An-Najah National University

Faculty of Graduate Student

Analgesic Effect of Local Wound Infiltration with Magnesium Sulfate Versus Bupivacaine in Reducing Postoperative Pain in Patients Undergoing Inguinal Hernia Repair Surgery: A Randomized, Double-blind, Controlled Study

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Dedication

This thesis is dedicated to:

The sake of Allah, my Creator and my Master,

My great teacher and messenger, Mohammed

(May Allah bless and grant him), who taught us the purpose of life,

My homeland Palestine, the warmest womb;

The great martyrs and prisoners, the symbol of sacrifice;

The An-Najah national University; my second magnificent home;

My favorite doctor Aidah Alkaissi who have raised me to be the person I am today;

The spirit of my father

My great mother, who never stop giving of herself in countless ways,

My dearest wife, who leads me through the valley of darkness with light of hope and support,

My beloved brothers and sisters; particularly my dearest brother,

Sami, who stands by me when things look bleak,

My beloved daughters: Alaa and Hoor whom I can't force myself to stop loving.

To all my family, the symbol of love and giving,

My friends who encourage and support me,

All the people in my life who touch my heart,

I dedicate this research

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In the Name of Allah, the Most Merciful, the Most Compassionate all praise be to Allah, the Lord of the worlds; and prayers and peace be upon Mohamed His servant and messenger.

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الإقرار

أنا الموقع أدناه، مقدم الرسالة التي تحمل العنوان:

Analgesic Effect of Local Wound Infiltration with Magnesium Sulfate Versus Bupivacaine in Reducing Postoperative Pain in Patients Undergoing Inguinal Hernia Repair Surgery: A Randomized, Double-blind, Controlled Study

أقر بأن ما اشتملت عليه هذه الرسالة أنما هو نتاج جهدي الخاص، باستثناء ما تمت الإشارة إليه حيثما ورد، وان هذه الرسالة ككل، أو أي جزء منها لم يقدم من قبل لنيل أيّ درجة أو لقب علميّ 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 from anywhere else, for any other degree or qualification.

Student`s Name: **اسم الطالب:**

Signature: **التوقيع**

Date: **التاريخ:**

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List of Abbreviations

ANOVA	Analysis of variance
ASA	American society of anesthesiologist
BMI	Body mass index
BP	Blood pressure
CO2	Carbon dioxide
ECG	Electrocardiogram
ETCO2	End tidal CO2
g	Gram
HR	Heart rate
Hrs.	Hours
IRB	Institutional review board
IV	Intravenous
LA	Local anesthesia
MANE	Morrow assessment of nausea and emesis
MG	Milligram
Mg	Magnesium sulfate
Min	Minutes
Ml	Milliliter
mmHg	Millimeter of mercury
Mo	Morphine hydrochloride
NIBP	Noninvasive blood pressure
NMDA	N-Methyl-D-Aspartate
NSAIDs	Non-steroidal anti- inflammatory drugs
PACU	Post anesthetic care unite
P-value	Probability value
RA	Rescue analgesia
s.c.	Subcutaneous
SpO2	Blood oxygen saturation
SD	Standard deviation
VAS	Visual analogue scale
%	Percent

Analgesic Effect of Local Wound Infiltration with Magnesium Sulfate Versus Bupivacaine in Reducing Postoperative Pain in Patients Undergoing Inguinal Hernia Repair Surgery: A Randomized, Double-blind, Controlled Study

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Abstract

Introduction

Postoperative pain is one of the most common problems after hernia repair. Reduction of postoperative pain accelerates functional recovery, reduces the duration of hospital stay and postoperative morbidity. Local wound infiltration with local anesthetics has been recommended to decrease postoperative opioid consumption and postoperative pain. The aim of the present study is to determine the analgesic effect of magnesium sulfate versus bupivacaine infiltration before closure of surgical incisions in decreasing incidence and intensity of postoperative pain and opioid use after groin hernia repair, to reduce analgesic consumption and increase the time for initial analgesics.

Method and Material

In a double-blind clinical trial, patients were recruited for elective inguinal hernia repair. After the approval of the Institutional Review Board and signature of the informed consent forms, 80 patients, ASA physical status I

and II, aged between 18 and 70 years, are submitted to inguinal hernia repair under general anesthesia induced with fentanyl, (2 ug/kg), propofol (2 mg/kg) and rocuronium (0,6 mg/kg) and maintained with 70%/30% nitrous oxide and oxygen and isoflurane in 0.5% to 1.5% concentration.

After anesthetic induction, patients were randomly divided into two groups and before closure of incision, local wound infiltration in: Bupivacaine group, 5 ml of bupivacaine 0.5% added to 5 ml normal saline infiltrated subcutaneously and in magnesium group, 10 ml magnesium sulfate 20% infiltrated subcutaneously. Intravenous morphine 2 mg I.V was used as rescue medication.

Pain values were measured using the visual analog scale (VAS) at 0.5, 1, 2, 3, 6, 12, 18 and 24 hours after anesthetic recovery. The total morphine consumption, the time of the first request for morphine dose and the side effects of the study drugs were documented.

Results

In this study, we compared wound infiltration with magnesium injection and bupivacaine to inguinal hernia surgical site before closure to control postoperative pain. Our results are displayed superior effect of bupivacaine compared to magnesium in reducing pain, reducing analgesic rescue medication and increase time for first analgesic dose request during 24 hr. after the operation.

In this study, homogeneity of participant was checked by Leaven's test, the sample was homogenous in age, weight, height (P value > 0.005) that mean no significant different between two group in demographic data.

Regarding the VAS scale during the total period of 24 hours after surgery reflecting the intensity of postoperative pain, the results showed that the VAS scale in the Mg group (mean (SD) (1.88 ± 0.53) is significantly higher than the VAS scale in Bupivacaine group (mean (SD) = 0.98 ± 0.61), p = 0,000. The results indicate that Bupivacaine is more effective in reducing postoperative pain than MgSO4.

The results showed that there were significant differences in the incidence of pain during the total period of 24 hours. Postoperatively between the two experimental groups (P-value = 0.000 <0.05), the results showed that the number of patients had an incidence of pain in mgso4 group (n (%) = 38 (95%)) is significantly higher than in bupivacaine group (n (%) = 18 (45%)), p = 0.000. The results indicate that bupivacaine is more effective in reducing incidence of postoperative pain than MgSO4.

Regarding morphine requirements during the total period of 24 hours after surgery, the results showed that the number of patients given morphine (2 mg i.v.) in mgso4 group (n (%) = 38 (95%)) is significantly higher than in bupivacaine group (n (%) = 17 (42.5%), p = 0.000 The result indicates that Bupivacaine is more effective in reducing the opioid consumption of rescue drug that is morphine than MgSO4.

