

An-Najah National University

Faculty of Graduate Studies

**Effects of Dexamethasone, Lidocaine, Dexamethasone
and Lidocaine Together on Patient Undergoing
Laparoscopic Cholecystectomy to Prevent Sore Throat,
Cough and Hoarseness**

By

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a Master Degree in Anesthesia Nursing, Faculty of Graduate Studies,
An-Najah National University, Nablus-Palestine.**

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Dedication

To my dear father, to my mother who planted in me the love of homeland and knowledge- seeking;

To my husband and my children whom I love

To my brothers and sisters

To all my friends and all those who supported me in this effort, I dedicate this work.

Acknowledgement

Now as my thesis has been completed, first, I would like to express my gratitude to Almighty Allah to enabling me to complete this research. I would like to thank everyone who supported the research from the very beginning. I am also thankful to the people who have made the essential information accessible to me. My appreciation especially goes to my supervisors, **Dr. Jamal Qaddumi, Dr. Nooraldein Almasri.**

Finally, I would like to deliver my sincere thanks to my colleagues and friends.

الاقرار

أنا الموقعة أدناه، مقدّمة الرسالة التي تحمل العنوان:

**Effects of Dexamethasone, Lidocaine, Dexamethasone and Lidocaine
Together on Patient Undergoing Laparoscopic Cholecystectomy to
Prevent Sore Throat, Cough and Hoarseness**

أقر بأن ما اشتملت عليه هذه الأطروحة إنما هو نتاج جهدي الخاص، باستثناء ما تمت الإشارة إليه حيثما ورد. وأن هذه الرسالة كاملة، أو أي جزء منها لم يقدم من قبل لنيل أي درجة أو لقب علمي أو بحثي لدى أي مؤسسة تعليمية أو بحثية أخرى.

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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Abstract

The aim of this study aim was to investigate the effects of Dexamethasone, Lidocaine, and their combination on patients undergoing lap cholecystectomy to prevent sore throat, cough and hoarseness. The study was conducted at Rafedia Hospital-Nablus and Jenin Governmental Hospital, on a sample of patients undergoing lap cholecystectomy. The sample includes (60) patients selected randomly from the study population. The study depends on the prospective study design, and the tool was the observation on the same operation day 3-24 hours.

The results showed that the group which took the mix of Dexamethasone and Lidocaine showed reduced incidence of sore throat, cough and hoarseness in patients undergoing laparoscopic cholecystectomy. This group showed the best effects followed by the group that took dexamethasone alone which showed more protective effects than the other two groups, then the group that took lidocaine alone and finally the group that took normal saline.

It was found that there were no statistically significant differences at the level of significance ($\alpha \geq 0.05$) in the effects of dexamethasone and lidocaine on patients undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness due to variables: (age, gender, and weight). But there were differences attributed to duration of operation. It was found that the more the time was longer, the more the patient was exposed to hoarseness after the operation.

Upon the study results, the researcher recommended using the combination of dexamethasone and lidocaine to prevent sore throat, cough and hoarseness in patients undergoing laparoscopic cholecystectomy which was more effective than lidocaine alone and normal saline. Furthermore, other studies are needed with different doses of both dexamethasone and lidocaine to support the results of our study.

Chapter One

Introduction & Background

1.1 Introduction

Postoperative sore throat, post-extubation coughing, and hoarseness are common complications after general anesthesia using endotracheal tubes. The reported incidence varies from 30% to 81%. These laryngopharyngeal complications contribute to postoperative morbidity and reduce patient satisfaction (Cho & et al, 2016).

According to (Tanaka & et al, 2009) there are various methods such as licorice gargle, inhaled fluticasone propionate, aspirin and benzydamine hydrochloride gargles, lidocaine spray, intracuff alkalinized lidocaine, magnesium lozenge, stellate ganglion blockade, dexamethasone, and lidocaine injection have been introduced to minimize the incidence and severity of these complications. Despite their effectiveness in alleviating the postoperative airway symptoms, many of these methods have limited applications because of their limited availability, requirement for patient cooperation, and patient inconvenience (Bagchi & et al., 2012).

Various methods are commonly used to prevent or reduce the incidence of post extubation reactions like using low pressure cuff endotracheal tubes, smaller-sized endotracheal tube, steroid-coated Endotracheal Tubes (EET), applying topical lignocaine and inhalation of steroids. In addition to the use of both lignocaine and lignocaine with

dexamethasone as intracuff fluid had similar effect on sore throat, hoarseness of voice and laryngospasm. Where the results of (Park & et al., 2008) study pointed out that the prophylactic use of 0.2 mg/kg of dexamethasone significantly decreased the incidence and severity of sore throat and hoarseness, 1 and 24 hours following tracheal extubation of a double-lumen endobronchial tube. However, administration of intravenous dexamethasone and lidocaine is simple, effective, easily available, and practicable in the operating room. Prophylactic dexamethasone injection prior to anesthesia induction reduces the incidence and severity of postoperative sore throat and hoarseness. In addition, intravenous lidocaine prior to intubation or at the end of surgery reduces the incidence of postoperative sore throat and cough.

Dexamethasone is a potent corticosteroid with analgesic, anti-inflammatory, and antiemetic effects. Recent studies indicated that dexamethasone may be an effective method for the prevention of postoperative sore throat. However, (Zhao & et al., 2014) reported that the prophylactic intravenous dexamethasone reduces the incidence of postoperative sore throat at 1 hour postextubation by 30%, with the efficacy being 60%, whereas (Ruangsri et al, 2012) reported that the intravenous dexamethasone had no significant effect against postoperative sore throat after endotrachea intubation. Therefore, the preventive effect of dexamethasone has not been clearly defined.

Furthermore the study of (Babu & et al., 2018) concluded the use of dexamethasone with lidocaine for filling, the ETT cuff to reduce post-extubation reactions was more effective than lidocaine alone. Therefore, the drug combination can be considered in clinical practice to reduce cough reflex in general anaesthesia and to improve tolerance to endotracheal tube in mechanically-ventilated patients in critical care units. A reduced cough reflex can be extremely useful in patients with raised intracranial and intraocular pressure as well as in pulmonary hyperreactivity cases

As mentioned in (Cho & et al, 2016) study, the efficacy of intravenous dexamethasone and lidocaine in minimizing the incidence and severity of postoperative airway symptoms is well-established. However, no study has compared the effects of dexamethasone plus lidocaine combination therapy with the effects of prophylactic dexamethasone alone.

Considering the multifactorial etiology of postoperative sore throat, the researchers hypothesized that combined dexamethasone and lidocaine would be more effective than dexamethasone alone in reducing postoperative throat problems.

In this study the researcher investigates the effects of dexamethasone and lidocaine on patient undergoing lap cholecystectomy to prevent sore throat, cough and hoarseness. The study is conducted at Rafedia Hospital-Nablus and Jenin Governmental Hospital, on a sample of patients of undergoing lap cholecystectomy.

1.2 Background

1.2.1. Dexamethasone

Entringer (2019) defined Dexamethasone as a corticosteroid, is similar to a natural hormone produced by adrenal glands. It is often used to replace chemical when the body does not make enough of it. It relieves inflammation (swelling, heat, redness, and pain) and is used to treat certain forms of arthritis; skin, blood, kidney, eye, thyroid, and intestinal disorders (e.g., colitis); severe allergies; and asthma. Dexamethasone is also used to treat certain types of cancer.

(Gebhart & Schmidt, 2013) developed the following definition for Dexamethasone, it is the long- acting parenteral or orally administrated steroid dexamethasone prevents the increased expression of COX-2, which is stimulated by bacterial lipopolysaccharide, cytokines, or growth factors.

Bronchial hyper-reactivity may be modulated by dexamethasone. In mice, dexamethasone inhibits cytokines involved in airway inflammation, suppresses airway reactivity in response to antigens and mucus accumulation by altering metabolism within the airway cell. This resulted in decreased airway hyper-reactivity, decreased mucus production and decreased eosinophilia. (Singer & et al , 2002).

1.2.2. Lidocaine

Lignocaine, commonly referred to as “Lidocaine”, is an amide local anesthetic agent and a Class 1b antiarrhythmic. Lignocaine is an essential drug on World Health Organization essential drug list, considered efficacious, safe and cost-effective for any health-care system. Despite its ubiquitous use in medicine and surgery, there are few detailed reviews of its pharmacokinetics and pharmacodynamics (Weinberg & et al., 2015).

Lidocaine has potential utility as a potent anti-inflammatory agent, although to date well-designed studies are lacking to substantiate its use in most clinical settings. A variety of lidocaine 's actions on inflammatory cells have been described. Accumulating data suggests that lidocaine 's powerful anti-inflammatory properties may be superior in many ways to nonsteroidal anti-inflammatory drugs and steroids, the traditional anti-inflammatory agents.(Cassuto & et al, 2006)

Lidocaine is not approved for this specific indication and potential risks of toxicity, particularly in unmonitored patients, may negate its beneficial antinflammatory effects. Unfortunately, the specific molecular mechanisms involved in the migration of polymorphonuclear granulocytes and free radicals are not well known. Sodium channel blockade can be however excluded. Firstly, because in vivo local anesthetic solutions are active at lower concentrations than those required for blockade of the sodium channel, and secondly because sodium channels in vitro are often

not even detectable in the cell lines that are being investigated.((Hollmann & Durieux, 2000)

1.2.3. Cough

Cough is usually initiated as a series of respiratory maneuvers that lead to a characteristic cough sound. It usually starts as a deep inspiration, followed by a strong expiration against a closed glottis, which then opens with an expulsive flow of air. Followed by a restorative inspiration: these are the inspiratory, compressive, expulsive, and recovery phases of cough (Mason & et al., 2010). Postoperative cough can be caused by laryngitis or laryngeal trauma related to orotracheal intubation, chronic and intractable coughs seriously affect postoperative rehabilitation and lower the quality of patients' life (Zhao & et al., 2014).

