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Transversus Abdominis Plane Block for Postoperative Analgesia in Patients Undergoing Laparoscopic Sleeve Gastrectomy: Randomized, Double- Blind, Controlled Trial

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Dedication

الى الذين سهروا الليالي بجانبي

الى الذين يحملون الطمأنينة لفلذات أكبادهم

الى والدي ووالدتي وأخوتي وعائلتي

الى عائلتي الصغيرة زوجتي وأطفالي الأعزاء

الى المشرفين الأكفاء على رسالتي

الى الذين ينتظرهم الأمل وطلوع الشمس

اليكم جميعا أقدم رسالتي الجامعية المتواضعة

Acknowledgement

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فكل كلمات الشكر والثناء لكم، فشكري لن يوفيكم حقكم بالرغم من اننا نعيش في ظروف صعبه وغير طبيعية الا اننا بذلنا الكثير من المجهودات المتواصلة لتقديم تلك الرسالة.

أساتذتي الأفاضل:

للنجاحات أناس يقدرون معناها، لذا فإنني أقدر جهودكم المضيئة, وللإبداع أناس يحصدونه، فأنتم أهل الشكر والتقدير، وواجب علي تقديركم، حفظكم الله ورعاكم من كل سوء.

كما أتقدم بالشكر الجزيل وعظيم الامتنان للمشرفين على رسالتي كل باسمه ومنصبه بعبارات ممزوجة بالمودة والاحترام على عملهم الدؤوب وجهودهم المتواصلة لإنارة طريق العلم لجميع ابناء الوطن, فقد كنتم السند والدعم في تقديم رسالتي بلغة علمية حديثة، تقوم على اساس علمي ومراجع هامة لتحقيق الغرض الرئيس.

وفي اخر الامر لا بد من رسالة حب وتقدير وتحية ووفاء واخلاص أبرقها اليكم ,فقد تتسابق الكلمات وتتزاحم العبارات لأعبر لكم عن شكري وتقديري لكم واختم بتوفيقي من الله عز وجل.

الاقرار

أنا الموقع أدناه، مقدّم الرسالة التي تحمل العنوان:

Transversus Abdominis Plane Block for Postoperative Analgesia in Patients Undergoing Laparoscopic Sleeve Gastrectomy: Randomized, Double- Blind, Controlled Trial

أقر بأن ما اشتملت عليه هذه الأطروحة إنما هو نتاج جهدي الخاص، باستثناء ما تمت الاشارة إليه حيثما ورد. وأن هذه الرسالة كاملة، أو اي جزء منها لم يقدم من قبل لنيل اي درجة او لقب علمي او 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.

Student's Name: **اسم الطالب:**

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Date: **التاريخ:**

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List of Abbreviations

Abbreviation	Full meaning
ASA	American Society of Anesthesia
BMI	Body Mass Index
cm	Centimeter
COX	cyclooxygenase enzyme
DBP	Diastolic Blood Pressure
DM	Diabetes Mellitus
et al.	And others
etCO_2	End-tidal Carbon Dioxide
ETT	Endotracheal Tube
FiO2	Fraction of inspired O2
Freq.	Frequency
H_0	Null Hypothesis
H_a	Alternative Hypothesis
HR	Heart Rate
HTN	Hypertension
IBW	Ideal Body Weight
IM	Intramuscular
IRB	Institutional Review Board
IV	Intravenous
kg	Kilogram
L/min	Liter per minute
LBM	Lean Body Mass
LoS	Length of Stay
mg/dL	Milligram per deciliter
mg/kg	Milligram per kilogram
NIH	National Institute of Health
NSAID	Non-steroidal Anti-inflammatory Drug
OSA	Obstructive Sleep Apnea
PACU	Post-anesthesia care unit
PhD	Doctor in Philosophy
PONV	Postoperative Nausea and Vomiting
PRN	Pro re nata (as needed)
RCT	Randomized Controlled Trial
RR	Respiratory Rate
SBP	Systolic Blood Pressure
SD	Standard Deviation
SpO2	Partial Pressure of O2 (Oxygen Saturation)
SPSS	Statistical Package for Social Sciences
TAP	Transverse Abdominis Plane

TBW	Total Body Weight
Temp	Temperature
TIVA	Total Intravenous Anesthesia
ug/kg	Microgram per kilogram
VAS	Visual Analogue Scale
WMA	World Medical Association
YO	Years Old

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Abstract

Introduction: laparoscopic sleeve gastrectomy is among the most preferable approaches in surgical interventions for treating morbid obesity in adults, and the selection of its candidate patients depends on several criteria, and one of them is related to anesthetic approaches, which is highly variant according to institutional protocols. In this study, we aimed to investigate the difference in postoperative pain measurements and postoperative nausea and vomiting (PONV), alongside patients' satisfaction and other outcomes, between using conventional anesthetic approach and the addition of transverse abdominis plane (TAP) block in laparoscopic sleeve gastrectomy patients.

Methodology: A double-blind randomized controlled trial (RCT) was conducted on a total of randomly selected 50 patients, allocated equally in two groups of conventional and conventional + TAP block groups (25 patients each). All patients are adult (18 – 65 YO), who underwent laparoscopic sleeve gastrectomy, with BMI > 35 kg/m^2), ASA score 1 and 2, and received no long-term analgesia in the past 12 hours preoperatively. The data collection was done using a researcher-developed data sheet that

contained information about patients' demographic data, comorbidities and characteristics, perioperative data regarding their intraoperative time, anesthetic agents, hemodynamics and intubation, and postoperative hemodynamics, pain and PONV scores and rescue medications' first need ant total dose, length of stay (LOS) and satisfaction.

Results: There were no significant differences in all selection criteria between TAP block and control groups in terms of age (mean = 32.56 ± 8.05 YO vs 30.60 ± 12.09 YO, respectively), BMI (mean = 52.23 ± 6.82 kg/m^2 vs 51.37 ± 4.28 kg/m^2), or any preoperative selection variables (p-value > 0.05). intraoperatively, 60% had difficult intubation, using direct laryngoscope, anesthesia done using propofol (200 mg), muscle relaxant (50 mg), fentanyl (200 mcg), and all patients received 30 mg of ketorolac, 1000 mg of optalgin and 1000 mg of paracetamol, while TAP block group received an extra 30 mL of 0.2% bupivacaine in the TAP area using USG. TAP block group had a significantly lower induction (p-value = 0.026), maintenance (p-value = 0.037) and emergence (p-value = 0.004) heart rate than control group, while postoperatively, TAP block group had significantly lower systolic and diastolic blood pressure and hear rate than control group in all time points (zero to 24 hours, p-value < 0.05). Also, TAP block group had significantly lower mean postoperative scores out of 10 (range = 2.50-4.58 vs 5.12-8.94, respectively, p-value < 0.05), mean PONV scores out of 6 (range = 2.33-2.58 vs 5.36-6, respectively, p-value < 0.05), with significantly less total dose and longer time needed for the first

dose of rescue analgesics and antiemetics. Lastly, TAP block group had significantly higher satisfaction scores (p-value < 0.001).

Conclusion: The adding of TAP block in laparoscopic sleeve gastrectomy surgeries is superior to using the conventional anesthetic approach only, as it showed less risk of higher intraoperative heart rate or higher postoperative blood pressure and heart rate. It is also associated with less mean postoperative pain and PONV scores with less total dose and longer time needed for the first analgesics dose, and higher satisfaction level.

Keywords: laparoscopic sleeve gastrectomy, transversus abdominis plane, TAP block, PONV, postoperative pain, satisfaction.

Chapter One
Introduction

1.1 Background

The recent medical field witnesses the spread of non-communicable diseases in which lifestyle and other environmental-related factors are considered the main reasons that these diseases develop. One of the main factors is obesity, which is considered and epidemic mainly in the United States and over the world, that leads to many negative consequences, most of them are avoidable (Macfater et al., 2019). Among the different solutions and plans that target the control of patients' weight, bariatric surgeries became and increasingly used method for successful and effective solution for obesity and its comorbidities, and sleeve gastrectomy is one of the most applied methods (Crawford et al., 2017). Despite the fact that bariatric surgery is primarily performed laparoscopically, pain management optimization remains critical in decreasing complications and increasing patient comfort (Ruiz-Tovar, et al 2016). Despite the fact that laparoscopic bariatric surgery is minimally intrusive, discomfort in the immediate postoperative period can range from mild to severe (Albrecht, et al 2013). Due to the obese patient's greater sensitivity to opioid-induced respiratory depression, pain control after bariatric surgery might be particularly difficult (Albrecht, et al 2013; Alimian, et al 2012; Sinha, et al 2013). Obese people are prone to opioid-induced airway obstruction due to the high prevalence of obstructive sleep apnea, and scientific guidelines underline the significance of opioid-sparing analgesic methods in these

patients (Alvarez, et al 2014; Gross, et al 2006). Patients who are morbidly obese require a multimodal painkiller technology that can provide painkillers without having a substantial detrimental impact on their respiratory function.

The selection of suitable patient to undergo laparoscopic or open sleeve gastrectomy is made upon various conditions, and the National Institution of Health (NIH) concluded that the suitable patients are whom at age between 18 and 64 YO, with body mass index (BMI) > 40 kg/m^2, or <35 kg/m^2 with the presence of one or more obesity-related comorbidity, like diabetes mellitus (DM) type 2, obstructive sleep apnea, osteoarthritis, and others, and the inability to sustain weight loss using previous weight-loss efforts (Chung et al., 2018). The previous factors are also part of the factors that affect the anesthetic choices during the surgery.

Rather than the selection criteria of patients who undergo sleeve gastrectomy, there is a difference in the anesthetic approaches that are used in the perioperative stages for these operations. This difference is affected by different anesthetic schools, as well as the difference in patients' characteristics and management goals, especially when speaking about pain management. Even that the patient is managed to have absent pain feeling intraoperatively, both intraoperative and postoperative management affect postoperative pain (Macfater et al., 2019). Anesthetic approaches in sleeve gastrectomy are considered in various procedures throughout the

perioperative stages, from choosing anesthesia method, through ventilation and monitoring toward recovery.

According to current research, wound infiltration with local anesthetic should be utilized as part of a multimodal postoperative pain treatment strategy (Moncada, et al 2016). In bariatric surgery, local anesthetic infiltration of the trocar sites is accepted as a stage of multimodal analgesia (Ruiz-Tovar, et al 2016). Bertin et al. (2014) used liposome bupivacaine, a new multivicular formulation of bupivacaine indicated for endosine infiltration to the surgical site to produce post-surgical analgesia, as part of a multimodal analgesic in a patient who had a history of chronic pain and was scheduled to undergo laparoscopic sleeve gastrectomy.

TAP block, a regional anesthesia technique that blocks neural efferents from the anterior abdominal wall (Petersen, et al 2013), has recently been described as an effective technique for reducing postoperative pain intensity and morphine consumption after lower abdominal surgery (Aveline, et al 2011). The typical posterior TAP block relieves pain below the level of the T10 dermatome, but it frequently fails to relieve discomfort above the umbilicus (Bhatia, et al 2014). TAP block applied subcostally has been shown to deliver analgesia to the supra-umbilical abdomen (Wu, et al 2013). After upper abdominal surgeries, this superior route has been found to provide acceptable postoperative analgesia (Bugada, et al 2013). TAP block's opioid-sparing action is advantageous in reducing airway consequences in obese patients. Less opioid use also reduces the incidence

of nausea and vomiting, which can be quite distressing for postoperative patients (Bugada, et al 2013).

In morbidly obese patients undergoing laparoscopic bariatric surgery, Sinha et al. (2013) used ultrasonic guided posterior TAP blocks as part of multimodal analgesic technique. After enport sleeve gastrectomy, Wassef et al. (2013) found that posterior TAP block provided adequate analgesia. Albrecht et al. (2013), on the other hand, found that adding bilateral TAP block to the trocar insertion site local anesthetic infiltration for laparoscopic gastric bypass surgery does not provide further analgesic benefits. Local anesthesia infiltration at trocar sites combined with regional techniques can be utilized in the context of multimodal analgesia to minimize opioid consumption after bariatric surgery (Ar DE) (2016).

Focusing on pain as one of the main aspects that obese patients have, the main site of pain is back pain, and is mainly moderate pain (mean of 4/10), and sleeve gastrectomy surgeries showed to significantly decrease back pain after the intervention (Gallart-Aragón et al., 2018). Of the main used intraoperative methods for anesthesia in sleeve gastrectomy are intravenous paracetamol (perfalgan), dipyrone (which has the trade name of optalgin, a powerful analgesic and antipyretic agent), ketorolac (non-steroidal anti-inflammatory drug, NSAID) and lidocaine as an infiltrative agent administered in the wound. The use of additional agents can be done according to difference in anesthetist’s preferences, availability of agents and individual differences of patients (Cooke et al., 2018).

The main aim of the study is to compare between two models of pain management in gastric sleeve, which are the use of intravenous paracetamol, ketorolac, dipyrone and local infiltration (Group one), and the use of transversus abdominis plane (TAP) block added to paracetamol, ketorolac, dipyrone and local infiltration (Group two), in pain outcomes postoperatively, especially the time needed for the administration of additional pain killer, rescue analgesia, alongside the length of stay as the main hospital outcome, and incidence of complications.

1.2 Problem statement

Most of the Palestinian surgeons and anesthetists are considering similar anesthetic approaches, and despite that sleeve gastrectomy, and bariatric surgeries in general, have little postoperative pain because anesthetists tend to consider various approaches of intraoperative and postoperative pain management methods (Sabharwal and Christelis, 2010), different pain and anesthetic agents are still used in different hospitals and surgical settings.

This difference in the use of pain management methods tend to affect different characteristics of pain in the postoperative stage, and one main aspect is the time until there will be a need to use a pain killer, mainly opioids, like pethidine. Moreover, there is a difference in hospitalization outcomes like length of stay and other complications (Tekeli et al., 2019).

1.3 Significance of the Study

Effective postoperative pain management is unquestionably a vital aspect of postoperative treatment. Pain relief is becoming an effective postoperative indicator of ‘Quality of treatment' due to substantial physiological benefits (Abrishami, et al 2011). It is impossible to overestimate the significance of this, particularly in bariatric patients. Many experiments have been carried out to evaluate VAS scores and pain after TAP blocks**.**

This study will provide the medical and anesthetic field in Palestine with the up-to-date clinical comparison between infiltrative administration of local anesthetic agent with intravenous paracetamol, ketorolac and dipyrone (optalgin), and the addition of tap block to all of the previous agents. The comparison is between both models in the time needed for the use of pain killer postoperatively, and other hospital outcomes like length of stay and incidence of complications.

1.4 Study question

1. What is the difference in postoperative pain outcome (consumption of rescue analgesia) between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals?

2. What is the difference in postoperative hospital outcomes (length of stay and incidence of complications) between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals?

3. What is the difference in postoperative symptoms (nausea, vomiting, dizziness, tinnitus, perioral numbness, lethargy, seizures, and signs of brain toxicity, dyspnea, flatus passage, bowel movement) between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals?

1.5 Hypothesis

H_0: There is no significant difference in postoperative pain outcome (consumption of rescue analgesia) at a significant level of 0.05 between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals.

H_0: There is no significant difference in postoperative length of stay in hospital between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals.

H_0: There is no significant difference in postoperative symptoms (nausea, vomiting, headache, drowsiness, dyspnea, flatus passage) at a significant level of 0.05 between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals.

Chapter Two
Literature Review

Literature review is based on searching scientific databases of PubMed, ScienceDirect, Google Scholar and other anesthesia-specific categories journals, and articles are pooled and a revised in order to select the most relevant ones for our aim. Specific keywords were used when searching are: sleeve gastrectomy, pain management in laparoscopic sleeve gastrectomy, anesthesia in laparoscopic sleeve gastrectomy, TAP block, infiltrative administration, lidocaine and bupivacaine, dipyrone, acetaminophen, and ketorolac.

2.1 Anesthetic agents used in sleeve gastrectomy

In this section, we will review some of the most used anesthetic drugs used in laparoscopic sleeve gastrectomy, especially in Palestine, focusing on drugs that are intended to be used in trial.

Definitions

Pain: An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (K. Hanoch Kumar1 , P. Elavarasi 2016).

Nausea and Vomiting : chemoreceptor trigger zone at the base of the fourth ventricle has numerous dopamine D_2 receptors, serotonin 5-HT_3 receptors, opioid_receptors, acetylcholine receptors, and receptors for substance P, stimulation of different receptors are involved in different

pathways leading to emesis, in the final common pathway substance P appears involved , the vagal and enteric nervous system inputs transmit information regarding the state of the system, irritation of the GI mucosa by chemotherapy, radiation, distention, or acute infectious gastroenteritis activates the 5-HT_3 receptors of these inputs.

Paracetamol (or acetaminophen) is a widely used analgesic and antipyretic medication. While the exact mechanism of action of analgesic action is not fully understood, acetaminophen may inhibit nitric oxide pathway that is mediated by many neurotransmitter receptors, which results in elevation in the pain threshold. On the other hand, the antipyretic action is resulted from the inhibition of prostaglandin synthesis and release in the central nervous system and prostaglandin mediated effect in the anterior hypothalamus's heat-regulation center (Ennis et al., 2016).

Lidocaine is a synthetic local anesthetic and antiarrhythmic agent, and its mechanism is based on stabilization of neuronal membrane by binding to and inhibition of voltage-gated sodium channels, which results in the inhibition of ionic fluxes that are required for initiation and conduction of impulses. Amide local anesthetics are widely used in minor surgeries or invasive procedures for the purpose of pain control, and they are not linked to elevated serum concentrations of enzymes, but can do so when given on continuous infusions or repeated injections, which affects liver mainly (Thomson et al., 1973).

Bupivacaine is an amide-type, long-acting local anesthetic agent, and its action is based on its reverse bind to specific sodium ion channels in the neuronal membrane, which results in decreasing membrane's permeability dependence to sodium ions, inhibition of depolarization and nerve impulses conduction, and a reversible loss of sensation (Beiranvand and Moradkhani, 2018). It has the trade name of Marcaine in our settings.

Dipyrone, or metamizole, has the trade name of optalgin, is an organic sodium salt of antipyrine, a commonly used powerful analgesic and antipyretic agent. It has many roles, including NSAID, non-narcotic analgesia, antirheumatic agent, peripheral nervous system drug, antipyretic and a prodrug (dos Santos et al., 2014).

Ketorolac is a synthetic form of pyrolizine carboxylic acid, and has an anti-inflammatory, analgesic and antipyretic activities. Mechanism of action is based on inhibition of the enzymes cyclooxygenase 1 (COX-1) and COX-2, where the inhibition of COX-1 prevents normal steady production of prostaglandins, and the inhibition of COX-2 prevents the conversion process that leads to the synthesis of pro-inflammatory prostaglandins. On the other hand, the inhibition process of COX-1 can lead to gastrointestinal toxicity, nephrotoxicity and inhibition of platelets aggregation (Hashem et al., 2019).

Meperidine (Pethidine): is a synthetic piperidine ester with opioid analgesic activity. Meperidine mimics the actions of endogenous neuropeptides via mu-opioid receptor, anti-shivering effect may involve the stimulation of

k-opioid receptors, meperidine has stimulant effects by inhibition of the dopamine transporter (DAT) and norepinephrine transporter.

Granisetron: is an indazole derivative with antiemetic properties, as a selective serotonin receptor antagonist, Granisetron competitively blocks the action of serotonin at 5-hydroxytryptamine3 (5-HT3) receptors, resulting in the suppression of chemotherapy- and radiotherapy-induced nausea and vomiting, serotonin type 3 (5-HT3) receptor antagonists are potent antiemetic's used for prevention of postsurgical or chemotherapy induced nausea and vomiting and for some agents as therapy of diarrhea-predominant irritable bowel syndrome, 5-HT3 receptor antagonists are associated with a low rate of transient serum enzyme elevations during therapy, but have been only rarely implicated in cases of clinically apparent liver injury.

2.2 Anesthesia in sleeve gastrectomy

A lot of studies are concerned about anesthetic management in sleeve gastrectomy patients across all phases. A systematic review that was conducted by Schumann (2011) stated that studies in general agree that the positioning of a blanket under the upper body part improves laryngoscopic view compared with the standard sniffing position, as well as that positioning patient in 25 to 30 degrees reversed Trendelenburg, head up or semi-sitting position may prolong the safe time of airway management during induction. For anesthesia maintenance during surgery, studies show that the use of isoflurane, desflurane and sevoflurane is safe for obese

patients undergoing sleeve gastrectomy for the purpose of maintaining general anesthesia. the review also stated that due the difference in pharmacodynamics and pharmacokinetics of various medications used in obsess patients, dosing differs according to many factors. For example, non-depolarizing neuromuscular blockers like vecuronium, rocuronium and cisatracurium have hydrophilic and polar structure, thus the limited volume of their distribution, and articles generally agree that they should be administered in a weight-based dose according to total body weight (TBW), although most manufacturers recommend the initial dose to be given according to ideal body weight (IBW), like succinylcholine that is dosed at 1 mg per kilogram (kg) of TBW. For propofol, it should be administered according to TBW to avoid its accumulation, with the necessity of focusing on other co-morbidities and physical status. Studies also showed that intraoperative and postoperative infusions of fentanyl according to TBW overestimates the requirements, which potentially leads to overdosing. In general, medications with unknown pharmacodynamics and pharmacokinetics should be administered according to lean body mass (LBM).

The previous review is parallel with the study conducted by Sabharwal and Christelis (2010) in that preoperative assessment should be conducted by multidisciplinary team, including endocrinologists, dieticians, psychologists, specialist nurses and experienced surgeons and anesthetics, in order to obtain the best overview of patient’s suitability for the surgery. For example, the researchers and other studies state that BMI per se isn’t

enough to be relied on for the decision of intubation difficulty, and other factors should be assessed, like Mallampati score of more or equal to 3, neck circumference, where it is found that intubation difficulty is up to 5% in 40 cm neck circumference, where it significantly increases to 35% in neck circumference of 60 cm (Soleimanpour et al., 2017). Regarding intraoperative positioning, Sabharwal and Christelis (2010) stated that laparoscopic gastrectomy patients should be place in a Lloyd Davis position (steep reverse Trendelenburg with spread legs and both arms out on arm boards). The researchers also agree that most of non-depolarizing agents should be dosed according to LBM (that is calculated by adding 20% of IBW), with remifentanil excepted. For the purpose of anesthetic maintenance during surgery, the study states that the use of desflurane is the most suggested, because of its low partition in blood gas that results in faster recovery, while other agents like propofol and remifentanil are also successfully used. Soleimanpour et al. (2017) stated that obese patients have reduced functional residual volume and limited O_2 reserves due to apnea, and thus preoxygenation in the reverse Trendelenburg position prior to intubation is necessary, in order to reach an arterial saturation of 100% for several minutes. Moreover, to best establish intubation for this kind of patients, a rapid induction of IV propofol and succinylcholine in addition to cricoid pressure should be performed.

