus dexamethasone, or air were assessed in anesthetized patients with controlled ventilation without N₂O. Our results showed a significant improvement of ETT induced emergence phenomena from general anesthesia when alkalized lidocaine, dexamethasone and, alkalized lidocaine plus dexamethasone was used instead of air to fill the ETT cuff, these results are consistent with the study results of (Estebe et al., 2005). In

addition, Laparoscopic surgery gives less pain than other major surgery and longer operating time.(Jiménez-Rodríguez et al., 2016). So we need to take advantage of these characteristics: The first is less pain and less need for analgesics. So we can prevent pain that can prevent the patient from coughing and masking the sore throat, which may affect the assessment of laryngo tracheal symptoms and give incorrect results. Other benefit is the long incubation time that allows for more diffusion of study medication through ETT.

5.2 Lidocaine alkalization

After intubation with presumed technique, ETT cuff was inflated by one of the highest risk drug lidocaine drug if the ETT cuff accidentally broke so that lidocaine was alkalized by addition of 8.4% sodium bicarbonate in a ratio of 19: 1 to achieve a physiological pH (7.4) and the small dose of lidocaine, this solution should certainly also be caused by unexpected rupture. (Estebe et al., 2014; Navarro, et al, 2012).

Lidocaine-convincing cuff rupture has never been described in vivo or in vitro. In the current study, all participants were extubated without any problems, and no documentation of cuff damage was described. The dose handled in the current study (1 ml 8.4% bicarbonate in 20 ml solution) was adequate to increment the pH of lidocaine solution and simplify its diffusion but is improbable to injure the trachea if any cuff damage occurs. The result is consistent with study results from Narravo et al (2012) declared that the amount of lidocaine used was never exceeded 5 mg / kg to

protect the patient from local anesthetic toxicity if the cuff is broken (Ali et al., 2009). Furthermore, the alkalization of lidocaine diffusion over the ETT-cuff membrane increases(Navarro et al., 2007). No evidence of cuff injury was observed in the current study.

This technique can also be used for patients who need postoperative ventilation support, as previous studies have documented ETT tolerance is significantly improved by filling the ETT cuff with buffered lidocaine (Estebe et al., 2002; Estebe et al., 2005). They may require smaller doses of drug for tube tolerance. The current study is in accordance with the studies conducted by Soltani et al., (2002)during the study, no cuff broke up and confirmed the safety of this method. Use of only the amount of lidocaine required to produce leakage occlusion (Soltani et al., 2002).

Tracheostomised patients who have to hold the tube for a long time and whose discomfort appears mainly from the inflated cuff could benefit from the use of this technique, as diffusion was found across the tracheostomy tube cuff as well (Hirota et al., 2000).Lidocaine 4% instillation in ETT cuff decreased significant after-intubation problems versus air and should therefore be used regularly in all intubated patients (Rao et al., 2013).

The results of the current study show that using lidocaine as a cuff inflator reduced the incidence of postoperative sorethroat, cough and hoarseness in comparison to air. It is suggested that the difference was produced by the continuous local anesthetic effect of lidocaine on tracheal

mucosa, the current study consistent with the study results conducted by (Ali et al., 2009).

Alkalinized local anesthetics in the ETT cuff provide the benefits of a minimal stress response in even tracheal extubation and cough-free origin. Estebe, et al. reported earlier that alkalization of L-HCl allowed diffusion of 65% of the neutral base form of L-HCl through the hydrophobic structure of the PVC cuff within a 6-hour period and showed that the use of a small dose (40 mg) alkalized L-HCl significantly improved ETT tolerance during the first postoperative day (Estebe et al., 2002; Estebe et al., 2005). Following the Henderson-Hasselbach equation (i.e., the ratio of ionised and nonionized species which is an objective of both the pK of the substance and the solvent's pH), the inclusion of NaHCO₃ to the alkalized L-HCl solution alkalizes. This gives the corresponding hydrophobic base and permits diffusion of this uncharged form over the hydrophobic PVC wall of the cuff lighter than the alkalized L-HCl, enabling the perfect release profile noticed with the lidocaine base (Dollo et al., 2001). In line with this concept of alkalization, studies previously reported that the amount of L-HCl diffusing across the ET cuff in the presence of NaHCO₃ was proportional to the dose of L-HCl applied (20-40 mg).(Dollo et al.,2001). In vitro and in vivo studies showed no cuff damage or obstruction (Estebe et al., 2002; Estebe et al., 2005)

In the current study, a high volume low pressure ETT, choose 7.5 mm for women and 8.0 mm for men, which standardize the type and size of the tube. Other variables commonly associated with postoperative pain in

the throat, including intubation technique, laryngoscopic blade, airway placement, suction technique and anesthesia technology were monitored. Guedel & Waters, (1928) demonstrated the cuffed endotracheal tubes. The endotracheal tube cuff has important features like assure the respiratory system contra aspiration by disposed an airtight seal against gas leakage and conceding sufficient positive pressure ventilation (Cobley et al., 1993).

State of extubation from anesthesia and consequent periods after it is accompanied with different undesired outcomes such as hypertension, tachycardia, agitation, cough and tracheal morbidity as throat, hoarseness and dysphonia (Fagan, et al., 2000). Different trials showed that lidocaine dispersed through the membrane in the endotracheal tube's cuff. The dispersion of local anesthesia was due to different elements such as the non-ionized portion of local anesthesia, alkalization, temperature, duration of surgery and consolidation of local anesthesia (Navarro et al., 2007).

5.3 Steroids

Ayoub et al., (1998) showed that topical application of betamethasone over ETT reduced the incidence of cough, hoarseness and sore throat postoperatively. Park et al., (2008) administered prophylactic intravenous dexamethasone with double lumen intubation and found a decrease in incidence and severity of sore throat and hoarseness after extubation. Tazeh-kand, et al., (2010) found that inhaled fluticasone propionate given prior to induction reduced the incidence and severity of postoperative cough, sore throat and hoarseness. Steroids with their anti-

inflammatory effect have been attributed to these results (Ayoub et al. 1998; Park et al., 2008; Tazeh-kand et al., 2010). In the study by (Kee et al., 2013) the authors speculated that it may be possible for Dexamethasone to diffuse through the ETT cuff, which acts on tracheal mucosa in contact with it, reducing the inflammatory process that occurs in tracheal mucosa. Measurement and detection of dexamethasone levels in venous blood samples of patients who had their ETTs inflated with dexamethasone may have confirmed this. Alkalinized lignocaine diffuses on the other hand and tracheal mucosa is assessed in contact with the cuff and reduces the repulsion of their annoying receptors (Tazeh-kand et al., 2010). These two mechanisms are likely to be responsible for the observed decrease in the incidence of coughing, hoarseness and sore throat in the postoperative period. In summary, both intra-cuff dexamethasone and alkalized lignocaine decreased the significance of hoarseness, which is compatible with the results of the current study.

5.4 ETT cuff pressure

Increasing ETT cuff pressure is an important cause of laryngotracheal complication after extubation. In this study, this variable is monitored by holding the cuff pressure 20-30 cm H₂O and checking to adjust it every 15 minutes. (Lakhe & Sharma, 2018).

5.5 Laryngotracheal scoring system

At 2, 8 and 24 hours after extubation, post-anesthesia care unit (PACU) and in surgical ward; sore throat, cough and hoarseness were assessed with a 4-

points scale -every symptom had 4 points according to severity of the symptom (Harding and McVey, 1987) that used in many studies to assess sore throat, cough and hoarseness (Furqan, et al., 2016; Gaikwad, et al, 2017;Sumathi,et al. 2008 Gupta, et al, 2013 and 2014) and others.

5.6 Demographic variables

In terms of gender, 77% of women were female and 23% of men without statistical differences between the groups ($p = 0.448$) and when compared age, BMI, cigarettes per day and year of smoking for this study, there were no statistical differences, and the P-values was 0.920, 0.233, 0.788, 0.788 respectively

Gender

Post-extubation Laryngeotracheal sore throat, cough and hoarseness are due to several factors, and the cause of these symptoms is multifactorial and differ by gender. (Jaensson,et al., 2012;Wittekamp,et al., 2009). No statistical differences in gender between study groups in the current study.

Age

Increased age leads to the likelihood of laryngotracheal complication increasing after extubation,(Epstein & Ciubotaru, 1998). No statistical differences in age between study groups in the current study.

Smoking habits

Many authors reported that smoking cigarettes are a major cause for developing tracheal damage and increasing incidence of sore throat, cough and hoarseness after tracheal enlargement (Schwilk et al., 1997) .

So it is a positive point in this study to be checked for these variables where there were no statistical differences in the number of cigarettes smoked per day or year of smoking among four study groups.