1.2.4. Hoarseness

Hoarseness is one complication of tracheal intubation. The causes include laryngeal edema, laryngeal nerve paralysis. Vocal cord granuloma, vocal cord polyp, vocal cord adhesion, and laryngotracheal membranous stricture. Laryngofibrosis also is a rare but severe sequel of tracheal intubation in which symptoms occur 45-60 days after extubation (Shimokojin & et al., 1998).

1.2.5. Cholecystectomy

Cholecystectomy is defined by (the American College of Surgeons, 2013) as a surgical removal of the gallbladder due to gallstones causing pain or infection.

Laparoscopic Cholecystectomy commonly referred to as a lapchole, involves the removal of the gallbladder through a laparoscopic approach. The gallbladder normally stores bile produced in the liver until it is needed for digestion. Unfortunately, the gallbladder often forms gallstones (Saia & et al., 2013). A laparoscope is a small, thin tube that is put into body through a tiny cut made just below navel. Surgeon can then see the gallbladder on a television screen and do the surgery with tools inserted in three other small cuts made in the right upper part of abdomen. Gallbladder is then taken out through one of the incisions (Tanaka & et al., 2015).

1.3 Problem Statement

We note that there are complications related to sore throat, hoarseness, and cough in most operations, and because we do not want to resort to any of the dangerous drugs that need the approval of specialized doctors, and because of the scarcity of studies that touched on this subject, especially local and Arab studies, so the researcher decided to do this study to examine the effect of two safe drugs that do not require signature or additional tests or health control. These two drugs work to expand the bronchi, and reduce irritation and swelling.

1.4 Significance of the study

There are several international studies on the effects of Dexamethasone and Lidocaine on patient to prevent sore throat, cough and hoarseness. However, in Palestinian hospitals the researcher did not find any study on this subject, which should be given some importance. The body of research is still growing in Palestine, new studies are recommended to be introduced in general, and new studies are still needed for the quality of care improvement at Palestinian Hospitals.

1.5 Aims of the study

The aim of this study is to assess the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness.

1.6 Specific aims

- 1- To identify the effect of adding (8 mg) of dexamethasone and (1.5mg/kg) of lidocaine to patients undergoing laparoscopic cholecystectomy in preventing sore throat, cough and hoarseness 3 and 24 h after extubation.
- 2- To assess the best medicine for the case.

1.7 Hypothesis

- There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to age.
- There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to gender.
- There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to weight.
- There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to duration of the operation.
- There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to group.

Chapter Two

Literature Review & Previous Studies

This chapter is divided into two sections: the first section deals with the literature review and the second section deals with previous studies related to the subject.

2.1 Postoperative sore throat

2.1.1 Definition of Postoperative sore throat

Postoperative sore throat is a widespread complication of anesthesia. It can cause a disturbance after surgery and can postpone and impede the patient's revert to ordinary routine activities. Several elements can play a role in the occurrence of sore throat after surgery. The postoperative sore throat occurrence is found to vary depending on the way the airway is administered (Ahmed, 2007).

In another definition, a sore throat is a prevalent trouble after surgery after the utilization of endotracheal intubation while general anesthesia. The occurrence of sore throat ranges differs from 14.4% to 50% after endotracheal intubation and from 5.8% to 34% after the insertion of the laryngeal mask. Various elements involve the size of the tracheal tube, kind of tube, cuff contours, tube cuff pressure, numerous efforts for endotracheal intubation, period of intubation, and surgery type (e.g. throat surgery) (Edomwonyi & et al., 2006).

2.1.2 Causes of postoperative sore throat

The causes of sore throat include mucosal corrosion occur by the cuff of the endotracheal tube, harm from intubation, and mucosal drought. Mucosal corrosion may be occurred by curvature or coughing of the patient, or rubbing between the tracheal mucosa and the endotracheal tube in general anaesthesia. Patients will recognize only postoperative complications, while medical crew may focus on averting difficulties during surgery. These complications can impact the patients' satisfaction with therapy. The spread of postoperative sore throat differs with the diameter and the kind of endotracheal tube utilized, which patients do not know about. The cuff pressure may also impact the spread and intensity of postoperative sore throat (Tanaka & et al., 2015).

The strong incentivize of laryngoscopy or moving the tube may stimulate sensory C fibers and produce subaltern neuroplasticity that is related to postoperative sore throat and cough (Petri, 2013).

Other elements that may cause postoperative sore throat include: annoying impact of unhumidified gases, utilization of throat pack. Earlier, female gender, endotracheal tube size, degree of difficulty in intubation and period of surgery were considered as the risk factors for postoperative sore throat (Kamble & Gajbhare, 2015).

2.1.3 Prevention of postoperative sore throat

Several procedures should be followed to assist decreasing the peril of POST, they comprise averting a preoperative antisialagogue if possible, averting trauma during laryngoscopy and intubation, utilizing a suitable ET tube size, lubricating the cuff of the ET tube with a jelly dissolves in water, utilizing the suitable ET tube cuff pressure and observing the cuff pressure, averting the utilization of a nasogastric or orogastric tube if possible, cautiously suctioning the oropharynx before extubation, and taking procedures to decrease the risk of the patient coughing or bucking before extubation. The utilization of a laryngeal mask airway instead of ET intubation may reduce the peril of POST. Moreover, pharmacologic interventions may reduce the occurrence of POST, including the use of local anesthetics and corticosteroids to the cuff of the ET tube (Kalil & et al., 2014).

2.2 Effects of Dexamethasone and Lidocaine to Prevent Sore Throat, Cough and Hoarseness

Postoperative sore throat, post-extubation coughing, and hoarseness are common complications after general anesthesia using endotracheal tubes. These laryngopharyngeal complications contribute to postoperative morbidity and reduce patient satisfaction. Various methods such as licorice gargle, inhaled fluticasone propionate, aspirin and benzydamine hydrochloride gargles, lidocaine spray, intracuff alkalinized lidocaine, magnesium lozenge, stellate ganglion blockade, dexamethasone, and

lidocaine injection have been introduced to minimize the incidence and severity of these complications (Lee & et al., 2017).

Despite their effectiveness in alleviating the postoperative airway symptoms, many of these methods have limited applications because of their limited availability, requirement for patient cooperation, and patient inconvenience. However, administration of intravenous dexamethasone and lidocaine is simple, effective, easily available, and practicable in the operating room (Ruangsri et al, 2012).

Prophylactic dexamethasone injection prior to anesthesia induction reduces the incidence and severity of postoperative sore throat and hoarseness. In addition, intravenous lidocaine prior to intubation or at the end of surgery reduces the incidence of postoperative sore throat and cough (Thomas & Beevi, 2007). As mentioned above, the efficacy of intravenous dexamethasone and lidocaine in minimizing the incidence and severity of postoperative airway symptoms is well-established. However, no study has compared the effects of dexamethasone plus lidocaine. This study hypothesized that combined dexamethasone and lidocaine would be more effective in preventing sore throat, cough and hoarseness after Laparoscopic Cholecystectomy (Cho & et al., 2016).

2.3 Previous Studies

In (2019) Upadhyay & et al. carried out a study in India entitled "Controlled comparison between betamethasone gel and lidocaine jelly applied over endotracheal tube in reducing postoperative sore throat, cough, and hoarseness of voice". The aim of the study was to evaluate and compare the efficiency of 0.05% betamethasone gel in reducing the incidence of the commonly occurring complications following endotracheal intubation and to compare its use with lignocaine jelly and control group. A prospective, randomized, hospital based experimental study including 180 patients (American Society of Anesthesiologists physical status I and II; age group 18–45 years; and scheduled for elective surgery requiring general endotracheal anesthesia were randomly allocated into three groups – Group I, II, and C). Incidence and severity of POST, C, and H were compared using betamethasone gel, lignocaine jelly, or when nothing was applied. Incidence of coughing or bucking and hemodynamic variability was also compared between the groups. Quantitative variables in various groups were expressed as mean $\pm$ standard deviation and compared using ANOVA and/or unpaired t test between the groups and paired T test within each group. Qualitative variables were expressed as frequencies/percentages and compared using Chi square test. The study findings revealed that the incidence and severity of POST, C, H, and coughing/bucking was maximum in Group C, followed by Group II and least in Group I ($P < 0.05$). In conclusion the study showed that Betamethasone gel applied over tracheal tube effectively reduces the incidence and severity of

POST, C, and H as compared to lignocaine jelly or when nothing was applied, lidocaine is widely used in clinical practice to lubricate the tracheal tube. The study also showed that there were no statistically significant differences attributed to the variables (gender, age, and weight).