Regarding anesthetic management and difficulty of intubation in specific laparoscopic sleeve gastrectomy patients, Tekeli et al. (2019) conducted a retrospective observational study on 60 adult (age = 18-65 YO) patients

who have BMI of more than 30 kg/m^2, with the presence of other comorbidities, to investigate intubation difficulties and its correlation with body characteristics. First, patients were pre-oxygenated using non-rebreathing face mask (100% 4 L/min O_2 for 3 minutes), then, the induction of anesthesia was performed by administering 1-2 mg/kg of propofol, 0.8 mg/kg of rocuronium and 0.1 ug/kg of fentanyl, taking in consideration that they were calculated according to IBW. Endotracheal tube size had internal diameter of 8.0 mm for men and 7.0 mm of women, and inserted using Macintosh standard blade laryngoscopy, and monitored using end-tidal CO_2 ($etCO_2$), with anesthesia being maintained using sevoflurane inhalation in a 0.5 O_2 oxygen air mixture. Results of this study showed that there is a significant correlation between limited neck extension during intubation with both BMI (p-value = 0.001) and weight (p-value = 0.001), while there was no significant correlation with height (p-value = 0.266). On the other hand, difficult intubation was not significantly correlated with BMI (p-value = 0.103), weight (p-value = 0.098) or height (p-value = 0.799).

2.3 Pain management in postoperative stage of sleeve gastrectomy

Soleimanpour et al. (2017) stated that the most important considerations of the postoperative phase of sleeve gastrectomy are pain control, wound care, deep vein thrombosis prophylaxis and fluid management, and pain is best controlled by patient-controlled analgesia, while IV opioids may induce respiratory depression, especially with continuous infusion method. Studies

were also concerned about postoperative phase of laparoscopic sleeve gastrectomy, like Jonsson et al. (2018), who stated many factors that affect postoperative aspects of the surgery. They stated that the mean LoS was 1.7 days, and early operating room start time and treating sleep apnea is correlated with decreased LoS (p-value < 0.05), while preoperative use of opioids is correlated with delayed discharge (p-value > 0.05). other factors that delayed discharge include creatinine level > 1.5 mg/dL and ejection fraction < 50%.

A systematic review concerned in specific pain management medications for laparoscopic sleeve gastrectomy was conducted by Macfater et al. (2019), who searched for 18 randomized controlled trials (RCTs) about available postoperative pain management methods. Briefly concluded, results showed that systemic non-opioids analgesics are widely used. Acetaminophen showed mixed differences in pain scores postoperatively, but with no significant difference when combined with diclofenac and tramadol. Studies also showed that gabapentinoids like gabapentin and pregabalin decrease pain scores and postoperative opioid consumption significantly. Other studies were concerned in drug combinations, where the review showed a significant lower opioid consumption and pain scores when combining dexamethasone, ondansetron and haloperidol, while there was no significant difference when ondansetron was combined with dexamethasone or with placebo. Lastly, studies have controversial findings regarding TAP block, where all studies agree that they significantly decrease level of postoperative pain, especially in the first 12 hours, while

they differ in the results regarding opioids consumption, where most of studies show no significant difference between TAP block and its absence in opioids consumption.

The review that was conducted by Schumann (2011) stated that the use of postoperative opioids in bariatric surgeries in general, and sleeve gastrectomy is no exceptions, is best to be avoided to achieve opioid-free or sparing because of the well-documented serious respiratory depression risk, especially in patients who are obese and complain of obstructive sleep apnea (OSA). Side effects also include pruritis, nausea, vomiting and delayed bowel function. Of the most strategies to overcome this problem is the use of multimodal analgesics, which are mainly non-steroidal anti-inflammatory drugs (NSAIDs) like ketorolac, and local anesthetic port and wound infiltration or infusion, like lidocaine. The use of these two agents should be the main alongside other non-opioid analgesics. The mentioned study also agrees with the study of Sabharwal and Christelis (2010) who stated that despite the relative little pain of laparoscopic sleeve gastrectomy patients, the use of adequate local anesthetic wound infiltration, patient-controlled analgesia and the use of rectus sheath block by surgeon should be considered for optimal pain management. This may include the use of regular intravenous (IV) acetaminophen, short-term use of NSAIDs if not contraindicated and tramadol.

A randomized, double-blind, placebo-controlled study was conducted by Cooke et al. (2018) to investigate the effect of intravenous acetaminophen when used in both induction and postoperative phases of sleeve gastrectomy on different postoperative complications, including pain. Taking in consideration that the method included the use of patient-controlled morphine infusion, the mean pain score in acetaminophen group was 2.9/10, while it was not significantly different in placebo group (3.6/10, p-value = 0.25). Also, 62% of patients who received acetaminophen have consumed narcotics, while 61% of placebo group patients consumed narcotics (p-value > 0.99), and the mean morphine dose consumed was not significantly different between both groups (2.1 mg for acetaminophen group and 2.4 mg for placebo group, p-value = 0.25). When speaking about patients who were enrolled in the mentioned study, it was noticed a control in most of the preoperative characteristics, including no difference in patients' mean BMI before surgery (46.6 for acetaminophen group and 47.3 for placebo group). Moreover, the researchers controlled intraoperative characteristics, where the mean anesthesia duration for acetaminophen group was 118.3 minutes, with a mean surgery duration of 88.5 minutes, while the mean anesthesia duration was 119.7 minutes with a mean surgery duration of 89.4 minutes in the controlled group. Lastly, there was no significant difference in the use of intraoperative mean crystalloids volume, fentanyl (263.2 ug vs 258.2 ug) and dilaudid (1.2 mg vs 1.3 mg), respectively.

An Egyptian prospective, randomized, double-blind controlled study was conducted by Elbakry et al. (2018) at Menoufia University Hospital on a total of 100 morbidly obese patients undergoing laparoscopic sleeve gastrectomy to compare total intravenous anesthesia (TIVA) with balanced intravenous and inhaled agent in terms of postoperative pain and other aspects. The general anesthesia in both groups was the same, where they received a premedication of oral sodium citrate 15 ml and intravenous 4 mg ondansetron 15 minutes prior to induction, and induction was performed by administering 0.5-1.0 ug/kg of remifentanil, 2-3 mg/kg of propofol and 0.6 mg/kg rocuronium. On the other hand, anesthetic maintenance was performed using remifentanil 0.05-2 ug/kg/min for both groups, and using propofol 100-200 ug/kg/min and dexmedetomidine 0.5-1 ug/kg/hr for TIVA group, and desflurane in an oxygen air mixture of 60/40% for the control group. Regarding postoperative pain management, there was a significant difference between desflurane and TIVA groups, regarding mean total morphine consumption (10.35 mg vs 5.36 mg), mean total paracetamol consumption (3.56 gm vs. 1.67 gm), and mean ketorolac consumption (210.35 mg vs. 150.36 mg), respectively, with a p-value < 0.0001.

A randomized controlled trial was conducted by Alamdari et al. (2018) to investigate the effect of using intraperitoneal bupivacaine hydrochloride on the postoperative pain alleviation after laparoscopic sleeve gastrectomy. The study was conducted on 120 eligible patients, who have BMI more than 40 kg/m^2, or 35 kg/m^2 with other comorbidities, excluding patients

who have allergies of anesthetic agents, revision gastrectomy surgeries, past history of foregut surgeries and patients who used analgesic drugs in the last 24 hours. First, all patient underwent general anesthesia, using midazolam 0.01 mg/kg and fentanyl 1 ug/kg as premedication, and nesdonal 5mg/kg and atracurium besylate 0.5 mg/kg as an induction prior to intubation. For anesthetic maintenance purpose, halothane with atracurium, O_2, and nitrous oxide were used, and patients were positioned in Lloyd Davis position. Patients were divided into two groups, where the interventional group received 30 ml of bupivacaine hydrochloride of 0.25% concentration in the intraperitoneal area added to conventional management, and the control group received conventional management only. Postoperatively, both groups received diclofenac suppository and IV paracetamol. Regarding postoperative pain, results showed that both groups didn't show a significant difference in pain according to BMI. On the other hand, results showed significant difference in pain scores between both groups at 6, 12 and 24 hours postoperatively, where the mean pain score was 7.9/10 vs 9.1/10 at 6 hours, 5.6/10 vs 7.8/10 at 12 hours and 3.4/10 vs 5.7/10 at 24 hours, for interventional and controlled group, respectively (p-value <0.001).

In Turkey, Sisik and Erdem (2019) conducted a case-control study to investigate the effect of trocar site bupivacaine administration on many postoperative factors including pain characteristics. The study was conducted on a total number of 168 patients who underwent laparoscopic sleeve gastrectomy, and divided into two similar groups, the study group

received local infiltration of bupivacaine and the control group did not. Patients were pre-medicated with 10 mg of diazepam 30 minutes prior to surgery, and general anesthesia was induced with propofol and fentanyl, and maintained with IV rocuronium and sevoflurane inhalation after intubation, and both groups received 150 ug of fentanyl, 100 mg of paracetamol and 100 mg of tramadol at the end of the surgery. Study group received 40 ml of bupivacaine 0.25% with 1:200,000 epinephrine mixture in the trocar entry site before incision, while the control group did not receive this mixture. Generally, results showed that there was no significant difference in pain (according to visual analogue score (VAS)) between both groups at 4^{th}, 8^{th}, 12^{th}, 24^{th} and 48^{th} hour postoperatively (p-value > 0.05), and the same for percentage of patients who required opioids (47.6% in both groups, p-value = 1.000) and the used opioid dose (28.5 mg vs. 38.1 mg, p-value = 0.685). On the other hand, when patients were compared regarding the first time of flatus passage, early flatus passage patients (before 12 hours) showed significant decrease in pain scores at the 48^{th} hour only (p-value = 0.036), and when compared according to surgery time, patients with longer operation time (more than 50 minutes) showed significant higher pain score at the 8^{th} hour postoperatively, with no significant difference in all other pain times.

Another American double-blind randomized controlled trial was conducted by Saber et al. (2019) to investigate the efficacy of transversus abdominis plane (TAP) block in laparoscopic sleeve gastrectomy patients. The study was conducted on 90 patients who were divided equally to three groups (30

patients each): placebo group, TAP block group and TAP block with epinephrine group. Agents were administered by the surgeon on each side of the transversus abdominis plane using long spinal needle attaches to a 30 ml syringe. TAP group received 20 ml of 0.25% bupivacaine in the site, while TAP and epinephrine group received the mixture of 1:200,000 epinephrine added to 20 ml of bupivacaine 0.25%. All patients received 900 mg of acetaminophen 90 minutes prior to surgery, pre-medicated with 10 mg of metoclopramide, 8mg of dexamethasone and 5000 units of heparin, and induction was done by administering propofol, midazolam and fentanyl according to body weight. Postoperatively, patients received 650 mg of acetaminophen q6 hours and 100 mg of gabapentin q8 hours, and if patient required more pain control, opioids (morphine and hydromorphone) were administered. Lastly, for PONV management, 10 mg of IV metoclopramide q6 hours and 4mg of ondansetron q6 hours PRN were given. Patients' characteristics have no differences among groups regarding operation time, estimated blood loss, obstructive sleep apnea, age, weight and BMI. The main results about pain is that there was significant difference (p-value = 0.036) in pain scores at the third hour postoperatively between the three groups, where the mean pain score for placebo was 7.87/10, while it was 6.9/10 for bupivacaine group and 6.46/10 for bupivacaine and epinephrine group. Other pain score times of 1, 6, 12, 18 and 24 hours were not significantly different between groups. The researchers also stated that the intention was to compare pain scores for the first 48 hours postoperatively, but due to that most of the patients (70 out of

90 patients) were discharged earlier than 30 hours, there was insufficient data to complete this comparison. Moreover, there was no significant difference in the use of postoperative pain control medications, where in placebo group, the mean total dose of paracetamol was 2645 mg, gabapentin was 445 mg, morphine was 4.45 and tramadol was 15 mg, where the mean paracetamol total dose was 2296 mg for bupivacaine only group, 327 mg of gabapentin, 2.85 mg of morphine, and for the bupivacaine + epinephrine group was 2690 mg of paracetamol, 354 mg of gabapentin, 4.09 mg of morphine and 22.5 mg of tramadol.

A prospective randomized study that was conducted in Spain by Ruiz-Tovar et al. (2017) to investigate pain characteristics when different analgesic schemes were used. The study was conducted on a sample of 147 laparoscopic sleeve gastrectomy patients, who were divided into three groups: first group received exclusive IV analgesia (2 g of metamizole q8 hours and 1 gm of acetaminophen q8 hours, alternated each 4 hours), second group received IV analgesia with epidural analgesia (thoracic epidural catheter at the level of T6-T7, with a continuous infusion of 6 ml/h of 0.125% levobupivacaine, removed 48 hours postoperatively) , and third group received IV analgesia with infiltrative administration of 10 ml of 0.25% bupivacaine (2 ml in each aponeurotic layer of each port). Pain assessment is made upon VAS and when it exceeded 50 mm, 5 mg of subcutaneous morphine was given. Results showed that there was no significant difference between groups in terms of operation time and complications as well as mortality rates and LoS, which indicates high

level of control and isolation of factors. Regarding pain, the mean pain score for the first group was 5/10, while it was 2.5/10 for the second group and 2/10 for the third group, with a significant difference between the first and second group (p-vale = 0.03), and between the first and the third group (p-value = 0.007), while there was no significant difference between the second and third groups (p-value = 0.456). Lastly, regarding morphine consumption, 16.3% of the first group patients have consumed it, while only 2% of the second and third group did, with a significant difference between the first and second groups (p-value = 0.014),and between first and third groups (p-value = 0.014), but not between second and third groups (p-value = 0.766). The study eventually concluded hat the use of port infiltration and epidural analgesia combined with conventional IV analgesia showed less pain scores and morphine consumption than exclusive analgesia, with no significant difference between them.

A Turkish study conducted by Coşkun et al. (2019) to investigate pain characteristics after laparoscopic sleeve gastrectomy between the use of bilateral subcostal TAP block and trocar site infiltration. The study was conducted on a sample of 45 patients who were between age of 18 and 65 YO, with a mean BMI of 50.24 kg/m^2 for TAP block group and 48.4 kg/m^2 for bupivacaine group (p-value = 0.43). Regarding anesthesia induction, both groups were induced with 2 mg/kg of propofol, 1 ug/kg of remifentanil and 0.6 mg/kg of rocuronium and maintained with desflurane 5-7% and 0.05 to 0.1 ug/kg/min remifentanil infusion. Neuromuscular block reversal was performed using 4 mg/kg of sugammadex before

extubation. For the subcostal TAP block procedure, it was performed by administering 20 ml of local anesthesia mixture (10 ml of 0.5% bupivacaine, 5 ml of 2% lidocaine and 5 ml of saline) in both sides of abdominal walls, under guidance of ultrasound, and waited for 30 minutes for its action. On the other hand, trocar site infiltration was performed using 25 ml of 0.25% bupivacaine, where 5 ml was injected in each trocar site. Postoperative pain assessment was done using VAS scale at 1st, 3rd, 6th, 12th, 24th, 36th and 48th hours postoperatively, both when patient is resting and coughing. Results showed no significant difference in pain score between both procedures at all assessment hours (except at the 6th hour, less in TAP block, p-value = 0.001 when resting and 0.012 when coughing), and thus the researchers stated that there is no difference between both procedures in pain control purpose, thus they recommended the use of trocar site infiltration as it is time-efficient.

Arı et al. (2017) are Turkish researchers who conducted a study to investigate the difference in pain scores and morphine consumption between both groups who underwent laparoscopic sleeve gastrectomy, where the first group used TAP block in the bilateral subcostal area and the second group received TAP block in bilateral subcostal and posterior area. Each group contained of 20 patients who are morbidly obese, and 30 ml of 0.2% bupivacaine was used to be injected in the intended site under guidance of ultrasound. Results showed no significant difference between both groups in pain scores according to VAS scale (at 30th minute, 2nd, 4th, 6th, 12th and 24th hours), and the same for both 24-hour morphine

consumption (mean dose for first group was 6.78 mg and 7.28 mg for the second group, p-value = 0.795) and first morphine requirement (mean time was 267.22 minutes for the first group and 207.80 for the second group, p-value = 0.154).

2.4 Other complications of sleeve gastrectomy

The study that was conducted by Sabharwal and Christelis (2010) stated some factors that would increase the risk of sleeve gastrectomy patients to have increased likelihood of postoperative complications, which are gastric bypass surgeries, male gender, BMI of more than 50 kg per m^2, age of more than 50 YO, a confirmed diagnosis of OSA, significant medical or surgical co-morbidity and previous abdominal surgeries.

The study that was conducted by Cooke et al. (2018) also investigated for other complications and characteristics regarding postoperative phase of sleeve gastrectomy. The median length of stay (LoS) was significantly different between acetaminophen group (1.87 days) compared with controlled group (1.96 days, p-value = 0.03), while the mean LoS was not significantly different. On the other hand, other complications were not significantly different between both groups, including postoperative nausea and vomiting (PONV) incidence (44.4% vs 57.8%, p-value = 0.37), and the use of PONV medications, which are ondansetron (89.3% vs 75.7%, p-value = 0.16) and metoclopramide (7.1% vs 10.8%, p-value = 0.69). The trial that was conducted by Alamdari et al. (2018) also stated that mean length of stay for patients who received intraperitoneal bupivacaine didn’t

significantly differ from patients who received conventional management only (p-value = 0.064). on the other hand, PONV occurrence was significantly lower among interventional group (11.7%) compared with controlled group (41.7%, p-value < 0.001).

The Egyptian study of Elbakry et al. (2018) also investigated for other postoperative aspects of laparoscopic sleeve gastrectomy, and the difference in them between desflurane and TIVA groups. First, in the intraoperative stage, there was no significant difference in mean surgery duration (102.45 minutes vs. 104.14 minutes, p-value 0.55) and mean recovery time (20.36 minutes vs. 19.56 minutes, p-value = 0.41), respectively. Postoperatively, there was a significant difference between both groups in incidence of nausea (30% vs. 10%, p-value = 0.01) and vomiting (28% vs. 6%, p-value = 0.003), while there was no significant difference in mean time of onset of bowel movement (10.36 hours vs. 11.33 hours, p-value = 0.16), respectively.

The American study by Saber et al. (2019) also investigated for PONV and LoS as secondary characteristics associated with the use of TAP block with and without epinephrine and compared with placebo. Due to the same cause of early patients' discharge, there was no possibility for the comparison of PONV for 48 hours, and results showed no significant difference in nausea/vomiting scores at 1^{st}, 3^{rd}, 6^{th}, 12^{th}, 18^{th} and 24^{th} hour postoperatively, and the same for nausea/vomiting medications given at the same time points (p-value > 0.05). Lastly, the mean LoS for placebo group

was 1.61 days, while it was 1.37 days for bupivacaine only group and 1.31 days for bupivacaine + epinephrine group, with no significant difference between them (p-value > 0,05).

Hariri et al. (2019) conducted a retrospective study about the effect of ketorolac administration on LoS in bariatric surgeries, among other postoperative characteristics. The sleeve gastrectomy sample (1255 patients) were divided into two groups, ketorolac-only group, and ketorolac with opioid group with the control of comorbidities, age and gender between groups (p-value > 0.05). results showed that LoS is significantly lower among ketorolac + opioid patient (mean = 1.7 days) compared to ketorolac-only group (mean = 2.0 days, p-value < 0.001). Regarding other corresponding factors, LoS was significantly shorter in patients who underwent sleeve gastrectomy (compared with Roux-en-Y gastric bypass), and normotensive patients (p-value < 0.001).

Chapter Three

Methodology

This chapter includes study design, site and setting, sample and sampling, inclusion and exclusion criteria, period of the study, data collection tool, randomization, blindness, assignment of intervention, anesthesia protocol, validity and reliability of the data sheet, pilot testing, statistical analysis and ethical consideration.

3.1 Study Design

A double-blind randomized controlled trial (RCT) design was conducted because it is the most suitable for our aims, and it is rigorous compared with other designs.

RCTs provide the essential background to practicing evidence-based medicine, because they provide the best estimate of the beneficial effects of treatment, as well as providing that a treatment is supposedly dangerous (Bulpitt, 1996). Stang (2011) also mentioned that one of the biggest advantages of randomized trials over non-randomized trials is that randomizations results in comparing the different groups of patients in the study based on their prognostic factors, which means that comparing will not be only regarding known prognostic factors, but also in respect to unknown factors. Also, randomization is beneficial in statistical analysis which is readily interpretable.

3.2 Site and Setting

The study was conducted in St. Joseph Hospital – Jerusalem. This hospital has highly qualified team specialized in laparoscopic sleeve gastrectomy, as well as the low percentage of complications, and criteria of patient selection is rigor and strict. Moreover, the number of surgeries that are done helps in data collection to be finished in less time period.

3.3 Sample and Sampling

Population included all patients who underwent laparoscopic sleeve gastrectomy in the targeted hospital. The sampling was done using a simple randomization method. The sequence generation was done by computer. All patients who met the inclusion criteria were randomized into two groups. The first group was the interventional group (with TAP block), and the second group was the control group (without TAP block). Sample size was calculated using G-power equation.

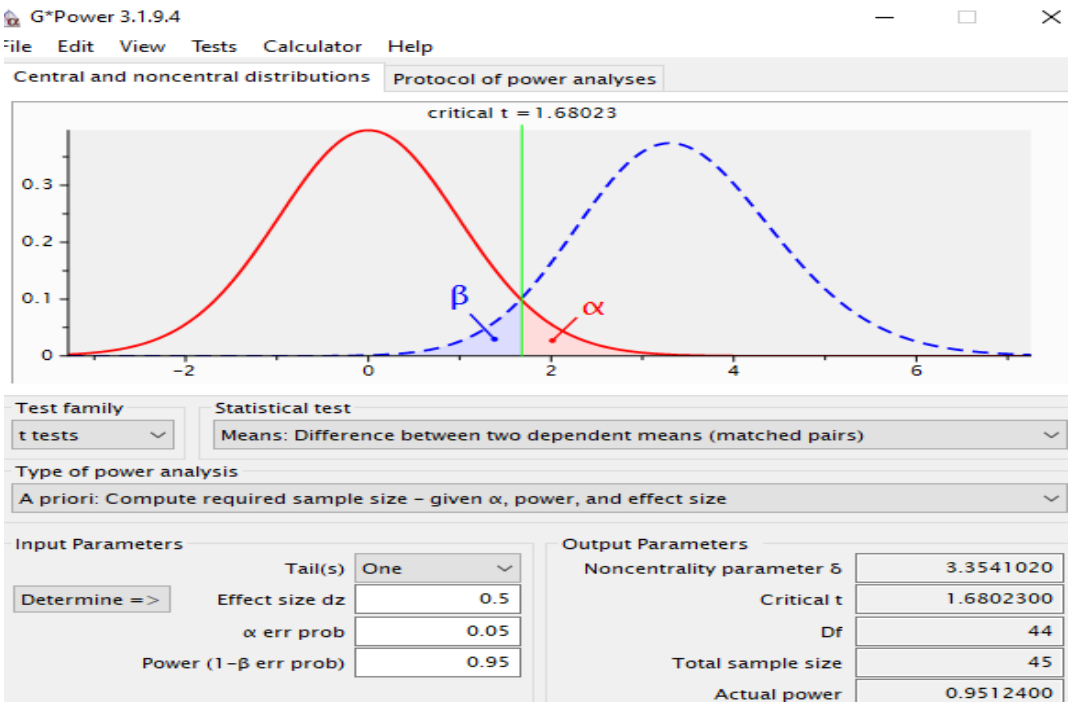

Figure 1: Randomization list.