There are significant differences in complete response. (no nausea, no vomiting, no rescue medication). between the two experimental groups (P-value = 0.004 <0.05), the results showed the number of patients who had a complete response in the mgso4 group (n (%) = 14 (35%)) is significantly less than in the bupivacaine group (n (%) = 27 (67.5%)), p = 0.004. The results indicate that more patients with complete response in bupivacaine than in MgSO4. There are significant differences in nausea between the two experimental groups (P value = 0.003 <0.05), the results showed that the number of patients who had nausea in mgso4 group (n (%) = 22 (55%)) is significantly higher than the one in the bupivacaine group (n (%) = 9 (22.5%)). And the results show that there are no significant differences in vomiting between the two experimental groups (P-value = 1,000> 0.05).

There are significant differences in blood pressure after 4 hr (S less 120 and D less 80) between the two experimental groups, p-value of the post hoc Multiple comparison test <0.05), number of patients whose blood pressure (S less 120 and D less 80) in MgSO4group (N(%)=8(20%)) is significantly less than that in bupivacaine group(N(%)=17(42.5%)). The result indicates more patients in Bupivacaine group had blood pressure less than 120/80 after 4 hr. There are significant differences in blood pressure after 16 hr. (S less than 120 and D less 80) between the two experimental groups (P-value of the post hoc Multiple comparison test <0.05), number of patients whose blood pressure after 16 hr. (S less than 120 and D less 80) in MgSO4 group(N(%)=16(40%)) is significantly less than that in bupivacaine

group(N(%)=27(67.5%)).The result indicates more patients in bupivacaine group had blood pressure less than 120/80 after 16 hr.

There are significant differences in blood pressure after 8 hr. (Stage 2 - S 140 or higher and D 90 or higher) between the two experimental groups(P-value of the post hoc Multiple comparison test <0.05), patients whose blood pressure after 8 hr(Stage 2 - S 140 or higher and D 90 or higher) in MgSO4 group(N(%)=10(25%)) is significantly higher than that in Bupivacaine group(N(%)=3(7.5%)). The result indicates that more patients in MgSO4 group had BP≥ 140/90. It could be as a result of pain. As a conclusion, the result indicates more patients in Bupivacaine group had blood pressure less than 120/80 MgSO4 groups (P-value=0.043<0.05).

There are significant differences in the total respiratory rate between the two group, the results exhibited that the RR in MgSO4 group (mean=16.88) is significantly higher than the RR in Bup group (mean=16.59). But the difference is not clinically significant.

Conclusion

Bupivacaine infiltration of wounds at the surgical site was more effective than magnesium sulfate filtration to reduce postoperative incidence and intensity of pain, reduce opioid consumption, and increase initial time to request postoperative rescue analgesics in patients undergoing inguinal hernia surgery.

Keywords

Local Wound Infiltration, Inguinal Hernia Repair, Bupivacaine, Magnesium sulfate, Morphine hydrochloride, Rescue analgesia.

Chapter One
Introduction

1.1 Introduction

Pain after surgery has the companion for compelling side effects on the physiology and can also drench the patient into psychological embarrassment. The element and breadth of nociceptive incitement change amid people and surgeries and thus multimodal analgesic accession have been animated for pain alleviation. With local infiltration, afferent inclinations from the location of incision and injury are decreased.

This decreasing the sensitization and subsequent hyperalgesia. The risks combined with parenteral disposition of analgesics, risks combined with central neuraxial block and the injury and injection to encompassing constructions in nerve and plexus blocks are warded off. As part of multimodal approach, there can be a devaluation in appeal of narcotics. Modesty and safeguarding are the explanation of the technique (Bhaskar, 2015).

Pain after surgery is one of the greater problems after wards herniorrhaphy. Around 10% of population are overwhelmed with hernia over their life-span. Abdominal hernia is a prevailing disease, which develops in 1.7% of all ages and in 4% of age over 45 (de Goede et al., 2015). Inguinal hernia is contracted for 75% of hernia. The uncertainty about progress for inguinal hernia is 24 - 27% in men and 3% in women (Primatesta & Goldacre, 1996).

One of the greater problems after herniorrhaphy is pain, and up to 80% of clients required narcotic analgesia (Goldstein et al., 2000). Utilitarian improvement will be tilted with declining pain after surgery, recession in hospital and after surgery morbidity. Unhampered pain after surgery proceeded to chronic pain and is a prevalent complication post herniorrhaphy (Kurmann et al., 2015). Even though narcotics are the fortitude of postoperative pain executive, high dose of narcotics has diverse after effect for instance nausea and vomiting, ileus, and respiratory desperation. In contrast, small narcotic dose would incline the percentage of pain after surgery in clients. One more reclamation to narcotics are Non-steroidal anti-inflammatory drugs (NSAIDs),nevertheless, NSAIDs are combined with many unsatisfactory effects, counting gastrointestinal hemorrhage, renal disorder, and diminished hemostasis (Garimella & Cellini, 2013).

Diverse therapeutics manners have been proposed and settled to be alternately efficient for the treatment of pain after herniorrhaphy. Ilioinguinal and iliohypogastric nerves block and intra-peritoneal bupivacaine injection are different manner to monitor pain of herniorrhaphy (Baerentzen et al., 2012). Local infiltration, sub-facial or subcutaneous organization of tramadol, bupivacaine, lidocaine, or meperidine in to wound location was also undertaken in divergent trials. Wound infiltration with local anesthetics is consistently utilized for pain alleviation after inguinal hernia operation (Kaki &Marakbi, 2008). Topical infiltrative bupivacaine is alike more effective than I.V. meperidine as

painkiller for post inguinal herniorrhaphy pain (Waechter et al., 2001). Still the argument is calm and local anesthetic infiltration has not been verified as an inevitable way (Tong et al., 2014).

Magnesium sulfate is associated with pain relief, which alienates calcium-like NMDA antagonists (Koinig et al., 1998; Kara et al., 2002). Magnesium and Bupivacaine provided safe and reduced drug expenditure to reduce postoperative pain and analgesic use and have been used as an effective driving force in postoperative pain management (Bhatia et al., 2004).Nonetheless, Magnesium sulfate infiltration has not been utilized for postoperative pain after inguinal hernia surgery (Bhatia et al., 2004).

Magnesium sulfate is the fourth exceedingly recognizable cation in the body. It has significant physiological act in enzymatic incitement of energy metabolism and protein amalgamation (James, 1992). The analgesic ramification was first exhibited in humans in 1996 when magnesium was accustomed i.v. all along the perioperative course (Tramer et al., 1996). It has been proposed to decrease post-operative pain killer urgency (Levaux et al., 2003; Koinig et al., 1998).