Another study carried out in India in (2019) by (Subedi & et al.) to recognize the effect of intravenous lidocaine, dexamethasone, and their combination on postoperative sore throat. This study followed the prospective, double-blind, randomized controlled study enrolled 180 patients requiring general anesthesia with endotracheal intubation for >90 minutes. They received 1 of the 4 intravenous agents just before induction of anesthesia: lidocaine (1.5 mg/kg-) in group L, dexamethasone (8 mg) in group D, lidocaine (1.5 mg/kg) with dexamethasone (8 mg) in group DL, and placebo as normal saline in group NS. Standard anesthesia protocol was followed. Incidence and severity of a sore throat, cough, and hoarseness of voice were assessed up to 24 hours postoperatively. The primary outcome was the incidence of POST, and the main effects of dexamethasone and lidocaine were the primary interest. The study results revealed that a data of 45 patients in D, 44 in L, 44 in DL, and 43 in NS groups were analyzed. The incidence of a sore throat was 36%, 43%, 25%, and 56% in group D, L, DL, and NS, respectively ($P = .02$). Dexamethasone with or without lidocaine reduced the incidence of the POST (odds ratio, 0.44; 95% confidence interval, 0.24–0.82; $P < .01$). However, lidocaine was not effective in reducing POST (odds ratio, 0.62; 95% confidence interval, 0.33–1.14; $P = .12$). No difference was observed

in the severity of a sore throat, incidence and severity of a cough, and hoarseness among the groups. The study concluded that Dexamethasone, with or without lidocaine, was effective in reducing the incidence of POST in patients requiring prolonged tracheal intubation. The study also concluded that there were no statistically significant differences attributed to the variables of (gender, age, and BMI), but there were statistically significant differences attributed to the duration of surgery when the duration of the operation is more than (1:30) and duration of intubation when the duration of intubation is more than (1) hour.

Chandra & et al. (2018) prepared a study in Indonesia; this study objective was to compare the incidence of sore throat post laryngeal mask airway insertion "LMA" insertion after 1.5 mg/kg of lidocaine inhalation and 10 mg of intravenous dexamethasone. This was a single-blinded randomized clinical trial, the sample consisted of 128 patients who underwent ophthalmic surgery under general anesthesia with LMA insertion, all participants were randomly divided into two groups: lidocaine inhalation group, which would receive lidocaine inhalation 2% 1.5 mg/kg (additional NaCl 0.9% until total 6 mL volume) and intravenous 2 mL NaCl 0.9%, and dexamethasone group, which would receive NaCl 0.9% inhalation (6 mL volume) and dexamethasone 10mg intravenously 10 minutes before LMA insertion. POST incidence and pain severity assessment were done 2 hours postoperatively. The study findings showed that there were 10.9% of subjects in the lidocaine inhalation group and 9.4% subjects in the dexamethasone group who suffer from POST

postoperatively ($P > 0.05$). The median of POST pain in the lidocaine inhalation group was 0 (0 - 1), whereas in the dexamethasone group it was 0 (0 - 3). Furthermore the study concluded that lidocaine inhalation 1.5 mg/kg was proportional to intravenous dexamethasone 10 mg in reducing the incidence and severity of POST after LMA insertion. There were significant differences in the lidocaine inhalation effect could extend and still equal to dexamethasone postoperatively. This might be due to the shorter duration of surgery in this study, which were all less than 105minutes, and still in lidocaine half-life time i.e. 150 minutes.

Furthermore, in (2017) a study about the effects of topical dexamethasone in postoperative sore throat conducted by (Lee & et al.) in Korea. The study examined the effects of dexamethasone gargle and endotracheal tube cuff soaking on the incidence and severity of POST. (90) patients undergoing laparoscopic cholecystectomy were randomly allocated into three groups: 0.9% normal saline gargling and tube soaking (group C), 0.05% dexamethasone solution gargling and 0.9% normal saline tube soaking (group G), 0.9% normal saline gargling and 0.05% dexamethasone tube soaking (group S). The incidence and severity of POST were then assessed and recorded at 24 hours after surgery. The study results showed that the total incidence of POST was significantly different among the groups ($P < 0.05$), and group S exhibited a significantly lower incidence of POST than group C ($P < 0.0167$). In addition, the POST intensity of group G and group S was less severe than those of group C (Both $P < 0.0167$). The study concluded that among patients undergoing laparoscopic

cholecystectomy, those who gargled with 0.05% dexamethasone solution exhibited lower severity of POST than the control group, and those whose endotracheal tube cuff was soaked in the dexamethasone solution before intubation exhibited significantly lower incidence and severity of POST than the control group. The study results also revealed that there were no statistically significant differences attributed to the variables of (gender, age, BMI, weight, height and operation time)

Cho & et al. (2016) study, the purpose of this study was to explore whether combined dexamethasone and lidocaine are superior to dexamethasone alone in reducing postoperative sore throat, cough, and hoarseness for 24 h after tracheal extubation. A sample of (70) female patients undergoing breast mass excision were randomized in a prospective, double-blinded manner into two groups: Group DL received intravenous dexamethasone (8 mg) plus lidocaine (1.5 mg/kg) 5 min before induction of anesthesia, and lidocaine was injected once more at the end of surgery. Group D received dexamethasone (8 mg) plus normal saline instead of lidocaine in the same manner as Group DL. The incidence and severity of postoperative sore throat, cough, and hoarseness was assessed after 1 and 24 h extubation. The study results showed that the incidence of sore throat for 24 h after tracheal extubation was significantly lower in Group DL (*received intravenous dexamethasone (8 mg) plus lidocaine (1.5 mg/kg)*) than in Group D (62.9% vs. 85.7%, respectively; $P = 0.029$). The severity of sore throat and hoarseness for 24 h after extubation was lower in Group DL than in Group D ($P < 0.05$). The incidence and severity of

cough did not differ between the two groups for 24 h after extubation. The study concluded that Lidocaine combined with dexamethasone is more effectively reduces the incidence and severity of sore throat and severity of hoarseness for 24 h after extubation in patients who have undergone breast mass excision surgery. The study results also stated that there were no statistically significant differences attributed to the study variables (gender, age, BMI, weight, duration of surgery and duration of intubation)

Furthermore, Ruangsin et al. (2012) conducted a study in Thailand to evaluate the effectiveness of two different doses of prophylactic dexamethasone intravenous administration in reducing the prevalence of postoperative sore throat following general endotracheal anesthesia. The study sample included (105 cases) of different procedures of elective surgery scheduled to have general anesthesia performed with endotracheal intubations were included. The participants were divided into three pre-operative intravenous substance/drug administrations, group I (35 cases) with normal saline 2 ml, group II (35 cases) with dexamethasone 4 mg, and group III (35 cases) with dexamethasone 8 mg, respectively. The prevalence of sore throat and its severity was assessed, using visual analogue scale (VAS), scores of 0 to 10; 0 = no pain, and 10= most severe pain. The study results stated that among three groups, the duration of surgery, and intubation-induced trauma had no statistical significance. The prevalence of sore throat at 1-hour/ 24-hour postoperative was 48.6/ 48.6%, 54.3/ 28.6%, and 54.3/42.9% in group I, II, and III respectively, and without statistical significance. The study concluded that the intravenous

dexamethasone had no significant effectiveness against postoperative sore throat after endotracheal intubation.

In India in (2007) (Thomas & Beevi) prepared a study about the Dexamethasone reduces the severity of postoperative sore throat. The study aimed to evaluate the efficacy of intravenously administered dexamethasone in reducing the incidence and severity of postoperative sore throat in patients receiving general anesthesia with endotracheal intubation. A randomized, double-blind and placebo-controlled study were followed, 120 patients receiving general anesthesia with endotracheal intubation were randomly assigned to two groups. Group 1 (control) patients received normal saline 2 mL iv and group 2 (D) patients received dexamethasone 8 mg iv. After surgery, visual analogue scale (VAS) scores at rest and with effort (swallowing movement) for postoperative sore throat were recorded by a blinded observer. The study outcomes revealed that the overall incidence of postoperative sore throat during the first 24 hr following surgery was lower in dexamethasone group (D) "who received dexamethasone 8 mg iv" compared to the control group (C). (11) (20%) patients in the dexamethasone group had postoperative sore throat, compared to 31 (56.3%) patients in the control group ($P < 0.01$). Postoperatively at one hour, three hours, six hours, 12 hr and 24 hr, the VAS scores for postoperative sore throat at rest and during effort were lower in the dexamethasone group (D) compared to the control group ($P < 0.01$) at corresponding time intervals. In conclusion the researchers indicated that preoperative administration of dexamethasone 8 mg iv

reduces the incidence and severity of postoperative sore throat in patients receiving general anesthesia with endotracheal intubation.