The total sample size is 45 patients, 10% of the sample was added to cover the dropout. So there were 50 patients, 25 patients in each group

3.4 Inclusion and Exclusion Criteria

Inclusion criteria:

1. Adult patient (18 – 65 YO)
2. BMI > 35 kg/m^2
3. Has a score of ASAS 1 to ASA 2 according to American Society of Anesthesia
4. Didn’t receive long-term analgesic agent 12 hours prior to surgery
5. Undergoing laparoscopic sleeve gastrectomy

6. Exclusion criteria

1. Local anesthetic allergy, coagulopathy, or infection in the area are all contraindications to peripheral nerve block.

2. A history of opioid use or a chronic pain condition3. ASA Grade 4 or more

3. Chronic kidney disease

4. Chronic liver disease

5. Chronic obstructive pulmonary disease

6. Any psychiatric illness

7. history of dysrhythmia .

8. chronic anti depressant drugs .

3.5 Period of the Study

The intended period of data collection was September 1st 2020 to January 31st 2021. This period is suitable for the intended number of sample to be collected.

3.6 Randomization

Patients were allocated in two groups, using a computer generated randomization sequence using http://www.randomization.com. The envelopes used for randomization were opaque and well-sealed. The sequence number was written on the envelope, and the type of the group

was written on the card within it. As patients arrived, the envelope was opened to reveal the group to which they would be assigned.

Experimental group: (n=25) received a TAP block,

Control group: (n=25) do not received TAP block

Random Permuations

Generate a random permutation of all integers from the smallest to the largest

Smallest integer 1

Largest integer 50

○ Single column

◉ 25 integers per line

A Random Permutation From http://www.randomization.com

Read this way ---->

48 17 35 45 47 34 24 11 23 39 21 3 19 49 44 6 30 2 22 50 7 20 18 46 42 25 16 14 38 13 9 36 29 27 43 26 1 37 5 15 33 28 4 31 12 40 32 41 10 8

3.7 Blindness

The treatment group allocation is unknown to the patients, health care providers involved in patient care, the person who collected and analyzed data, and outcome adjudicators.

Prior to incision, the surgeon applied 4 mL of 0.25% bupivacaine to each trocar insertion site. During surgery, the intra-abdominal pressure was kept to a maximum of 15 mm Hg. Paracetamol, dipyrone, and ketorolac were given to patients intraoperatively.

3.8 Assignment of Interventions

Study drugs were processed by a nurse unrelated to the study. Medication was administered in a 50 mL syringe. The anesthetist administered TAP was not involved in patients' care postoperatively.

All patients in intervention group received USG-guided TAP block after the completion of surgery. At each injection location, 30 cc of 0.2% bupivacaine was used in an ultrasound-controlled TAP block. The TAP block was performed with a linear ultrasound probe. The probe was positioned across the mid axillary line between the iliac crest and the costal border for the posterior approach. The transverse abdominis, the inner oblique border, and the outer oblique muscles are all visible. The probe was positioned obliquely on the upper abdomen wall along the subcostal border near the midline for the subcostal block. The probe was gradually pushed laterally along the subcostal border after identifying the rectus abdominis

muscle to detect the transverse abdominal muscle behind the rectus muscle. The muscles of the outer and inner oblique were also seen. In all treatments, a Pajunk needle (22-gauge) was introduced anteriorly into the plane. The needle was inserted into the fascia between the internal oblique and transverse abdominis muscles, and 2 ml of 0.9% saline was injected to confirm proper needle placement. Following a negative aspiration, the fascia was injected with 30 ml of 0.2% bupivacaine. A black oval form was detected between two muscles as the injected solution spread. A black oval form was detected between two muscles as the injected solution spread. An assistance was necessary to pull the abdomen away for the rear TAP block.

Lidocaine dose according to weight = 3-4mg/kg

Bupivacaine dose according to weight = 2-3 mg/kg

Data collection tool is self-made by researchers, and includes three parts. The first part includes demographic data about the patient (number, age, BMI, comorbidities, obstructive sleep apnea, difficult intubation scores like Mallampati score, anesthesia time, operation time, recovery time, Aldrete score), the second part collects data about postoperative pain incidence and intensity (pain scores at zero minute, 30 minutes,2, 4, 6, 12, and 24 hours postoperatively using VAS during the first hour and 0-10 point scale , afterwards, first rescue analgesia time and total 24-hour analgesia dose), and the third part collects data about LOS, PONV (first vomiting event and total 24-hour dose of antiemetic), rescue antiemetic medications, headache,

drowsiness, dyspnea, flatus passing, bowel movement. The data was collected by an anesthesiologist who was unaware of the groupings.

Outcomes. The patients were taught how to use the 10 cm visual analogue scale (VAS) to rate their pain from 0 (no pain) to 10 (extreme pain) before the operation (most severe pain). After TAP blocks, the pain level was measured at various periods (0 min, 30 min, 2 hours, 4 hours, 6 hours, 12 hours, and 24 hours). After the TAP block, patients were monitored in the recovery room for 30 minutes. Patients were given 100 mg pethidine (25 mg I.V. and 75 mg I.M.) on the surgical ward if their VAS exceeded 4. Pethidine consumption (24 hours) time to the first Pethidine need, rescue painkillers required (yes / no), occurrence of postoperative nausea and vomiting (PONV), time to the first Ondansetron need, and patient satisfaction was recorded. The moment the patient was given the first dose of morphine is regarded as the time for the first morphine requirements. Antiemetics are not given as a preventative measure. On a Likert scale of 0 to 6, the presence of PONV during the study period is noted as none (0), very mild (1), mild (2), moderate (3), severe (4), very severe (5), and intolerable (6). A 5-point Equal scale was used to assess patient satisfaction with analgesics 24 hours after the TAP block (5: excellent; 4: good; 3: fair; 2: bad; 1: very bad). Patients were observed for signs of local site infection, hematoma development, and local anesthetic toxicity (dizziness, tinnitus, perioral numbness, lethargy, convulsions, and indicators of brain toxicity) related to intravascular injection (Irritability, Confusion).

3.9 Anesthesia Protocol

All patients were pre-medicated with 2 gm of cephazolin antibiotic, 2-3 mg of midazolam IV, and induction begin with pre-oxygenation and standard monitoring with entidal CO2 and using using 2 ug/kg fentanyl, 0.5 mg/kg atracurium and 2 mg/kg propofol, then were intubated (difficult intubation kit was ready, including stylet ETT, video laryngoscope, bougie, invasive airway kit (cricothyrotomy or tracheostomy kit).. etc.) with help of cricoid pressure. Anesthesia maintenance was done using inhalation anesthesia (isoflurane, MAC = 1.15, and pure air, with oxygen). Patients were continuously monitored via cardiac monitor, and after the end of surgery, isoflurane is shut, patient is oxygenated with FiO2 = 100%, then switched to spontaneous ventilation, and waiting for full recovery, indicated by cough reflex, eye opening, spontaneous breathing, and/or good tidal volume. Finally, atropine 1 mg with 2.5 mg neostigmine mixture is given IV for reverse effect before extubation).

3.10 Validity of data sheet

For determining the validity of the data sheet and determining whether the data sheet and its sections truly measure what they are intended to measure. One arbitrator with a Ph.D. in anesthesia, two anesthesiologists, two PACU nurses, and one statistician reviewed the data sheet. The items were adopted after we received feedback on the consistency and suitability of its components and variables from arbitrators.

3.11 Pilot Testing

Prior to the study, 10% of the sample was chosen at random and a data collection tool was used on them to provide feedback on data collection barriers as well as suggestions for improving the data collection process. There have been no changes to the data sheet as a result of the pilot testing.

3.12 Statistical Analysis

IBM Statistical Package for Social Sciences (SPSS) version 25.0 will be used for the purpose of statistical analysis. Results include observational findings, which are frequencies, percentages, means, standard deviation and other observational data was calculated for all variables. Other results are inferential findings, which will be calculated to investigate the relationships and their significance between independent and dependent variables.

A t-test was done for homogenous variables such as age, height, weight, BMI, duration of operation, morphine use, and time to first morphine requirement, according to the Kolmogorow-Smirnow normality test. The Mann Whitney U-test was used to assess heterogeneous variables (VAS scores). PONV and patient satisfaction were assessed using the Chi-square test, whereas gender, ASA score, and the need for a rescue analgesic were assessed using Fisher's exact test. Statistical significance is defined as a p-value of less than 0.05.

3.13 Ethical Consideration

The study was conducted in compliance with the Declaration of Helsinki, which was established by the World Medical Association (WMA) as a set of ethical standards for human medical research (2018). The researcher recognizes that research is a personal and private matter, and as such, he or she has an ethical obligation to uphold key ethical standards like respect, informed consent, and beneficence. nonmaleficence, veracity, and justice are all examples of virtues.

Ethical approval was gained formally by Institutional Review Board (IRB) of An-Najah National University. Arabic consent form was read to each participant verbally before starting surgery, and the consent form emphasized that the data was collected in anonymous method, the participation was voluntarily, privacy and confidentiality of data were ensured, and data will be used for research goals only, and the patient could withdraw from study at any time without any penalty.

Chapter Four
Results

This chapter reviews the descriptive and analytical results regarding the study sample. The descriptive results include frequencies, percentages, means, standard deviation and other descriptive statistics regarding patients' demographic data, perioperative information (surgery and analgesia data and vital signs), postoperative data (PONV, rescue medications and length of stay) and complications. Moreover, analytical results include the investigation of the association between the selected independent and dependent variables in order to answer study's questions and test its hypotheses.

The total number of the sample is 50 patients who underwent laparoscopic sleeve gastrectomy surgery, and were divided in to two groups (interventional and control) in an equal way, including 25 patients in each group. As explained earlier, all patients received the same induction medications, as well as the same intraoperative analgesics and sedation, but the experimental group received TAP block over the convenient management. In this part, descriptive results are shown for the sample as a whole, and for each of the two groups.

First, normality test was conducted to investigate whether sample has a normal distribution or not. Using SPSS, normality tests (Kolmogorov-Smirnov and Shapiro-Wilk) had a significant level (p-value) of 0.063,

indicating that study sample follow normal distribution, which results in the use of parametric tests for the hypotheses testing.

4.1. Descriptive results of patients' demographic data

After meeting the study's eligibility requirements, fifty patients were enrolled. In terms of age, gender, height, weight, and BMI, both groups were comparable. There were no patients who were not followed up on (Table 4.1).

Table 4.1 shows that the mean age of the patients is 31.58 years old, ranging from 16 to 67 years old, with about half of them (40%) are between 20 and 29 years old, and more than three fourths are females (76%). Moreover, the mean patients' weight is 135.88 Kg, ranging from 107 to 178 Kg, with more than one third of them are between 120 and 139 Kg, while the mean patients' height is 165.74 cm, ranging from 151 to 191 cm, with more than half of them (54%) are between 160 and 169 cm, resulting in a mean BMI of 46.70, ranging from 35.78 to 60.00, with 40% of them are between 40 and 44.99 Kg/m^2.

Less than half of the patients (44%) have other comorbidities, which are mainly morbid obesity, followed by hypertension (HTN), diabetes mellitus (DM), hyperlipidemia and hypothyroidism, among others. More than one fourth (28%) of the patients have sleep apnea associated with their obesity. Other sociodemographic data showed that about three fourths (74%) of the patients have university degree, with the same percentage living in cities, and about two thirds (62%) are married.

Most of the patients (86%) have the third ASA classification, with 68% of the patients did not have previous surgeries. Of the patients who have previous surgeries, the most common complications are nausea followed by vomiting and postoperative pain. More than half of the patients (52%) have the third class of Mallampati score.

The second table (4.2) shows the differences between TAP block (experimental) and control group in sociodemographic data, while the following figures illustrate the distribution of demographic data for the whole sample and between groups.

Table 4.1: Distribution of patients' demographic information (whole sample).

Variable	**Values**	**No. (%)**	**Mean (SD)**
Age	Younger than 20 years old	5 (10%)	31.58 (10.21)
	20 – 29 years old	20 (40%)	
	30 – 39 years old	17 (34%)	
	40 years and older	8 (16%)	
Gender	Male	12 (24%)	
	Female	38 (76%)	
Weight	100 – 119 Kg	12 (24%)	135.88 (20.92)
	120 – 139 Kg	18 (36%)	
	140 – 159 Kg	14 (28%)	
	160 Kg and more	6 (12%)	
Height	Less than 160 cm	8 (16%)	165.74 (8.48)
	160 – 169 cm	27 (54%)	
	170 – 179 cm	12 (24%)	
	180 cm and more	3 (6%)	
BMI	35 – 39.99 Kg/m^2	2 (4%)	46.70 (5.36)
	40 – 44.99 Kg/m^2	20 (40%)	
	45 – 49.99 Kg/m^2	17 (34%)	
	50 – 54.99 Kg/m^2	8 (16%)	
	55 – 59.99 Kg/m^2	3 (6%)	
Comorbidities	Yes	22 (44%)	
	No	28 (56%)	
Sleep apnea	Yes	14 (28%)	
	No	36 (72%)	
Educational level	Illiterate	0 (0%)	
	Elementary school	0 (0%)	
	High school	13 (26%)	
	University degree	37 (74%)	
Residency	City	37 (74%)	
	Village	11 (22%)	

	Camp	2 (4%)	
Marital status	Single	19 (38%)	
	Married	31 (62%)	
	Widowed or divorced	0 (0%)	
ASA classification	First class	4 (8%)	
	Second class	3 (6%)	
	Third class	43 (86%)	
	Fourth, fifth or sixth class	0 (0%)	
Previous surgeries	No	34 (86%)	
	Yes (any complications?)	16 (32%)	
	None	5 (10%)	
	Nausea	8 (16%)	
	Vomiting	6 (12%)	
	Postoperative pain	6 (12%)	
Mallampati score	Class (I)	26 (52%)	
	Class (II)	7 (14%)	
	Class (III)	17 (34%)	

Table 4.2: Distribution of patients' demographic information (experimental vs control groups).

Variable (Mean ± SD)	**Values**	**TAP block group**	**Control group**	**P-Value**
Age **(32.56 ± 8.05 vs 30.60 ± 12.09)**	Younger than 20 years old	0 (0%)	5 (20%)	0.503
	20 – 29 years old	10 (40%)	10 (40%)	
	30 – 39 years old	12 (48%)	5 (20%)	
	40 years and older	3 (12%)	5 (20%)	
Gender	Male	8 (32%)	4 (16%)	0.551
	Female	17 (68%)	21 (84%)	
Weight **(136.68 ± 26.04 vs 135.08 ± 14.63)**	100 – 119 Kg	8 (32%)	4 (16%)	0.790
	120 – 139 Kg	8 (32%)	10 (40%)	
	140 – 159 Kg	5 (20%)	9 (36%)	
	160 Kg and more	4 (16%)	2 (8%)	
Height **(165.40 ± 10.46 vs 166.08 ± 6.09)**	Less than 160 cm	8 (32%)	0 (0%)	0.780
	160 – 169 cm	9 (36%)	18 (72%)	
	170 – 179 cm	5 (20%)	7 (28%)	
	180 cm and more	3 (12%)	0 (0%)	
BMI **(52.23 ± 6.82 vs 51.37 ± 4.28)**	35 – 39.99 Kg/m^2	2 (8%)	0 (0%)	0.669
	40 – 44.99 Kg/m^2	11 (44%)	9 (36%)	
	45 – 49.99 Kg/m^2	4 (16%)	13 (52%)	
	50 – 54.99 Kg/m^2	6 (24%)	2 (8%)	
	55 – 59.99 Kg/m^2	2 (8%)	1 (4%)	
Comorbidities	Yes	11 (44%)	11 (44%)	0.633
	No	14 (56%)	14 (56%)	
Sleep apnea	Yes	6 (24%)	8 (32%)	0.239
	No	19 (76%)	17 (68%)	
Educational level	Illiterate	0 (0%)	0 (0%)	0.612
	Elementary school	0 (0%)	0 (0%)	
	High school	6 (24%)	7 (28%)	
	University degree	19 (76%)	18 (82%)	
Residency	City	16 (64%)	21 (84%)	0.776
	Village	8 (32%)	3 (12%)	
	Camp	1 (4%)	1 (4%)	
Marital status	Single	7 (28%)	12 (48%)	0.555
	Married	18 (72%)	13 (52%)	
	Widowed or divorced	0 (0%)	0 (0%)	

ASA classification	First class	2 (8%)	2 (8%)	0.912
	Second class	3 (12%)	0 (0%)	
	Third class	20 (80%)	23 (92%)	
	Fourth, fifth or sixth class	0 (0%)	0 (0%)	
Previous surgeries	No	20 (80%)	14 (56%)	0.994
	Yes (any complications?)	5 (20%)	11 (44%)	
	None	1 (4%)	4 (16%)	
	Nausea	4 (16%)	4 (16%)	
	Vomiting	4 (16%)	2 (8%)	
	Postoperative pain	3 (12%)	3 (12%)	
Mallampati score	Class (I)	13 (52%)	13 (52%)	0.543
	Class (II)	2 (8%)	5 (20%)	
	Class (III)	10 (40%)	7 (28%)	

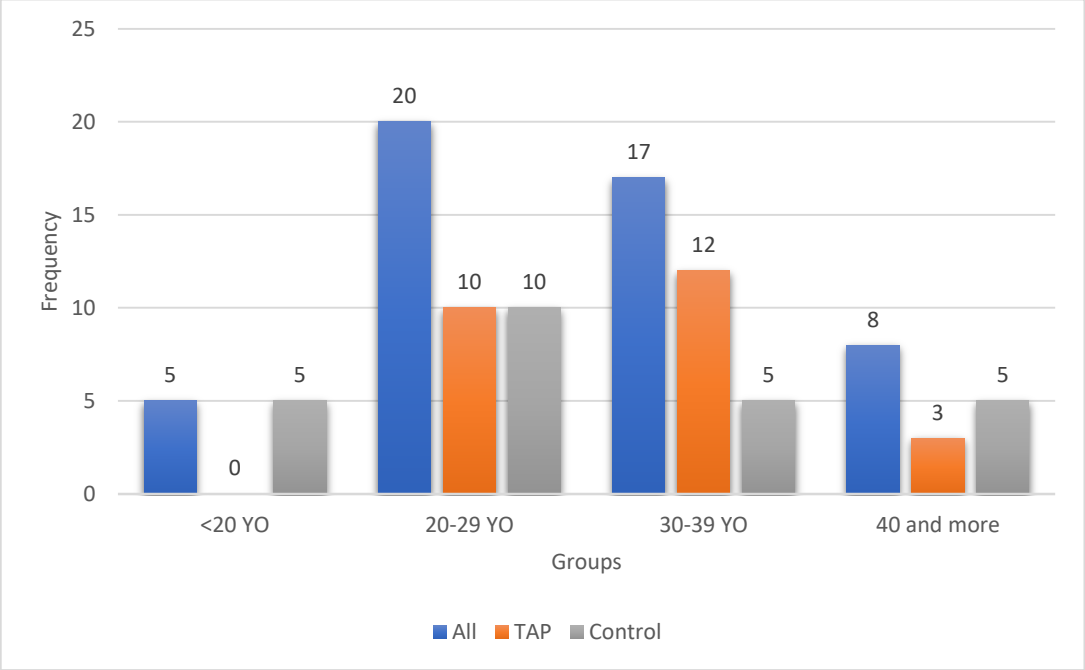

Figure 4.1: Distribution of participants' age.

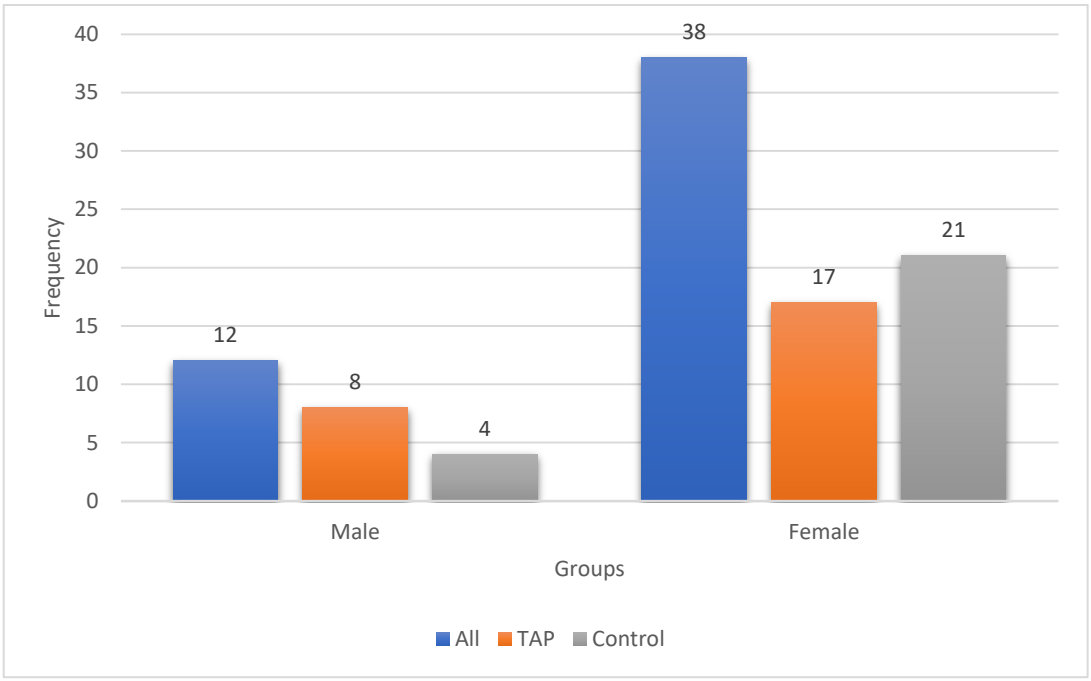

Figure 4.2: Distribution of participants' gender.

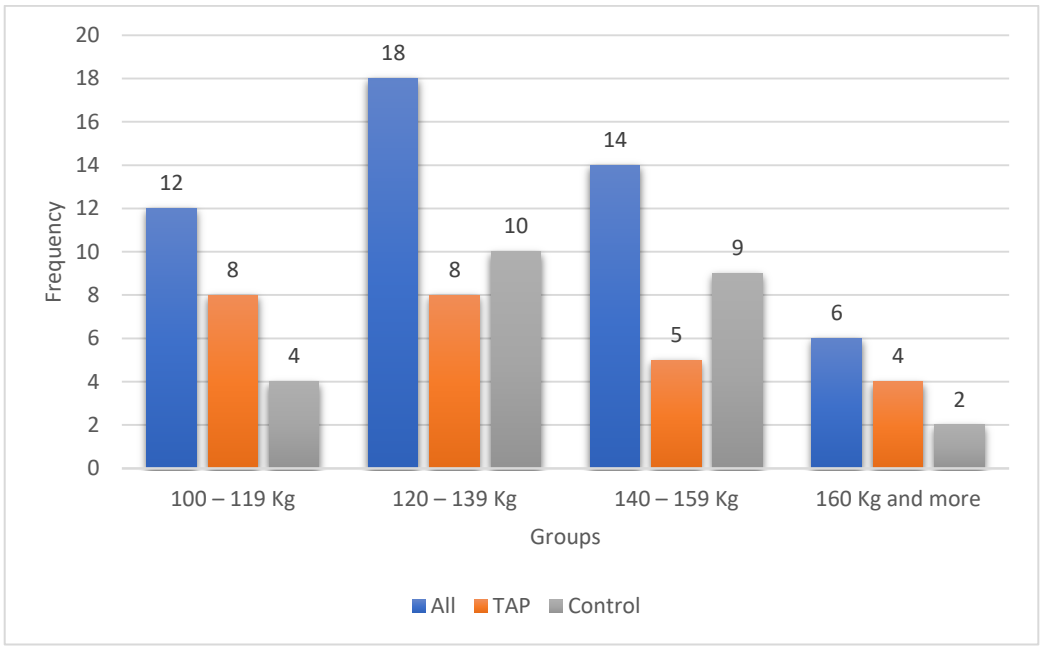

Figure 4.3: Distribution of participants' weight.