Bupivacaine is the steadfast local anesthetic in caudal, epidural and vertebral anesthesia and is paramount utilized clinically to stem with acute and chronic pain (Meaghan & Gabriela, 2015).Further to blocking Na channels, bupivacaine influences the activity of divergent channels, comprehending NMDA receptors. It is significant that bupivacaine forbids NMDA receptor-mediated synaptic transmission in spinal dorsal horns,

afield sincerely included in centralized sensitization (Meaghan & Gabriela, 2015). Rising concentrations of bupivacaine decreased GluN2 subunit channel transparency and pH-independent ways by inclining the average period of closures and decreasing median time for openings (Meaghan & Gabriela, 2015).

1.2 Aim and Objectives

The aim of the present study is to determine the analgesic effect of magnesium sulfate versus bupivacaine infiltration before closure of surgical incisions in decreasing incidence and intensity of postoperative pain and opioid use after groin hernia repair, to reduce analgesic consumption and increase the time for initial analgesics.

1.3 Problem Statement

Pain after surgery may cause discomfort for the clients, lengthen convalescence and may also has financial emanations. Likewise, wound pain is the exceedingly frequent dispute after open repair of the inguinal hernia, knowledge on postoperative pain handling in the literature remnant finite. Pain after surgery is one of the higher prevailing drawbacks after inguinal hernia. Reducing of pain in clines utilitarian recovery, reduced length of stay in hospital and morbidities after surgery.

Narcotics are the background of pain handling after surgery, increment dose of narcotics have many unfortunate effects such as respiratory

depression, ileus, nausea and vomiting. The reduction of narcotic dose would increases the grade of pain in clients after surgery.

Some complications can be stagnated when decreasing pain after surgery in inguinal hernia. Undisciplined pain after surgery convinced chronic pain which is a prevailing complication after hernia repair (Kurmann, et al., 2015)). Diverse therapeutic manners have been suggested and exist to be in consistently efficient for over sight of pain induced by inguinal hernia. Wound infiltration with local anesthetics is occasionally utilized for alleviation of pain after inguinal hernia surgery. Nonetheless, altercation still encounters and local anesthetic infiltration has not been authorized as an utmost manner (Tong, et al., 2014)). MgSO4 is a complementary for pain handling, which antagonizes calcium-like NMDA antagonists (Koinig, et al, 1998; Kara, et al., 2002). MgSO4 and Bupivacaine donate secure and low expenditures of drugs to decrease pain after surgery and painkillers utilization and have been used as impressive relief in postoperative pain handling (Bhatia, et al., 2004). MgSO4 filtration has not been utilized for the control of postoperative inguinal hernia pain. Accordingly in the present study the author made a comparison of analgesic effect of MgSO4 versus Bupivacaine wound infiltration in reducing postoperative pain after inguinal hernia repair surgery.

1.4 Significance of the Study

Post- operative pain handling is a fundamental factor in surgery. It greatly increments clients satisfaction, and affects the hospital length of stay.

Local wound infiltration has occasionally been conducted to manage postoperative pain induced by hernia surgery, with the usage of the traditional local anesthetics such as bupivacaine. Leverages from local infiltration in the wound prior closing the skin after hernia repair with bupivacaine have been settled to be effective that one may reduce opioids requirements S.C, I.M or I.V. (Slavica, et al., 2009; Seyed et al., 2015). The usage of MgSO4 for local wound infiltration is modernized and not yet proficient in Palestine.

Surgical procedures are associated with tissue damage and the preponderance of patients treated will feel some grade of pain after surgery. Multitude of patients suffer from moderate or severe pain after surgery.

Magnesium sulfate is impetus that antagonizes calcium similar to the NMDA receptor antagonists (Koinig et al,. 1998; Kara et al., 2002).MgSO4 and bupivacaine secure and cheap drugs to diminish pain after surgery and analgesic expenditure and have been processed as efficient incentive for postoperative pain handled (Bhatia et al., 2004). Postoperative recovery may be protracted by postoperative pain and complications may occur more periodically (Spreng, 2011).

Confer to our knowledge, no data have been published about the incidence of pain after inguinal hernia surgery or the effect of post-operative pain handling in Palestine. The utmost vision is to enhance postoperative pain handling to the point where pain after surgery can be avoided and surgery becomes "painless". Pain is an impending after effect of all surgery and appropriate deliberation to sources of pain and its handling will afford relevant advantages for the clients.

1.5 Research Question

Is there a preference for one of the other drugs, which is magnesium and bupivacaine to reduce postoperative pain and opioid expenditure in patients undergoing inguinal hernia repair?

1.6 Research Hypothesis

There is a significant difference at a level of 0.05 related to the incidence of post-operative pain between MgSO4 and bupivacaine (marcaine®) in patients undergoing inguinal hernia repair surgery.

There is a significant difference at a level of 0.05 related to the intensity of post-operative pain between MgSO4and bupivacaine (marcaine®) in patients undergoing inguinal hernia repair surgery.

There is a significant difference at a level of 0.05 related to the consumption of rescue medication that is Morphine (opioid) between MgSO4 and bupivacaine (marcaine®) in patients undergoing inguinal hernia repair surgery.

There is a significant difference at a level of 0.05 related to the adverse effects that are (nausea, vomiting) between MgSO4 and bupivacaine (Marcaine®) in patients undergoing inguinal hernia repair surgery.

Chapter Two
Background

Background

Inguinal hernia repair

Uttermost prevailing surgery completed by surgeons is inguinal hernia repair. Overrun 800,000 hernia repair surgery accomplished every year. Inguinal hernia is attributed as an opening in the myofascial plain of the oblique and transversal is muscles that can acquiesce for herniation of intra-abdominal or extra-peritoneal organs. Sort of repair is an open or laparoscopic approach can be utilized with the aim of defect blockage and a strain -free repair. A mesh is prevalent utilized for a strain-free repair. When the mesh is contravene, main stitch repair can be performed (Mohamad& Jeffrey, 2020).

Uttermost prevailing hernia is an abdominal hernia, the percentage is 1.7% for all ages, for aged more than forty-five, percentage is 4%. Inguinal hernias constitute for seventy five percent of abdominal wall hernias (John & Patrick, 2008).

There are various cofactors increment risk of pervasiveness of inguinal hernia likewise family history, it increments anticipation of incidence eight times likewise who has free family history from inguinal hernia. Age, sex: male more than female, smoking, chronic obstructive pulmonary disease

wound up chronic cough and increment or decline of body mass index (Andre et al., 2007; Dieter, 2016).

Regional anesthesia

Regional anesthesia extends to develop into backup advent to accustomed anesthesia when pertinent, regional anesthesia may be utilized after hand for after surgery analgesia. Regional anesthesia is an anesthesia procedure which accomplice the right employment of a needle or catheter adjoining to nerve plexus that innervate the field of the body where surgery is to be achieved. It is a secure procedure and an efficient manner to afford good anesthesia and analgesia during intra and post-operative, which consist of spinal anesthesia, epidural anesthesia; and peripheral nerve block (morgan, 2013).