Why smokers have been recruited in the current study

In smokers, rapid alignment of stretch receptors in tracheal mucosa is believed to be the annoying receptors intended for coughing (Guo et al., 1999). These receptors are very sensitive to mechanical stimuli such as touch, displacement and stretching (Schelegle & Green, 2001). Tracheal intubation with ETT, cuff inflation and the resulting hyperinflation, in turn stimulates these receptors, thereby producing cough in normal patients during extubation (ETT-induced cough) (Fagan et al., 2000). In chronic smokers, threshold stimulation for cough receptors is reduced (Dicpinigaitis & Gayle, 2003; O'connell, Thomas, Studham, Pride, & Fuller, 1996; Wong & Morice, 1999).

Long-term smoking causes neutrophil infiltrations in vulnerable smokers who feel the cough-sensitive nerves through release of sensory neuropeptides and direct stimulation of the nerves / receptors (Lalloo, 2003). Therefore smokers tend to be hired more often and violently in the

course of general anesthesia. Stimulation of these receptors also results in the release of substance P (causing mucosal vasodilation, plasma exudation and airway mucosa secretion), calcitonin-related peptide (causing mucosal vasodilation) and neurokinin A (causes bronchoconstriction) (Jaichandran, et al., 2009).

This study was limited to smokers because this group has underlying respiratory irritation. Strategies for attenuating growth phenomena include extubation in a deeper drug plan, drug use (Nordin, 1977) and the use of lidocaine (Hirota et al., 2000; Huang et al., 1998; Estebe et al., 2002). A study of nebulized lidocaine prior to induction of anesthesia showed a significant reduction in procedure-related complications in smokers (Nishina, et al., 1995). Altintas et al. showed lower incidence of bucking at extubation time using intracuff lidocaine (Altintaş et al., 2000). When lidocaine is used to blow up the ETT cuff, a higher tolerance for the air tube is well proven (Nordin, 1977; Hirota et al., 2000; Estebe et al., 2002; Altintaş et al., 2000). A study that did not show the effect of non-alkalized 4% lidocaine that was not alkalized to reduce cough during the onset of general anesthesia in smokers lasting 90 minutes. The main reason for this lack of effect may be due to a lower drug diffusion rate through the cuff due to low drug pH since lidocaine was not alkalized (Estebe et al., 2002). In the current study, the incidence of cough was apparently lower in LD, D and L groups compared with the A group. In the proportions used in this study (19 ml lidocaine: 1 ml bicarbonate) a solution of pH 7.43 (alkalized

lidocaine) was obtained. This probably allows for faster diffusion of lidocaine through the cuff membrane.

5.7 Anesthetic data

A 100% of patients had ASA II score. Mallampati scores were [1] in 71% and [2] in 29% of total patients, with no significant differences between four groups ($p = 0.158$).

Fentanyl, propofol, atracurium and dormicum were used in operation and were given based on the patient's weight and without any significant difference in four study groups where the P-value of fentanyl was 0.944, for propofol 0.123, for atracurioma .0953 and for dormicum.0956.

Anesthesia time was 74.34 ± 17.15 min without statistical difference between four study groups $P = 0.41$ and this is acceptable to study criteria to provide sufficient and same time for study medication to diffuse across the ETT cuff membrane.

All of the above factors were kept constant because these variables were usually associated with postextubation sore throat, including intubation techniques, laryngoscopic blades, airway placement, suction and anesthetic techniques, all of which were controlled.

5.8 Duration of operation

The average operating time in the current study was approximately 63 minutes. By using lidocaine-based cuffs for expanded operations bid in better outcomes because dispersion across the membrane of the cough is an

action of time (Bennett, et al., 2000). Alkalinized intracuff lidocaine augmented cuff strength but the local anesthetic response did not suppress the swallowing response so that the patient could conserve the respiratory tract (Estebe et al., 2002). Estebe, et al. reported that lidocaine hydrochloride solo had a minor dispersion rate over the ETT cuff. For a clinical usage, large doses of lidocaine (200-500 mg) foreseen indispensable. The contact between the ionized and non-ionized description is an operation of the pK of the substance and the pH of the dispersed media. The addition of NaHCO₃ to L-HCl alkalizes the solution. This gives the hydrophobic base and capitate dispersion of this uncharged form through the polyvinyl chloride pathway of the cuff lighter than L-HCl, permissive the outstanding release profile noted with the lidocaine base (Jaichandran et al., 2008; Estebe et al., 2005).

5.9 Time from first spontaneous breathing until extubation

There is a significant time difference from first spontaneous breathing until extubation between study groups in the current study. The post-hoc tests showed that the differences for the L (Lidocaine) group (Mean = 10.12 min) and LD (Lidokain + Dexametason) group (Mean = 9.08 min) were significantly higher than the A group (Mean = 4, 88) and D (dexamethasone) group (mean = 6), $p = 0.000$. The results were in favor of dexamethasone and air groups. The authors speculated that patients in lidocaine and lidocaine dexamethasone groups may have sedative effects due to lidocaine diffusion. Lidocaine administered in ET cuff can produce sedation and prolongation of first spontaneous breathing until extubation

due to the use of intra-cuff lidocaine. The current study is in accordance with the study by Caranza,et al.(1997) as described under general anesthesia, the use of intravenous lidocaine has been used with the intention of suppressing cough reflexes. Lidocaine administered intravenously, however, may produce sedation and prolong the anesthesia monitoring process(Yukioka,et al.,1985).

The results from the current study are also compatible with study of Ahmady,et al., (2013a) where prolongation of time to spontaneous ventilation prior to extubation was significantly longer in the lidocaine group compared with the saline group (16.4 ± 3.1 min and $9, 4 \pm 1.7$ min respectively). Also compatible with the studies by Rafiei et al., (2012) and Estebe et al., (2005).

The results of the current study are not in line with the study by Navarro et al., (2012), which showed that patients did not experience any prolongation of the anesthetic agitation due to the use of intracuff lidocaine. In fact, the time elapsed since the interruption of anesthetics until the extubation was shorter in the L group. Navarro et al., (2012a) speculated that this may be due to a smoother emergence period experienced by patients with intracuff lidocaine, while the high incidence of cough formation during onset delayed extubation in the saline group. This result can be explained by induced effective rest of the tracheal mucosa through released lidocaine over the cuff membrane, preventing early complaining from ET and trying to remove it. This explanation was also reported in the studies by Ahmady et al., (2013), and Estebe et al.,

(2005), the good tolerance of the ETT was associated with less cough and restlessness before suction and extubation.

5.10 Hemodynamic Parameters

In the current study, the systolic and diastolic blood pressure and the map of all participants during extubation and consequent periods were documented. The results show that there are no statistically significant differences between the four study groups in all variables: MAP during OP, MAP during the emergence phase, MAP in PACU, HR during OP, HR during development phase and RR during emergence phase (all P- values > 0.05). The local anesthetic development caused by dispersion of lidocaine and/or dexamethasone over the membrane of the cuff proceeded in a more constant blood pressure at the extubation time and during the consecutive period.

Controversially, the results of the current study are not consistent with the study results performed by (Rao et al., 2013) declared that the mean systolic blood pressure was basically high at the time of extubation but it was progressively decreasing over time. It was noted that the systolic BP was diminished in the group Lidocaine in comparison to group Air. It was also noted that there was a statistically significant difference in blood pressure from standard (i.e., extubation) at 2, 5, 10, 30 and 60 min. The increment in blood pressure during extubation and consequent periods would be correlated to the over-sensitiveness caused by the ETT and its cuff on the mucosa of larynx and trachea. Regarding cardiac rate in the

current study, there were no significant differences between the four study groups in the heart rate, consistent with Navarro et al., (2012) and Fagan et al., (2000).but in Cho et al., (2016), it was significantly different for the heart rate between groups D and LD compared to group A, heart rate in group D and group LD were lower than group A.

The hemodynamic parameters of the patients in Rao et al., (2013) study included registration of heart rate at extubation time and 1, 2, 5, 10, 30 and 60 min after a particular. It was noted that heart rates were significantly greater at extubation time and deliberately declined correspondingly. Rao et al noted that the ordinary heart rates were less in the group Lidocaine comparing to Air group. Even the difference in heart rate from the baseline (i.e., extubation) was statistically significant at 5, 10, 30 and 60 min after extubation. It was described that the heart rates were less and more constant in the lidocaine group.(Rao et al., 2013) The results of Rao et al., (2013) was not consistent with the current study outcomes. This incompatibility can be illustrated by the difference between lidocaine concentration; we use 2% but in the other study 4% lidocaine was used.

The current study results are not consistent with the study results conducted by El Batawi et al., (2013) and Choubsaz,et al., (2016)reported that in patients under general anesthesia lidocaine reduced the heart rate that our study did not confirm these results. The current study is also not consistent with the study results conducted by Altintaş et al., (2000), they use a 10% lidocaine as compared to saline. There was a significant difference in MAP and HR between two groups related to high concentration of lidocaine that

could explain why there was no significant difference in MAP and HR between control group and study groups in our study. Also, the result in this study, considered BP and heart rate, was also compatible with Rafiei et al., (2012), where no significant difference was recorded in arterial blood pressure and heart rate between lidocaine, dexamethasone and normal saline. And in agreement with Estebe et al., (2005), where no significant differences were recorded in arterial blood pressure and heart rate between lidocaine and air groups.