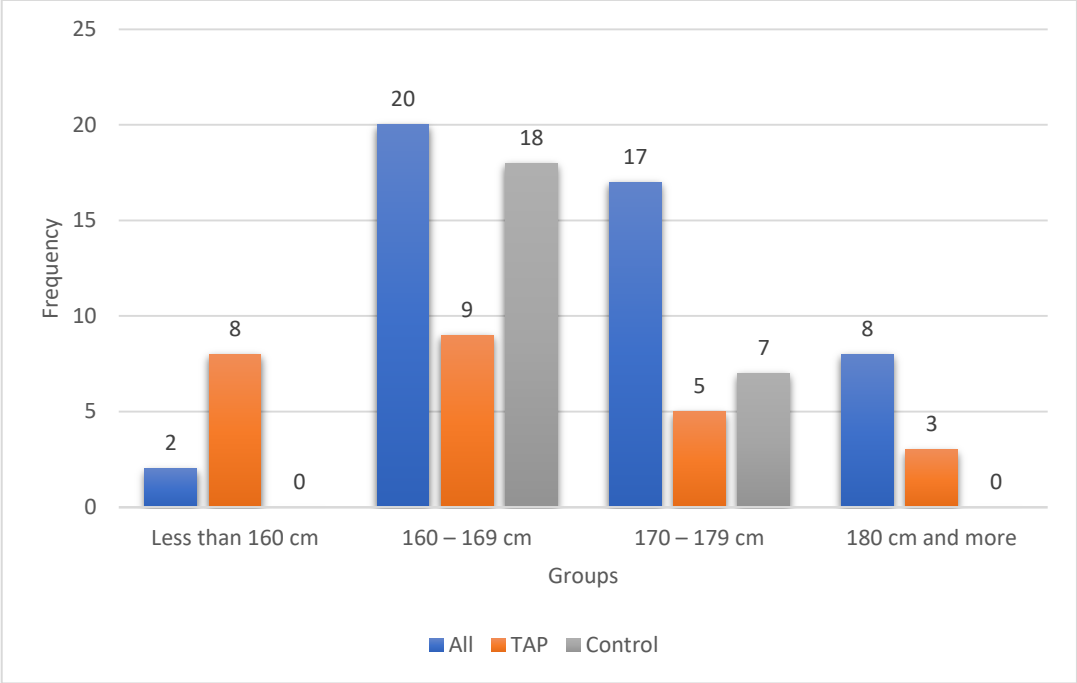

Figure 4.4: Distribution of participants' height.

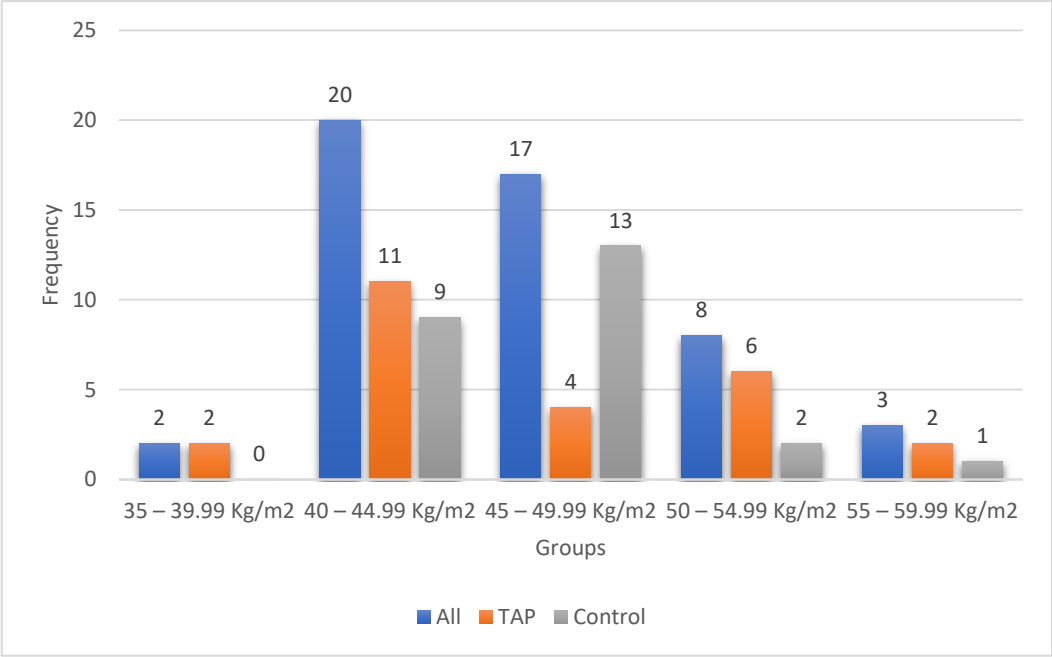

Figure 4.5: Distribution of participants' BMI.

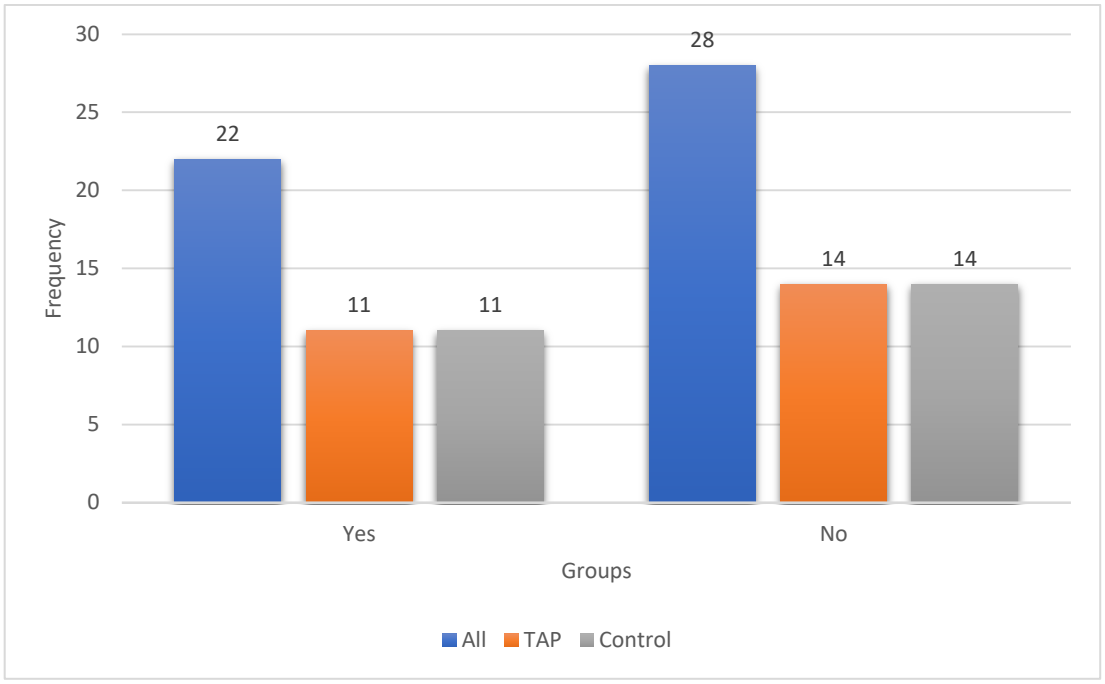

Figure 4.6: Distribution of participants' comorbidities.

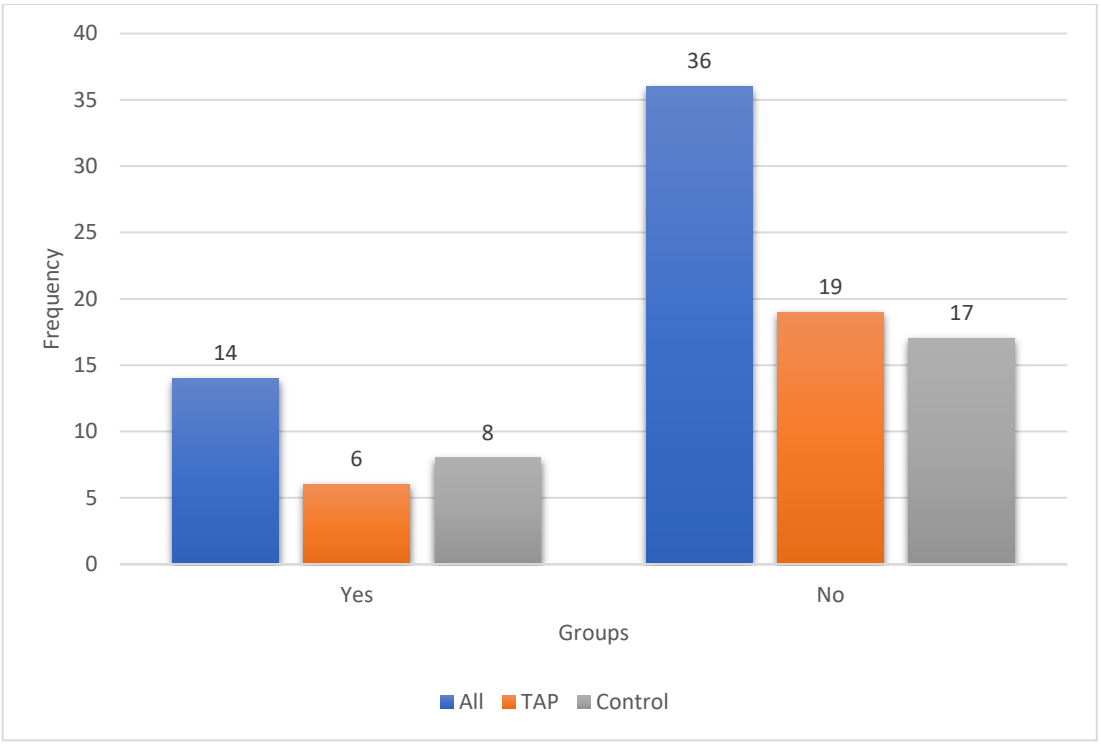

Figure 4.7: Distribution of participants' sleep apnea.

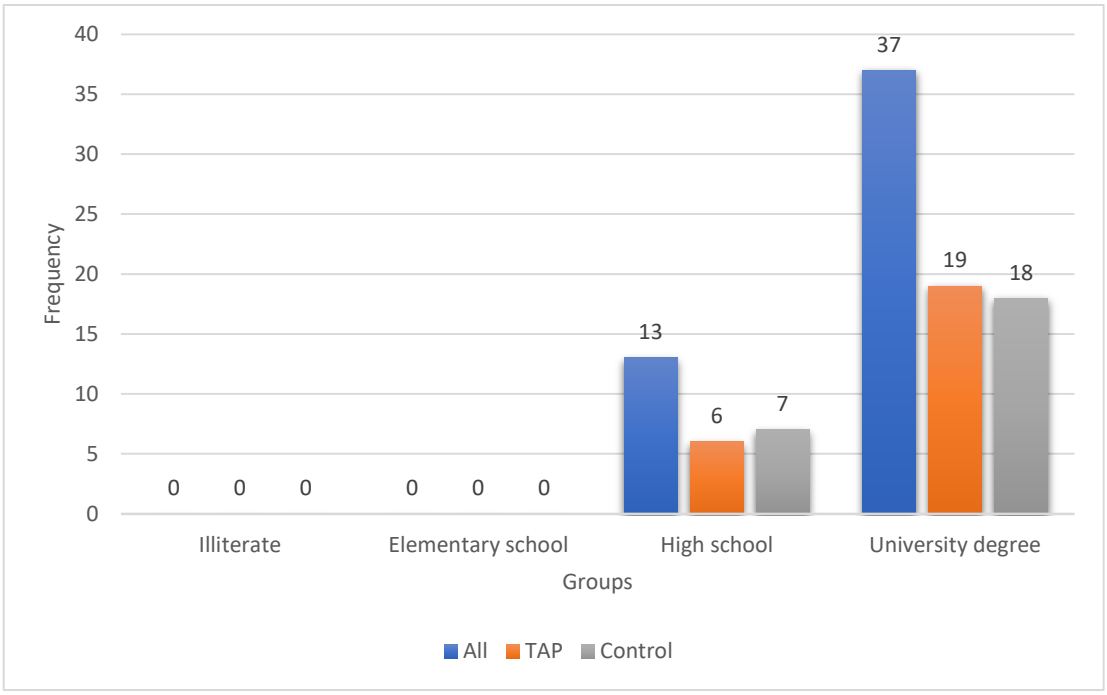

Figure 4.8: Distribution of participants' education.

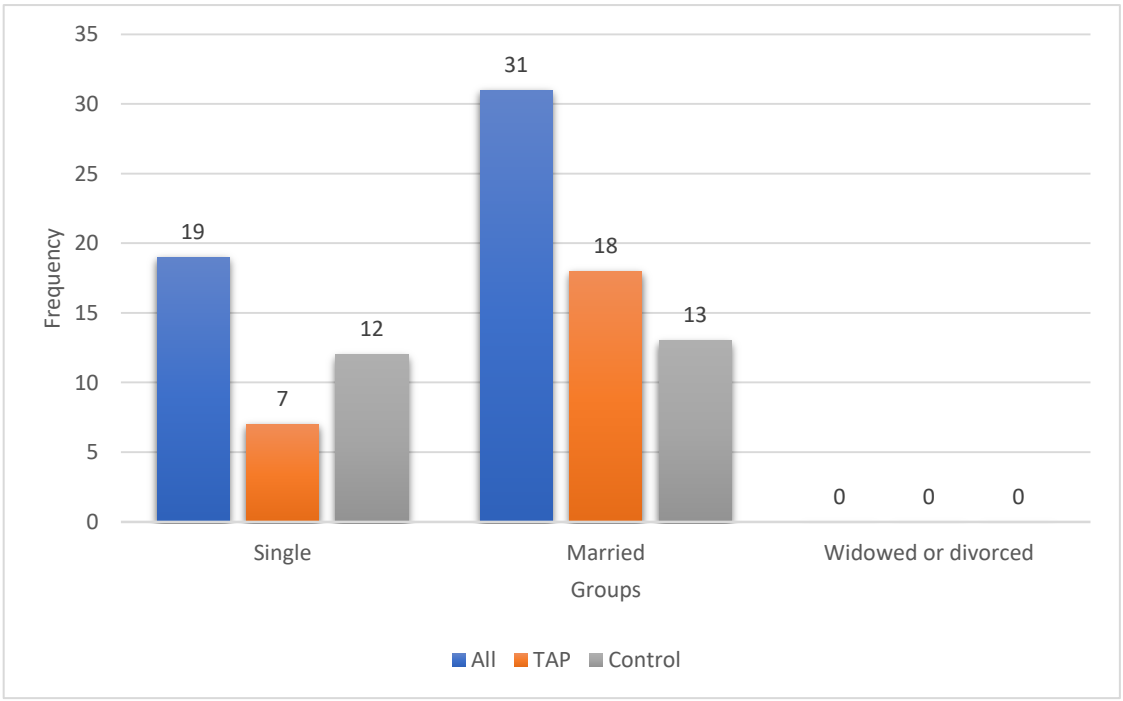

Figure 4.9: Distribution of participants' marital status.

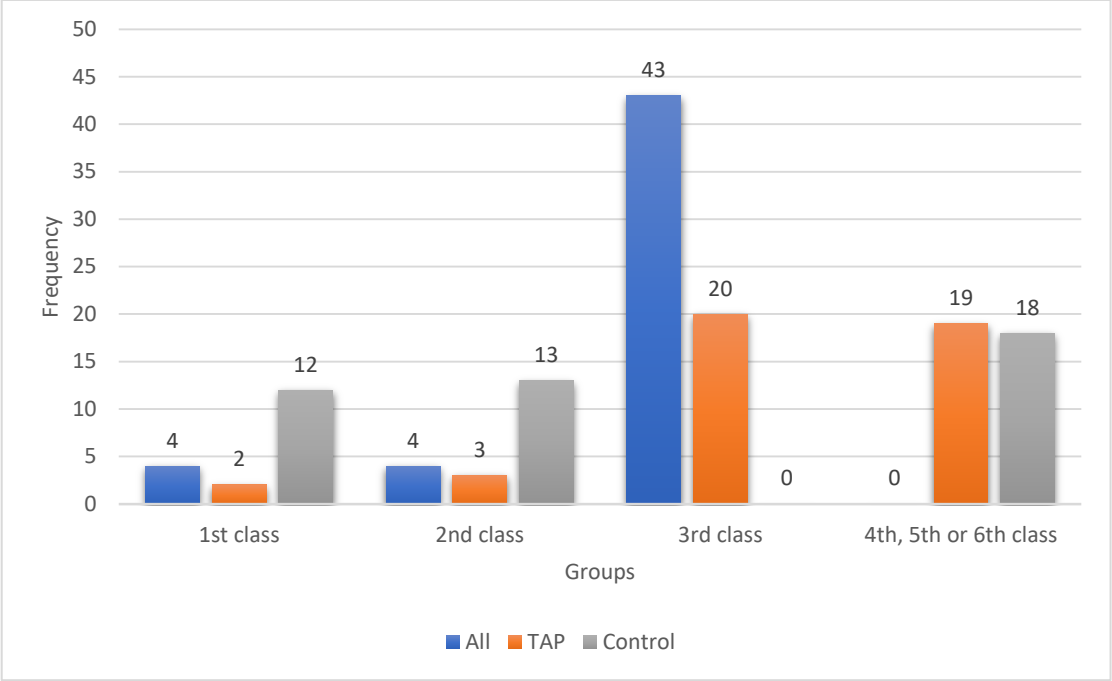

Figure 4.10: Distribution of participants' ASA calss**.**

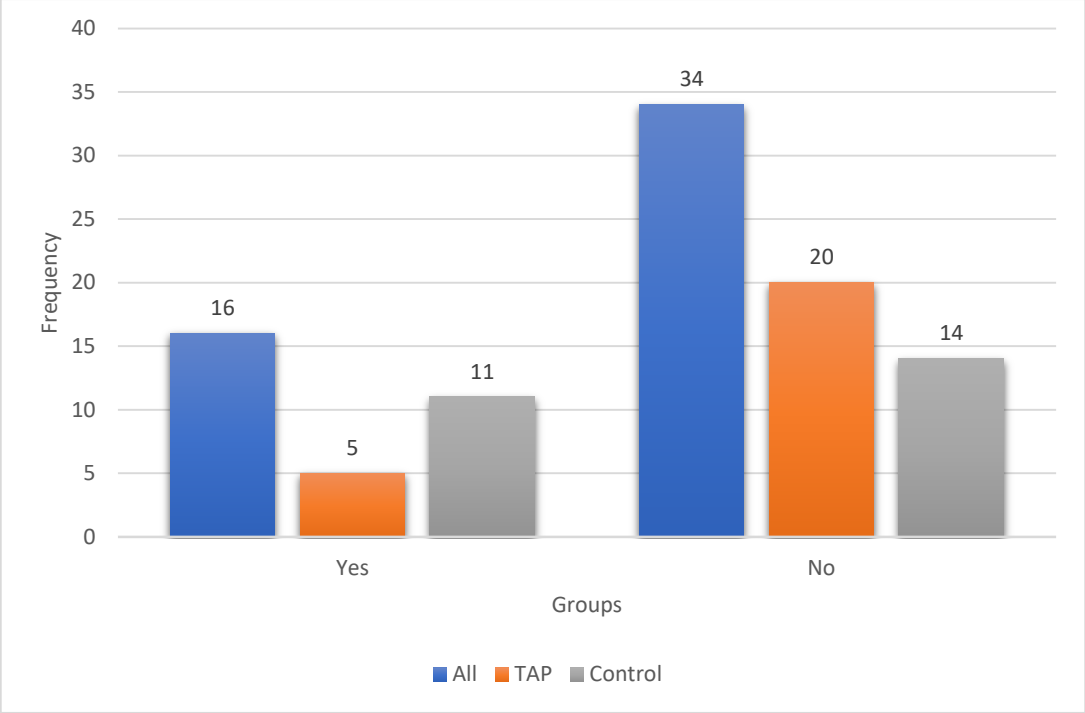

Figure 4.11: Distribution of participants' prev. surgeries.

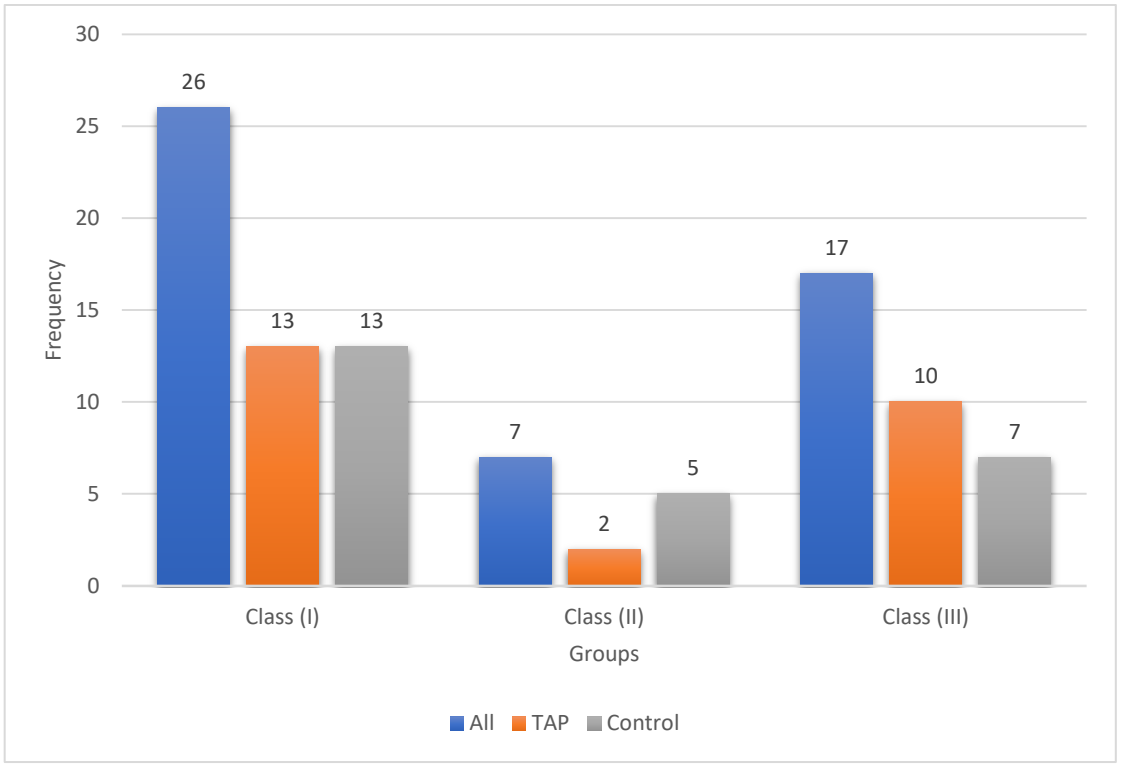

Figure 4.12: Distribution of participants' Mallampati score.