Whereas, (Soltani & Aghadavoudi, 2002) prepared a study in Iran about the effect of different lidocaine application methods on postoperative cough and sore throat. The study objective was to evaluate the efficacy of various ways of lidocaine application in reducing postoperative cough and sore throat. The researchers used the double-blind, randomized method. The study sample consisted of (204) ASA physical status I and II patients scheduled for cataract surgery with general anesthesia in the University of Affiliated Hospital. Patients were randomized to six groups (G1, G2, G3, G4, G5, and G6), according to lidocaine application method. Before endotracheal intubation, in the G1 and G2 groups, 10% lidocaine was sprayed on the distal end of the endotracheal tubes (ETTs; G1) and laryngopharyngeal structures (G2). In the G3 group, the distal ends of the ETTs were lubricated with 2% lidocaine jelly. Intravenous (IV) lidocaine was administered to the G4 group at the conclusion of surgery. Intracuff lidocaine was used in the G5 group; in the G6 group, the terminal end of the ETTs were lubricated with normal saline. The measurements at the end of surgery and after extubation, patients were observed to record the number of coughs. At 1 hour and at 24 hours following extubation, sore throat was evaluated. The study outcomes showed that in the recovery room, 64.4% of the patients experienced cough, with greatest frequency in the G3, G6, and G2 groups, and the least in the G5 and G4 groups. The frequency of sore throat was significantly different among the six groups at

1 hour and at 24 hours, with greater frequency in the G3, G2, and G6 groups. The study also concluded that using lidocaine to inflate the endotracheal tubes (ETT) cuff or IV lidocaine at the end of surgery decreases the frequency of postoperative cough and sore throat and would provide better outcome for patients and the physician.

Chapter Three

Methodology

This section explains the main decisions taken including the research design, population, and sample and analysis. The section also shows the various aspects of data collection methods and the instruments used to gather primary data in order to provide valid and reliable study.

3.1 Design

The design depends on the prospective study design. The prospective study watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor (s). The outcome of interest should be common; otherwise, the number of outcomes observed will be too small to be statistically meaningful (indistinguishable from those that may have arisen by chance). All efforts should be made to avoid sources of bias such as the loss of individuals to follow up during the study. Prospective studies usually have fewer potential sources of bias and confounding than retrospective studies. (<https://www.statsdirect.com/help/basics/prospective.htm>)

I chose Prospective design because I want to give Dexa and Lido to the patient five minutes before the intubation is installed to prevent symptoms, so it must be monitored after the operation for 3 hours to 24 hours, and I did not choose the period shorter than 3 hours because the patient is not

fully conscious to understand the symptoms and I chose the patients randomly, I did not choose any particular patient to take the specific drug. I chose them by the method of lottery. The names of the groups were written on four sheets of paper, and each patient chose a piece of paper for the doctor and I to give him his share in the lottery of the drugs. The patient and the nurse in the surgical wards were not aware of the share of the medicine in the sense of double blinded

3.2 Procedures

After I obtained the supervisor's approval, I waited for the IRB when I obtained it , I took the approval of MOH , then I started working in the operating rooms in Jenin and Rafedia hospitals. The sample was divided into four groups, group one took (8 mg Dexamethasone) group two took (1.5 mg /kg Lidocaine), and group three took (8 mg Dexamethasone+1.5 mg /kg Lidocaine together), and group four took (10cc of normal saline).

The doctor gave the drugs to the patients before intubation (prophylactic), and then the nurse monitored the patients for 24 hours after the operation.

The dexta is 2ml, and we added 8 ml of normal saline to become 10 ml, and the lido is approximately 5 ml to 7 ml, and we add to it, to become 10 ml

Consequent to patient's landing at the operating station:

1- IV cannula 16 FG was processed.

2- Ringer's lactate solution (20 ml / kg) was given .

- 3- Standard monitoring of ECG, NIBP and pulse oximeter settled.
- 4- Baseline MAP , HR , SPO2 accessed using standard monitors every five minutes.
- 5- The participants were oxygenated for 3 minutes.
- 6- Anesthesia was induced by:
 - Fentanyl 2 mcg / kg IV.
 - Propofol 2 mg / kg .
 - Atracurium 0.4-0.5 mg/kg.
- 7- Adherent direct laryngoscopy by (a 7-8 ETT tube size) and endotracheal intubation . I inflate the ETT tube about 4-5 cc air ranged from (25-30 cmH₂O) ensuring that no leakage exists every (7 minutes)
- 8- Anesthesia was maintained by using isoflurane 0.5-1.5% well-organized with air and oxygen.
- 9- Atracurium 0.08-0.1 mg/kg was repeated as necessary.
- 10- IV fentanyl was given intermittently when necessary.
- 11- Gently suction to the upper airway and mouth .
- 12- Reversal of muscle relaxation was completed after (1:20 hour to 1:40 hour)

** neostigmine 0.05 mg / kg.

** atropine 0.02 mg / kg.

Study tools:

The nurse asked the patients what of these symptoms occurred with him or her from 6 to 24 hours (sore throat, cough ,hoarseness)

3.3 Setting

The setting of data collection was Rafedia Hospital located in Nablus–West Bank and Jenin Governmental Hospital located in Jenin – West Bank.

3.4 Study Population

The research community consisted of all the patients of cholecystectomy at Rafedia Hospital and Jenin Governmental Hospital, about (220)patients in the period between June and August / 2020 according to the information of the researcher.

3.5 Sample Size

The sample included (60) patients selected randomly from the study population.

According to the previous studies, the sample size was nearly 40-50 patients, I took (60) patients for increased validity and credibility.

3.6 Inclusion & exclusion Criteria

3.6.1 Inclusion Criteria

All cholecystectomy patients, at Rafedia Hospital who were willing to participate in the study, from 18 years to 70 years of age, not having any other uncontrolled diseases, no exceptions.

ASA 1: A normal healthy patient:-

3.6.2 Exclusion Criteria

Any patient not willing to participate in the study, under 18 years of age, more than 70 years of age, patients who have more than one attempt of intubation , patients who have uncontrolled diseases, smokers, exceptions, surgical history on ipsilateral lung, current treatment with anxiolytics, preexisting sore throat , hoarseness, and cough.

ASA 2: A patient with a mild systemic disease. Example: Patient with no functional limitations and a well-controlled disease (e.g., treated hypertension, obesity with BMI under 35, frequent social drinker or is a cigarette smoker).

ASA 3: A patient with severe systemic disease.

ASA4 : A patient with severe systemic disease that is a constant threat to life.

3.7 Study period

Jan. 2020-Jan.2021.

3.8 Study Measures (Variables)

3.8.1 Independent variable

1- Age

2- Gender

3- Weight

4- Duration of operation

3.8.2 Dependent variable

Effects of Dexamethasone and Lidocaine on patient undergoing Laparoscopic Cholecystectomy to prevent sore throat, cough and hoarseness.

3.9 Study Tool

The observation on the same operation day 3-24 hours.

The sample was divided into four groups, group one took (8 mg Dexamethasone) group two took (1.5 mg /kg Lidocaine), and group three took (8 mg Dexamethasone+1.5 mg /kg Lidocaine together), and group four took (10cc of normal saline). The doctor gave the drugs to the patients

before intubation (prophylactic), and then the nurse monitored the patients for 24 hours after the operation.

3.10 Data Analysis Plan

SPSS Version 20 was used for data analysis. Descriptive statistics (frequency, percentage) were used. T test and One Anova test are used to analyze the results. A $p < 0.05$ is considered significant.

3.11 Ethical Considerations

The study presented in this dissertation was conducted in accordance with the Helsinki Declaration and was approved by the Institutional Committee (IRB) and the Palestinian Ministry of Health, confidentiality is guaranteed. For that reason, the ethical dilemma is considered to be small. The results were presented in a way that ensured that it is not possible to identify any of the individuals. The study protocol concentrated on the patient's health and well-being.

Chapter Four

Results

The sample size was (60) participants with 100% respondent rate; and they were selected using randomized sampling. Data was collected through a patient continuation file.

This chapter presents the findings of the current study as follows:

- Participant profile.
- Research questions.
- Testing hypothesis.

4.1 Participant Profile

Table (1) below contains the data of the participating sample in terms of age, gender, weight, duration of operation and group respectively.

Table (1): Descriptive Statistics of Demographic Variables (N=60)

Demographic Variables		Frequency	Percentage
Age	less than 25	5	8.3
	25- 40	22	36.7
	more than 40	33	55.0
	Total	60	100.0
Gender	male	25	41.7
	female	35	58.3
	Total	60	100.0
Weight	<60	5	8.3
	60- 75	30	50.0
	>75	25	41.7
	Total	60	100.0
Duration of operation	<1	8	13.3
	1- 1.5	48	80.0
	>1.5	4	6.7
	Total	60	100.0

Group	mix	15	25.0
	lido	15	25.0
	dexa	15	25.0
	normal s	15	25.0
	Total	60	100.0

As shown in the above table according to age, the sample included (8.3%) less than 25 years (36.7%) 25-40 years, and (55.0%) more than 40 years. The percentages are shown in the following figure:

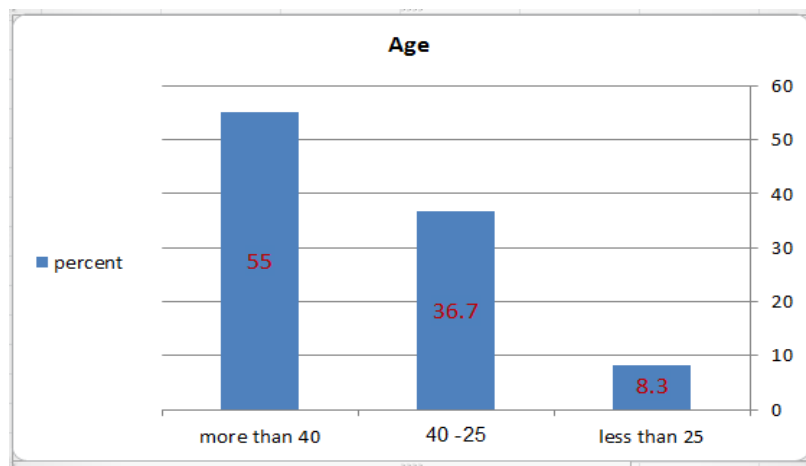


Figure (1): Sample characteristics according to age.