Controversially, the current study is consistent with the study results conducted by Gaumann et al., (1992) reported patients under general anesthesia who had received lidocaine had no significant increase in heart rate from the baseline after the introduction of the stiff bronchoscope. Other study conducted by Yaghoobi, et al., (2013) reported that after combination of lidocaine and dexamethasone, the heart rate was reduced compared to dexamethasone alone but different were not significant that our study confirmed it. Choubasaz et al., (2016) study showed that the addition of dexamethasone alone or combination dexamethasone and lidocaine to tube cuff reduced cardiac rate after anesthesia compared with control group ($P < 0.05$), but none for lidocaine alone. Therefore, dexamethasone has more reluctance to reduce heart rate in general anesthesia compared to lidocaine, which the current study did not confirm these results. The current study results regarding dexamethasone added to the intra component lidocaine have a positive effect on reducing respiratory

complications following general anesthesia, which is not consistent with the study conducted by (Choubsaz et al., 2016).

5.11 PONV in PACU

In the current study, the incidence of PONV in group D (4 (16%)) is significantly higher than Group A (0 (0%)), $p = 0.015$ and group LD (0 (0%)). These results are not congruent with the study of Estebe et al., (2002) showed that alkalization of intra-cuff lidocaine enhances endotracheal tube-convincing progression phenomena. There was a reduced frequency of postoperative nausea and vomiting (PONV) during the postoperative period was noted.

5.12 Laryngotracheal morbidity data

5.12.1 Cough

Cough after extubation, at emergence phase

In the current study, there are statistically significant differences between the study groups according to the post-extubation cough $p = 0.001$. The number of patients with cough in group A (12 (48%)) is significantly higher than group L (3 (12%)) $p = 0.004$ and group D (1 (4%)), $p = 0.000$, and group LD (0%)), $p = 0.000$. The results indicate that the incidence of cough in emergence of general anesthesia was significantly lower in groups Ld, D and L than group A. Thus, the main results in the current study included a decrease in incidence of cough at emergence of the general anesthesia in the LD groups, D and L. The results of the current study are

consistent with the study by Navarro et al., (2012a), which showed that the main findings included the incidence of cough at the emergence of general anesthesia were significantly lower in the L group ($p < 0.001$), when compared to the saline group, which shows an advantageous effect of the alkalaized lidocaine by suppressing the irritation stimuli of the ETT cuff on tracheal mucosa as compared to the ETT cuff inflation with saline. The results also show that the incidence of cough in group L (3 (12%)) is significantly higher than the group LD (0 (0%)). This result indicates that LD therapy is significantly better than L, $p = 0.037$. The most important results in the present study included a decrease in incidence of cough at the emergence of general anesthesia in groups L, LD and D. The best group for cough after extubation is directly (LD).

The results of the current study are also consistent with the study results performed by Huang et al., showed that the incidence of cough and the frequency of sore throat were significantly lower than the control group when lidocaine 4% and alkalized lidocaine were performed. They suggested using alkalized lidocaine as primed in the ETT cuff for smoother emergence from general anaesthesia (Huang et al., 1998). The incidence of coughing on emergence from general anesthesia in the presence of ETT has been estimated to range from 38% to 96% (Fagan et al., 2000). Estebe et al., (2005) was reported a significant difference between air and lidocaine according to frequency of cough at emergence phase. Fagan et al., (2000) reported that the frequency of cough over time after 0 to 2 min was 38% and 44% for air and saline respectively, where as in the lidocaine group, the

incidence of coughing was 16%, From 2 to 4 min, the incidence of coughing in the air group was 38%, whereas the incidence of coughing was comparable in the lidocaine and saline group, 11% and 11.1%, respectively. These results compared with an incidence of cough of 34% with air and 15% with saline, indicating a statistically significant difference between the groups with P less than 0.05.

The incidence of cough in PACU and on 2, 8 and 24h post-operatively

In the current study there are statistically significant differences between the study groups according to the incidence of cough in PACU ($P = 0.009$). The incidence of cough in group A (7 (28%)) is significantly higher than group D (1 (4%)) and group LD (0 (0%)), compared the four groups, the best group with cough in PACU is (LD), then (D), then (L), and the worst group is (A). The results of the current study indicated that, there was a significant difference between air group and dexamethasone group, which compatible with Kee et al., (2013) and Rafiei et al., (2012).

There are also statistically significant differences between the study groups of the incidence of cough on 2 hours $p = 0.001$. Group A (22 (88%)) is significantly higher than Group L (10 (40%)) ($P = <0.001$) and Group D (4 (16%)) ($P = <0.001$) and Group LD (32%)) ($P = <0.001$) and there are no significant differences between groups (L, D and LD), but it is obvious that the highest proportion is for group (L) and (LD) so we can say that the group (D) is best. Furthermore, the results of the current study is in agreement with the study results conducted by Jarahzadeh et al., (2014), the

rate of incidence of coughing in the patients in the Dexamethasone group decreased at 1, 6, and 24 h after the removal of the tube. These results are also in agreement with Estebe et al., (2005) who reported occurrence of cough after 1 hour from PACU, (A=70%) and (L=5%).

In the current study there are statistically significant differences between the study groups according to the occurrence of cough on 8 hours $p = 0.0001$. Group A (21 (84%)) is significantly higher than Group L (1 (4%)) $p = 0.0001$ and Group D (1 (4%)) $p = 0.0001$ and Group LD (0 (0%)), $p = 0.0001$, so we can say that all groups are better than group (A). Even in the current study, the incidence of coughing in 24 hours, in Group A (3 (12%)), is significantly higher than group L (0 (0%)) ($p = 0.037$) and group D (0%) = 0.037) and group LD (0 (0%)) ($p = 0.037$), so all groups are better than group (A). The results of the current study are consistent with study results from Rao et al., (2013) was shown that the frequency of cough at extubation was greater in the air in comparison to lidocaine. Fagan et al., (2000). Proposed that local anesthetic lidocaine demonstrated into the endotracheal tube cuff may be an explanation of anesthesia in the trachea by diffusing over the polyvinyl chloride membrane. Anesthesia should be restricted to the mucous membrane in touch with the cuff. The possessive cough reflexes over the tube sleeve and under the vocal band would persist unblemished. This may be a apprehension for the retention of cough reflexes during the post-study period . (Fagan et al., 2000). Wetzel, et l. proposed identical conclusion in the intra-cuff lidocaine group versus the saline group (Wetzel et al., 2008).

The current study follows the study results from Estebe et al., (2005) showed that cough in its control group was reported in 70% of patients. These findings were also consistent with previous studies (Dollo et al., 2001; Fagan et al., 2000; Gonzales, et al., 1994 ;Estebe, et al., 2004). Soltani, et al., (2002) showed that the most effective techniques for reducing postoperative cough were intracuff lidocaine on laryngopharyngeal structures. The results from the current study are not in accordance with the study conducted by Choubsaz et al., (2016) there was no significant difference for cough after anesthesia between control group (air) and lidocaine group.

The incidence of coughing in the current study was lower and statistically significant in the dexamethasone and alkalinized lidocaine and dexamethasone plus lidocaine groups compared to Air group. These results are not in agreement with the study results conducted by Kee et al., (2013) demonstrated that the incidence of coughing in their study was lower but not statistically significant in the dexamethasone and alkalinized lignocaine groups.

The incidence of coughing in the air group was higher in the studies conducted by Estebe et al. (2002, 2005) (70% and 96% respectively) compared to our study (48%) and more compatible with Kee et al., (2013) and Jaichandran et al., (2008) reported cough in air group (43%) and (55%), this difference can be explained using N₂O in Estebe trials.

Regarding the severity of cough, which was compatible with our results, Ahmady et al., (2013) reported a reduction of severe cough by comparing lidocaine and saline ($p = 0.014$) in PACU and at extubation time; Rafiei et al., (2012) and Cho et al., (2016) reported that dexamethasone had a superiority of lidocaine to reduce the severity of cough, which was not noted in our results.

Another study by Rafiei et al., (2012) reported that lidocaine was more effective in the incidence of cough and dexamethasone is more effective on post-extubation cough severity but there is no significant difference in the incidence of cough between the two groups consistent with our outcome.