4.2. Descriptive result of patients' intraoperative data

Table 4.3 shows the distribution of patients' intraoperative data, and shows that more than half of the patients (60%) had a difficult intubation at the beginning of the surgery, with 60% of the patients intubated via direct laryngoscope technique, and 40% of them had laryngeal view of (I). the table also showed that patients mostly (68%) had a propofol dose of 200 mg (range = 150 – 260 mg, mean = 210.6 mg), 64% had 50 mg of muscle relaxant (range = 40 – 60 mg, mean = 48.1 mg), while 56% had fentanyl dose of more than 200 mg (range = 150 – 250 mg, mean = 208.6 mg).

Regarding analgesics doses, all patients received the same dose of 30 mg of ketorolac, 1000 mg of optalgin and 1000 mg of paracetamol. On the other hand, in reverse medications, most patients received 1 mg of atropine

(92%) and 2.5 mg of neostigmine (92%). Lastly, 70% of the patients had an operation time between 50 and 60 minutes (range = 40 – 75 minutes, mean = 58.4 minutes), with 46% of them having anesthesia time less than 60 minutes (range = 40 – 75 minutes, mean = 58.34 minutes).

All patients had an Aldrete score of 9, while 2 patients needed extra fentanyl dose of 50 mg (4%). The table also shows the differences in intraoperative data between experimental and control groups.

Table 4.3: Distribution of patients' intraoperative data (whole sample and between groups).

Variable	**Values**	**All sample**	**TAP block**	**Control**
		Freq. (%)	**Freq. (%)**	**Freq. (%)**
Intubation difficulty	Yes	30 (60%)	15 (60%)	15 (60%)
	No	20 (40%)	10 (40%)	10 (40%)
Intubation technique	Direct laryngoscope	30 (60%)	15 (60%)	15 (60%)
	Boogie	17 (34%)	8 (32%)	9 (36%)
	Video laryngoscope	3 (6%)	2 (8%)	1 (4%)
Laryngoscope view	I	20 (40%)	10 (40%)	10 (40%)
	II	10 (20%)	5 (20%)	5 (20%)
	III	17 (34%)	8 (32%)	9 (36%)
	IV	3 (6%)	2 (8%)	1 (4%)
Propofol dose	< 200 mg	1 (2%)	0 (0%)	1 (4%)
	200 mg	35 (70%)	17 (68%)	18 (72%)
	> 200 mg	14 (28%)	8 (32%)	6 (24%)
Muscle relaxant dose	< 50 mg	15 (30%)	7 (28%)	8 (32%)
	50 mg	30 (60%)	16 (64%)	14 (56%)
	> 50 mg	5 (10%)	2 (8%)	3 (12%)
Fentanyl dose	< 200 mg	7 (14%)	3 (12%)	4 (16%)
	200 mg	20 (40%)	8 (32%)	12 (48%)
	> 200 mg	23 (46%)	14 (56%)	9 (36%)
Ketorolac dose	30 mg	50 (100%)	25 (100%)	25 (100%)
Optalgin dose	1000 mg	50 (100%)	25 (100%)	25 (100%)
Paracetamol dose	1000 mg	50 (100%)	25 (100%)	25 (100%)
Atropine in reverse dose	1 mg	46 (92%)	24 (96%)	22 (88%)
	2 mg	4 (8%)	1 (4%)	3 (12%)
Neostigmine in reverse dose	2.5 mg	46 (92%)	24 (96%)	22 (88%)
	5 mg	4 (8%)	1 (4%)	3 (12%)
Operation duration	< 50 minutes	2 (4%)	1 (4%)	1 (4%)
	50 – 60 minutes	35 (70%)	17 (68%)	18 (72%)
	> 60 minutes	13 (26%)	7 (28%)	6 (24%)
Anesthesia time	< 60 minutes	23 (46%)	13 (52%)	10 (40%)
	60 minutes	14 (28%)	5 (20%)	9 (36%)
	> 60 minutes	13 (26%)	7 (28%)	6 (24%)
Aldrete score	Nine	50 (100%)	25 (100%)	25 (100%)
Need for extra fentanyl	Yes	2 (4%)	1 (4%)	1 (4%)
	No	48 (96%)	24 (96%)	24 (96%)

Table 4.4 shows the intraoperative hemodynamics for the whole sample, as well as the differences between experimental and control groups in them, and the description of used lidocaine and Marcaine doses of TAP block group. It is noticed that the hemodynamics, in general, have insignificant differences between experimental and control groups, except for heart rate in the three phases of intraoperative part (induction, maintenance, and emergence), taking in consideration that all patients had normal electrocardiogram (ECG) findings with no arrhythmias during the three intraoperative phases. Figures that follow the table illustrate the distribution of hemodynamic means in the whole sample and between the experimental and control groups.

Table 4.4: Distribution of patients' intraoperative hemodynamics (whole sample and between groups).

Variable	All sample			TAP block			Control			p-value
	Range	Mean	SD	Range	Mean	SD	Range	Mean	SD	
Induction SBP	101-168	127.24	14.09	103-168	130.84	14.77	101-148	124.64	12.65	0.070
Induction DBP	61-90	77.40	6.82	66-86	78.72	5.35	61-90	76.08	7.92	0.174
Induction HR	70-120	91.14	12.75	70-112	87.16	11.65	70-120	95.12	12.77	0.026
Induction RR	17-21	18.40	0.67	18-19	18.36	0.49	17-21	18.44	0.82	0.677
Induction SpO_2	87-100	97.04	2.42	87-100	96.84	2.75	93-100	97.24	2.09	0.565
Induction Temp	36.6-37.4	36.82	0.13	36.6-37.0	36.80	0.09	36.6-37.4	36.84	0.17	0.346
Maintenance SBP	110-165	133.22	10.45	112-165	135.04	11.17	110-148	131.40	9.55	0.221
Maintenance DBP	66-92	81.72	6.05	66-88	81.96	5.59	70-92	81.48	6.59	0.782
Maintenance HR	70-120	95.46	10.97	70-120	92.24	10.23	78-118	98.68	10.93	0.037
Maintenance SpO_2	95-100	97.86	1.47	95-100	97.76	1.48	95-100	97.96	1.49	0.636
Maintenance Temp	36.2-37.1	36.75	0.16	36.3-37.1	36.76	0.17	36.2-36.9	36.74	0.16	0.735
Emergence SBP	105-145	123.66	8.07	113-145	125.52	8.29	105-138	121.80	7.54	0.103
Emergence DBP	65-88	75.60	5.20	68-82	75.28	3.93	65-88	75.92	6.28	0.668
Emergence HR	68-102	86.40	9.03	68-102	82.80	8.13	78-102	90.00	8.57	0.004
Emergence RR	12-14	12.32	0.71	12-14	12.28	0.68	12-14	12.36	0.76	0.696
Emergence SpO_2	95-100	98.22	1.33	96-100	98.24	1.30	95-100	98.20	1.38	0.917
Emergence Temp	36.1-37.1	36.66	0.25	36.1-37.0	36.63	0.26	36.1-37.1	36.69	0.24	0.369
Lidocaine dose				125-250	159.32	33.79				
Marcaine dose				90-160	121.04	19.05				

SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure, HR = Heart Rate, RR = Respiratory Rate, SpO_2 = Oxygen Saturation, Temp = Temperature, SD = Standard Deviation.

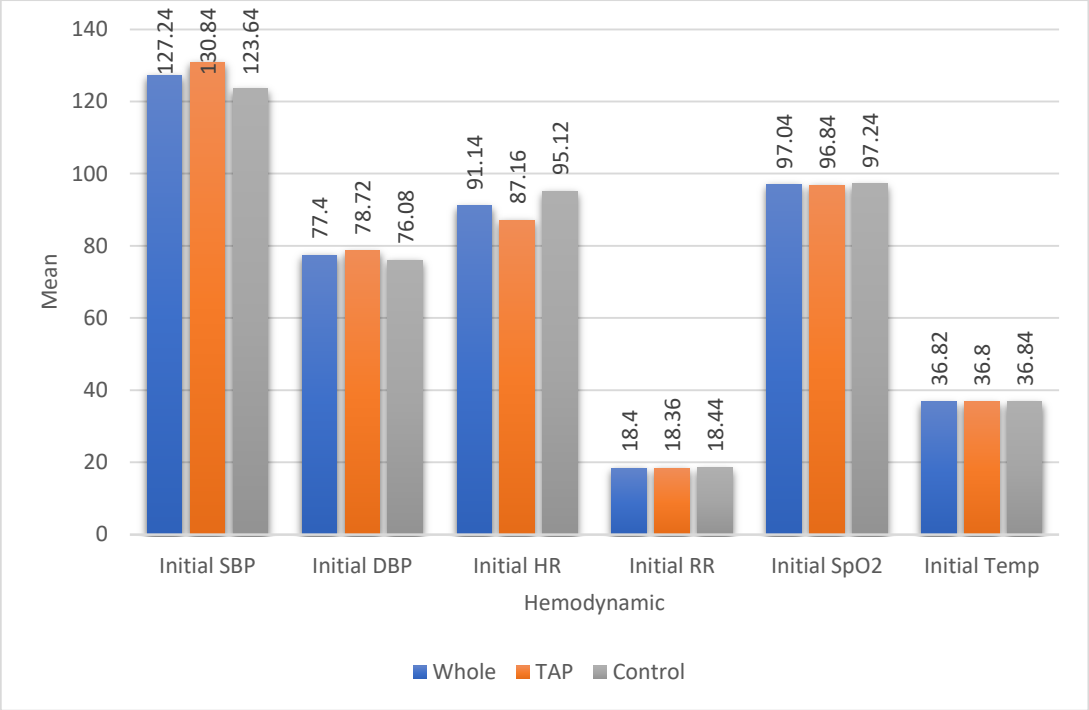

Figure 4.13: Initial hemodynamic means.

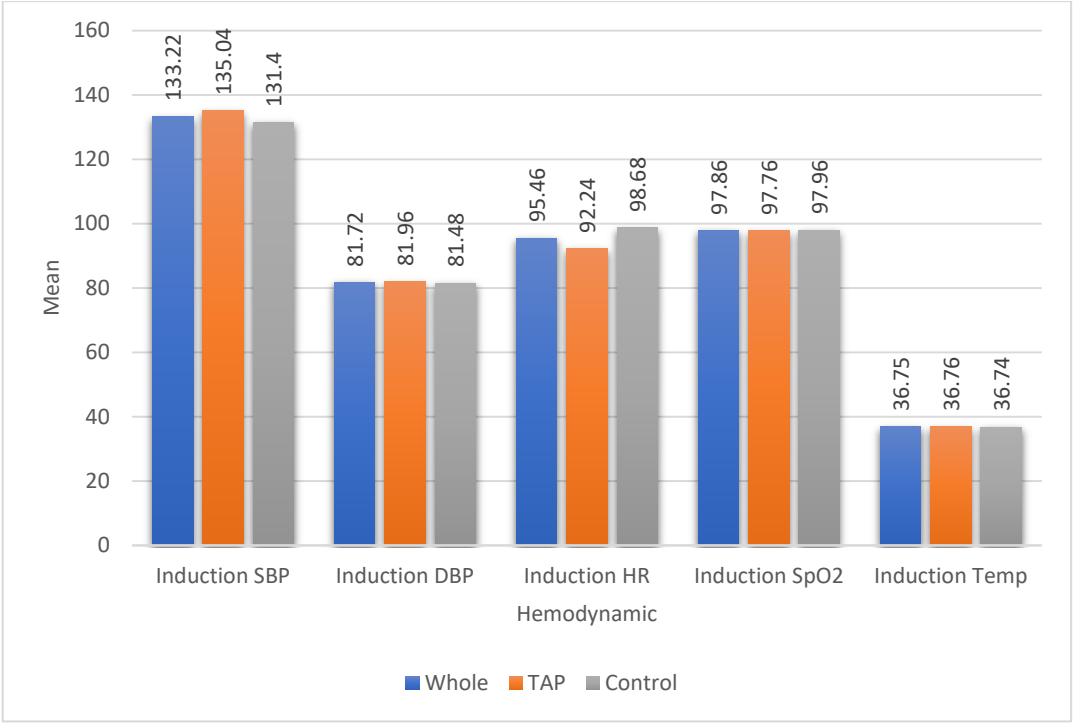

Figure 4.14: Induction hemodynamic means.

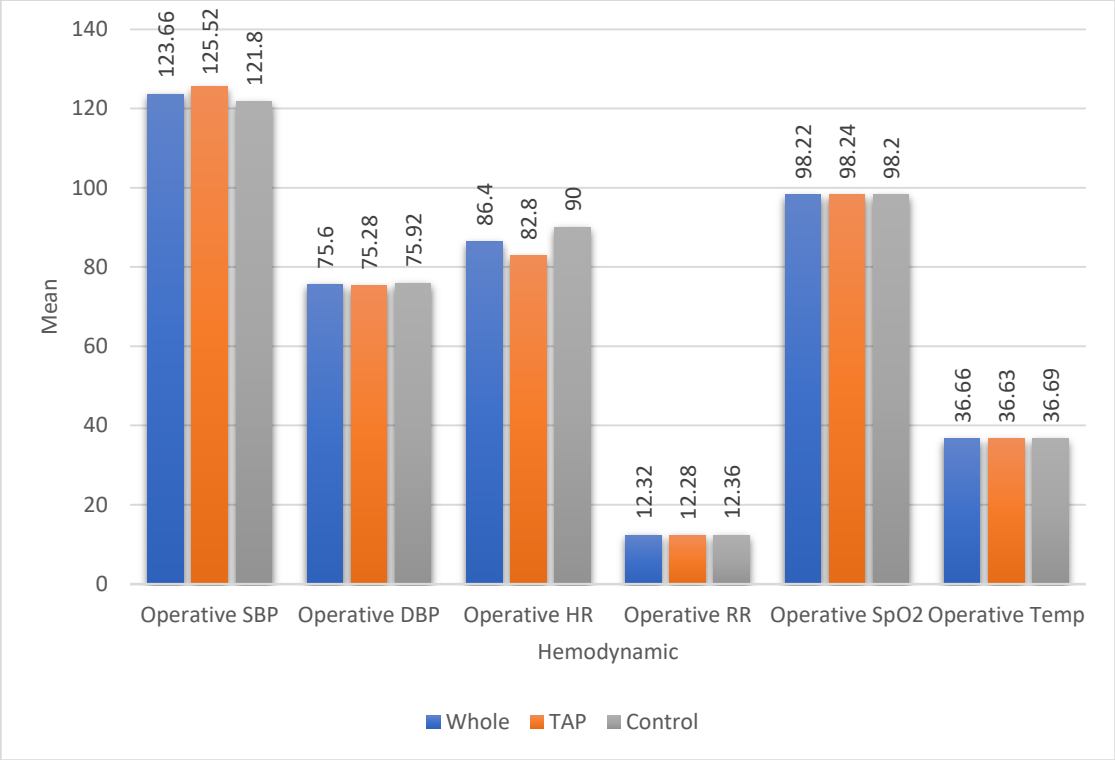

Figure 4.15: Operative hemodynamic means.

4.3. Descriptive results of postoperative data

The following tables (4.5, 4.6 and 4.7) show the distribution of patients' hemodynamic data during the postoperative phase, from zero minute until 24 hours postoperatively. Means and standard deviations are used to show the data for each time point, where Table 4.5 showed them for the whole sample, and Table 4.6 showed them for experimental group only, while Table 4.7 showed them for the control group only. Figures follow the tables to illustrate postoperative hemodynamic means between the whole sample and both experimental and control groups.

Tables, in general, show that patients' blood pressure starts to increase in the first 6 to 12 hours and then decreases to less than 130s mmHg postoperatively, and the same is for heart rate, where it increases to around

96.8 bpm after 12 hours, and then decreases to a mean of 87.5 bpm at the 24^{th} hour postoperatively. Patients' respiratory rate doesn't change significantly, but it follows the same pattern of increasing. On the other hand, SpO_2 and body temperature have no specific pattern of changing, and they are not significantly changing.

On the other hand, when comparing each time point' hemodynamic data between experimental and control group, the pattern of difference is not clear, by which each time point has a different higher or lower hemodynamic data between both groups.

Table 4.5: Distribution of patients' postoperative hemodynamic data (whole sample)

Time	**Zero min**		**30 min**		**2-hour**		**4-hour**		**6-hour**		**12-hour**		**24-hour**	
Variable	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
SBP	135.2	11.5	141.1	10.2	137.9	19.2	139.3	8.9	140.6	19.7	146.8	8.5	136.7	9.8
DBP	82.4	4.8	89.7	6.2	85.9	6.2	85.1	5.5	87.1	6.7	90.5	4.6	83.8	4.8
HR	95.5	12.9	100.6	11.4	99.0	10.7	98.3	12.3	100.0	8.9	104.3	8.8	95.0	9.4
RR	18.5	0.8	18.4	1.4	18.4	1.4	17.7	1.9	17.7	2.0	18.1	1.9	17.3	1.6
SpO_2	97.7	12.6	98.5	1.3	98.0	1.2	97.4	1.5	97.3	1.5	97.1	1.5	97.2	1.7
Temp	36.8	0.2	36.8	0.2	36.6	1.4	36.6	1.4	36.8	0.1	36.8	0.2	36.7	0.2

SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure, HR = Heart Rate, RR = Respiratory Rate, SpO_2 = Oxygen Saturation, Temp = Temperature, M = Mean, SD = Standard Deviation.

Table 4.6: Distribution of patients' postoperative hemodynamic data (experimental group)

Time	**Zero min**		**30 min**		**2-hour**		**4-hour**		**6-hour**		**12-hour**		**24-hour**	
Variable	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
SBP	127.8	14.1	134.4	11.6	134.6	9.5	132.8	10.6	130.5	26.6	141.3	7.6	128.2	9.4
DBP	76.4	3.8	82.6	5.7	82.4	5.9	80.8	5.0	80.1	7.5	85.5	4.6	79.1	5.0
HR	83.5	10.0	89.2	9.2	90.6	11.3	88.5	9.7	90.2	9.7	96.8	7.9	85.9	9.7
RR	18.4	0.5	18.2	1.1	18.5	1.6	17.2	1.8	17.6	2.2	18.0	2.0	17.0	1.8
SpO_2	99.6	0.6	98.5	1.0	98.4	1.0	97.7	1.5	97.3	1.5	97.4	1.4	97.3	1.9
Temp	36.8	0.1	36.8	0.1	36.4	2.0	36.4	2.0	36.8	0.2	36.8	0.2	36.7	0.2

SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure, HR = Heart Rate, RR = Respiratory Rate, SpO_2 = Oxygen Saturation, Temp = Temperature, M = Mean, SD = Standard Deviation.

Table 4.7: Distribution of patients' postoperative hemodynamic data (control group)

Time	**Zero min**		**30 min**		**2-hour**		**4-hour**		**6-hour**		**12-hour**		**24-hour**	
Variable	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD	M	SD
SBP	142.6	8.4	147.9	8.8	140.8	25.0	145.7	7.0	150.6	8.6	152.4	9.1	145.1	10.3
DBP	88.5	5.4	92.8	6.8	89.4	6.3	89.5	6.1	94.1	5.1	95.5	4.7	88.5	4.6
HR	107.4	14.0	112.1	12.2	107.4	10.2	108.2	14.3	109.8	7.6	111.7	9.7	104.0	8.9
RR	18.6	1.0	18.7	1.6	18.2	1.3	18.2	1.9	17.9	1.9	18.3	1.8	17.7	1.4
SpO_2	95.8	17.7	98.6	1.5	97.6	1.2	97.2	1.5	97.3	1.5	96.8	1.6	97.2	1.6
Temp	36.8	0.2	36.8	0.2	36.8	0.2	36.8	0.1	36.8	0.1	36.8	0.1	36.7	0.2

SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure, HR = Heart Rate, RR = Respiratory Rate, SpO_2 = Oxygen Saturation, Temp = Temperature, M = Mean, SD = Standard Deviation.

Table 4.8: Differences between TAP block and control groups in postoperative hemodynamics

Time	**Zero min**	**30 min**	**2-hour**	**4-hour**	**6-hour**	**12-hour**	**24-hour**
Variable	p-value	p-value	p-value	p-value	p-value	p-value	p-value
SBP	0.002	< 0.001	< 0.001	0.022	< 0.001	0.001	0.013
DBP	0.001	< 0.001	< 0.001	0.032	< 0.001	0.021	0.032
HR	< 0.001	< 0.001	< 0.001	0.002	< 0.001	0.002	0.039
RR	0.435	0.184	0.837	0.154	0.853	0.722	0.099
SpO_2	0.333	0.995	0.913	0.799	0.896	0.982	0.734
Temp	0.776	0.845	0.287	0.965	0.877	0.786	0.825

SBP = Systolic Blood Pressure, DBP = Diastolic Blood Pressure, HR = Heart Rate, RR = Respiratory Rate, SpO_2 = Oxygen Saturation, Temp = Temperature

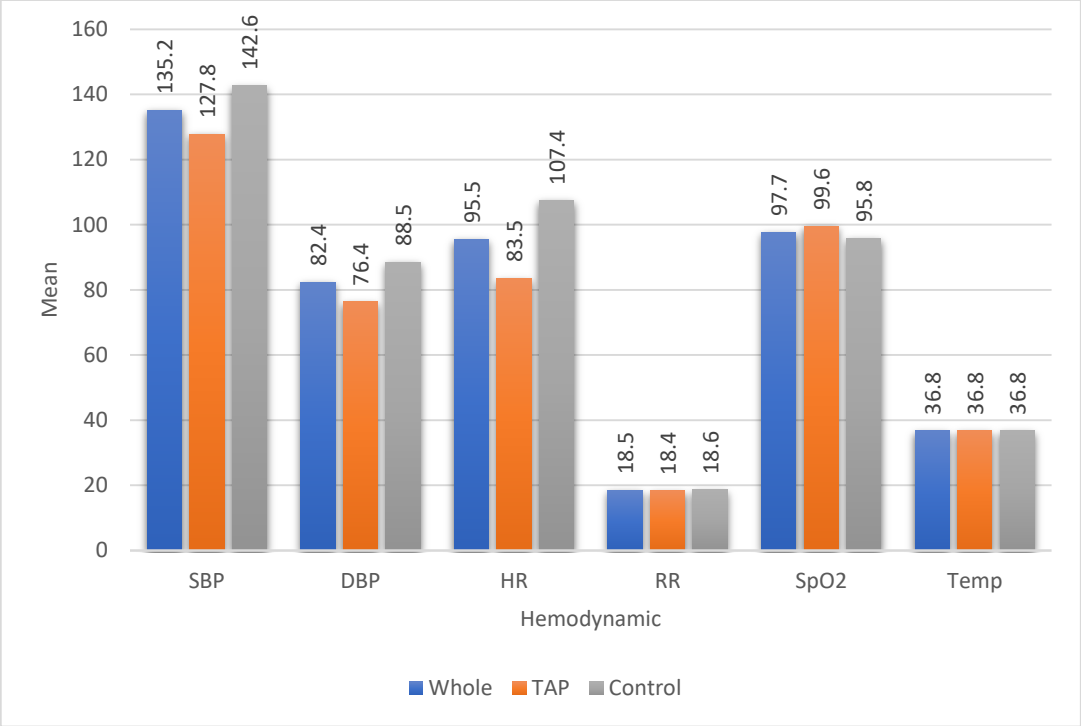

Figure 4.16: Zero-minute postoperative hemodynamic.