Bupivacaine

Bupivacaine is a forcible local anesthetic with exclusive attribute from the amide class of local anesthetics that utilized in local anesthetics as regional anesthesia, epidural anesthesia, spinal anesthesia, and local infiltration, it has gradual outset of response (about 5-10 minutes after injection) but its accouterments ending excess longer, for about 4-8 hours. Bupivacaine acts as any local anesthesia drug introduces nerve fibers as a neutral free base. Ionized compose and the cationic compose blocks conduction by its reciprocal action on the inner surface of the Na+ channel (Fourutan et al., 2020).

Magnesium sulfate

Magnesium is a crucial body mineral that confidential as a fourth cation in body. Magnesium sulfate acts on Non-competitive N-methyl-D -aspartate (NMDA) receptor and calcium channel antagonist. Magnesium has various physiological enterprises, containing animating of many enzymes elaborate in energy metabolism and protein synthesis (James, et al 1992). Magnesium likewise has anti-nociceptive possessions in animals and human models of chronic pain (Feria, et al 1993; Tramer, et al 1998). Its influences are dominantly build on the settlement of calcium influx into the cell, ie “natural physiological calcium antagonism” (Iseri, et al 1994) and antagonism of N-methyl-o-aspartate (NMDA) receptor. Outcomes from jn vitro studies proposed that NMDA receptor activation increments cytoplasmic calcium consolidation in unfledged spinal nerves (MacDermott, et al 1986). Discrepancy in the intracellular calcium consolidation can margin to enduring discrepancy in the excitability of the dorsal horn cells (Coderre, et al., 1986) and subsequently plays a crucial role in pain perception. In rats, magnesium repressed NMDA-induced pain combined with detrimental effects after discernment injury (Feria, et al 1993). NMDA receptor antagonists also forbid induction and maintenance of central sensitization developments and abolishes hypersensitivity once entrenched (Woolf, et5 al 1993). Sensitization is commonly demonstrated as a pain after pain threshold and hypersensitivity to the recall reflex. These statistics proposed that NMDA receptor antagonists which magnesium has the capability to avert and treat pain.

Tramer, et al (1996) stated that the role of the magnesium as postoperative analgesic has been demonstrated. Magnesium application led to a compelling reduction in morphine expenditure through the postoperative period in patients after abdominal surgery. Furthermore, there is a converse relationship between the intensity of pain and the magnesium consolidation in serum in females during childbirth and in clients with different medical conditions (e.g. myocardial infarction, pancreatitis, and burns) (Weissberg, et al 1991).

Magnesium sulfate has (Anesthesia _ Analgesia sparing effect) that advantageous to anesthesiologist to perform intra and after surgery and it is constructive to decline pain after surgery, analgesic expenditures, length of stay in hospital and accomplish clients satisfaction. Magnesium sulfate utilized as ancillary drug when utilized systemic with another analgesic drugs, magnesium sulfate is not a primary analgesia itself, part of trials described magnesium sulfate is efficient to diminish postoperative pain (Sang-Hwan, 2013).

Morphine hydrochloride

Morphine is a robust opioid; it is assorted as a painkiller. It operates on Mu receptor in the cranial nervous system and peripheral nervous system. It is utilized to alleviate severe pain that is either acute pain or chronic. Morphine metabolized by liver through glucuronidation action that turn over morphine into morphine-6-glucuronide and morphine-3-glucuronide, the two of these are eradicate by the kidneys (Soleimanpour et al., 2016).

Chapter Three
Literature review

Literature review

In a double-blind trial performed by Razavi et al. (2015) to correlate after surgery painkiller enact of infiltration of MgSO4 versus bupivacaine in a herniorrhaphy surgery. Eighty clients were recruited. In the bupivacaine group, 5 ml of bupivacaine 0.5% was combined with 5 ml of NaCl 0.9%, and in the MgSO4 group, 10 ml of MgSO4 twenty percent was given s.c. Pain score was appraised adopting numerical rating (NRS) at one, three, six, twelve, and twenty four hours after operation. If NRS was more than three, one mg of morphine was given as a rescue drug until the client felt convenient or NRS <3. The outcomes displayed that pain after surgery which was recordedafter one and three hours did not vary significantly between bupivacaine and MgSO4 groups. Nonetheless, at six, twelve and twenty four hours after operation, pain scores were significantly less in the bupivacaine group in comparison to MgSO4 group. The sum of clients whore quested somewhat one dose of rescue morphine next 24 hours and the sum dose of morphine needed were significantly less in the bupivacaine group in comparison to MgSO4 group (Razavi et al. 2015).

In a randomized controlled study performed by Niyirera et al. (2017) to correlate the efficacy and cost efficiency of tramadol versus bupivacaine in incision infiltration after herniorrhaphy in diminishing pain after operation. Randomization was performed by adopting a locked envelope including the

name of drug to be utilized for local incision infiltrations. Outcomes suggested that a sum of fifty two clients were enrolled equitably in the both of trial groups. Tramadol was launched to be superior to bupivacaine in managing pain after operation. Pain liberal time was 4.7±1.3 hours in bupivacaine group while it was greater than twelve hours in tramadol group. Appendage of painkiller was demanded in the two groups and it was significantly divergent, in the mainstream of tramadol. No detrimental effects were expressed in the two groups. Bupivacaine was existed to be five times more overpriced than tramadol (Niyirera et al., 2017).

In a trial operated by Mustafa et al. (2014) to assess the impact of inguinal canal block accompanying with intra-wound injection of tramadol versus bupivacaine 0.25% on pain relief during and after surgery in patients went through inguinal hernioplasty pinned of general anesthesia on sixty men. Clients were randomly recruited into three groups: control group (n = 20),bupivacaine 0.25% group (n = 20)], and tramadol group (n = 20)]. The amount of intraoperative fentanyl demand, visual analogue score, sedation scores, and nausea and vomiting were documented; participants' and surgeons' satisfaction were documented. Outcomes displayed that during surgery, mean arterial blood pressure, heart rate, and fentanyl need were statistically less in bupivacaine and tramadol groups in comparison with the control. The visual analogue score after surgery was statistically less in the bupivacaine and the tramadol groups in comparison with the control group. Nausea and vomiting after surgery were statistically greater in the tramadol group in comparison with the control and the bupivacaine groups. The

rating of patients' satisfaction after surgery was statistically greater in the tramadol group in comparison with the bupivacaine and the control groups (Mustafa et al., 2014).