5.12.2 Incidence and severity of Sorethroat on 2, 8 and 24 hour

In the current study, there are statistically significant differences between the study groups according to incidence of sorethroat on 2 hour $p = 0.001$, in group A(18(72%)) is significantly higher than group L(2(8%)) ($p = 0.001$) and group LD (5(20%)) ($p = 0.001$). So the best group is (L) then (LD) then (D) and the worst group is (A). According to the severity of sorethroat on 2 hour (Moderate), there are statistically significant differences between the study groups $p = 0.0001$. The result shows a significant increasing in a severity of sorethroat in air group comparing with other three groups.

There are also statistically significant differences in the current study between the study groups according to incidence of sorethroat on 8 hour $p=0.001$. In group A(18(72%))is significantly higher than group L(0(0%))(p= < 0.001) and group LD(1(4%))(p= < 0.001), the results also show that group D(10(40%)) is significantly higher than group L(0(0%))(p= <0.001) and group LD(1(4%))(p= 0.001), so the best group is group(L), then (LD), then (D) and the worst group is (A).

Also, in the current study there are also statistically significant differences between the study groups according to incidence of on 24 hour $p=0.001$. In group A(8(32%))is significantly higher than group L(0(0%))(p <0.001) and group D(0(0%)) (p <0.001) and group LD(0(0%))(p <0.001).

Cuff lubrication with lidocaine or spray has been associated with increased morbidity during the development of anesthesia due to the adhesion of ETT to tracheal mucosa (Walmsley,et al., 1988). In contrast to the current study, the ETT tubes were lubricated with a water-soluble gel; this method is consistent with the study by Navarro et al., (2012), demonstrated that cuff lubrication with a water-soluble gel in conjunction with alkalized lidocaine increases the tracheal tolerance and reduces the incidence of postoperative sore throat (Walmsley et al., 1988). It has been proposed that sore throat is caused by activation of tracheal receptors (Yukioka et al., 1985). Therefore, the proposal for the continuous application of local anesthesia to block these nociceptive receptors would seem logical in order to reduce the incidence of sore throat. After tracheal extubation, sore throat has been reported in 15% to 80% (Altıntaş et al., 2000 ;Estebe et al., 2004)). In the

study of Navarro et al., (2012), the incidence of sore throat was 20% and 12% in the saline group at the time of discharge from PACU and 24 h after extubation. In the L group, no patient was diagnosed with a sore throat. The authors explained that this high positive outcome was unexpected and could be related to the combination of three different techniques recognized as protection against sore throat: use of low ET cuff pressure, use of intracuff alkalinized lidocaine and water soluble lubricant use. These results are consistent with the results of the current study used by low ET cuff pressure, use of intracuff alkalinized lidocaine and water soluble lubricant use.

The results of the current study are also consistent with the results of Huang, et al., showed that the frequency of sore throat was significantly lower than the control group when lidocaine 4% and alkalized lidocaine were performed. They proposed using alkalized lidocaine as primed in the ETT cuff for serene emergence from standard anaesthesia (Huang et al., 1998).

In a study of Navarro et al., The rate of sore throat at the period of release from PACU was decreased in the lidocaine group than the air and saline group. The authors correlated the frequency of sore throat 24 hours after the operation. It was the smallest in the Lidocaine group. The particular results were statistically significant ($p = 0.003$). The outcomes were consistent with previous studies (Navarro & Baughman, 1997) and the results of the current study.

In the study of Porter et al., Lidocaine, air and saline had identical properties on postoperative sore throat. Different factors combined with ETT-cuff design, ETT size, intubation approach, laryngoscopic bladder, airway employment, suction method. Therefore, the above-mentioned factors can also influence the results (Porter,et al0., 1999). In a comprehensive review of Tanaka et al., Published in the Cochrane Library 2009, different randomized controlled studies for the result of concern, ie postoperative sore throat, was studied. The study investigation wrapped up that topical and systemic lidocaine treatment decreases the frequency and intensity of sore throat after general anesthesia with endotracheal intubation (Tanaka et al., 2009).

In this study, the incidence and severity of postoperative sore throat was significantly less in 24 hours in the group L (0 (0%)) ($p < 0.001$), group D (0 (0%)) ($p < 0.001$) and group LD (0 (0%)) ($p < 0.001$) compared to group A (8 (32%)). The results of the current study are in accordance with the study results of Ali et al., (2009)observed that the occurrence and severity of postoperative pain in the throat was significantly less in the L group compared to both the Air and distilled water group. The incidence was only 28% in group L compared with 40% and 63% in respective distilled water and air respectively.

The current study is consistent with the study results conducted by Navarro & Baughman, (1997)used lidocaine as a single cuff inflator and found that there was a significant decrease in incidence and severity of postoperative pain in the throat compared to control group .

Controversially, the results of the current study are not in line with another study conducted by Porter et al., (1999) compared lidocaine, air and normal saline. This study found no statistical significance between the groups. Bennett et al., (2000) observed statistical significance between air and saline groups for sore throat.

The frequency of postoperative sore the throat of the present study is comparable to previous studies (Soltani,et al., 2002;Navarro & Baughman, 1997; Mandøe,et al., 1992;Choubsaz et al., 2016) and significantly reduced by intra-cuff lidocaine.In a double blind clinical trial (Rafiei et al., 2012)patients were randomly assigned to saline, lidocaine and dexamethasone groups. The three medications were not significantly divergent in debilitating post-extubation repercussion such as hoarseness, sore throat and laryngospasm. Lidocaine, nonetheless, was more efficient at the cough while dexamethasone had superior effect at reduced cough rate. However the scoring of sore throat was unlike our study and there is a different in the method by using a N2O and difference in control group.

The current study results do not match the study results performed by Choubsaz et al., (2016), there was no significant difference between adding lidocaine or dexamethasone for endotracheal tube cuff filling versus air group to reduce cough, nausea or vomiting ($P > 0.05$). Although lidocaine was more effective in cough incidence than dexamethasone, but this was not significant in two groups.

The study by Thomas et al. (2007) examined the effect of Dexamethasone on reducing sore throat intensity after surgery. They found that the administration of Dexamethasone before surgery reduced sore throat due to tracheal intubation, which was consistent with our results. Furthermore, Bagchi et al., (2012) reported that the administration of intravenous Dexamethasone reduced the incidence of sore throat at 1, 6 and 24 hours after surgery. It should be noted that in the Thomas,et al (2007) and Bagchi et al. (2012) studies, Dexamethasone was administered intravenously, while Dexamethasone in the present study was introduced into the intracuff of the endotracheal tube. Despite the difference, the current study showed that the intracuff of Dexamethasone is also effective in reducing sore throat.

Most studies have dealt with the study of the effect of intravenous administration of Dexamethasone on sore throat due to intra-tracheal tube (Rafiei et al., 2012; Park et al., 2008; Ruangsri,et al, 2012; De Oliveira,et al, 2011). A few studies have focused on LMA complications and also on the effect of the local administration of glucocorticoids on sore throat and coughing after surgery. Sumathi et al., (2008), conducted a comparative study of effect of the application of Bethametasone gel and lidocain gel on reducing sore throat, coughing, and hoarseness after surgery. The findings indicated that the application of Bethametasone gel on the intra-tracheal tube leads to a reduction in the incidence and intensity of sore throat, coughing, and hoarseness.

In a previous study by Kee et al., (2013) to compare between dexamethason , alkalinized lidocain and air, there was a compatible result with the current study regarding the comparing between air and lidocain at 2 and 24 hours – sore throat evaluated just at these time- where was sore throat decreased significantly in lidocain comparing with air group; regarding to dexamethason there was a significant difference in incident of sore throat comparing with air group, that is incompatible with the results of the current study at 2 hours post PACU evaluation, this may be explain for the difference in sore throat scoring system.

The frequency of sore throat in the present trial at 24 h postoperatively was 32% which, in line with the study by Kee et al., (2013) study which was 43%, which was comparable to that found in a study by Biro et al., (2005). There was minimal or no complaint for sore throat in dexamethasone and alkalinized lignocaine groups at 2 and 24 hours post-surgery, and this was statistically significant compared to the air group in the current study. The intensity of the throat for all three groups in the present study was mild and similar to that reported by (Estebe et al., 2005;Kee et al., 2013).

The lignocaine's ability to diffuse out of ETT cuffs was first described by Sconzo et al., (1990).Estebe et al., (2002) showed increased diffusion of lignocaine when it was alkalized and plasma lignocaine levels were detected in venous blood samples by patients who had their ETT cuff inflated with alkalized lignocaine. Lignocaine diffusion was possible

because the ETT cuff is semipermeable, making it a potential drug reservoir (Estebe et al., 2002).

At the severity of the sore throat that is compatible with our results , Ahmady et al., (2013b), a reduction in severity of pain in the throat was compared with lidocaine and saline ($p = 0.031$) in PACU. Ali et al., (2009) reported a reduction in the severity of sore throat in the lidocaine group's in comparison with air and distilled water as well as including Altıntaş et al., (2000) showed that severity in the sore throat was lower in the lidocaine group at 1 h and 24 h after extubation compared with saline.