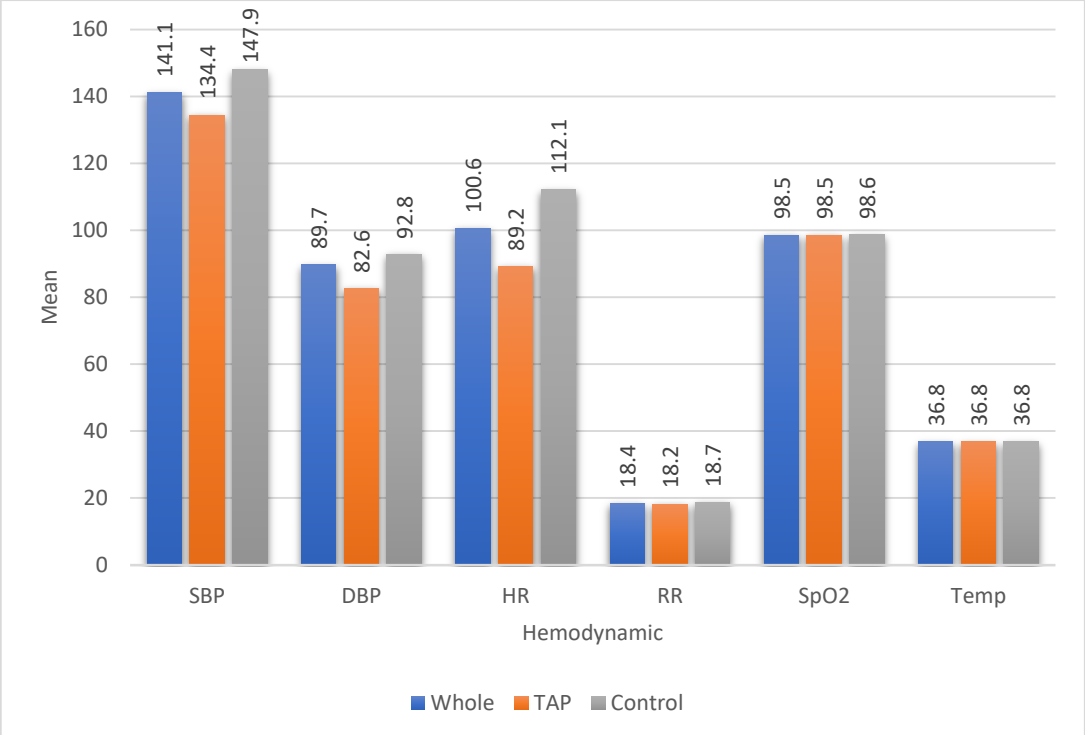

Figure 4.17: 30-minute postoperative hemodynamic.

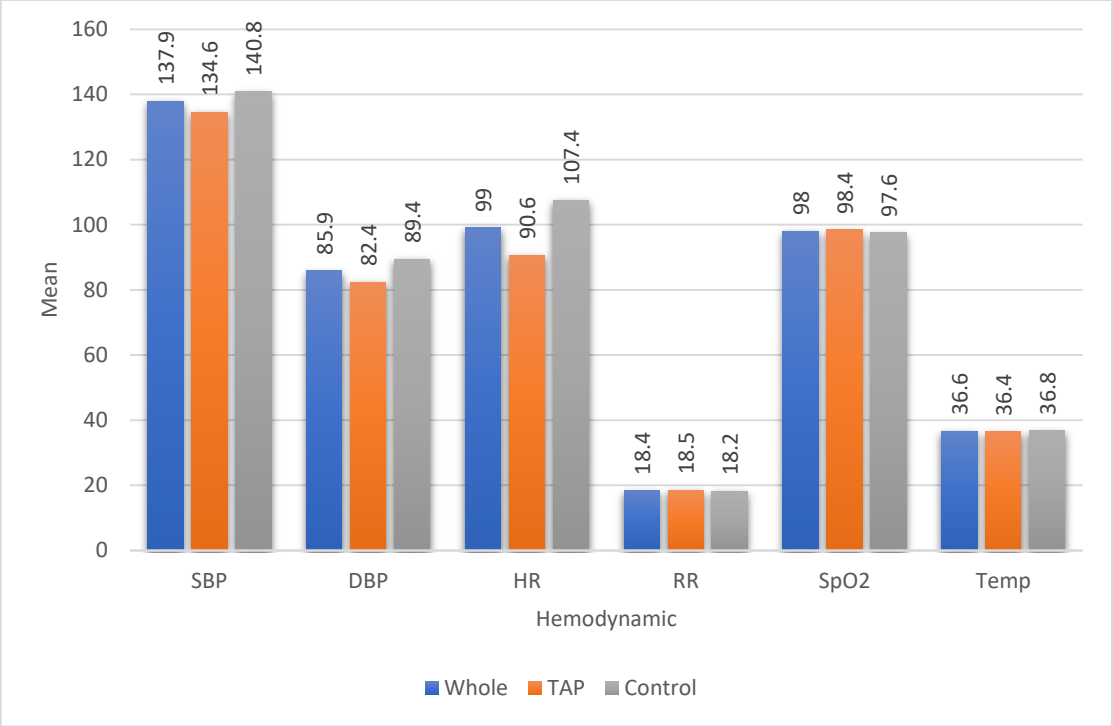

Figure 4.18: 2-hour postoperative hemodynamic.

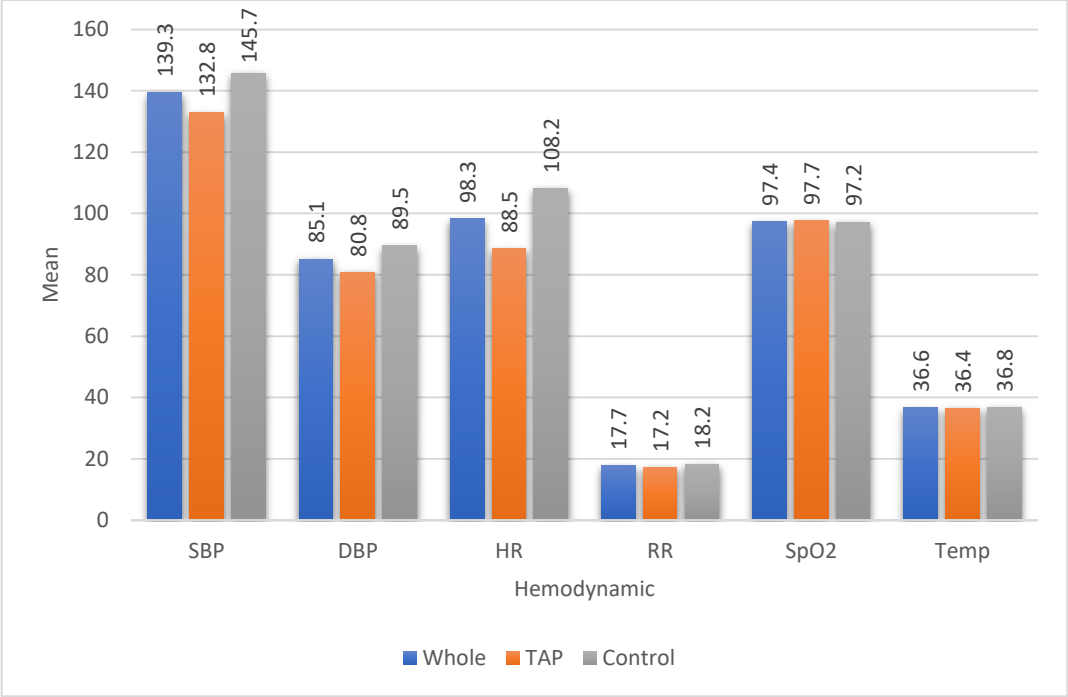

Figure 4.19: 4-hour postoperative hemodynamic.

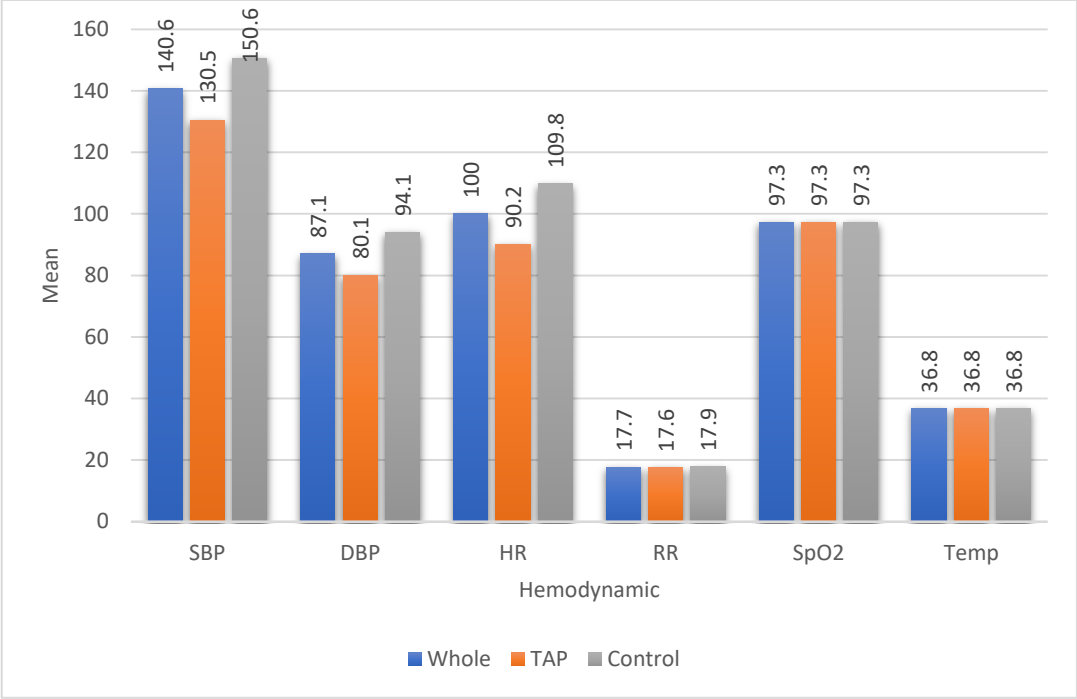

Figure 4.20: 6-hour postoperative hemodynamic.

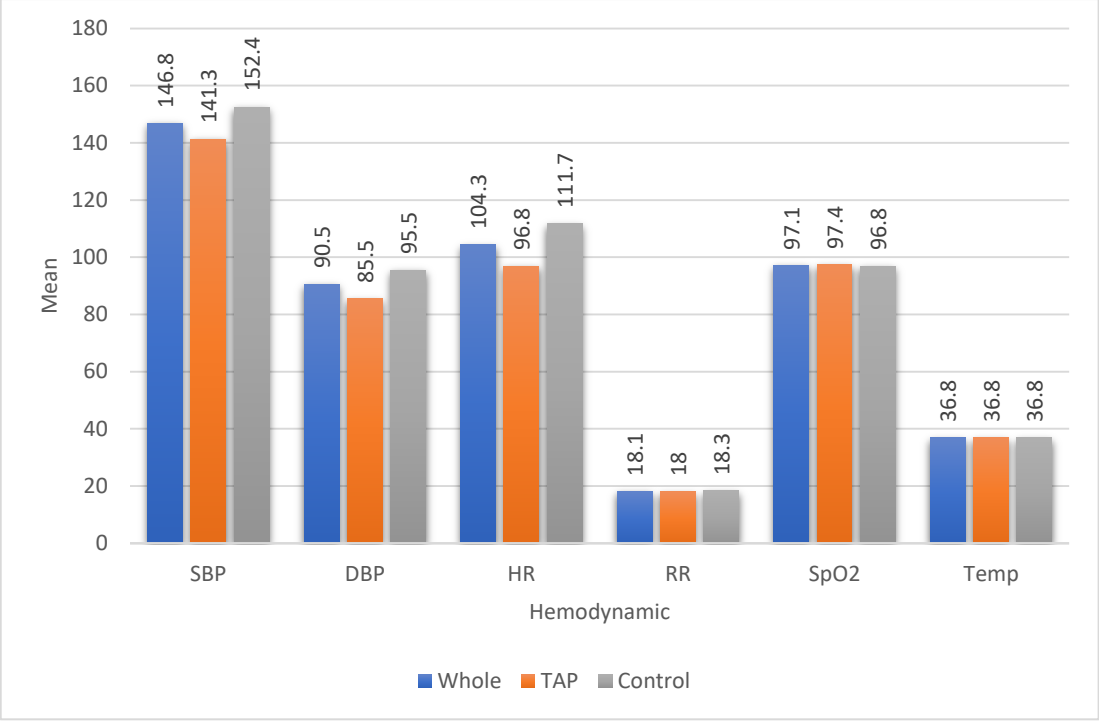

Figure 4.21: 12-hour postoperative hemodynamic.

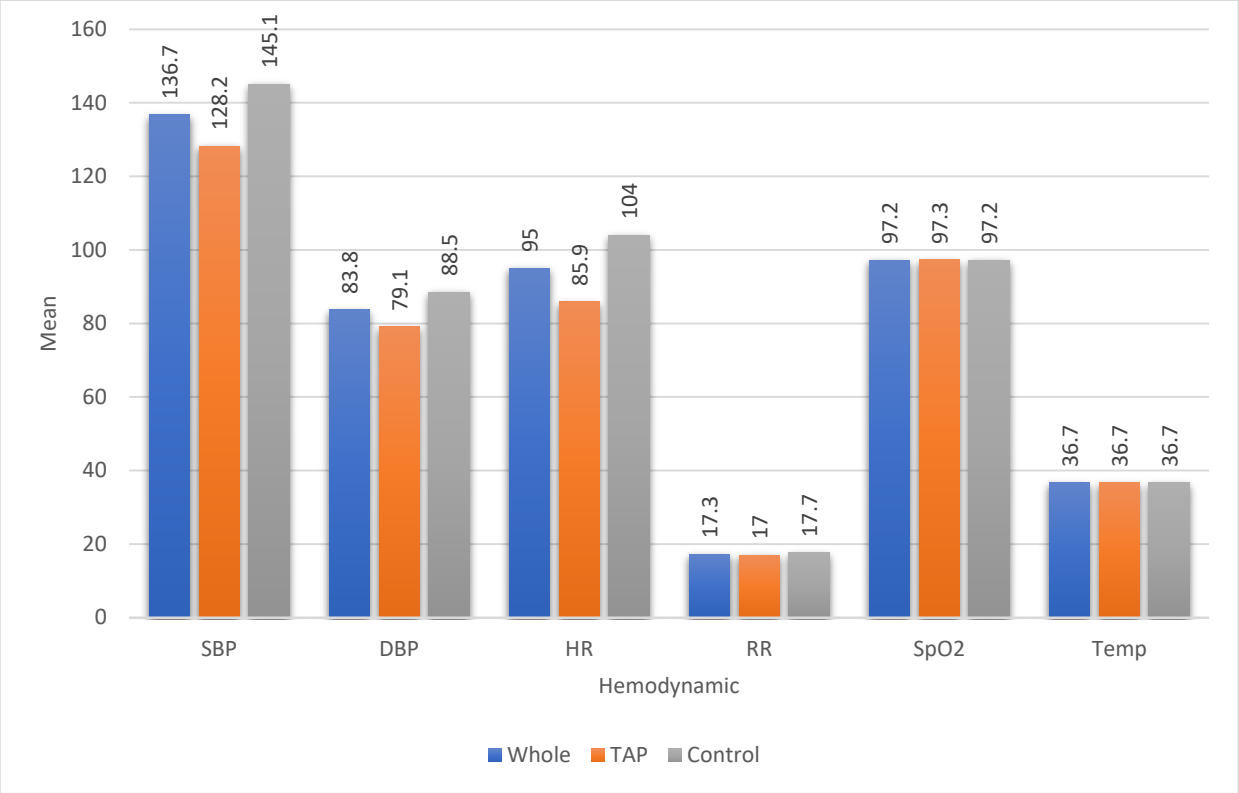

Figure 4.22: 24-hour postoperative hemodynamic.

4.4: Descriptive results of patients' PONV, pain and rescue medications.

Table 4.8 shows the postoperative pain in a quantitative way for the patients, and pain was followed-up over multiple time points using a scale out of 10, where "zero" is equal to no pain, and "10" is equal to severe non-tolerated pain. The table shows that the highest pain mean score is around 30 minutes postoperatively (6.62/10), and the least at the second hour postoperatively (3.86/10), with a significantly higher pain scores in the control group than in the TAP block group at all-time points (p-value < 0.05), where mean pain scores range from 2.50/10 to 4.58/10 in the TAP block group, while it ranges from 5.12/10 to 8.94/10 in the control group. The first choice in pain management time at 30 min , starting from 2 hours

postoperatively, pethidine takes the place. The table shows that there was a significant difference between both groups in pethidine consumption at all-time points, where it was around 50 mg in mean dose of pethidine for the TAP block group, while it was between 75.55 mg and 100 mg of pethidine in the control group, and, in general, the rescue medications' consumption was decreasing by time.

Table 4.9: Postoperative pain and rescue medications (whole sample and between groups).

Time	Mean pain score (/10) Mean (SD)			p-value	Mean pethidine use (mg) Mean (SD)			p-value
	All	TAP	Control		All	TAP	Control	
Zero	5.25 (1.3)	2.50 (1.2)	6.16 (1.4)	<0.001	--	--	--	--
30min	6.62 (2.1)	2.81 (2.2)	8.94 (2.4)	0.043	83.33 (15.9)	50.00 (10.5)	100.0 (0.0)	0.044
2nd h	3.86 (1.1)	2.82 (1.0)	5.33 (2.3)	<0.001	68.42 (21.4)	57.14 (11.9)	100.0 (0.0)	<0.001
4th h	5.04 (2.2)	3.44 (1.4)	6.07 (2.5)	<0.001	71.15 (21.7)	54.16 (10.7)	85.71 (7.9)	0.021
6th h	5.69 (1.4)	3.00 (1.1)	7.61 (2.2)	0.019	67.00 (25.9)	54.16 (15.2)	75.55 (29.4)	<0.001
12th h	6.16 (1.6)	4.58 (1.2)	8.27 (2.4)	0.020	67.38 (18.8)	55.20 (12.2)	83.61 (23.9)	<0.001
24th h	4.50 (1.5)	3.25 (1.1)	5.12 (3.1)	<0.001	66.67 (22.2)	50.00 (10.5)	75.00 (25.9)	0.003

The following table (Table 4.9) shows the mean scores of patients' subjective data of nausea on a scale out of 6, and it showed that the mean score decreases gradually from 4.2/6 at the first reading (30 minutes postoperatively) to 3.28/6 after one day, with a significant difference between interventional and control group at all time points (p-value < 0.05), where the mean PONV score ranged from 2.25/6 to 2.58/6 for the TAP block group, while it ranged from 5.36/6 to 6/6 for the control group. Moreover, there was a significantly higher consumption of PONV rescue medication (ondansetron) in the control group (p-value < 0.05) at all time

points, starting from the first dose at 30-minute time point, where it ranged from a mean of 1.00 to 2.35 mg for the TAP block group, while it was 3 mg in control group at all-time points.

Table 4.10: PONV and antiemetic medications use (whole sample and between groups).

Time	PONV mean scale (of 6)			p-value	Antiemetic mean dose (mg)			p-value
	All	TAP	Control		All	TAP	Control	
Zero	--	--	--	--	--	--	--	--
30min	4.20	2.4	6.00	<0.001	2.2	1.4	3.00	<0.001
2nd h	4.15	2.47	5.93	<0.001	2.66	2.35	3.00	<0.001
4th h	4.11	2.25	5.60	0.042	2.25	1.00	3.00	0.019
6th h	3.72	2.30	5.50	0.013	2.23	1.55	3.00	<0.001
12th h	4.05	2.58	5.36	0.016	2.33	1.58	3.00	<0.001
24th h	3.28	2.33	5.00	< 0.001	1.85	1.22	3.00	0.009

Table 4.10 shows a summary of the first rescue medications for pain and nausea in terms of the time mean time needed for the first morphine and pethidine (for pain) and ondansetron (for nausea) dose. It showed that the first time required for pethidine dose is not significantly different between both groups, because both groups received it at a relatively near time points, only during the first 30 minutes. On the other hand, there was a significantly longer time needed for the first pethidine dose in the TAP block group (mean = 210.4 minutes) compared to control group (mean = 101.60 minutes, p-value = 0.005), and a significantly longer time needed for the first ondansetron dose in the TAP block group (mean = 218.9 minutes) compared to control group (113.6 minutes, p-value = 0.009).

Table 4.11: Postoperative rescue medications time (whole sample and between groups)

Requirement type	All	TAP	Control	p-value
First pethidine requirement (minutes)	177.00	210.40	101.60	0.005
First ondansetron requirement (minutes)	169.08	218.90	113.60	0.009

The last table (Table 4.11) shows the postoperative data not related to pain or nausea. In terms of postoperative patient's satisfaction, about half of the patients (48%) reported their overall satisfaction as "Good", with a significantly higher satisfaction level in the TAP block group (56% rated as excellent) compared to control group (48% rated as good, p-value < 0.001). On the other hand, there was an equal percentage of patients who stayed 48 hours postoperatively (1 patient in each group) and 72 hours postoperatively (24 patients in each group), with no patient having any of the questioned complications, and thus there was no significant difference between interventional and control groups in terms of postoperative LOS or complications.

Table 4.12: Postoperative patient satisfaction, LOS and complications.

Variable	Values	Freq (%)			p-value
		All	TAP	Control	
Postoperative satisfaction	Excellent	14 (28%)	14 (56%)	0 (0%)	< 0.001
	Good	23 (46%)	11 (44%)	12 (48%)	
	Fair	8 (16%)	0 (0%)	8 (32%)	
	Bad	5 (10%)	0 (0%)	5 (20%)	
	Very bad	0 (0%)	0 (0%)	0 (0%)	
Total LOS	48 hours	2 (4%)	1 (4%)	1 (4%)	---
	72 hours	48 (96%)	24 (96%)	24 (96%)	
Postoperative complications	None	50 (100%)	25 (100%)	25 (100%)	---

Chapter Five
Discussion and Recommendations

5.1 Discussion

This chapter reviews the discussion of the study results, where they are compared with the previous literature, and are criticized from the researcher's point of view.

In terms of patients' demographic data, results show that most of the patients are between 20 and 39 YO (74%), and this can be interpreted by that these patients tried a lot of solutions of increased body weight, and thus they used sleeve gastrectomy as one of the last choices to relieve the physical and/or psychological impact of obesity. Moreover, 76% of the patients are female, and this is expected as females are more concerned about the psychological impact of obesity among relatives, friends and other social groups. Most of the patients who underwent the surgery are between 40 and 50 Kg/m^2 in BMI (74%), which are near to extreme levels of obesity, and they are associated with further physical and health complications if not solved, and this appears in that about half of the patient (44%) have comorbidities, which are mostly related to obesity in some way, like osteoporosis, cardiac problems and thyroid dysfunction, even that they are mostly in age groups of less than mean age for these diseases compared to normal or above-normal weight people.

Of the most common complications of obesity that may concern the patients to seek for a final solution is sleep apnea. Results show that it is reported by 28% of the patients, and this can be less than the actual percentage, and it is either due to misdiagnosis when asking the patient about the signs and symptoms, and the fact that diagnosis of sleep apnea is mostly objective and recently it is conducted using modern technologies of sleep tracking and not just subjective data.