According to gender the sample included (41.7%) males and (58.3%) females. The percentages are shown in the following figure:

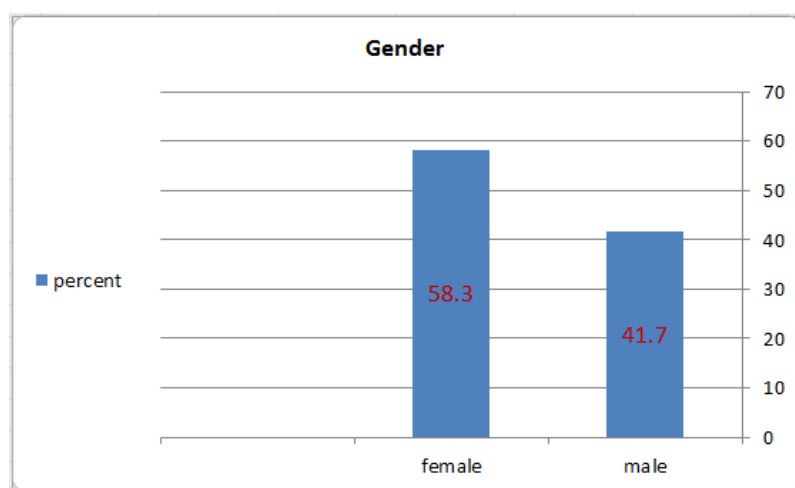


Figure (2): Sample characteristics according to gender.

According to weight, the sample included (8.3%) less than 60kg (50%) 60-75 kg, and (41.7%) more than 75 kg. The percentages are shown in the following figure:

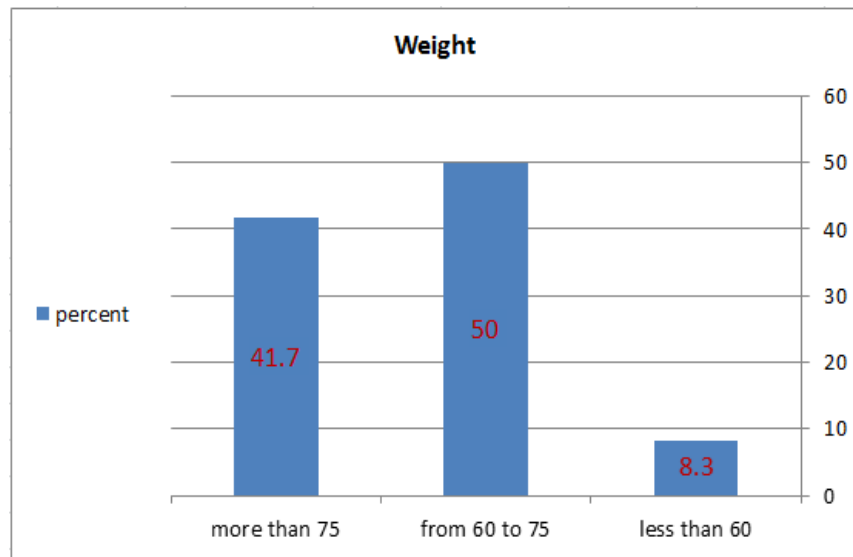


Figure (3): Sample characteristics according to weight.

According to duration of operation, the sample included (13.3%) less than 1:00, (80%) 1:00-1:30 and (6.7%) more than 1:30. The percentages are shown in the following figure:

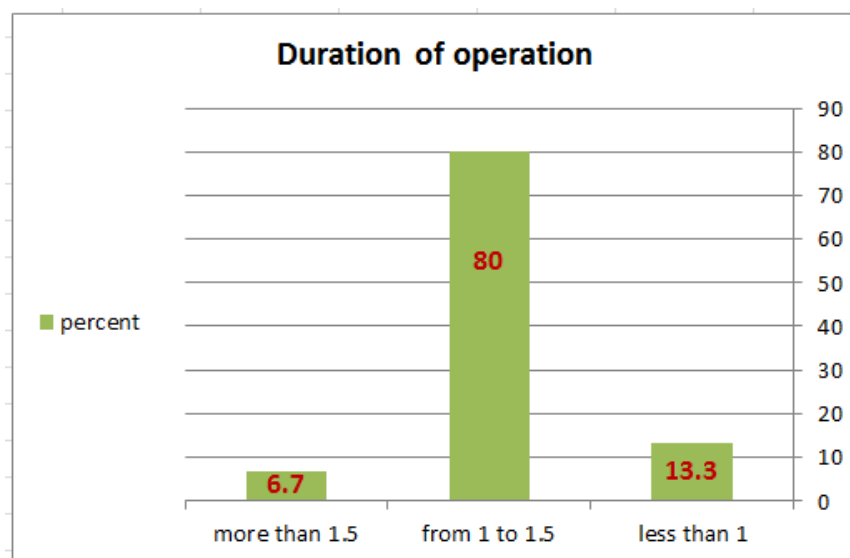


Figure (4): Sample characteristics according to duration.

And according to type or group of drug, the sample included (25%) who were given a mixture of (lido+dexa), (25%) were given lido only, (25%) were given dexa only, and (25%) were given normal saline. The percentages are shown in the following figure:

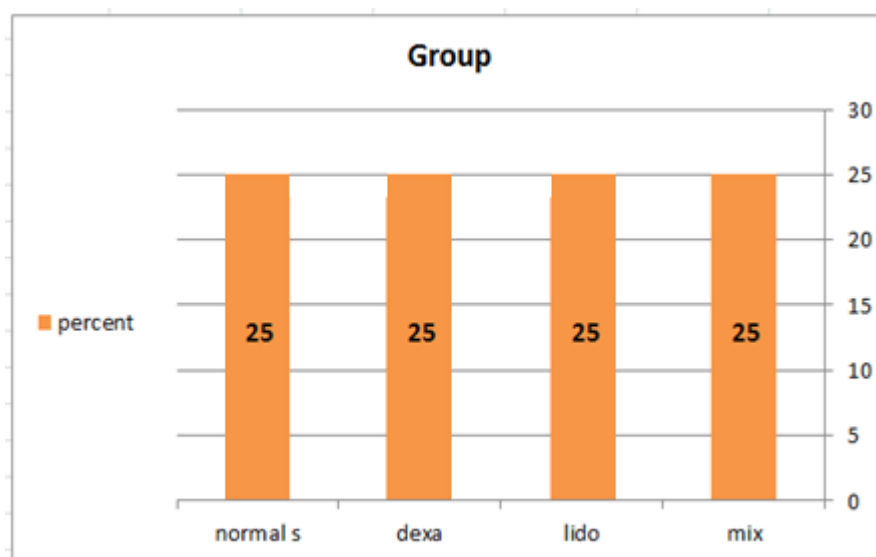


Figure (5): Sample characteristics according to group.

4.2. Results related to study questions

In order to answer the study question: what is the effect of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness, the frequencies and the percentages of the incidence of sore throat, cough and hoarseness were found for each of the four groups and the results are shown in the following table:

Table (2): frequencies and percentages for each of the four groups

Group	Frequency	Percent
Normal s N=15		
Sore throat incidence	9	64.3
hoarseness incidence	12	85.7
cough incidence	4	28.6
Lido N=15	Frequency	Percent
Sore throat incidence	3	21.4
hoarseness incidence	3	21.4
cough incidence	2	14.3
Dexa N=15	Frequency	Percent
Sore throat incidence	3	17.6
hoarseness incidence	3	17.6
cough incidence	2	11.8
Mix N=15	Frequency	Percent
Sore throat incidence	2	13.3
hoarseness incidence	1	6.7
cough incidence	1	6.7

The table shows that:

In the normal saline group: (64.3%) of the patients had sore throat, (85.7%) had hoarseness, and (28.6%) had cough.

In the Lido group: (21.4%) of the patients had sore throat, (21.4%) had hoarseness and (14.3%) had cough.

In the Dexa group: (17.6%) of the patients had sore throat, (17.6%) had hoarseness and (11.8%) had cough.

In the Mix group: (13.3%) of the patients had sore throat, (6.7%) had hoarseness and (6.7%) had cough.