5.12.3 Hoarseness

Hoarseness in this study was evaluated at 2,8 and 24 hours after PACU, the result show there was a significant differences all the time during 24 hours between control group and other three groups, and there was a decreasing in hoarseness by the time. There are statistically significant differences between the study groups according to hoarseness on 2 hour $P=0.001$. In group A(21(84%)) is significantly higher than group L(13(52%)) ($p= 0.014$) and group D(8(32%)) ($p<0.001$) and group LD(9(36%)) ($p<0.001$), so the worst group is(A). There are statistically significant differences between the study groups according to hoarseness on 2 hour (Noted By patient only) $p= 0.015$.

There are also statistically significant differences between the study groups according to hoarseness on 8 hour $p=0.001$. In group A(21(84%)) is significantly higher than group L(6(24%)) ($p= 0.009$), and group

LD(7(28%))(p= 0.009), so the worst group is (A). And, there are statistically significant differences between the study groups according to hoarseness on 8 hour (Noted By patient only) since the P-value =(0.033). There are statistically significant differences between the study groups according to hoarseness on 8 hour (Easily noted) since the P-value =(0.003). There are also statistically significant differences between the study groups according to hoarseness on 24 hour p=0.001. In group A(10(40%)) is significantly higher than group L(0(0%))(p=<0.001), and group D(0(0%))(p=<0.001), and group LD(1(4%))(p= 0.001), so all groups are better than group(A).

The results of the current study are congruent with a study by Navarro et al., (2012) showed the incidence of hoarseness at the period of release from the PACU was lesser in the lidocaine group than the air and the saline group. The authors compared the frequency of sore throat in the 2 groups 24 hours after the operation. It was smallest in group Lidocaine. These findings were statistically significant (p = 0.003). The results were in congruence to the early trials (Navarro & Baughman, 1997). Bennett et al., (2000) observed statistical significance between air and saline groups for hoarseness for the welfare of saline group.

There are significant differences regarding severity of hoarseness on 24 hour (Noted By patient only) between L (0%), D (0(0%)), and LD (1(4%)) compared to A group 10(40%). The result of the current study is not congruent with the study result of Navarro et al., (2012b) despite all techniques applied for preventing tracheal morbidity, the incidence of

hoarseness was similar in Lidocaine and saline groups, suggesting that this symptom is unlikely related to the cuff pressure or to the cuff inflation solution. But, the result of the current study is in accordance with the study results of Ali et al., (2009), it was observed that the incidence and severity of postoperative hoarseness was considerably less in the group L compared to both group Air and distilled water .yet, the results of the current study was not in agreement with studies that were shown that the incidence of hoarseness was not significantly different between the two groups as was the case in our study (Bagchi et al., 2012; Jarahzadeh et al., 2014).

On the other hand, The current study results are in agreement with studies showed that the incidence of hoarseness was significantly lower in the alkalinized lignocaine and lidocaine groups (Shroff & Patil, 2009;Kee et al., 2013). Also The incidence of hoarseness in Kee et al., (2013)study was lower in dexamethasone group compared to air group, although hoarseness was significantly reduced, the results of the current study confirmed these results.

In the case of dexamethasone in cuff impact on hoarseness, our result was consistent with Kee et al., (2013)study, which was shown to be significantly different in comparison between air group and dexamethasone and lidocaine groups, lidocaine and dexamethasone were as superior to air at the emergence phase. Rafiei et al., (2012)compared saline, lidocaine and dexamethasone; which was not significantly different between three groups according to hoarseness, unlike our study, the control group was saline, this can explain why Rafiei et al. Study is incompatible with our results.

In the case of lidocaine effect on hoarseness, all previous studies compared to lidocaine with air intra-ETT cuff were significantly better than air in decreasing hoarseness (Ali et al., 2009; Estebe et al., 2005; Rao et al., 2013; Navarro et al., 2007), which complies with our results. In Shroff & Patil, (2009), lidocaine, saline and air intra-ETT cuff were compared, the best to decreasing hoarseness was significant lidocaine and there was no significant difference between saline and air. Regarding the severity of hoarseness, the study results performed by Ahmady et al., (2013a) were incompatible with our reported results, which showed no differences in severity of hoarseness when compared to lidocaine and saline ($p = 0.449$). Ali et al., (2009) reported a reduction of severe hoarseness in lidocaine group compared with air and distilled water, which is consistent with our results.

5.12.4 Laryngospasm

In the current study, there was no significant difference between four groups with respect to laryngospasm, which P value was 0.057, this result is an agreement with Fagan et al., (2000) where was the p-value = 0.55 and Rafiei et al., (2012) where was the p-value = 0.998 and compatible with Estebe et al., (2005) and Cho et al., (2016) which was ($P > 0.05$) for laryngospasm in study groups.

6. Conclusion

The combination of alkalize lidocaine and dexamethasone in ETT cuff or lidocaine alone had a superior effect in reducing incidence and the severity of post-extubation morbidities such as cough, sore throat and hoarseness and softening extubation and no risk of ETT cuff failure.

7. Nurse anesthetic implications

Lidocaine, Lidocaine plus Dexamethasone and Dexamethasone decrease the incidence of cough and decrease the severity of cough and sore throat. Lidocaine had a superior benefit to decrease the severity of hoarseness in patients undergoing general anesthesia.

8. Limitation

The PACU time period was so short which effect the evaluation of cough and preventing from evaluate the sore throat and hoarseness in this period because patient still unable to verbalization.

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Appendix 1

Consent Form

موافقة الاشتراك في البحث العلمي

اسم الباحث اسلام جميل يونس الزغارنه - طالب ماجستير تمرير التخير.

مشرف على البحث د. نور المصري- أخصائي طب تخدير

جامعة النجاح الوطنية

عنوان البحث: تأثير الديدوكائين القلوي والديكساميثازون والمزيج بينهما مقابل الهواء في كفة الأنبوب الرغامي لتقييم الاعتلال بعد نزع الأنبوب لدى المرضى المدخنين الذين يخضعون لعملية المنظار البطني. دراسته عشوائية مزدوجة التعمية.

أنت مدعو/ة للمشاركة في بحث علمي سريري الرجاء اخذ الوقت الكافي لقراءة المعلومات التالية/تأني قبل اتخاذ قرار المشاركة.

بإمكانك/ي طلب إيضاحات أو معلومات اضافية عن أي شيء مذكور في هذه الاستمارة أو عن هذه الدراسة ككل من الباحث.

عند التخير العام يتم إدخال الأنبوب بالقصبه الهوائية للمحافظة على عملية التنفس وهذا الأنبوب له تأثيرات جانبية بالعادة.

الهدف من البحث/ تقليل التأثيرات الجانبية لهذا الأنبوب بعد العملية.

في حال وافقت على المشاركة في هذه الدراسة سيبقى اسمك في طي الكتمان ولن يكون لأي شخص -ما لم ينص القانون على ذلك- حق الاطلاع على ملفك الطبي باستثناء الباحث والطبيب المشرف على الدراسة ومشرف الدراسة من جامعة النجاح الوطنية.

موافقة الباحث

لقد شرحت بالتفصيل للمشارك في البحث الطبي ل-----

طبيعته ومجرياته وآثاره السلبية . ولقد أجبت على كل أسئلته بوضوح تام.-----

الطبيب

الباحث

موافقة المشارك

لقد قرأت استمارة القبول هذه وفهمت مضمونها . وتمت الاجابة على أسئلتي جميعها . وبناءا عليه فأنتي حرة ومختارة أجاز إجراء هذا البحث وأوافق على الاشتراك فيه . واني اعلم أن الباحث والطبيب سيكونون مستعدين للاجابة عن أسئلتي . وانه باستطاعتي الاتصال بهم على الرقم 0568448155 . كما إنني اعرف تمام المعرفة بأنه لي الحق في الانسحاب من الدراسة في أي وقت بعد توقيع الموافقة ودون الاضطرار لتقديم أي سبب او عذر . ولن يؤثر هذا على الخدمة الطبية المقدمة لي . واعلم أيضا أنني سوف احصل على نسخه طبق الأصل من هذه الموافقة .

اسم المشارك في البحث-----

التوقيع-----

التاريخ-----

Appendix 2

An-Najah
National University
Faculty of medicine
& Health Sciences
Department of Graduate
Studies



جامعة النجاح
الوطنية
كلية الطب وعلوم الصحة
دائرة الدراسات العليا

IRB Approval Letter

Study Title :

The effect of intracuff alkalinized lidocain combining with dexamethason on post-extubation morbidity in smoker patients undergoing laparoscopic surgery under general anesthesia. a randomized double blind study

Submitted by:

Islam Jamil Younis Alzagharneh, Aidah Al Qasi, Dr. Nour Al-Masri

Date Reviewed:

10th May 2017

Date Approved:

28th May, 2017

Your Study titled "The effect of intracuff alkalinized lidocain combining with dexamethason on post-extubation morbidity in smoker patients undergoing laparoscopic surgery under general anesthesia. a randomized double blind study" with achieved number 5th May. 2017 was reviewed by An-Najah National University IRB committee and was approved on 28th May..2017.