Most of the patients are classified with the third class according to ASA classification score (86%), which is under the description of “severe systemic disease”, and thus the surgery can be helpful and lifesaving for them. It is worth mentioning that most of the mean demographic data are similar between interventional and control groups. The complications of obesity may also appear in intubation process at the beginning of the surgery, and this was found in that 60% of patients had difficult intubation process according to anesthesiologist’s description. On the contrary, the study of Tekeli (2019) found that the significant correlation between higher BMI was with difficulty of neck extension during intubation process, while the term “difficult intubation” was not associated with neither weight or BMI. The difference between our findings and the previous study can be related to different methodological approaches, where the previous study was conducted using retrospective observational design, and this can lead to missing of patients’ follow-up during data collection process.

Also, the percentage of patients who were intubated via direct laryngoscope is less than the normal of non-obese patients (60%), where it can be caused by severe compression of fatty tissues and what is described as “short-neck” patients, taking in consideration that there was no significant difference between interventional and control groups in these descriptive results regarding intubation difficulty.

Regarding induction, opioid and maintenance medications that were used in surgery, doses are regulated by the hospital’s protocols, and they were not different in both study groups. Regarding operation and anesthesia times, they were mostly between 50 and 60 minutes for the operation time (70%) and around 60 minutes ideally for anesthesia time, but unfortunately there are no previous data in literature to compare these results with, and timing of the operation is highly dependent on several factors, like surgeon’s preferences, hospital’s readiness and patient’s own characteristics. Patients mostly didn’t need an extra fentanyl dose during the surgery (96%).

Regarding intraoperative hemodynamics, it is expected to have no significant difference in most of the vital signs between interventional and control groups, because all of the patients are fully sedated, and cardiopulmonary parameters are mostly controlled via operative machines. On the other hand, induction, maintenance and emergence heart rate are the only significantly different parameters between the groups, where mean heart rate was higher in control group during the three time points, although

all of them are in the normal range of adult heart rate. Similar results were found in the postoperative hemodynamics, there were significant difference but clinically it does not have any effect. It was within normal range, and this can be interpreted by that the difference between both groups (addition of TAP block for the interventional group) doesn't have a physiological impact on hemodynamics, especially that TAP block is aimed to decrease skeletal muscle pain, and has no significant or direct impact on the sympathetic nervous system.

Regarding postoperative pain, the 10-point scale was used because it is more representative of pain for adults, and is more suitable for quantitative studying. Moreover, and according to hospital's protocol, morphine was used for pain relief as a rescue medication during the first 30 minutes postoperatively, because in this time period the patient is still in recovery room or under close observation by the nurse, and switched to pethidine after that because it has less effect on respiratory system, and thus is safer, and this is supported by several articles, like the systematic review that was conducted by Schumann (2011) and the study of Sabharwal and Christelis (2010), especially for patients who are obese and complain of obstructive sleep apnea. The main overcoming strategy for postoperative opioid consumption is the use of multimodal analgesics, which is used in our study in both groups, where acetaminophen, ketorolac and dipyrone, with the local infiltration, were used intraoperatively, our study revealed that there is a significantly less mean pain scores in the TAP block group than in the control group in all time points postoperatively.

The current findings agree with those of Mittal, et al (2018), who found that the difference in VAS scores between test (TAP) and control (Non-TAP) subjects was statistically significant both at rest and during movement. The TAP group had a higher patient satisfaction score than the control group (p value 0.001), and the patients who got TAP block had a higher satisfaction score than the control group (p value 0.001). Also, in comparison to the non-TAP subjects, patients who received TAP block demonstrated earlier readiness for discharge, ambulation, and resumption of bowel function, as well as a lower incidence of PONV, these results are in agreement within another randomized double-blind case control study found that using the USG-TAP as part of a multimodal analgesic procedure reduces opioid usage, pain score, sedation, early ambulation, and increases patient satisfaction in morbidly obese patients (Sinha, et al 2013)

When comparing the current study with the study of Alamdari et al. (2018), there is a great similarity in sedation induction and maintenance, and in the application on bupivacaine intraperitonially for the interventional group. Although there was a great similarity in sedation choices, the previous study of Alamadri et al. diclofenac suppository in the postoperative management of pain alongside IV paracetamol. But they showed a significant difference in pain scores at different time points. On the other hand, the difference in the use of postoperative pain management may be the cause that the difference in pain scores was at the 6^{th}, 12^{th}, and 24^{th} hour time points, while in our study it was different in all time points.

Additionally, the overall mean pain scores in our study were less than in the previous study of Alamdari et al.

The randomized controlled trial of Saber et al. (2019) shares some similarity with our study. First, there is no significant difference in the allocated patients between groups in term of age, gender, BMI, … etc., and this leads to homogeneity in the study sample, as in our study. On the other hand, there is a difference between our study and the study of Saber et al. in that their pain scores and PONV were not significantly different at almost all time points, even between the control (placebo) group and the rest of groups, and this can be interpreted by that their postoperative pain management is hugely different than our study, as they started the patients on regular pain killers and antiemetics postoperatively, and gave the patients opioids when needed, and this led to a difference in pain scoring between the two studies. Also, the previous study of Saber et al. had the limitation of that they tended to compare the difference in pain scores and PONV for 48 hours, which limits the comparison for most of the patients (70 out of 90) after the 24^{th} hour, as they were discharged, so, it is recommended to investigate the patients' outcomes with hospital's policies being taken in the consideration.

There was a similarity between our results and the Spanish study of Ruiz-Tovar et al. (2017), where they found a significant difference between conventional group who received regular analgesics only and the group who received infiltrated bupivacaine in each aponeurotic layer of each port,

and in our study, there was no significant difference in all time points. On the other hand, the previous study didn't state the exact time points where mean pain scores were different, while in our study we divided pain scores assessment into 7 time points, and thus the pain comparison in the previous study may not be compared to our pain assessment. Moreover, the previous study allocated patients where they receive regular analgesics postoperatively, while in our study, no regular postoperative analgesics were used. As there was a significant difference in pain scores between groups in the previous study, it is expected to manifest a significant difference in their overall consumption of opioids, with a significant less opioid consumption in the TAP block group, which is consistent with our findings. It is also recommended to investigate the difference in postoperative pain management and its effect on pain scores at different time points, and to compare between different approaches.

The main critique for the Turkish study of Coşkun et al. (2019) is that they didn't compare the pain assessment in both groups of trocar site and subcostal infiltrations with a control group of patients who didn't receive any of them. Although there was no significant difference in pain scores at most of the time points, there may be a difference between using both of these infiltration techniques and not using them at all, because their technique in choosing infiltration sites is different than other previous studies and our study, too, and the same is for the Turkish study of Arı et al. (2017). The benefit from the first study could be that some procedures may be more time- or cost-efficient, where they stated that trocar site

infiltration is more time-efficient than the other technique, and thus it is recommended to conduct further studies where one aim is to compare the efficiency of time and cost for different pain management strategies. On the other hand, the similarity between our study and the study of Coşkun et al. is that they had controlled allocated groups with no significant difference in their BMI, which allowed for outcomes control and less bias in both studies. Another difference is regarding the used anesthetic approaches in induction and in the postoperative pain management.

There is a difference in the postoperative pain scores and opioid consumption in our study and the study of Sisik and Edrem (2019). The main difference may be related to the noticeable difference in the induction and maintenance sedation in both studies, and that their infiltration was in the trocar site, whereas in our study it was in the TAP area. The difference between both studies was also in the postoperative time span of follow-up, where it stopped at the 24^{th} hour in hours study, compared to the 48^{th} hour in the study of Sisik and Edrem, and in our study we chose to stop at the 24^{th} hour because of the possibility of being discharged after only one day postoperatively according to hospital’s protocol.

Mittal, et al. performed a report on the volume and concentration of ropivacaine (2018) 40 ml of 0.375 percent ropivacaine was injected in the fascial plane for a bilateral TAP block and observed to disperse between the two layers on either side. It's conceivable that if we'd provided more

bupivacaine in a higher amount and concentration of 30 ml of 0.2%, we might have minimized postoperative pain on all measures.

Some studies suggest that patient-controlled analgesia is the best for pain management postoperatively (Soleimanpour et al., 2017). On the other hand, in our settings, patient-controlled analgesia is not established, due to several factors. It is recommended to conduct controlled trials for the difference between conventional pain control protocols and the patient-controlled analgesia in our settings, which will help in establishing specific protocols regarding it.

Because there is a significant difference in postoperative pain scores and PONV and their management between both groups in our study, it is expected to have a significantly higher satisfaction level among TAP block group related to lower pain and PONV scores with less need for rescue medications. On the other hand, TAP block doesn't interfere with all complications that were questioned in the data collection sheet (infection, peripheral neurological function or dizziness), and thus there was no significant difference found between both groups in terms of postoperative complications, although there was no complication found in any patient in the first place, and thus it may be found if the sample was larger. Studies like the one conducted by Soleimanpour et al. (2017) emphasize the importance of monitoring postoperative complications for laparoscopic sleeve gastrectomy cases. Lastly, and similar to other postoperative data that are not linked to TAP block action, there was no significant difference

between both groups in the total LOS. The study of Jansson et al. (2018) stated that the mean LOS of laparoscopic sleeve gastrectomy patients is 1.7 days (around 40 hours), which is close to our findings, where most patients have stayed for 48 hours postoperatively. On the other hand, the difference between our study and the previous one is that they conducted correlational tests to investigate the most common factors related to LOS.

Studies like the one that was conducted by Schumann (2011) stated some anesthetic strategies to facilitate intubation process, from reversed Trendelenburg position to placing a blanket under the upper body part, which will facilitate and improve the laryngoscope view. In the current study, these factors were not studied whether they were used or not, and thus it is recommended to first use these techniques and adopt them, and second to conduct more research in our settings to compare their effect on intubation difficulty compared to the current used methods. The previously mentioned study has an advantage of trying cost-effective and easy means to facilitate intubation. In terms of anesthesia maintenance, there was a similarity between previous and current studies in propofol dosage, which was according to total body weight of the patient, and it was controlled equally for both groups, and the adoption of such weight-based dosing is based upon the abundance of studies that support the use of total body weight for these medications and not lean body mass, because their pharmacodynamics are well-studied.

The current study is similar to the study conducted by Sabharwal and Christelis (2010) in that overall assessment is done preoperatively, but the difference is that laparoscopic sleeve gastrectomy-focused assessment is not fully conducted by the multidisciplinary team, as the total assessment is conducted by the nurse and surgeon only, mentioning that the initial assessment for the patient when being admitted, as well as the follow-up assessment intraoperatively have holistic approach that include some international tools, like Mallampati score, in the previous study of Sabharwal and Christelis stated that a score of 3 or more is considered to be a difficult intubation, while in our study, 34% of the patients had a score of 3, while it rises to 60% when assessing the difficulty according to when actual intubation is done.

The study of Sabharwal and Christelis (2010) found a significant correlation between some demographic and operative factors with the postoperative complications of sleeve gastrectomy, including OSA, older than 50 YO of age, and others, while in our study there was no significant difference in complications as there was no complications noticed, including complications related to site infection and neurological complications, and this can be related to the relatively smaller sample of patients in our study compared to other studies. On the other hand, there was no significant difference in postoperative complications between different patients allocated to different groups in Cook et al. (2018) and Alamdari et al. (2018), which is inconsistent with the previously mentioned study of Sabharwal and Christelis.

5.2 Recommendations

1. It is recommended, in general, to use nerve block anesthesia for postoperative pain management to minimize the side effects of opioids.

2. Conduct further studies to compare the effect of infiltrating bupivacaine in different surgery sites, as it was done by other previous studies.

3. Also, it is recommended to conduct further studies to investigate the difference between different pain management strategies in terms of non-physical or non-patient-related factors, like efficiency in time and cost.

4. Other factors related to patient can also be studied, including mean surgery time, mean recovery time, mean time of starting bowel movement, … etc.

5.3 Limitations

1. The main limitation is regarding the acceptance of TAP block idea in our setting, and thus more effort was needed to start conducting the study
2. There were no studies conducted previously in our region to compare their results with them.
3. There was a huge difference in infiltration techniques between the previous studies, and between them and our study, either in the solution used or infiltration site, and thus the comparison and discussion of different findings was very hard.

References

- Abrishami A, Chan J, Chung F, Wong J (2011) **Preoperative pain sensitivity and its correlation with postoperative pain and analgesic consumption**. Anesthesiology 114:445–457

- Alamdari, N. M., Bakhtiyari, M., Gholizadeh, B. & Shariati, C. (2018). ***Analgesic Effect of Intraperitoneal Bupivacaine Hydrochloride After Laparoscopic Sleeve Gastrectomy: a Randomized Clinical Trial***. **J Gastrointest Surg**, 22**,** 396-401.

- Albrecht E, Kirkham KR, Endersby RVW, Chan VW, Jackson T, et al. (2013) **Ultrasound-guide transversus abdominis plane (TAP) block for laparoscopic gastric-bypass surgery: a prospective randomized controlled double-blind trial**. Obes Surg 23: 1309-1314.

- Alimian M, Imani F, Faiz SH, Pournajafian A, Navadegi SF, et al. (2012) **Effect of oral pregabalin premedication on post-operative pain in laparoscopic gastric bypass surgery**. Anesth Pain Med 2: 12-16.

- Alvarez A, Singh PM, Sinha AC (2014) **Postoperative analgesia in morbid obesity.** Obes Surg 24: 652-659.

- ARı, D. E., Ar, A. Y., Karip, C. S., Köksal, C., Aydın, M. T., Gazi, M. & AKGÜN, F. (2017). ***Ultrasound-guided subcostal-posterior transversus abdominis plane block for pain control following laparoscopic sleeve gastrectomy.*** **Saudi Med J**, 38**,** 1224-1229.

- Aveline C, Le Hetet H, Le Roux A, Vautier P, Cognet F, et al. (2011) ***Comparison between ultrasoung-guided transversus abdominis plane and conventional ilioinguinal/iliohypogastric nevre blocks for day-case open inguinal hernia repair***. **Br J Anaesth** 106: 380-386.

- Beiranvand, S. & moradkhani, M. . (2018). **Bupivacaine Versus Liposomal Bupivacaine For Pain Control**. Drug Res (Stuttg), 68**,** 365-369.

- Bertin PM (2014) L***iposome bupivacaine for postsurgical pain in an obese woman with chronic pain undergoing laparoscopic gastrectomy: a case report***. **J Med Case Rep** 8: 21.

- Bhatia N, Arora S, Wig J, Kaur G (2014) C***omparison of posterior and subcostal approaches to ultrasound-guided transversus abdominis plane block for postoperative analgesia in laparoscopic cholecystectomy***. **J Clin Anesth** 26: 294-299.

- Bugada D, Nicola FG, Carboni V, Allegri M (2013) **TAP block for opioidfree postoperative analgesia in obese surgery**. Minerva Anesthesiol 79: 1447-1448.

- Bulpitt, C. J. (1996). T**he Advantages and Disadvantages of Randomised Controlled Trials**. Randomised Controlled Clinical Trials. Boston, MA: Springer.

- Chung, A. Y., Thompson, R., Overby, D. W., Duke, M. C. & Farrell, T. M. (2018). ***Sleeve Gastrectomy: Surgical Tips***. **J Laparoendosc Adv Surg Tech A,** 28**,** 930-937.

- Cooke, F. E., Samuels, J. D., Pomp, A., Gadalla, F., WU, X., Afaneh, C., Dakin, G. F. & Goldstein, P. A. (2018). **A Randomized, Double-Blind, Placebo-Controlled Trial of Intravenous Acetaminophen on Hospital Length of Stay in Obese Individuals Undergoing Sleeve Gastrectomy**. Obes Surg, 28**,** 2998-3006.

- Coşkun, M., Yardimci, S., Arslantaş, M. K., Altun, G. T., Uprak, T. K., Kara, Y. B. & Cingi, A. (2019). S**ubcostal Transversus Abdominis Plane Block for Laparoscopic Sleeve Gastrectomy, Is It Worth the Time?** Obes Surg, 29**,** 3188-3194.

- Crawford, C., Gibbens, K., Lomelin, D., Krause, C., Simorov, A. & Oleynikov, D. (2017). **Sleeve gastrectomy and anti-reflux procedures.** Surg Endosc, 31**,** 1012-1021.

- Dos Santos, G. G., Dias, E. V., Teixeira, J. M., Athie, M. C., Bonet, I. J., Tambeli, C. H. & Parada, C. A. (2014). T***he analgesic effect of dipyrone in peripheral tissue involves two different mechanisms: neuronal K(ATP) channel opening and CB(1) receptor activation***. **Eur J Pharmacol**, 741**,** 124-31.

- Elbakry, A. E., Sultan, W. E. & Ibrahim, E. (2018). ***A comparison between inhalational (Desflurane) and total intravenous anaesthesia (Propofol and dexmedetomidine) in improving postoperative recovery for morbidly obese patients undergoing laparoscopic sleeve gastrectomy: A double-blinded randomised controlled trial***. **J Clin Anesth**, 45**,** 6-11.

- Ennis, Z. N., Dideriksen, D., Vaegter, H. B., Handberg, G. & Pottegård, A. (2016). **Acetaminophen for Chronic Pain: A Systematic Review on Efficacy.** Basic Clin Pharmacol Toxicol, 118**,** 184-9.

- Gallart-Aragón, T., Fernández-Lao, C., Galiano-Castillo, N., Cantarero-Villanueva, I., Lozano-Lozano, M. & Arroyo-Morales, M. (2018). I***mprovements in Health-Related Quality of Life and Pain: A Cohort Study in Obese Patients After Laparoscopic Sleeve Gastrectomy***. **J Laparoendosc Adv Surg Tech A**, 28**,** 53-57.

- Gross JB, Bachenberg KL, Benumof JL, Caplan RA, Connis RT, et al. (2006) **American Society of Anesthesiologists Task Force on Perioperative Management. Practice guidelines for the perioperative management of patients with obstructive sleep apnea: a report by the American Society of Anesthesiologists Task Force on Perioperative Management of patients with obstructive sleep apnea**. Anesthesiology 104: 1081-1093.

- Hariri, K., Hechenbleikner, E., Dong, M., Kini, S. U., Fernandez-Ranvier, G. & Herron, D. M. (2019). **Ketorolac Use Shortens Hospital Length of Stay After Bariatric Surgery: a Single-Center 5-Year Experience**. Obes Surg, 29**,** 2360-2366.

- Hashem, A., Ghobrial, F. K., Elbaset, M. A., Atwa, A. M., Fadallah, M., Laymon, M., El-Assmy, A., Sheir, K. Z. & Abol-Enein, H. (2019). **Efficacy of pethidine, ketorolac, and lidocaine gel as analgesics for pain control in shockwave lithotripsy: A single-blinded randomized controlled trial**. Investig Clin Urol, 60**,** 251-257.

- Jonsson, A., Lin, E., Patel, L., Patel, A. D., Stetler, J. L., Prayor-Patterson, H., Singh, A., Srinivasan, J. K., Sweeney, J. F. & Davis, S. S. (2018). ***Barriers to Enhanced Recovery after Surgery after Laparoscopic Sleeve Gastrectomy***. **Journal of the American College of Surgeons**, 226**,** 605-613.

- Kim, E. K. E., Cooper, B. & Desai, M. S. (2018). ***Popular Literature as an Educational Aid for History of Anesthesia.*** **Journal of Anesthesia History,** 4**,** 123-127.

- MacFater, H., Xia, W., Srinivasa, S., Hill, A. G., Van De Velde, M. & Joshi, G. P. (2019). ***Evidence-Based Management of Postoperative Pain in Adults Undergoing Laparoscopic Sleeve Gastrectomy***. **World J Surg,** 43**,** 1571-1580.

- Moncada R, Martinaitis L, Landecho M, Rotellar F, Sanchez-Justicia C, et al. (2016) **Does Preincisional Infiltration with Bupivacaine Reduce Postoperative Pain in Laparoscopic Bariatric Surgery?** Obes Surg 26: 282-288.

- Petersen PL, Mathiesen O, Stjernholm P, Kristiansen VB, Torup H, et al. (2013) T***he effect of transversus plane block or local anesthetic infiltration in inguinal hernia repair***. **Eur J Anaesthesiol** 30: 415-421.

- Ray, W. T. & Desai, S. P. (2016). ***The history of the nurse anesthesia profession***. **J Clin Anesth,** 30**,** 51-8.

- Ruiz-Tovar J, Muñoz JL, Gonzalez J, Zubiaga L, García A, et al. (2016) **Postoperative pain after laparoscopic sleeve gastrectomy: comparison of three analgesic schemes (isolated intravenous analgesia, epidural analgesia associated with intravenous analgesia and port-sites infiltration with bupivacaine associated with intravenous analgesia).** Surg Endosc.

- Ruiz-Tovar, J., Muñoz, J. L., Gonzalez, J., Zubiaga, L., García, A., Jimenez, M., Ferrigni, C. & Durán, M. (2017). **Postoperative pain after laparoscopic sleeve gastrectomy: comparison of three analgesic schemes (isolated intravenous analgesia, epidural analgesia associated with intravenous analgesia and port-sites infiltration with bupivacaine associated with intravenous analgesia)**. Surg Endosc, 31**,** 231-236.

- Saber, A. A., Lee, Y. C., Chandrasekaran, A., Olivia, N., Asarian, A., Al-Ayoubi, S. & Digregorio, R. (2019). ***Efficacy of transversus abdominis plane (TAP) block in pain management after laparoscopic sleeve gastrectomy (LSG): A double-blind randomized controlled trial.*** **Am J Surg**, 217**,** 126-132.

- Sabharwal, A. & Christelis, N. (2010). **Anaesthesia for bariatric surgery.** Continuing Education in Anaesthesia Critical Care & Pain, 10**,** 99-103.

- Schumann, R. 2011. **Anaesthesia for bariatric surgery.** Best Pract Res Clin Anaesthesiol, 25**,** 83-93.

- Sinha A, Jayaraman L, Punhani D (2013) **Efficacy of ultrasoundguided transversus abdominis plane block after laparoscopic bariatric surgery: a double blind, randomized, controlled study.** Obes Surg 23: 548-553.

- Sisik, A. & Erdem, H. (2019). **Effect of Trocar Site Bupivacaine Administration, Time of First Passage of Flatus, and Duration of the Surgery on Postoperative Pain After Sleeve Gastrectomy: a Case Control Study**. Obes Surg, 29**,** 444-450.

- Soleimanpour, H., Safari, S., Sanaie, S., Nazari, M. & Alavian, S. M. (2017). **Anesthetic Considerations in Patients Undergoing Bariatric Surgery: A Review Article**. Anesth Pain Med, 7**,** e57568.

- Stang, A. (2011). **Randomized controlled trials-an indispensible part of clinical research.** Dtsch Arztebl Int, 108**,** 661-2.

- Tekeli, A. E., Eker, E., Bartýn, M. K. & Öner, M. Ö. (2019). ***Anesthesia Management and Difficult Intubation Evaluations in Laparoscopic Sleeve Gastrectomy Cases.*** **Eastern J Med,** 24**,** 335-339.

- Thomson, P. D., Melmon, K. L., Richardson, J. A., Cohn, K., Steinbrunn, W., Cudihee, R. & Rowland, M. (1973). **Lidocaine pharmacokinetics in advanced heart failure, liver disease, and renal failure in humans**. Ann Intern Med, 78**,** 499-508.