In a prospective, randomized, double blind study performed by Sadaqa et al. (2018) to compare the analgesic impact of intra-peritoneal instillation of bupivacaine added to morphine hydrochloride versus bupivacaine added to magnesium sulfate in participants went through laparoscopic cholecystectomy under general anesthesia for better pain alleviation and less narcotics expenditures through the first twenty four hours after surgery. Hundred participants, 18 and 60 years old went through laparoscopic cholecystectomy were randomized to one of the subsequent groups by the closed envelope: (Mo group) (n=50) getting intra-peritoneal instillation of 30 ml 0.25% bupivacaine and 3 mg morphine and (Mg group) (n=50) getting intra-peritoneal instillation of 0.25% bupivacaine plus50 mg/kg magnesium sulfate to a volume of 30 ml. Outcomes displayed that patients' attributed of age, gender and BMI were proportional in the two groups. There was no significant variations between the groups in regards to the operation time. Age, gender and BMI have no impact on the mean of VAS. There are significant variation between Morphine and Mg groups in the total VAS score (p value<0.05). In the Morphine group, the mean of total VAS (2.09) was significantly less than the mean of total VAS in the Mg group (2.71); which indicated that clients in the morphine group had significantly lower severity of pain than clients in the Mg group (Sadaqa et al., 2018).

Chapter Four

Material and Methods

4.1 Material and Methods

The present trial was revised and endorsed by institutional review board (IRB) of An-Najah National University and Ethics Committee of Palestinian Ministry of Health. Instruction respecting the study was performed extensive by word of mouth and in writing. Entirely participants award their acquainted drafted consent before their recruitment in the trial.

4.2 Design of the study

A prospective, randomized, double blind comparison study, 80 participants went through planned inguinal hernia repair recruited in the current trial and inconstantly selected to lone of the two groups: MgSO4 (M group) or Bupivacaine (B group) count on random sum engender by computer to every participant. A totalize of 80 patients were recruited consistently in the two study groups, forty clients in each group.

4.3 Sites and settings

All clients were appropriated from Al - Turki Hospital, Tubas, Palestine. Al-Turki Hospital was conscripted because of accessibility and clinical supervisors were accessible at Al-Turki Hospital, and the author's endeavor at that hospital, which salvage work and time and compose data collection uncomplicated.

4.4 Sample and sampling

The sample of the trial was participants from the context which are steadfast, the clients were conscripted inconsistently, subsequently obtaining the form consent and recognition to arrange the study and assure confidentiality.

4.5 Sample size calculation

In a trial performed by Razavi, et al., (2015), a correlation of the sum of clients required somewhat one dose of salvage morphine was conducted amidst the two groups. In MgSo4 group, 36 /40 (90%) participants requested at least 1 dose of morphine and in Bupivacaine group 22/40 (55%) participants requested rescue analgesic, which was significantly less in bupivacaine group.

A blueprint (i.e. Pocock's sample size formula) that can be precisely practiced for correlation of proportions P_1 and P_2 in two equally sized groups:

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

$$n \approx 23 \text{ patients}$$

Hence, overall, of 46 clients (23 for every group) should bead dressed for enrollment into the trial. Never the less, accordingly the preceding trials which enrolled 40 patients in every group (Razavi, et al., 2015) and to take

in deliberation the withdrawal of clients, we were enrolled forty clients in every group, the overall of 80 patients were addressed for enrollment into the trial.

4.6 The involvement criteria

- One-sided inguinal hernia.
- American Society of Anesthesiologists one or two.
- Age amidst eighteen- seventy years.
- Men and women.

4.7 The exclusion criteria

- Clients with hepatic or renal disorder.
- Usage of narcotics over the last 24 hrs. preceding the trial.
- Steroids therapy preceding the trial.
- Medication or alcohol misconduct.
- Allergy to any of the trial drug.
- Constant pain by virtue of neural disorder.
- Severe cardiac, respiratory and renal disorder.
- Pregnancy.

4.8 Study period

Study was executed amidst 2019 January and December 2019 .

4.9 Randomization

Randomization was performed by completing impenetrable and fit -locked envelopes. Sequential propagation was performed with a computer. The sum was engraved on envelopes and the character of the group was drafted on the label in sync with the sequential number. Although the participants landed, envelopes were free to recognize the group to be appointed. Randomization was implemented with reference to computer engendered. Random lists, which are then converted into locked envelopes localized in the theater to approach them.

4.10 Blindness

The trial was double-blind, means that only the anesthesiologist realized the drug that was accomplished because he / she was the one who processed it and handled it to the surgeon to be accessible for infiltration. Participants, researchers, and custodian who were assigned to care for participants after surgery turned into blind to the medication being executed. Medications are dispatched in the ditto size syringe and the ditto color by the anesthesiologist.

4.11 Anesthesia protocol

All participants obtained the ditto anesthesia method. General anesthesia was initiated. The introduction guideline was ideal for all participants. Clients are overseeing for electrocardiograms, heart rate, oxygen saturation, non-invasive blood pressure and end tidal CO2. The 18-widthi.v. cannula was administered into an appropriate vein on the back of the non-prevailing hand.

All participants obtained ringer lactate at an average of 10 ml / kg / h. Participants are oxygenated for three to five minutes. Anesthesia was indoctrinated by i.v. Fentanyl (2 μg / kg), propofol (2 mg / kg) and to streamline endotracheal intubation recuronium (1 mg / kg). Intubation had been implemented under smooth direct laryngoscopy. Endotracheal tube magnitude is conscripted post laryngoscopy during forthright visualization. Anesthesia was preserved using isofluorane 1%, O2 30% / N2O 70%. No other narcotics or painkillers were given under anesthesia. Ventilation was accommodated to keep ETCO2 between 35 and 40 mmHg.

4.12 Mg SO_4 and Bupivacaine Infiltration

Total operations were implemented by usage the ditto approach through general anesthesia. Equitable prior closing of the wound, Local Wound Infiltration was accomplished:

Bupivacaine (B group), five milliliter of Bupivacaine 0.5% combined with five milliliter NaCl infiltrated subcutaneously.

Magnesium (M group), 10 ml MgSO4 20% infiltrated s.c.

4.13 Variable definitions

Dependent variable

Pain score apprised by VAS (0-10) in PACU.

Pain score apprised by VAS (0-10) in the surgical ward.

Dose frequency of rescue painkiller in PACU and in the surgical ward (totalize dose of morphine demand)**.**

Detrimental symptoms as (Nausea measured by (0-6) Lickert scale, number of vomiting and dizziness).

Dose of salvage antiemetic in PACU and in the surgical ward.

Blood pressure.

Heart rate.

Respiratory rate.

Independent variable

Infiltration of Bupivacaine.

Infiltration of Magnesium Sulfate.

Age.

Gender.

Time of surgery.

Time of anesthesia.

BMI.