Hasan Fitian, MD

IRB Committee Chairman

An-Najah National University

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Appendix 3

Data collection sheet

*Date
Number.....

*Participant

*Hospital file number.....
surgery.....

*Type of

*Age.....*Gender.....*Weight[kg]..... *Height.[cm].....
ETT size....

BMI

* The number as the group number randomized scheduled

History

***Smoking habit**

How many cigarette in a day.....

How long have you been smoker[in years]

do you stop smoking before surgery. when.....

*** Current Respiratory problems.....**

***Allergy**

did you have an allergic before

if yes, select and detail [medicine..... ,food.....,other.....]

***Medical history**

Disease.....HTN.....

Medications.....

Surgical history.....*Intra operation room*****Quick anesthetic and airway assessment****-did you have anesthesia before****if yes, type..... ,and any problems.....****-ASA class.....****- Mallampati score*****all Medication given in operation.**

Time	Drug given+ dose	Note
0-15 min		
15-30 min		
30-45 min		
45-60 min		
60-75 min		
60-90 min		
90-120 min		

***inhalation agent and its MAC**

***Intracuff pressure every 15 min**

Time	Pressure [cmH ₂ O]
0	
15 min	
30 min	
45 min	
60 min	
75 min	
90 min	
105 min	
120 min	

***Initial volume inserted in cuff.....**

*** Volume withdrawal during operation to stabilize pressure**

***Final volume withdrawal from cuff.....**

***Anesthesia duration [from induction until first spont breathing].....min**

***Surgical duration [from first incision until final suture]....min**

***Hemodynamic status and VS during operation**

TIME	NIBP	HR	ETCO ₂	RR	Temp	Sat	MAP
0 min							
15min							
30min							
45min							
60min							
75min							
90min							
105min							
120min							

***Emergence Phase**

-Hemodynamic status and V.S every 3 min from first spontaneous breathing until transfer to PACU.

TIME	NIBP	HR	Sat	RR	EtCO2	TV	MAP
0 min							
3 min							
6 min							
9 min							
12 min							
15 min							
18 min							

-TIME from first spont breathing until Extubation.....

-COUGH after extubation in OR;if yes how many time

[yes].....

[No]

-head tilt support after extubation duration.....sec

-happened of laryngospasm;

[Yes].....

[No]

PACU Phase*-Hemodynamic status and V.S just two times.**

Time	NIBP	HR	RR	Sat	Temp	MAP
1						
2						

-COUGH ;if yes how many time

[yes]..... [No]

-head tilt support; if yes how long

[Yes]..... [No]

-occurrence of laryngospasm;

[Yes]..... [No]

-Aphonia

[Yes]..... [No]

-PONV

[Yes] [No]

-Duration of PACU.....

-Medication given in PACU.....

After 2 hour in ward**-Hemodynamic status and V.S**

Time	NIBP	HR	RR	Sat	Temp	MAP
1						

sore throat

0 No pain in the throat

1 Mild pain in the throat

2 Moderate pain in the throat

3 Severe pain in the throat

Cough

0 No cough

1 Mild (less than what is seen in common cold)

2 Moderate (like what is seen in common cold)

3 Severe (more than what is seen in common cold)

Hoarseness of the voice

0 No evidence of hoarseness at the time of interview

1 Hoarseness at the time of interview noted by patient only

2 Hoarseness that is easily noted at the time of interview

3-Aphonia

-PONV

[Yes]

[No]

After 8 hour in ward**-Hemodynamic status and V.S**

Time	NIBP	HR	RR	Sat	Temp	MAP
1						

sore throat

0 No pain in the throat

1 Mild pain in the throat

2 Moderate pain in the throat

3 Severe pain in the throat

Cough

0 No cough

1 Mild (less than what is seen in common cold)

2 Moderate (like what is seen in common cold)

3 Severe (more than what is seen in common cold)

Hoarseness of the voice

0 No evidence of hoarseness at the time of interview

1 Hoarseness at the time of interview noted by patient only

2 Hoarseness that is easily noted at the time of interview

3-Aphonia

-PONV

[Yes]

[No]

After 24 hour in ward**-Hemodynamic status and V.S**

Time	NIBP	HR	RR	Sat	Temp	MAP
1						

sore throat

0 No pain in the throat

1 Mild pain in the throat

2 Moderate pain in the throat

3 Severe pain in the throat

Cough

0 No cough

1 Mild (less than what is seen in common cold)

2 Moderate (like what is seen in common cold)

3 Severe (more than what is seen in common cold)

Hoarseness of the voice

0 No evidence of hoarseness at the time of interview

1 Hoarseness at the time of interview noted by patient only

2 Hoarseness that is easily noted at the time of interview

3-Aphonia

-PONV

[Yes]

[No]

Appendix4

ASA physical status classification system for assessing a patient before surgery.

I. Normal healthy patient .

II. Patient with mild systemic disease .

III. Patient with severe systemic disease .

IV. Patient with severe systemic that is a constant threat to life .

V. Moribund patient who is not expected to survive without the operation .

VI. Patient declared brain dead whose organs are to be harvested for donor purposes .

جامعة النجاح الوطنية

كلية الدراسات العليا

تأثير الليدوكائين القلوي والديكساميثازون والمزيج بينهما مقابل الهواء في
كفة الأنبوب الرغامي لتقييم الاعتلال بعد نزع الأنبوب لدى المرضى
المدخنين الذين يخضعون لعملية المنظار البطني. دراسة عشوائية
مزدوجة التعمية.

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إشراف

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د. نور المصري

قدمت هذه الأطروحة استكمالاً لمتطلبات الحصول على درجة الماجستير في برنامج تمريض
التخدير، بكلية الدراسات العليا، في جامعة النجاح الوطنية، نابلس-فلسطين.

2019

ب

تأثير الليدوكائين القلوي والديكساميثازون والمزيج بينهما مقابل الهواء في كفة الأنبوب الرغامي لتقييم الاعتلال بعد نزع الأنبوب لدى المرضى المدخنين الذين يخضعون لعملية المنظار البطني. دراسة عشوائية مزدوجة التعمية.

إعداد

إسلام الزغارنه

إشراف

د. عائده القيسي

د. نور المصري

الملخص

مقدمه: التنبيب الرغامي هو الطريقة المثلى للحفاظ على وظيفة المجرى التنفسي للمريض خلال عملية التخدير الكامل. إلا أن التنبيب الرغامي اظهر انه يسبب بعض المشاكل بعد العملية كالسعال وحة الصوت وتقرح الحلق.

يعتبر السعال بعد نزع الأنبوب الرغامي في التخدير العام الذي يحدث في غرفة العمليات أو في وحدة ما بعد التخدير مشكله حقيقية. حيث يحدث هذا السعال بنسبة 15 إلى 94 بالمئة مما قد يكون عامل اخطار لحدوث مضاعفات خطيرة كزيادة ضغط الدم واحتشاء عضلة القلب وعدم انتظام في الدورة الدموية وضربات القلب وتضييق القصبات الهوائية ونزف جرح العملية وارتفاع الضغط القحفي و ضغط العين.

التدخين هو احد اكبر عوامل الخطر التي تجعل المريض عرضة لمواجهة صعوبات المجرى التنفسي قبل العملية.

الدراسات السابقة استخدمت عقاري الليدوكائين والديكساميثازون لوضعهما داخل كفة الأنبوب الرغامي حيث ترشح هذه الأدوية إلى العشاء المخاطي للقصبة الهوائية من خلال كفة الأنبوب الرغامي مما يؤدي إلى تقليل التهيج الموضعي والتفاعلات الالتهابية للمجرى التنفسي.

هدف الدراسة: الهدف من الدراسة الحالية هو المقارنة بين تأثير الخليط بين الليدوكائين القلوي 2% والديكساميثازون. والليدوكائين القلوي 2% على حده. والديكساميثازون على حده. والهواء عند نفخ كفة الأنبوب الرغامي بهذه المواد على المضاعفات التنفسية بعد العملية (السعال وتقرح الحلق وبرة الصوت) بعد نزع الأنبوب.

طبيعة المشاركين والطريقة: مئة مريض بالغ من الدرجة الأولى والثانية حسب تصنيف جمعية أطباء التخدير الأمريكية، وحصلوا على درجتى 1 و 2 عند تقييمهم على مقياس مالاباتي، مدخنون ومن كلا الجنسين خضعوا لعمليات المنظار البطني تم إشراكهم في هذه الدراسة التجريبية العشوائية مزدوجة التعمية.