The percentages of incidence of (sore throat, hoarseness, and cough among the four groups are shown in the following figure:

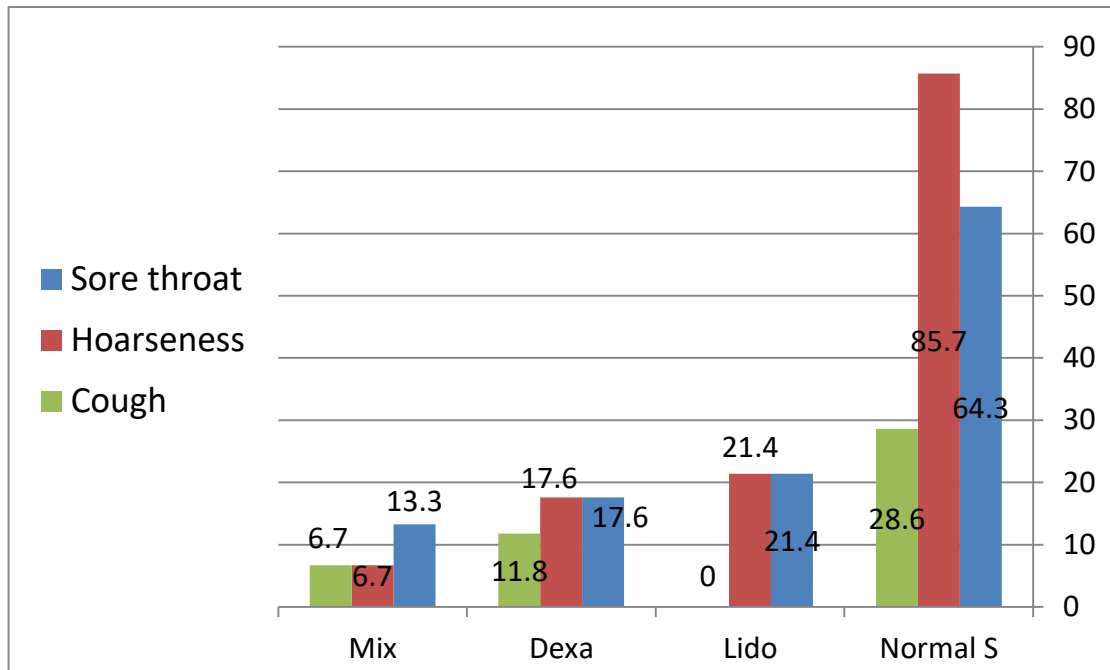


Figure (6): Percentages of incidence of (sore throat, hoarseness, and cough among the four groups.

4.3 Results related to study hypotheses

Hypothesis 1: There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to age.

Oneway Anova test was conducted to test the differences attributed to age and the results are shown in the following table:

Table (3): Oneway Anova test for the differences attributed to age.

		df	F	Sig.
Sore throat	Between Groups	2	1.293	.282
	Within Groups	57		
	Total	59		
Hoarseness	Between Groups	2	2.113	.130
	Within Groups	57		
	Total	59		
Cough	Between Groups	2	.685	.508
	Within Groups	57		
	Total	59		
total	Between Groups	2	2.077	.135
	Within Groups	57		
	Total	59		

The table shows that there were no statistically significant differences at the level of statistical significance ($\alpha = 0.05$). The value of the statistical significance on the sore throat domain was (0.28) and on the hoarseness domain (0.13) as well as on the cough domain (0.50) and all these values are higher than the assumed statistical significance value, that is, there are no differences in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of (0.05) related to age.

Hypothesis 2: There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to gender.

T-Test was conducted to test the differences attributed to gender and the results are shown in the following table:

Table (4): T test for the differences attributed to gender.

		t-test for Equality of Means		
		t	df	Sig. (2-tailed)
Sore throat	Equal variances assumed	1.189	58	.239
	Equal variances not assumed	1.202	53.746	.235
Hoarseness	Equal variances assumed	.618	58	.539
	Equal variances not assumed	.627	54.554	.533
Cough	Equal variances assumed	1.321	58	.192
	Equal variances not assumed	1.390	57.931	.170
total	Equal variances assumed	1.241	58	.220
	Equal variances not assumed	1.278	56.487	.206

The table shows that there were no statistically significant differences at the level of statistical significance ($\alpha = 0.05$). The value of the statistical significance on the sore throat domain was (0.23) and on the hoarseness domain (0.53) as well as on the cough domain (0.19) and all these values are higher than the assumed statistical significance value, that is, there are no differences in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of (0.05) related to gender.

Hypothesis 3: There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to weight.

Oneway Anova test was conducted to test the differences attributed to weight and the results are shown in the following table:

Table (5): T test for the differences attributed to weight.

		df	F	Sig.
Sore throat	Between Groups	2	.036	.965
	Within Groups	57		
	Total	59		
Hoarseness	Between Groups	2	1.016	.368
	Within Groups	57		
	Total	59		
Cough	Between Groups	2	.070	.933
	Within Groups	57		
	Total	59		
total	Between Groups	2	.353	.704
	Within Groups	57		
	Total	59		

The table shows that there were no statistically significant differences at the level of statistical significance ($\alpha=0.05$). The value of the statistical significance on the sore throat domain was (0.96) and on the hoarseness domain (0.36) as well as on the cough domain (0.93) and all these values are higher than the assumed statistical significance value, that is, there are no differences in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of (0.05) related to weight.

Hypothesis 4: There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to duration of operation .

Oneway Anova test was conducted to test the differences attributed to duration of operation and the results are shown in the following table:

Table (6): Oneway Anova test for the differences attributed to duration.

		N	Mean	Std. Deviation	F	Sig.
Sore throat	<1	8	1.92	.212	3.056	.055
	1- 1.5	48	1.65	.349		
	>1.5	4	1.45	.443		
	Total	60	1.68	.353		
Hoarseness	<1	8	1.92	.212	3.927	.025
	1- 1.5	48	1.64	.329		
	>1.5	4	1.40	.489		
	Total	60	1.66	.344		
Cough	<1	8	1.90	.282	.442	.645
	1- 1.5	48	1.90	.214		
	>1.5	4	1.80	.163		
	Total	60	1.90	.219		
total	<1	8	1.91	.235	3.426	.039
	1- 1.5	48	1.73	.230		
	>1.5	4	1.55	.354		
	Total	60	1.74	.248		

The table shows that there were statistically significant differences at the level of statistical significance ($\alpha = 0.05$). The value of the statistical significance on the sore throat domain was (0.05) and on the cough domain (0.64) and these values are higher than the assumed statistical value which means that there are no significant statistical differences on these domains. While on the hoarseness domain the value of significance was (0.02) which is lower than the assumed statistical significance value, that is, there are significant differences in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of (0.05) related to duration of operation.

Hypothesis 5: There is a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to group.

Oneway Anova test was conducted to test the differences attributed to group and the results are shown in the following three tables :

Table (7): Oneway Anova test for the differences in sore throat attributed to group.

		N	Mean	Std. Deviation	F	Sig.
3h	mix	15	1.90	.301	1.647	.189
	lido	14	1.85	.363		
	dexa	17	1.71	.462		
	normal s	14	1.57	.513		
	Total	60	1.75	.436		
6h	mix	15	1.90	.301	2.617	.060
	lido	14	1.64	.497		
	dexa	17	1.47	.511		
	normal s	14	1.42	.513		
	Total	60	1.58	.497		
12h	mix	15	2.00	.000	4.292	.009
	lido	14	1.50	.518		
	dexa	17	1.57	.507		
	normal s	14	1.35	.497		
	Total	60	1.58	.497		
24h	mix	15	2.00	.000	6.178	.001
	lido	14	1.64	.497		
	dexa	17	1.90	.300		
	normal s	14	1.42	.513		
	Total	60	1.75	.436		
Sore throat	mix	15	1.96	.120	5.917	.001
	lido	14	1.68	.330		
	dexa	17	1.69	.300		
	normal s	14	1.42	.414		
	Total	60	1.68	.353		

The table shows significant statistical differences in the effect of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat related to group after 12 hours , 24 hours and on the total sore throat, where the values of significance are (0.09), (0.01), and (0.001) which are lower than the assumed statistical value . As the means indicate that the effect of using (mix of dexa and lido) was the higher, followed by (dexa only) then (lido only) then normal saline.

Table (8): Oneway Anova test for the differences in hoarseness attributed to group.

		N	Mean	Std. Deviation	F	Sig.
3h	mix	15	1.90	.301	1.911	.138
	lido	14	1.78	.425		
	dexa	17	1.71	.462		
	normal s	14	1.50	.518		
	Total	60	1.71	.454		
6h	mix	15	1.90	.301	3.902	.013
	lido	14	1.55	.363		
	dexa	17	1.82	.511		
	normal s	14	1.42	.513		
	Total	60	1.65	.480		
12h	mix	15	1.90	.301	4.395	.008
	lido	14	1.57	.513		
	dexa	17	1.71	.462		
	normal s	14	1.28	.468		
	Total	60	1.61	.490		
24h	mix	15	2.00	.000	6.522	.001
	lido	14	1.64	.497		
	dexa	17	1.76	.436		
	normal s	14	1.28	.468		
	Total	60	1.66	.475		
Hoarseness	mix	15	1.94	.180	10.537	.000
	lido	14	1.62	.278		
	dexa	17	1.79	.307		
	normal s	14	1.32	.309		
	Total	60	1.66	.344		

The table shows significant statistical differences in the effect of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent hoarseness related to group after 6 hours, 12 hours, 24 hours and on the total hoarseness, where the values of significance are (0.013), (0.008), (0.001) and (0.00) which are lower than the assumed statistical value . As the means indicate that the effect of using (mix of dexta and lido) was the higher, followed by (dexta only) then (lido only) then normal saline.

Table (9): Oneway Anova test for the differences in cough attributed to group.