4.14 Postoperative Pain Measurement

Visual Analogue Scale "VAS" score (0-10):

Commonly the suspended rate of VAS was ≥ four for salvage medication manifestation. Although VAS ≥ 4, rescue painkiller was given. Prior induction of anesthesia participants are briefed how to utilize a 10 number of VAS (VAS-0 with end-point denominate “no pain” and 10 to “worst conceivable pain”). The incidence and severity of pain after surgery were appraise at 0.5, 1, 4, 8, 12, 16, 24 hrs. Utilizing the VAS score.

When participant landed to PACU, a competent nurse unsighted to the groups of trial appraise pain and analgesic expenditures. Pain score was appraised using VAS (0-10) at 0.5, 1, 4,8, 12 and 24 hours postoperative. If VAS is ≥ 4 , two milligram morphine I.V, was disposed as rescue painkiller until client perceived satisfying or VAS <4.

All detrimental effects containing nausea and vomiting were deliberated during 24 hours after surgery. The number of clients requesting salvage analgesia was computed in every group during alongside twenty four hours. Postoperative overseeing that comprised noninvasive blood pressure, heart rate and respiration. Nausea was employed with metoclopramide (10 mg). Rescue analgesia: morphine 2 mg I.V. was employed on demand.

4.15 Morrow Assessment of Nausea and Emesis

In case that the vomiting recurrence was twofold or greater and / or the participant had nausea ≥ on Likert type scale (0-6), it was a manifestation to proceed antiemetic (Pramin ® 10 mg i.v.). Nausea was rated by a Lickert-type score, which is titled Morrow Assessment of Nausea and Emesis(Morrow 1984). This scale (0-6) was utilized in daily clinical practice in PACU at our hospital. Symptom's intensity was rated on the scale (0-6) to answer the question "how would you illustrate your nausea at its worst" from 0= none, 1= very mild, 2= mild, 3= moderate, 4= severe, 5= very severe and, 6= intolerable. MANE has been clinically verified and a test-retest reliability coefficient has been steadfast (Morrow 1984).

4.16 Statistical Analysis and Statistical Methods

SPSS version 20 is utilized for data analysis. Descriptive statistics (frequencies, percentages, Means, Standard Deviations) are utilized. The succeeding tests and methods are utilized to analyze the results where the P-Value < 0.05 is express significant:

1. Chi-Square test: tests the variation between groups of participants for qualitative variables such as Morphine request, Blood Pressure, Nausea and Vomiting, American Society of Anesthesiologists and gender.

2. Two Independent Samples T test: tests the variations between groups of participants for quantitative variables such as VAS, Heart Rate, Respiratory Rate, Operation duration, Anesthesia duration, Age, Weight, Height, and body mass index.

3. Adjusted Z-test for Post Hoc Multiple comparisons.

4.17 Consideration of ethics

The current study was implemented in a conformance with the Helsinki announcement and endorsed by the Institutional Review Board of An-Najah National University (IRB) and it was endorsed by the research ethical committee of Palestinian Ministry of Health. Consent forms were accessed from participants before attendance. As the research is counting human subjects, it is essential to pursue rigorous ethical principles. The clients are querying to provide their consent, and they are guaranteed that

attendance and instruction given will not be utilized against them. They are also guaranteed of their right to confidentiality and inconspicuousness. Inconspicuousness is preserved by giving a code the clients and by wrecking the names associated with numbers.

Result

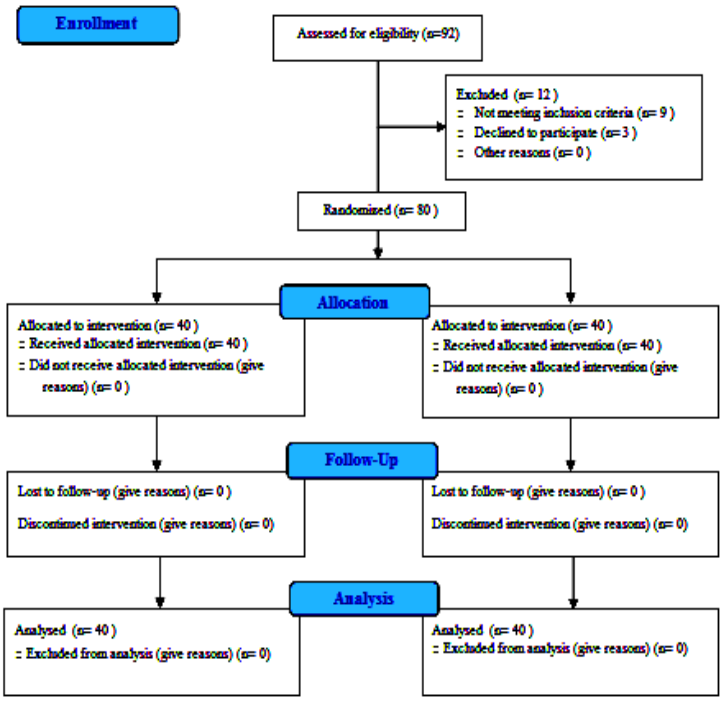

Figure (1): Consort Flow Diagram

In a randomized clinical study, 80 participants were randomized appointed to one of the two trial groups. Where there was no significant difference between the two groups in demographic variables including age, gender and BMI and American Society of Anesthesiologists (P> 0.05) (Table 1, 2). Duration of operation and duration of anesthesia were significantly different between the two groups of study respectively (P = 0.006), (p= 0.030) (Table 3).

Table (1): Frequencies, Percentages and Chi-square test results for differences between the two groups of types of infiltration and gender, American Society of Anesthesiologists.

		TYPE OF INFILTRATION		Chi-square	P-value
		Bup n(%)	Mg n(%)		
GENDER	Male	37(92.5%)	33(82.5%)	1.829	0.176
	Female	3(7.5%)	7(17.5%)		
American Society of Anesthesiologists	ASA 1	24(60%)	17(42.5%)	2.452	0.117
	ASA 2	16(40%)	23(57.5%)		

The results in the table (1) overhead display that there are no significant differences between the two experimental groups in Gender, and American Society of Anesthesiologists (P-values>0.05).

Table (2): Means, Standard deviations and independent samples T-test results for differences between the two groups of types of infiltration and Age, Weight, Height, Body Mass Index.

	TYPE OF INFILTRATION		t	P-value
	Bup Mean± SD	Mg Mean± SD		
AGE	41.38+9.9	43.65+10.73	-0.986	0.327
WEIGHT	79.48+9.93	78.7+9.97	0.348	0.728
HEIGHT	170.28+4.15	169.73+4.07	0.598	0.551
BODY MASS INDEX	27.45+3.58	27.32+3.4	0.160	0.873

In this trial, the participants' homogeneity was reviewed, the sample was homogeneous in age, weight, height, body mass index and gender (P-value> 0.005), which does not mean any significant differences between two groups in demographic data. The results in the table (2) overhead display that there are no significant differences between the two experimental groups in Age, Weight, Height, and Body Mass Index (P-values>0.05).