تم تقسيم المشاركين عشوائيا إلى أربعة مجموعات ، كل مجموعه تحتوي على 25 مريض، تم تخصيص المشاركين عشوائيا ليتلقوا أربعة أصناف من المواد داخل كفة الأنبوب الرغامي.

مجموعة الليدوكائين (عدد:25 تلقوا الليدوكائين القلوي 2% داخل كفة الأنبوب الرغامي)، مجموعة خليط الليدوكائين والديكساميثازون (عدد:25 تلقوا الليدوكائين القلوي 2% +الديكساميثازون داخل كفة الأنبوب الرغامي)، مجموعة الديكساميثازون (عدد:25 تلقوا الديكساميثازون داخل كفة الأنبوب الرغامي)، مجموعة الهواء (عدد:25 تلقوا الهواء داخل كفة الأنبوب الرغامي).

أعطيت هذه المواد بحيث يتم الحفاظ على ضغط كفة الأنبوب الرغامي ما بين 20-30 سنتيمتر مائي طوال فترة العملية.

تمت مراقبة وتحليل حدوث السعال وتقرح الحلق وبرة الصوت وضغط الدم ومعدل ضربات القلب ومعدل التنفس وغثيان وتقيؤ ما بعد العملية طوال فترة العملية وعلى فترات متفاوتة بعد انتهاء العملية.

النتائج: كل المرضى اللذين اشتركوا وانطبقت عليهم الشروط أتموا الدراسة حتى النهاية وكانوا مئة مريض وبعد مقارنة المجموعات الأربعة ببعضها كانت النتائج كالتالي:

الوقت من النفس التلقائي الأول وحتى نزع الأنبوب الرغامي

كان الوقت المستغرق منذ التنفس التلقائي الأول وحتى نزع الأنبوب أطول في مجموعة الليدوكائين حيث كان 3.35 ± 10.12 دقيقة وفي مجموعة الخليط بين الليدوكائين والديكساميثازون استغرق الوقت 4.01 ± 9.08 دقيقة. ومقارنة مع مجموعة الديكساميثازون استغرق الوقت 2.66 ± 6 دقيقة ومجموعة الهواء استغرق 2.39 ± 4.88 دقيقة. ($p=0.000$)

ويمكن تفسير هذا الاختلاف في استتالة المدة بين مجموعتي الليدوكائين وخليط الليدوكائين والديكساميثازون ومجموعي الديكساميثازون والهواء بأن الليدوكائين يرشح إلى القصبة الهوائية ويعمل كمخدر موضعي هناك مما يقلل من شعور المريض بوجود الأنبوب الرغامي.

السعال

تشير النتائج إلى اختلاف في حدوث السعال في مرحلة الإفاقة بين مجموعات الاختبار ومجموعة الهواء حيث كان حدوث السعال في مجموعة الهواء بنسبة ((48% (12)). وفي مجموعة الليدوكائين. $p=0.004$ ((12% (3)) وفي مجموعة الديكساميثازون $p=0.000$ ((4% (1)). وفي مجموعة الخليط بين الليدوكائين والديكساميثازون $p=0.000$ ((0% (0)).

وتشير النتائج أيضا إلى وجود اختلاف بالنسبة للسعال في مرحلة الإفاقة بين مجموعة الليدوكائين ((12% (3)) ومجموعة الخليط بين الليدوكائين والديكساميثازون ((0% (0)) حيث كانت نسبة السعال أعلى بشكل واضح في مجموعة الليدوكائين $p=0.037$.

تشير النتائج إلى اختلاف في حدوث السعال في وحدة ما بعد التخدير بين مجموعتي الديكساميثازون وخليط الليدوكائين والديكساميثازون ومجموعة الهواء حيث كان حدوث السعال في مجموعة الهواء بنسبة ((28% (7)). وفي مجموعة الديكساميثازون $p=0.015$ ((4% (1)). وفي

مجموعة الخليط بين الليدوكائيين والديكساميثازون $p=0.001$ (0 (0%)) ليس هناك فرق من ناحيه إحصائية بين مجموعة الليدوكائيين (8% (2)) ومجموعة الهواء (28% (7)) ولن ارتفاع النسبة في مجموعة الهواء واضح $p=0.052$.

تشير النتائج إلى أن نسبة حدوث السعال بعد ساعتين أعلى بشكل ملحوظ في مجموعة الهواء (88% (22)). حيث أن هذه النسبة أعلى من مجموعة الليدوكائيين ($P<0.001$) (40% (10)). وأعلى من مجموعة الديكساميثازون ($P<0.001$) (16% (4)). وكذلك أعلى من مجموعة الخليط بين الليدوكائيين والديكساميثازون ($P<0.001$) (32% (8)). ولا يوجد هنالك اختلاف بين مجموعات التجربة الثلاث /الليدوكائيين/الديكساميثازون/ والخليط بين الليدوكائيين والديكساميثازون.

حدوث السعال بالدرجة المتوسطة بعد ساعتين كان بالنسب التالية. في مجموعة الليدوكائيين (0% (0)) وفي مجموعة الديكساميثازون (0% (0)). وفي مجموعة الخليط بين الليدوكائيين والديكساميثازون (4% (1)). وهذه النسب كانت اقل من مجموعة الهواء بشكل ملحوظ ($p=0.000$). وهذا يشير إلى زيادة ملحوظة في شدة السعال للدرجة المتوسطة في مجموعة الهواء مقارنة بالثلاث مجموعات التجريبية الأخرى.

تشير النتائج إلى أن نسبة حدوث السعال بعد 8 ساعات أعلى بشكل ملحوظ في مجموعة الهواء (84% (21)). حيث أن هذه النسبة أعلى من مجموعة الليدوكائيين ($P<0.001$) (4% (1)). وأعلى من مجموعة الديكساميثازون ($P<0.001$) (4% (1)). وكذلك أعلى من مجموعة الخليط بين الليدوكائيين والديكساميثازون ($P<0.001$) (0% (0)). ولا يوجد هنالك اختلاف بين مجموعات التجربة الثلاث /الليدوكائيين/الديكساميثازون/ والخليط بين الليدوكائيين والديكساميثازون. وهذا يعني أن جميع المجموعات الثلاث أفضل من مجموعة الهواء.

حدوث السعال بالدرجة الطفيفة بعد 8 ساعات كان بالنسب التالية. في مجموعة الليدوكائيين (4% (1)) وفي مجموعة الديكساميثازون (4% (1)). وفي مجموعة الخليط بين الليدوكائيين والديكساميثازون (0% (0)). وهذه النسب كانت اقل من مجموعة الهواء بشكل ملحوظ (72% (18)).

($p=0.000$). وهذا يشير إلى زيادة ملحوظة في شدة السعال للدرجة الطفيفة في مجموعة الهواء مقارنة بالثلاث مجموعات التجريبية الأخرى.

تشير النتائج إلى أن نسبة حدوث السعال بعد 24 ساعة أعلى بشكل ملحوظ في مجموعة الهواء ((12% 3)). حيث أن هذه النسبة أعلى من مجموعة الليدوكائين ($P<0.05$)) (0(0%)). وأعلى من مجموعة الديكساميثازون ($P<0.05$)) (0(0%)). وكذلك أعلى من مجموعة الخليط بين الليدوكائين والديكساميثازون ($P<0.05$) (0(0%)). ولا يوجد هنالك اختلاف بين مجموعات التجربة الثلاث /الليدوكائين/الديكساميثازون/ والخليط بين الليدوكائين والديكساميثازون. وهذا يعني أن جميع المجموعات الثلاث أفضل من مجموعة الهواء.

تقرح الحلق

تشير النتائج إلى أن نسبة حدوث تقرح الحلق بعد ساعتين أعلى بشكل ملحوظ في مجموعة الهواء ((72% 18)). حيث أن هذه النسبة أعلى من مجموعة الليدوكائين ($P<0.05$)) (2(8%)). وأعلى من مجموعة الخليط بين الليدوكائين والديكساميثازون ($P<0.05$) (5(20%)). بينما لم يلاحظ وجود اختلاف بين مجموعة الهواء والديكساميثازون ((56% 14)).

حدث تقرح الحلق بالدرجة المتوسطة بعد ساعتين كان بالنسب التالية. في مجموعة الليدوكائين 0(0%) وفي مجموعة الديكساميثازون 5(20%). وفي مجموعة الخليط بين الليدوكائين والديكساميثازون 0(0%). وهذه النسب كانت أقل من مجموعة الهواء بشكل ملحوظ (56% 14) ($p=0.000$). وهذا يشير إلى زيادة ملحوظة في شدة تقرح الحلق للدرجة المتوسطة في مجموعة الهواء مقارنة بالثلاث مجموعات التجريبية الأخرى.