		N	Mean	Std. Deviation	F	Sig.
3h	mix	15	2.00	.000	2.933	.051
	lido	14	1.90	.000		
	dexta	17	1.95	.300		
	normal s	14	1.71	.468		
	Total	60	1.90	.302		
6h	mix	15	2.00	.000	2.390	.078
	lido	14	2.00	.000		
	dexta	17	1.95	.218		
	normal s	14	1.78	.425		
	Total	60	1.93	.251		
12h	mix	11	2.00	.000	1.786	.160
	lido	14	2.00	.000		
	dexta	21	1.85	.358		
	normal s	14	1.78	.425		
	Total	60	1.90	.302		
24h	mix	15	2.00	.000	1.786	.160
	lido	14	2.00	.000		
	dexta	17	1.85	.358		
	normal s	14	1.78	.425		
	Total	60	1.90	.302		
Cough	mix	15	2.00	.000	4.459	.007
	lido	14	1.87	.000		
	dexta	17	1.93	.214		
	normal s	14	1.75	.325		
	Total	60	1.90	.219		

The table shows significant statistical differences in the effect of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent cough related to group on the total cough, where the value of significance is (0.007) which is lower than the assumed statistical value . As the means indicate that the effect of using (mix of dexta and lido) was the higher, followed by (dexta only) then (lido only) then normal saline.

Chapter Five

Discussion

Discussion

The purpose of the current research was to investigate the effects Of Dexamethasone, Lidocaine, and their combination on patients undergoing Laparoscopic Cholecystectomy to prevent sore throat, cough and hoarseness. And to achieve this goal, the experimental approach was used for its suitability for the purposes of this research. The study sample consisted of (60) patients of cholecystectomy at Rafedia Hospital and Jenin Governmental Hospital. The sample was divided into four groups, group one took (8 mg Dexamethasone), group two took (1.5 mg /kg Lidocaine), group three took (8 mg Dexamethasone+1.5 mg /kg Lidocaine together), and group four took (10cc of normal saline). The drugs were given to the patients before intubation (prophylactic), and then the observation tool was used on the same operation day 3-24 hours. The research concluded the following results:

In the normal saline group: (64.3%) of the patients had sore throat, (85.7%) had hoarseness, and (28.6%) had cough. In the Lido group: (21.4%) of the patients had sore throat, (21.4%) had hoarseness and (14.3%) had cough. In the Dexa group: (17.6%) of the patients had sore throat, (17.6%) had hoarseness and (11.8%) had cough. And in the Mix group: (13.3%) of the patients had sore throat, (6.7%) had hoarseness and (6.7%) had cough.

The results suggest that there was a significant difference in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness at a level of 0.05 related to group.

The study found that the incidence of postoperative sore throat, cough, and hoarseness of__voice in patient undergoing laparoscopic cholecystectomy was significantly less when a mixture of dexamethasone and lidocaine was used.

This result may be attributed to the fact that lidocaine is used as an anti-inflammatory substance as confirmed by the study of (Caracas et al, 2009). (Singer & et al, 2002) pointed out that Bronchial hyper-reactivity may be modulated by dexamethasone and he added that in mice, dexamethasone inhibits cytokines involved in airway inflammation, suppresses airway reactivity in response to antigens and mucus accumulation by altering metabolism within the airway cell and this resulted in decreased airway hyper-reactivity, decreased mucus production and decreased eosinophilia.

Regarding Lidocaine, we also mentioned that it was proved that it has potential utility as a potent anti-inflammatory agent. A variety of lidocaine's actions on inflammatory cells have been described. Accumulating data suggests that lidocaine's powerful anti-inflammatory properties may be superior in many ways to nonsteroidal anti-inflammatory

drugs and steroids, the traditional anti-inflammatory agents.(Cassuto & et al, 2006)

This result is consistent with the results of (Subedi & et al., 2019) which revealed that Dexamethasone, with or without lidocaine, was effective in reducing the incidence of POST in patients requiring prolonged tracheal intubation. In addition to (Chandra & et al. 2018) study which showed that lidocaine inhalation 1.5 mg/kg was proportional to intravenous dexamethasone 10 mg in reducing the incidence and severity of POST after LMA insertion. The study of (Cho & et al., 2016) concluded that Lidocaine combined with dexamethasone is more effectively reduces the incidence and severity of sore throat and severity of hoarseness for 24 h after extubation in patients who have undergone breast mass excision surgery.

As for the effect of Dexamethasone, the study of (Lee & et al., 2017) reported an effective effect of Dexamethasone for patients whose endotracheal tube cuff was soaked in the dexamethasone solution before intubation exhibited significantly lower incidence and severity of POST. The study of (Thomas & Beevi, 2007) confirmed that preoperative administration of dexamethasone reduces the incidence and severity of postoperative sore throat in patients receiving general anesthesia with endotracheal intubation. While the study of (Ruangsinn et al., 2012) showed an opposite result, as it showed that the intravenous dexamethasone had no significant effectiveness against postoperative sore throat after endotracheal intubation.

Furthermore, (Upadhyay & et al., 2019) study revealed that lidocaine is widely used in clinical practice to lubricate the tracheal tube. (Soltani & Aghadavoudi, 2002) study also added that using lidocaine to inflate the endotracheal tubes (ETT) cuff or IV lidocaine at the end of surgery decreases the frequency of postoperative cough and sore throat and would provide better outcome for patients and the physician.

It was found that there were no statistically significant differences at the level of significance ($\alpha \geq 0.05$) in the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness due to variables: (age, gender, and weight).

This result may be attributed to the fact that the medicine was administered in fixed proportions, i.e. (ideal). Men and women were given the same amount of the medicine, the older person was not given a larger amount, but everyone was given fixed proportions, regardless of age, and also for weight, the higher weights were not given a greater amount of medicine, but the proportions allowed for everyone were given.

This result is consistent with the results of (Subedi & et al., 2019) which showed that there were no statistically significant differences attributed to the variables of (gender, age, and BMI) in the effect of intravenous lidocaine, dexamethasone, and their combination on postoperative sore throat. Furthermore, (Lee & et al., 2017) and (Cho & et al., 2016) studies concluded that there were no statistically significant differences attributed to the variables of (gender, age, BMI, weight and height).

But there were differences attributed to duration of operation. It was found that the more the time was longer, the more the patient as exposed to hoarseness after the operation.

This may be attributed to the fact that the long existence of co₂ inside the abdomen may affect the lung normal breathing which was concluded by the study of (El-Boghdadly et al, 2016) .

This result is consistent with the results of (Subedi & et al., 2019) study which confirmed that there were statistically significant differences attributed to the duration of surgery when the duration of the operation is more than (1:30) and duration of intubation when the duration of intubation is more than (1) hour. But (Lee & et al., 2017) study does not support these results, this study revealed that there were no statistically significant differences attributed to operation time in the effects of dexamethasone gargle and endotracheal tube cuff soaking on the incidence and severity of POST, in addition to (Cho & et al., 2016) study which confirmed that there were no statistically significant differences attributed to duration of surgery and duration of intubation in reducing postoperative sore throat, cough, and hoarseness. The study of (Ruangsinn et al., 2012) showed that the duration of surgery, and intubation-induced trauma had no statistical significance against postoperative sore throat after endotracheal intubation.

In conclusion, both dexamethasone alone and in combination with lidocaine reduced the incidence of sore throat, cough and hoarseness in patient undergoing laparoscopic cholecystectomy with the combination drugs showing more protective effects.

Limitations

The limitation in the current study is that we used 8 mg of dexamethasone as the fixed dose. There is a wide variation in the doses of dexamethasone tested for post operation sore throat, hoarseness , and cough , with some using fixed dose (4 mg, 8 mg), while others have used doses based on body weight (ranging from 0.1 to 0.2 mg/kg). Another limitation is that the geographic regions only covered Jenin and Nablus, therefore, our results limited generalizability to the regions.

Recommendations

At the end of the study, the researcher recommends a set of practical recommendations that contribute to achieving a good effect of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness, and these recommendations are represented in the following points:

- Using dexamethasone with lidocaine to prevent sore throat, cough and hoarseness in patient undergoing laparoscopic cholecystectomy was more effective than lidocaine alone and normal saline.

- Other studies are needed with different doses of both dexamethasone and lidocaine to support the results of our study .
- We need to study the effects of other demographic factors such as BMI, Height or other variables

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Appendix



استمارة موافقة مشارك

أنا:

أوافق على المشاركة في البحث العلمي الذي سيجرى في مستشفى رفيديا الجراحي-نابلس ومستشفى جنين الحكومي - جنين للمرضى الذين يخضعون لعمليات منظار القنوات المرارية وسيتم البحث عن طريق أخذ اربع مجموعات من المرضى 25 مريض في كل مجموعة وسيتم اعطاء المجموعة الاولى (دواء الديكساميثازون 8 ملغم) في الوريد ويستخدم لعلاج العديد من أمراض الجلد والأنسجة الرخوة النابعة من الحساسية أو الالتهاب والمجموعة الثانية (الليدوكايين 1.5ملغم/كغم) في الوريد وهو بمثابة وسيلة للأمان والراحة للمرضى الخاضعين للتخدير، لأنه يقلل من حدوث السعال، أو أي ضرر للقصبة الهوائية قد يحدث بسبب التخدير، أما المجموعة الثالثة سيتم إعطاؤها الدوائين السابقين معا (الديكساميثازون 8 ملغم + الليدوكايين 1.5 ملغم/كغم) والمجموعة الرابعة سيتم إعطاؤها محلول نورمال سلاين. 9 (10 سم) وسيتم قياس مقدار السعلة والتهاب الحلق وخشونة الصوت بعد العملية في كلا المجموعات الأربعة عن طريق مقياس النظر الشفهي.