- Wassef M, Lee DY, Levine JL, Ross RE, Guend H, et al. (2013) ***Feasibility and analgesic efficacy of the transversus abdominis plane block after single-port laparoscopy in patients having bariatric surgery*****. J Pain Res** 6: 837-841

- Wu Y, Liu F, Tang H, Wang Q, Chen L, et al. (2013) **The analgesic efficay of subcostal transversus abdominis plane block compared with thoracic epidural analgesia and intravenous opioid analgesia after radical gastrectomy**. Anesth Analg 117: 507-513.

Appendices

Appendix 1

Data Collection Sheet

Transversus abdominis plane block for postoperative analgesia in patients undergoing laparoscopic sleeve gastrectomy. Randomized, Double- blind, controlled trial

الكبح العصبي لعضلة البطن لتسكين الالم ما بعد الجراحة في المرضى الذين يخضعون لاستئصال المعدة بالمنظار. تجربة عشوائية مراقبة، مزدوجة التعمية

استكمالا لدرجة الماجستير في تمريض التخدير في جامعة النجاح الوطنية، أنا الطالب معتز علان أقوم بإجراء مشروع رسالتي الذي يهدف إلى التعرف على تأثير الكبح العصبي لعضلة البطن لتسكين الالم ما بعد الجراحة في المرضى الذين يخضعون لاستئصال المعدة بالمنظار، وهي دراسة من نوع التجربة العشوائية المراقبة، مزدوجة التعمية، أي أن كلا المريض والباحث لا يعلم إن كان المريض الحالي من مجموعة المراقبة أو التدخلية. سيتلقى المرضى في كلا المجموعتين الأدوية الآتية: الباراسيتامول والكيتورولاك والديبيرون والتسلل لعامل التخدير الموضعي، أما المجموعة التدخلية فستتلقى الكبح العصبي لعضلة البطن إضافة لما ذكر. بعد الجراحة سيتم مقارنة المرضى في مجموعات التدخل والسيطرة وفقًا لحدوث وشدة آلام ما بعد الجراحة واستخدام مسكنات الألم الإنقاذية، والنتائج الثانوية مثل الغثيان والقيء ومدة الإقامة في المستشفى

نؤكد في دراستنا هذه على سرية المعلومات المجموعة، إذ لن يتم الاحتفاظ باسم المريض/ة، وستستخدم المعلومات المجموعة لأغراض البحث فقط لا غير، كما ويحق للمريض/ة الانسحاب من الدراسة في أي وقت ودون ضرورة إبداء السبب.

المخاطر المتوقعة والخصوصية:

ليست هنالك اي مخاطر الدراسة سواء نفسية ام جسدية، سيتم حفظ خصوصيتك كمشاركة بالدراسة وسوف يتم التكتم على هويتك وسيبقى اسمك طي الكتمان والمكان الوحيد الذي سيتم ذكر اسمك فيه هو نموذج الموافقة على المشاركة في الدراسة. سوف يتم التعامل مع المعلومات الخاصة بك بطريقة الترميز حماية لخصوصيتك، ويحق لك الانسحاب من البحث متى شئت من دون أن يؤثر ذلك عليك او على الرعاية الطبية التي سوف تتلقينها.

طريقة التواصل مع الباحث:

إذا كانت لديك اي سؤال او استسفار عن الدراسة يمكنك التواصل مع الباحث (معتز علان) بكل رحابة وفي اي وقت عن طريق (الهاتف:) 00972598553078 E-mail: mutazallan92@gmail.com

توقيع المشاركة في البحث: _____

لقد حصلت على شرح مفصل عن الدراسة وأهدافها وإجراءاتها، ومنافعها، والمخاطر المحتملة. ولقد فهمت كافة المعلومات التي قدمت لي وتمت الإجابة كل أسئلتي. لذا فأنني أوافق وبمحض ارادتي على ألمشاركة في هذه الدراسة.

الاسم: .....

التاريخ: .....

Part One: Demographic data

Number:_____

Question	Options
Age (years)	
Gender	1- Male
	2- Female
Weight (Kilograms)	
Height (cm)	
Body Mass Index (BMI)	
Comorbidities?	1- Yes, mention: _____ _____
	2- No
Presence of sleep apnea	1- Yes
	2- No
Educational level	1- Illiterate
	2- Elementary school
	3- High school
	4- University
Residency	1- City
	2- Village
	3- Camp
Marital status	1- Single
	2- Married
	3- Widowed
	4- Divorced
ASA classification	I | II | III | IV | V | VI
Previous surgeries	1- Yes
	2- No
If "YES", what surgeries complications occurred?	1- None
	2- Nausea
	3- Vomiting
	4- Postoperative pain
Mallampati score	

Part Two: Intraoperative data

Question	Options			
Intubation difficulty	1- Easy			
	2- Difficult			
Intubation technique	1- Direct laryngoscope			
	2- Boogie			
	3- Video laryngoscope			
Laryngoscope view	1	2	3	4
Operation duration (min)				
Anesthesia time (min)				
Aldrete score				
Did the patient need an extra dose of intraoperative fentanyl?	1- Yes, mention the dose (mcg):_____			
	2- No			

Intraoperative hemodynamics

Time	BP (MAP)	HR (bpm)	RR (breath/min)	SpO2 (%)	ECG	Temp. (^{o}C)
Baseline	/ ( )					
At induction	/ ( )					
During operation	/ ( )					

Did the patient receive bilateral ultrasound-guided TAP block? Yes No

Part Three: Postoperative Data

Postoperative hemodynamics

Time	BP (MAP)	HR (bpm)	RR (breath/min)	SpO2 (%)	ECG	Temp. (^{o}C)
0 minute	/ ( )					
30 minutes	/ ( )					
2 hours	/ ( )					
4 hours	/ ( )					
6 hours	/ ( )					
12 hours	/ ( )					
24 hours	/ ( )					

Postoperative pain scores, rescue analgesics, PONV and antiemetics

Time	Pain score (VAS) of 10	Rescue analgesic dose (if used)		PONV scale (0 to 6 scale)	Antiemetic dose (if used)
			Pethidine		
0 minute					
30 minutes					
2 hours					
4 hours					
6 hours					
12 hours					
24 hours					

Time for the first pethidine requirement: _____ (minutes)

Time for the first ondansetron requirement: _____ (minutes)

Patient's satisfaction about the 24-hour analgesia:

Excellent - Good - Fair - Bad - Very bad

Total length of stay (hours) : _____

Did the patient develop any of the following side effects/complications?

• Local site infection	• Hematoma formation	• Local anesthetic toxicity	• Dizziness	• Tinnitus
• Perioral numbness	• Lethargy	• Seizures	• Irritability	• confusion

Appendix 2

IRB Form

AN-NAJAH UNIVERS

PROTOCOL FOR HUMAN SUBJECTS RESEARCH

PLEASE BE SURE TO COMPLETE ALL SECTIONS

Current Date of Submission: July 28, 2020

IRB office use only: Date received in IRB office (stamp)_____

If this is a revision in response to an IRB Report of Action (ROA)-approval pending, indicate the date of the ROA: _____

Title of Research: Transversus abdominis plane block for postoperative analgesia in patients undergoing laparoscopic sleeve gastrectomy. Randomized, Double- blind, controlled trial

Principal Investigator: Mutaz Allan
Department/School: Nursing – Medicine and health sciences
Phone : 00972598553078 E-mail : mutazallan92@gmail.com
****Faculty Sponsor (for Student Research): Dr. Aidah Alkaissi**
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****Faculty Sponsor (for Student Research): Dr. Munther Samhan**
Department/School: Nursing – St. Joseph Hospital - Jerusalem
Phone : +972 59-9135901 E-mail :

Type of Research (please check):
Dissertation _____ (PLEASE NOTE: IRB review of dissertation research requires prior successful proposal defense.) **PhD Defense Date: _____**
Master's Thesis (✔)
Class project _____
all other projects_____
**** If the primary investigator is a student, check here to indicate that your faculty sponsor has read the entire application, including cover letters, informed consents, and data collection instruments, and asserts that**

this application is accurate and complete.
Dates Human Subjects Portion of Research Scheduled: from: October 1, 2020 to October 30, 2020
Site(s) of Human Subject Data Collection: St. Joseph Hospital - Jerusalem **(*NOTE: If sites are administratively separate from the University, please submit approval letters, or indicate when they will be forthcoming.)*** **Funding Agency (if applicable): No fund is available**

I. NATURE OF THE RESEARCH

In the judgment of the Principal Investigator, this research qualifies for which of the following types of review:

Review Type: _____exempt (category) ✔expedited (category) _____full Board[1]

II. PURPOSE OF RESEARCH

Briefly describe the objective(s) of the research (please keep description jargon free and use 100 words or less; the IRB will file this information in our descriptions of approved projects).

1- Investigate the difference in postoperative pain outcome (Incidence and intensity of postoperative pain) between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals
2- Investigate the difference in postoperative pain outcome (consumption of rescue analgesia) between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals.
3- Investigate the difference in postoperative hospital outcomes (length of stay and incidence of complications) between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals.
4- Investigate the difference in postoperative symptoms (nausea, vomiting, dizziness, tinnitus, perioral numbness, lethargy, seizures, and signs of brain toxicity, dyspnea, flatus passage, bowel movement) between presence and absence of tap block added to intravenous paracetamol, dipyrone, ketorolac and infiltrative administration of local anesthetic agent in patients undergo sleeve gastrectomy in Palestinian hospitals.

[1] All research that is either externally funded or greater than minimal risk must be reviewed by the full Board

III. METHODS

Approximate number of subjects: 50 laparoscopic sleeve gastrectomy patients

Subjects will be (check only if applicable):

___minors (under 18)

✔involuntarily institutionalized

___mentally handicapped

Describe <u>in detail</u> how the subjects will be selected and recruited:

The sampling process will take full randomized method to ensure the application of all criteria needed for randomized controlled trial design. Randomization is done through opaque and well-sealed envelopes. The sequence generation was done by computer. Number will be written on envelope and group was written on the card within it along with the serial number. As and when patients come, envelop will be opened to see the group to be allotted.

Describe <u>exactly what will be done</u> to subjects once they have agreed to participate in the project:

After recruiting patients, verbal consent form will be read to them, which will explain the aims of the study, and ensure anonymity and confidentiality of the data. After patient's agreement, and according to patients' distribution, control group will receive the conventional anesthetic and pain management methods, which are paracetamol, ketorolac, dipyrone and infiltrative administration of local anesthetic agent, and the interventional group will receive transversus abdominis plane (TAP) block procedure added to the conventional method. After the surgery, patients in interventional and control groups will be compared according to incidence and intensity of postoperative pain and the use of rescue pain medications, and secondary outcomes like nausea, vomiting and length of stay … etc.

Study drugs will processed by a nurse unrelated to the study. Medication will be administered in a 50 mL syringe. The anesthetist administered TAP will not involve in patients' care postoperatively.

An ultrasound-controlled TAP block will be performed using 30 ml of 0.2% bupivacaine at each injection site. A linear ultrasound probe will be used for the TAP block. For the posterior approach, the probe will placed across the midaxillary line between the iliac crest and the cost margin. The outer oblique muscles, the inner oblique edge and the transverse abdominis are visualized. For the subcostal block, the probe is placed obliquely on the upper abdominal wall along the subcostal margin near the midline. After identifying the muscle in the rectus abdominis, the probe is gradually moved laterally along the subcostal margin to identify the transverse abdominal muscle behind the rectus muscle. The outer and inner oblique muscles are also visualized. A

Pajunk needle (22-gauge) will be inserted anteriorly into the plane of both techniques. The needle entered the fascia between the internal oblique and transverse abdominis muscles; 2 ml of 0.9% saline will be injected to verify the correct positioning of the needle. Following negative aspiration, 30 ml 0.2% bupivacaine will be injected into the fascia. The spread of the injected the solution will be observed as a dark oval shape between 2 muscles. For the rear TAP block was an assistant required to pull the abdomen away.

What incentives will be offered, if any? No

IV. RISKS/BENEFITS TO PARTICIPANTS

Identify possible risks to subjects:

(NOTE: These may be of a physical, psychological, social or legal nature. If subjects are vulnerable populations, or if risks are more than minimal, please describe what additional safeguards will be taken.)

The TAP block is a relatively safe procedure with minimal complications. In addition to the common complications associated with any peripheral nerve block (ie, local anesthetic toxicity, intravascular injection, nerve injury, bleeding, and infection), inadvertent peritoneal puncture is a risk with this block but it is rare

What are the benefits and how will they be optimized?

This study will provide the medical and anesthetic field in Palestine with the up-to-date clinical comparison between infiltrative administration of local anesthetic agent with intravenous paracetamol, ketorolac and dipyrone (optalgin), and the addition of tap block to all of the previous agents. The comparison is between both models in the time needed for the use of pain killer postoperatively, and other hospital outcomes like length of stay in the hospital and incidence of complications.

Also, as most of these patients have sleep apnea, the reduction of opioids use has positive results regarding nausea and vomiting.

Do benefits outweigh risks in your opinion? Yes ✔ No _____

Are there potential legal risks to the Principal Investigator or University? Yes No ✔

V. INFORMED CONSENT

Describe how participants will be informed about the research before they give their consent. Be sure to submit with this protocol a copy of the informed consent/assent letter(s) you will use. Please prepare your informed consent letter at the 8th grade reading level or lower as dictated by the needs of the subjects. (See IRB website for required elements of an informed consent.)

بعد تجنيد المرضى في الدراسة ، سيتم قراءة نموذج الموافقة اللفظية لهم ، والذي سيشرح أهداف الدراسة ، ويضمن عدم الكشف عن هويته وسرية البيانات. بعد موافقة المريض ، ووفقًا لتوزيع المرضى ، ستتلقى المجموعة الضابطة طرق التخدير التقليدية وإدارة الألم ، وهي الباراسيتامول والكيتورولاك والديبيرون والتسلل لعامل التخدير الموضعي ، وستتلقى المجموعة التدخلية مادة التخدير الموضعي بالطريقة البطنية العرضية (TAP) . بعد الجراحة سيتم مقارنة المرضى في مجموعات التدخل والسيطرة وفقًا لحدوث وشدة آلام ما بعد الجراحة واستخدام مسكنات الألم الإنقاذية ، والنتائج الثانوية مثل الغثيان والقيء ومدة الإقامة في المستشفى

المخاطر المتوقعة والخصوصية:

ليست هنالك اي مخاطر الدراسة سواء نفسية ام جسدية، سيتم حفظ خصوصيتك كمشاركة بالدراسة وسوف يتم التكتم على هويتك وسيبقى اسمك طي الكتمان والمكان الوحيد الذي سيتم ذكر اسمك فيه هو نموذج الموافقة على المشاركة في الدراسة. سوف يتم التعامل مع المعلومات الخاصة بك بطريقة الترميز حماية لخصوصيتك، ويحق لك الانسحاب من البحث متى شئت من دون أن يؤثر ذلك عليك او على الرعاية الطبية التي سوف تتلقينها.

طريقة التواصل مع الباحث:

إذا كانت لديك اي سؤال او استسفار عن الدراسة يمكنك التواصل مع الباحث (معتز علان) بكل رحابة وفي اي وقت عن طريق (الهاتف:) 00972598553078 E-mail : mutazallan92@gmail.com

توقيع المشاركة في البحث:

لقد حصلت على شرح مفصل عن الدراسة وأهدافها وإجراءاتها، ومنافعها، والمخاطر المحتملة. ولقد فهمت كافة المعلومات التي قدمت لي وتمت الإجابة كل أسئلتي. لذا فأنني أوافق وبمحض ارادتي على ألمشاركة في هذه الدراسة.

الاسم:.....

التوقيع:.....

التاريخ:.....

VI. PRIVACY/CONFIDENTIALITY

Please describe whether the research would involve observation or intrusion in situations where subjects have a reasonable expectation of privacy. If existing records are to be examined, has appropriate permission been sought; i.e. from institutions, subjects, physicians? What specific provisions have been made to protect the confidentiality of sensitive information about individuals?

The study is conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of An-Najah National University (IRB) and will be approved by the An-Najah National University hospital's Research Ethics Committee. Forms of consent will be obtained from the patients. Because research involves human participants, it is necessary to follow strict ethical principles. The participants ask to give their consent. They are also assured of their right to privacy and anonymity. Anonymity is maintained by coding the participants and by destroying the names attached to the numbers.

Integrity:

Confidentiality is ensured by leading to unauthorized access to the information. All patients participating in the study were fully informed about the purpose of the research and assured that their anonymity would be maintained during analysis and reporting of the results. Patients will be assured that the presentation of the data will not be associated with any individual names to protect the patient's anonymity and confidentiality. All data will be kept in a closed cabinet, no access to the data by unauthorized people.

Refusal to participate \ withdraw from the study:

All participants are informed about the purpose and procedure of the study and will say that they will be able to withdraw from the study at any time.

Harm:

No harm will be done to the participants and the names of the participants will never be mentioned to anyone.

Appendix 3

IRB Confirmation Letter

An-Najah
National University
Health Faculty of medicine&
Sciences
IRB

جامعة النجاح
الوطنية
كلية الطب وعلوم الصحة
لجنة اخلاقيات البحث العلمي

Ref: Mas. July /2020/27

IRB Approval Letter

Study Title:

"Transversus abdominis plane block for postoperative analgesia in patients underoing laparoscopic sleeve gastrectomy. Randomized, Double- blind, controlled trial"

Submitted by:
Mutaz Allan

Supervisor:
Aidah Alkaissi , Munther Samhan

Date Approved:
29th July 2020

Your Study Title **"Transversus abdominis plane block for postoperative analgesia in patients underoing laparoscopic sleeve gastrectomy. Randomized, Double- blind, controlled trial"** was reviewed by An-Najah National University IRB committee and was approved on 29th July 2020.

Hasan Fitian, MD
IRB Committee Chairman
An-Najah National University

IRB

جامعة النجاح الوطنية

كلية الدراسات العليا

الكبح العصبي لعضلة البطن لتسكين الالم ما بعد الجراحة في المرضى الذين يخضعون لاستئصال المعدة بالمنظار: تجربة عشوائية مراقبة، مزدوجة التعمية

إعداد

معتز جمال علان

إشراف

د. عايدة القيسي

د. منذر سمحان

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

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الملخص

مقدمة: تعتبر عملية استئصال المعدة بالمنظار من أكثر الإجراءات المفضلة من التدخلات الجراحية لمعالجة السمنة المفرطة، واختيار المرضى لإجراء هذه العملية يخضع لشروط اختيار المريض حسب معايير متعددة، منها ما يتعلق باختيار طريقة تخدير المريض، والتي تتغير من مستشفى لآخر حسب السياسات المتبعة في كل مستشفى. في هذه الدراسة، استهدفنا التحري عن الاختلافات في مقاييس الألم، والغثيان والقيء ما بعد عملية استئصال المعدة بالمنظار، وكذلك مستوى رضى المريض وحدوث مضاعفات ما بعد العملية بين المرضى الذين يتم تخديرهم باستخدام الطريقة الاعتيادية والمرضى الذين يتم إضافة الكبح العصبي لعضلة البطن إلى التخدير الاعتيادي

المنهجية: تم اختيار منهجية التجربة العشوائية المراقبة مزدوجة التعمية لتطبيق الدراسة على مجموعة تتكون من 50 مريضا تم إجراء عملية استئصال المعدة بالمنظار لهم وتم تقسيمهم إلى مجموعتين متساويتين بين التخدير الاعتيادي والتخدير باستخدام الكبح العصبي لعضلة البطن المضافة للتخدير الاعتيادي. كل المرضى بالغون (من عمر 18 إلى 65 عاما)، يمتلكون مؤشر كتلة الجسم أعلى من 35 كلغم/متر مربع، مع مقياس ASA من الدرجة الأولى والثانية، ولم يتناولوا مسكن ذو المدى الطويل خلال 12 ساعة ما قبل العملية. تم استخدام ورقة جمع بيانات من تطوير الباحث، والتي تحتوي على أسئلة عن المعلومات الديموغرافية، والطبية، والأمراض المصاحبة، ومعلومات عن المراحل حول العملية، مثل العلامات الحيوية خلال وبعد العملية، وقت

العملية، التخدير المستخدم وكميته، وإدخال التنفس الصناعي، ومقاييس الألم والغثيان والقيء ما بعد العملية، والوقت وكمية المسكنات ومضادات القيء المستخدمة، بالإضافة إلى مستوى رضى المريض والمكوث داخل المستشفى.

النتائج: لم يكن هنالك اختلاف ملحوظ بين مجموعتي الكبح العصبي والمجموعة المراقبة من ناحية العمر (معدل = 32.56 مقابل 30.6 سنة، على التوالي) مقايس مؤشر كتلة الجسم (معدل = 52.23 مقابل 51.37، على التالي) أو أي من معايير اختيار المرضى، صعوبة إدخال أنبوب التنفس الصناعي وجدت عن\ 60% من المرضى، وتم التخدير باستخدام 200 ملغم بروبوفول، 50 ملغم مرخي العضلات، 200 ملغم فنتانيل، وتم إعطاء جميع المرضى 1000 ملغم من الكيترولاك و1000 ملغم من الباراسيتامول داخل الوريد. زيادة على ما سبق، تم إعطاء مجموعة الكبح العصبي لعضلة البطن 30 ملم من دواء البابيفكائين تركيز 0.2% في منطقة العضلة المستهدفة TAP باستخدام الألتراساوند. تم إيجاد فرق ملحوظ بين المجموعتين من ناحية تعداد نبض قلب أقل في فترات قبل التخدير (قيمة المعامل = 0.026)، المحافظة (معامل = 0.037)، والظهور (معامل = 0.004) عند مجموعة الكبح العصبي، بينما كان هنالك فرق ملحوظ من ناحية قراءات أقل لضغط الدم عند مجموعة الكبح العصبي في فترة ما بعد العملية خلال جميع نقاط الزمن (من صفر إلى 24 ساعة ما بعد العملية، قيمة المعامل < 0.05). إضافة إلى ذلك، كان معدل مقياس الألم من 10 أقل عند مرضى مجموعة الكبح العصبي مقارنة بالمجموعة المراقبة (مدى من 2.50 – 4.58 مقابل 5.12 – 8.94، على التوالي)، ومعدل أقل لمقياس الغثيان والقيء من 6 (مدى من 2.33 – 2.58 مقابل 5.36 – 6.0، على التوالي) على جميع نقاط الوقت من صفر إلى 24 ساعة، وكذلك جرعة كلية أقل من المسكنات ومضاد القيء ما بعد العملية ووقت أطول للحاجة لأول مسكن ومضاد للقيء (معامل < 0.05). أخيرا، مرضى مجموعة الكبح العصبي كان لديهم مستوى رضى أعلى من مرضى المجموعة المقابلة (معامل < 0.001).

الملخص: إن إضافة الكبح العصبي لعضلة البطن إلى عمليات استئصال المعدة بالمنظار مفضل على استخدام التخدير الاعتيادي فقط، حيث أنه أظهر خطرا أقل لارتفاع معدل نبض قلب المريض خلال العملية، أو لارتفاع معدل ضغط الدم أو ضربات القلب ما بعد العملية. أيضاً، ترافق ذلك مع معدلات أقل لمقاييس الألم والغثيان والقيء ما بعد العملية على جمع نقاط الوقت من صفر إلى 24 ساعة، وكذلك حاجة أقل بشكل ملحوظ لاستخدام مضادات الألم ومضادات القيء، ومستوى أعلى لرضى المريض.

كلمات مفتاحية: استئصال المعدة بالمنظار، الكبح العصبي لعضلة البطن، ألم ما بعد العملية، غثيان وقيء ما بعد العملية، مستور الرضى.