بالنسبة إلى حدوث تقرح الحلق بعد 8 ساعات لوحظ أنه أعلى في مجموعة الهواء ((68% 17)). حيث أن هذه النسبة أعلى من مجموعة الليدوكائين ($P<0.05$)) (0(0%)). وأعلى من مجموعة الخليط بين الليدوكائين والديكساميثازون ($P<0.05$) (1(4%)). وأعلى من مجموعة الديكساميثازون ($P<0.05$)) (40% 10). وبمقارنة مجموعة الديكساميثازون مع مجموعتي

الليدوكائيين و الخليط بين الليدوكائيين والديكساميثازون نجد أن نسبة تقرح الحلق أعلى بشكل ملحوظ في مجموعة الديكساميثازون. لذلك فإن مجموعتي الليدوكائيين والخليط بين الليدوكائيين والديكساميثازون هما الأفضل ثم مجموعة الديكساميثازون والاسوا هي مجموعة الهواء.

وكذلك اشارت تحليلات النتائج بالنسبة إلى حدوث تقرح الحلق بعد 24 ساعة إلى انه أعلى في مجموعة الهواء ((32% 8)). حيث أن هذه النسبة أعلى من مجموعة الليدوكائيين $(P=0.05)$ وأعلى من مجموعة الخليط بين الليدوكائيين والديكساميثازون $(0(0\%))$ $(P=0.05)$. وأعلى من مجموعة الديكساميثازون $(0(0\%))$ $(P=0.05)$. ولا يوجد هناك اختلاف بين مجموعات التجربة الثلاث /الليدوكائيين/الديكساميثازون/ والخليط بين الليدوكائيين والديكساميثازون. وهذا يعني أن جميع المجموعات الثلاث أفضل من مجموعة الهواء. وهناك زيادة ملحوظة في شدة تقرح الحلق للدرجة الطفيفة في مجموعة الهواء مقارنة بالثلاث مجموعات التجريبية الأخرى $p=0.000$.

بحة الصوت

تشير النتائج إلى أن نسبة بحة الصوت بعد ساعتين أعلى بشكل ملحوظ في مجموعة الهواء ((84% 21)). حيث أن هذه النسبة أعلى من مجموعة الليدوكائيين $(P=0.001)$ $(52% 13)$. وأعلى من مجموعة الديكساميثازون $(P=0.001)$ $(32% 8)$. وكذلك أعلى من مجموعة الخليط بين الليدوكائيين والديكساميثازون $(P=0.001)$ $(36% 9)$. ولا يوجد هناك اختلاف بين مجموعات التجربة الثلاث /الليدوكائيين/الديكساميثازون/ والخليط بين الليدوكائيين والديكساميثازون.

حدوث بحة الصوت بالدرجة الملحوظة من المريض وحده بعد ساعتين كانت بالنسب التالية. في مجموعة الليدوكائيين $(48% 12)$ وفي مجموعة الديكساميثازون $(16% 4)$. وفي مجموعة الخليط بين الليدوكائيين والديكساميثازون $(16% 4)$. وهذه النسب كانت أقل من مجموعة الهواء بشكل ملحوظ $(44% 11)$. وهذا يشير إلى زيادة ملحوظة في شدة بحة الصوت للدرجة الملحوظة من المريض وحده في مجموعة الهواء والليدوكائيين مقارنة بمجموعة الديكساميثازون ومجموعة خليط الليدوكائيين والديكساميثازون.

وكذلك لوحظ أن حدوث بحة الصوت بالدرجة السهل ملاحظتها بعد ساعتين كانت بالنسب التالية. في مجموعة الليدوكائين (4%) وفي مجموعة الديكساميثازون (16%) 4 . وفي مجموعة الخليط بين الليدوكائين والديكساميثازون (20%) 5. وهذه النسب كانت اقل من مجموعة الهواء بشكل ملحوظ (40%) 10. وهذا يشير إلى زيادة ملحوظة في شدة بحة الصوت للدرجة السهل ملاحظتها في مجموعة الهواء مقارنة بالمجموعات الأخرى. ($P=0.05$).

وكانت نسبة حدوث بحة الصوت بعد 8 ساعات في مجموعة الهواء بنسبة ((84% 21) وهذه النسبة أعلى بشكل ملحوظ من مجموعة الليدوكائين ($p = 0.009$) ((24% 6) وكذلك أعلى من مجموعة الخليط بين الليدوكائين والديكساميثازون ($p = 0.009$) ((28% 7). ولا يوجد فرق بين مجموعة الهواء ومجموعة الديكساميثازون ((36% 9). لذلك فإن الأفضلية هنا لمجموعتي الليدوكائين والخليط بين الليدوكائين والديكساميثازون.

تشير التحليلات الإحصائية فيما يتعلق بشدة بحة الصوت بعد 8 ساعات انه يوجد اختلاف واضح بين مجموعة الهواء والثلاث مجموعات الأخرى في شدة الصوت على درجة البحة الملحوظة بسهولة ودرجة البحة الملحوظة من المريض فقط $P=0.033$. وهذا يعني أن الثلاث مجموعات أفضل من الهواء لتقليل شدة بحة الصوت.

تشير النتائج إلى أن نسبة بحة الصوت بعد 24 ساعة أعلى بشكل ملحوظ في مجموعة الهواء ((40% 10). حيث أن هذه النسبة أعلى من مجموعة الليدوكائين ($P=0.001$) ((0% 0). وأعلى من مجموعة الديكساميثازون ($P=0.001$) ((4% 1). وكذلك أعلى من مجموعة الخليط بين الليدوكائين والديكساميثازون ($P=0.001$) ((4% 1). ولا يوجد هنالك اختلاف بين مجموعات التجربة الثلاث /الليدوكائين/الديكساميثازون/ والخليط بين الليدوكائين والديكساميثازون.

وهناك أيضا اختلاف بالنسبة لشدة بحة الصوت من الدرجة الملاحظة من المريض فقط. حيث كانت في مجموعة الليدوكائين (0%). وفي مجموعة الديكساميثازون (0%) وفي مجموعة الخليط بين الليدوكائين والديكساميثازون (4%). بينما كانت هذه النسبة أعلى في مجموعة الهواء (40%)

$p=0.000$. وهذه النتيجة تشير إلى أن جميع مجموعات التجربة أفضل من مجموعة الهواء بالنسبة لشدة بحة الصوت بعد 24 ساعة.

الخلاصة

المزيج بين الليدوكائين القلوي والديكساميثازون داخل كفة الأنبوب الرغامي لديه الافضليه والفائدة في تقليل حدوث السعال في مرحلة الافاقه. الليدوكاين القلوي والخليط بين الليدوكائين القلوي والديكساميثازون متساويين في تقليل حدوث السعال وتقرح الحلق وبحة الصوت في جميع المراحل ابتداء من ساعتين بعد وحدة ما بعد التخدير وحتى 24 ساعة .

الديكساميثازون ليس ذو فائدة في تقليل حدوث تقرح الحلق عند الساعتين و 8 ساعات بعد وحدة ما بعد التخدير وكذلك ليس ذو فائدة في تقليل بحة الصوت عند الثمان ساعات. ولكنه يمتلك نفس التأثير لتقليل حدوث السعال تماما مثل الليدوكائين القلوي والخليط بين الليدوكائين القلوي والديكساميثازون.

بالنسبة لشدة حدوث الأعراض /السعال/ وتقرح الحلق/ وبحة الصوت. فان المجموعات الثلاث /الليدوكائين القلوي/ والديكساميثازون/ والخليط بين الليدوكائين القلوي والديكساميثازون أفضل من الهواء لتقليل شدة الأعراض عند وقت الساعتين بعد وحدة ما بعد التخدير. بالنسبة لشدة حدوث بحة الصوت فان الليدوكائين القلوي هو الأفضل لتقليله.

الليدوكائين القلوي والخليط بين الليدوكائين القلوي والديكساميثازون يعمل على تحسين انسجام القصبة الهوائية للأنبوب الرغامي ويجعل عملية نزع الأنبوب أكثر سهوله.

وبشكل عام نستطيع القول أن الليدوكائين القلوي والخليط بين الليدوكائين القلوي والديكساميثازون داخل كفة الأنبوب الرغامي أفضل من الديكساميثازون والهواء. ولا يوجد فرق بين الليدوكائين القلوي والخليط بين الليدوكائين القلوي والديكساميثازون.

تطبيقات تمرير التخدير: المزيج بين الليدوكاين القلوي والديكساميثازون أو الليدوكاين القلوي لوحده داخل كفة الأنبوب الرغامي يؤدي إلى تأثيرات جيدة لمنع حدوث اعتلالات القصبة الهوائية (السعال وتفرح الحلق وحة الصوت) بعد نزع الأنبوب. بالإضافة إلى جعل عملية نزع الأنبوب أكثر سهوله وقل خطورة.

الكلمات المفتاحية: التخدير. الليدوكاين. الديكساميثازون. السعال. بحة الصوت. تفرح الحلق.