أدرك أن البحث سيجرى بالطريقة التي تم وصفها شفهيًا ونظرًا من قبل الباحث.

ستُعاد نسخة من استمارة الموافقة هذه إليّ مع ملاحظاتي لاعتمادهما وستظل معلوماتي طبي الكتمان. أفهم أنني أستطيع بحريتي أن أغير أية ملاحظات أو أن انسحب من البحث في أي وقت.

أوافق على المشاركة في الخضوع للبحث وأخذ الدواء المسكن للألم قبل العملية الجراحية، وقد فهمت المعلومات المبينة في نموذج الموافقة وما قاله لي الممثل الصحي.

اسم المريض (الاسم بوضوح.....:)

التوقيع.....:)

التاريخ.....:)

اسم الباحث (الاسم بوضوح.....:)

التوقيع.....:)

التاريخ.....:)

لقد أخبرت الشخص/الأشخاص أعلاه بهذا البحث وأنا متأكد من أنه/أنهم يفهمون محتوى البحث العلمي وتم شرح ما سيتم فعله وأنه لا يوجد أي مخاطر جسدية أو نفسية مكن أن يتعرضوا لها وفهم استمارة موافقة المريض

Patient Name:

Date of operation :

Hospital Name:

patient No.	Age	gender	weight	Group (N=(25)	Duration of operation	Notes
Sore throat	1h					
	3h					
	6h					
	overall					
Hoarseness	1h					
	3h					
	6h					
	overall					
cough	1h					
	3h					
	6h					
	overall					



Please provide the following information to apply for research data collection permission at the Palestinian Ministry of Health institutions:

Research Title اسم البحث	Effects of Dexamethasone, Lidocaine and their combination on patient undergoing Laparoscopic Cholecystectomy to Prevent Sore Throat, Cough and Hoarseness
University Name اسم الجامعة	An-Najah National University
Principal Investigator/ Supervisor's name اسم الباحث/ المشرف	د. جمال قديمي Dr. Jamal Qaddumi د. نورالدين المصري Dr. Nooraldein Almasri
Students participating in the research أسماء الطلاب المشاركين في البحث	سماح فايد Samah Fayed
Specialty التخصص	Master of nursing anesthesia
Abstract ملخص الدراسة	Abstract Introduction: As mentioned in (Cho & et al, 2016) study, the efficacy of intravenous dexamethasone and lidocaine in minimizing the incidence and severity of postoperative airway symptoms is well-established. However, no study has compared the effects of dexamethasone plus lidocaine combination therapy with the effects of prophylactic dexamethasone alone. Considering the multifactorial etiology of postoperative sore throat, the researchers hypothesized that combined dexamethasone and lidocaine would be more effective than dexamethasone alone in reducing postoperative throat problems. In this study the researcher will investigate the effects of dexamethasone and lidocaine on patient undergoing lap cholecystectomy to prevent sore throat, cough and hoarseness. The study will be conducted at Rafedia Hospital-Nablus and Jenin Governmental Hospital, on a sample of patients of undergoing lap cholecystectomy. Problem Statement: We note that there are complications related to sore throat, hoarseness, and cough in most operations, and because we do not want to resort to any of the dangerous drugs that need the approval of specialized doctors, and because of the scarcity of studies

	that touched on this subject, especially local and Arab studies, so the researcher decided to do this study to examine the effect of two safe drugs that do not require signature or additional tests or health control. These two drugs work to expand the bronchi, and reduce irritation and swelling. Aim: The aim of this study is to assess the effects of dexamethasone and lidocaine on patient undergoing laparoscopic cholecystectomy to prevent sore throat, cough and hoarseness. Design: The design used a randomized study design. All efforts should be made to avoid sources of bias such as the loss of individuals to follow up during the study. Setting: The setting of data collection will be Rafedia Hospital located in Nablus –West Bank and Jenin Governmental Hospital located in Jenin – West Bank. Study Population: The research community consists of all the patients of cholecystectomy at Rafedia Hospital and Jenin Governmental Hospital (220) according to the information of the researcher. Sample Size :The sample includes (60) cholecystectomy patients (30) at Rafedia Hospital, and (30) at Jenin Governmental hospital, except for those do not meet the criteria of this research. Study Tools: The observation is used as the instrument to gather information from the target population for research study. The observation includes medical tests and medical file follow up to monitor the patient's health. The sample will be divided into four groups, group one will take (8 mg Dexamethasone) group two will take (1.5 mg /kg Lidocaine), and group three will take (8 mg Dexamethasone+1.5 mg /kg Lidocaine together), and group four will take (10cc of normal saline).I intend to give the drugs to the patients before intubation (prophylactic), then I will monitor the patients for six hours after the operation.
Methodology منهجية البحث	The design depends on the prospective study design (randomized)
Data collection methods and tools طرق جمع البيانات والأدوات	The sample will be divided into four groups, group one will take (8 mg Dexamethasone) group two will take (1.5 mg /kg Lidocaine), and group three will take (8 mg Dexamethasone+1.5 mg /kg Lidocaine together), and

	group four will take (10cc of normal saline). The doctor will give the drugs to the patients before intubation (prophylactic), then I will monitor the patients for 24 hours after the operation.
Dates and time of data collection تواريخ ووقت جمع البيانات	Jan. 2020-Mar.2010.
Sample size حجم العينة	60
Who will collect data or samples من سيجمع البيانات أو العينات	The researcher
Questionnaire or questions of the interview (copy) استبيان أو أسئلة المقابلة (نسخة)	attached
Ethical considerations الاعتبارات الأخلاقية	The study presented in this dissertation is conducted in accordance with the Helsinki Declaration and will be approved by the Institutional Committee (IRB) and the Palestinian Ministry of Health, confidentiality is guaranteed. For that reason, the ethical dilemma is considered to be small. The results are presented in a way that ensured that it is not possible to identify any of the individuals. The study protocol concentrates on the patient's health and well-being.

جامعة النجاح الوطنية

كلية الدراسات العليا

آثار الديكساميثازون واليدوكاين والديكساميثازون واليدوكاين معا على
المريض الذي يخضع لاستئصال المرارة بالمنظار لمنع التهاب الحلق
والسعال وبحة في الصوت

إعداد

سماح خالد حسين فايد

إشراف

د. جمال القدومي

د. نور الدين المصري

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

2021

ب

آثار الديكساميثازون واليدوكاين والديكساميثازون واليدوكاين معا على المريض الذي يخضع لاستئصال المرارة بالمنظار لمنع التهاب الحلق والسعال وبحة في الصوت

إعداد

سماح خالد حسين فايد

إشراف

د. جمال القدومي

د. نور الدين المصري

الملخص

كان الهدف من هذه الدراسة هو البحث في تأثير استخدام دواء ديكساميثازون، ليدوكاين، وكلاهما معا، في منع التهاب الحلق والسعال وبحة الصوت لدى المريض الذي يخضع لعملية استئصال المرارة بالمنظار. وقد أجريت الدراسة في مستشفى رفيديا - نابلس ومستشفى جنين الحكومي، على عينة من المرضى الذين خضعوا لعملية استئصال المرارة بالمنظار، وتضمنت العينة (60) مريضاً تم اختيارهم عشوائياً من مجتمع الدراسة، واعتمدت الدراسة على تصميم الدراسة المستقبلية، وكانت الأداة هي الملاحظة في نفس يوم العملية من 3-24 ساعة.

أظهرت النتائج أن المجموعة التي تناولت مزيج الديكساميثازون والليدوكاين أظهرت انخفاضاً في نسبة حدوث التهاب الحلق والسعال وبحة في الصوت لدى المرضى الذين خضعوا لعملية استئصال المرارة بالمنظار. أظهرت هذه المجموعة أفضل التأثيرات تليها المجموعة التي تناولت الديكساميثازون بمفرده والتي أظهرت تأثيرات وقائية أكثر من المجموعتين الأخريين ، ثم المجموعة التي تناولت الليدوكاين بمفرده، وأخيراً المجموعة التي تناولت المحلول الملحي العادي.

كما أظهرت الدراسة أنه لا توجد فروق ذات دلالة إحصائية عند مستوى الدلالة ($\alpha \geq 0.05$) في تأثير استخدام دواء ديكساميثازون، ليدوكاين، وكلاهما معا، في منع التهاب الحلق والسعال وبحة الصوت لدى المريض الذي يخضع لعملية استئصال المرارة بالمنظار تعزى لمتغيرات: (العمر،

ج

والجنس، والوزن). لكن كانت هناك اختلافات تعزى لمتغير مدة العملية، حيث وجد أنه كلما طال الوقت كلما تعرض المريض لـبحة في الصوت بعد العملية.

وبناءً على نتائج الدراسة أوصت الباحثة باستخدام مزيج من الديكساميثازون والليدوكاين للوقاية من التهاب الحلق والسعال وبحة الصوت لدى المرضى الذين يخضعون لعملية استئصال المرارة بالمنظار والذي كان أكثر فعالية من الليدوكاين بمفرده والمحلل الملحي الطبيعي. علاوة على ذلك، هناك حاجة لدراسات أخرى بجرعات مختلفة من كل من الديكساميثازون والليدوكاين لدعم نتائج الدراسة الحالية.