Table (3): Means, standard deviations and independent samples T-test results for differences between the two groups of types of infiltration and operation and anesthesia time.

Operation And Anesthesia Time	TYPE OF INFILTRATION		t	P-value
	Bup Mean± SD	Mg Mean± SD		
OPERATION TIME	50.78+8.64	56.65+10.03	-2.807	0.006
ANESTHESIA TIME	71+10.02	76.1+10.67	-2.204	0.030

The results in the table (3) above show that there are significant differences in the operation time between the two experimental groups (P-value=0.006<0.05), the results exhibited that the mean of operation time in Mg group (mean=56.65 min) is significantly lower than the mean of operation time in Bup group (mean=50.78 min). And the results in the table above show that there are significant differences in the Anesthesia Time between the two experimental groups (P-value=0.03<0.05), the results exhibited that the mean of anesthesia time in Mg group (mean=76.1 min) is significantly higher than the mean of anesthesia time in Bup group (mean=71 min).

Table (4): Means, standard deviations and independent samples T-test results for differences between the two groups of types of infiltration and VAS scale.

VAS	TYPE OF INFILTRATION			T	P-value
	Bup Mean± SD	Mg Mean± SD			
VAS after 30 min	1.58±1.45	2.95±1.38		-4.353	0.000*
VAS after 1 hour	2.05±1.41	2.6±1.52		-1.678	0.097
VAS after 4 hour	1.4±1.46	2.48±1.74		-2.991	0.004*
VAS after 8 hour	0.65±0.7	2.08±1.56		-5.274	0.000*
VAS after 12 hour	0.45±0.6	1.45±1.28		-4.478	0.000*
VAS after 16 hour	0.43±0.78	1.08±0.8		-3.685	0.000*
VAS after 24 hour	0.5±0.55	0.75±0.59		-1.955	0.054
VAS Total	0.98±0.61	1.88±0.53		-7.081	0.000*

Postoperative pain results at different times were compared between the two study groups. The results in the table (4) above show that there are significant differences in the total VAS of 24 period between the two experimental groups (P-value=0.000<0.05), the results exhibited that VAS scale in Mg group (mean=1.88) is significantly higher than VAS scale in Bup group (mean=0.98). Regarding VAS scale after 30 min, the results exhibited that the VAS scale in Mg group (mean=2.95) is significantly higher than VAS scale in Bup group (mean=1.58). Regarding VAS scale after 4 hours, the results exhibited that the VAS scale in Mg group (mean=2.48) is significantly higher than VAS scale in Bup group (mean=1.4). Regarding VAS scale after 8 hours, the results exhibited that the VAS scale in Mg group (mean=2.08) is significantly higher than VAS scale in Bup group (mean=0.65).Regarding VAS scale after 12 hours, the

results exhibited that the VAS scale in Mg group (mean=1.45) is significantly higher than VAS scale in Bup group (mean=0.45). Regarding VAS scale after 16 hours, the results exhibited that the VAS scale in Mg group (mean=1.08) is significantly higher than VAS scale in Bup group (mean=0.43).On the other hand, the results show that there are no significant differences in the VAS scale at 1 hour or at 24 hour between the two experimental groups(P-values>0.05).The results suggest that bupivacaine is more effective in reducing the intensity of postoperative pain than magnesium sulfate.

Table(5): Frequencies, Percentages and Chi-square test results for differences between the two groups of types of Infiltration in Incidence of Pain.

Incidence of Pain(Moderate to Severe(VAS>=3))	TYPE OF INFELTATION		Chi-square	P-value
	Bup n(%)	Mg n(%)		
Incidence of Pain after 0.5 hr	10(25%)	25(62.5%)	11.429	0.001*
Incidence of Pain after 1 hr	11(27.5%)	20(50%)	4.266	0.039*
Incidence of Pain after 4 hr	7(17.5%)	16(40%)	4.943	0.026*
Incidence of Pain after 8 hr	0(0%)	13(32.5%)	15.522	0.000*
Incidence of Pain after 12 hr	0(0%)	6(15%)	6.486	0.011*
Incidence of Pain after 16 hr	1(2.5%)	1(2.5%)	0.000	1.000
Incidence of Pain after 24 hr	0(0%)	0(0%)	----	----
Incidence of Pain Total	18(45%)	38(95%)	23.810	0.000*

The results in the table (5) above show that there are significant differences in incidence of Pain between the two experimental groups(P-value=0.000<0.05) in the total period of 24 hr. Postoperative, the results

exhibited that number of patients had incidence of pain in Mg group (n (%) =38(95%)) is significantly higher than that in Bup group (n(%)=18(45%)).The results also show that there are significant differences in incidence of pain between the two experimental groups after 0.5 hr, after 1hr, after 4 hr, after 8 hr, and after 12 hr(P-values <0.05). Regarding incidence of pain after 0.5 hr, the results exhibited that number of patients who had incidence of Pain in Mg group (n(%)=25(62.5%)) is significantly higher than that in Bup group(N(%)= 10(25%)). Regarding incidence of pain after 1hr, the results exhibited that number of patients who had Pain in Mg group (N(%)=20(50%)) is significantly higher than that in Bup group(N(%)=11(27.5%)). After 4hr, the results exhibited that number of patients who had Pain in Mg group (N(%)=16(40%)) is significantly higher than that in Bup group(N(%)=7(17.5%)). After 8hr, the results exhibited that number of patients who had incidence of Pain in Mg group(N(%)=13(32.5%)) is significantly higher than that in Bup group(N(%)=0(0%)). After 12hr, the results exhibited that number of patients who had pain in Mg group(N(%)=6(15%)) is significantly higher than that in Bup group(N(%)=0(0%)).On the other hand, the results show that there are no significant differences in incidence of pain at 16 hours and at 24 hours between the two experimental groups(P-values>0.05). The results suggest that bupivacaine is more effective in reducing the incidence of postoperative pain than magnesium sulfate.

Table (6): Frequencies, Percentages and Chi-square test results for differences between the two groups of types of infiltration and Morphine requirement (given 2 mg i.v.) .

Morphine requirement(given 2 mg i.v.)	TYPE OF INFILTRATION		Chi-square	P-value
	Bup n (%)	Mg n (%)		
MO requirement after 0.5 hr	4(10%)	17(42.5%)	10.912	0.001*
MO requirement after 1 hr	7(17.5%)	11(27.5%)	1.147	0.284
MO requirement after 4 hr	6(15%)	15(37.5%)	5.230	0.022*
MO requirement after 8 hr	0(0%)	11(27.5%)	12.754	0.000*
MO requirement after 12 hr	0(0%)	6(15%)	6.486	0.011*
MO requirement after 16 hr	1(2.5%)	1(2.5%)	0.000	1.000
MO requirement after 24 hr	0(0%)	0(0%)	---	---
MO requirement Total	17(42.5%)	38(95%)	25.658	0.000*

The results in the table (6) above show that there are significant differences in the total morphine requirement in the total period of 24 hr. Postoperative between the two experimental groups(P-value=0.000<0.05), the results exhibited that number of patients whose given morphine (2 mg) at least one time in Mg group (N(%)=38(95%)) is significantly higher than that in Bup group (N(%)=17(42.5%)). The results also show that there are significant differences in morphine requirement between the two experimental groups after 0.5 hr, after 4 hr, after 8 hr, and after 12 hr (P-values <0.05). Regarding morphine requirement after 0.5 hr, the results exhibited that number of patients whose given morphine(2 mg) in Mg group (N(%)=17(42.5%)) is significantly higher than that in Bup group (N(%)=4(10%)). Regarding morphine requirement after 4 hr, the results exhibited that number of patients whose given morphine (2 mg) in Mg group (N(%)=15(37.5%)) is significantly higher than that in Bup group

(N(%)=6(15%)). Regarding morphine requirement after 8 hr, the results exhibited that number of patients whose given morphine (2 mg) in Mg group (N(%)=11(27.5%)) is significantly higher than that in Bup group (N(%)=0(0%)). Regarding morphine requirement after 12 hr, the results exhibited that number of patients whose given morphine (2 mg) in Mg group (N(%)=6(15%)) is significantly higher than that in Bup group (N(%)=0(0%)). On the other hand, the results show that there are no significant differences in morphine requirement between the two experimental groups at 1 hr, after 16 hr, and after 24 hr (P-values>0.05).

Table (7): Means, standard deviations and independent samples T-test results for differences between the two groups of types of infiltration and heart rate.

Heart Rate (HR)	TYPE OF INFILTRATION		T	P-value
	Bup Mean± SD	Mg Mean± SD		
HR after 0.5 hr	78.3+9.45	80.73+8.11	-1.231	0.222
HR after 1 hr	77.73+9.94	80.35+7.78	-1.315	0.192
HR after 4 hr	77.43+10.11	78.88+8.48	-0.695	0.489
HR after 8 hr	75.85+8.97	76.63+7.83	-0.412	0.682
HR after 12 hr	73.23+8.55	75.98+7.7	-1.512	0.135
HR after 16 hr	71.53+7.78	74.65+7.06	-1.881	0.064
HR after 24 hr	70.85+7.39	73.08+6.33	-1.446	0.152
HR Total	75.11+7.89	77.36+6.2	-1.418	0.160

The results in the table (7) above show that there are no significant differences in the heart rate scale between the two experimental groups in all times (all P-values >0.05).

Table (8): Means, standard deviations and independent samples T-test results for differences between the two groups of types of infiltration and respiratory rate.

Respiratory Rate (RR)	TYPE OF INFILTRATION		T	P-value
	Bup Mean± SD	Mg Mean± SD		
RR after 0.5 hr	17.3+0.72	17.53+0.75	-1.365	0.176
RR after 1 hr	17.25+0.84	17.43+0.87	-0.913	0.364
RR after 4 hr	16.85+1.05	17.18+0.84	-1.525	0.131
RR after 8 hr	16.53+0.99	16.55+0.9	-0.118	0.906
RR after 12 hr	16.05+0.9	16.6+0.81	-2.865	0.005*
RR after 16 hr	15.8+1.11	16.18+0.84	-1.697	0.094
RR after 24 hr	15.78+1.12	16.1+0.84	-1.467	0.146
RR Total	16.59+0.72	16.88+0.52	-2.057	0.043*

The results in the table (8) above show that there are significant differences in the total respiratory rate between the two experimental groups (P value=0.043<0.05), the results exhibited that the RR in Mg group (mean=16.88) is significantly higher than the RR in Bup group (mean=16.59).The results also show that there are significant differences in the RR after 12 hours between the two experimental groups (P-value=0.005<0.05), the results exhibited that the RR after 12 hours in Mg group (mean=16.6) is significantly higher than the RR after 12 hours in Bup group (mean=16.05). From the other hand, the results in the table above show that there are no significant differences in the RR between the two experimental groups in the following times: after 0.5 hr, after 1 hr, after 4 hr, after 8 hr, after 16 hr, after 24 hr (all P-values >0.05).

Table (9): Frequencies, Percentages and Chi-square test results for differences between the two groups of types of infiltration and Blood Pressure Scale.

Blood Pressure		TYPE OF INFILTRATION		Chi-square	P-value	Post hoc Multiple comparison test
		Bup	Mg			
BP after 0.5 hr	NL - S less than 120 and D less than 80	14(35%)	8(20%)	4.753	0.191	N.S
	ELEVATED - S 120-129 and D less than 80	9(22.5%)	10(25%)			N.S
	STAGE 1 - S 130-139 and D 80-89	12(30%)	10(25%)			N.S
	stage 2 - S 140 or higher and D 90 or higher	5(12.5%)	12(30%)			N.S
BP after 1 hr	NL - S less than 120 and D less than 80	14(35%)	8(20%)	3.205	0.361	N.S
	ELEVATED - S 120-129 and D less than 80	9(22.5%)	11(27.5%)			N.S
	STAGE 1 - S 130-139 and D 80-89	10(25%)	9(22.5%)			N.S
	stage 2 - S 140 or higher and D 90 or higher	7(17.5%)	12(30%)			N.S
BP after 4 hr	NL - S less than 120 and D less than 80	17(42.5%)	8(20%)	5.556	0.135	<0.05
	ELEVATED - S 120-129 and D less than 80	7(17.5%)	12(30%)			N.S
	STAGE 1 - S 130-139 and D 80-89	10(25%)	10(25%)			N.S
	stage 2 - S 140 or higher and D 90 or higher	6(15%)	10(25%)			N.S
BP after 8 hr	NL - S less than 120 and D less than 80	19(47.5%)	11(27.5%)	6.875	0.076	N.S
	ELEVATED - S 120-129 and D less than 80	14(35%)	12(30%)			N.S
	STAGE 1 - S 130-139 and D 80-89	4(10%)	7(17.5%)			N.S
	stage 2 - S 140 or higher and D 90 or higher	3(7.5%)	10(25%)			<0.05
BP after 12 hr	NL - S less than 120 and D less than 80	21(52.5%)	15(37.5%)	10.192	0.017	N.S
	ELEVATED - S 120-129 and D less than 80	14(35%)	8(20%)			N.S
	STAGE 1 - S 130-139 and D 80-89	5(12.5%)	13(32.5%)			<0.05
	stage 2 - S 140 or higher and D 90 or higher	0(0%)	4(10%)			N.S

BP after 16 hr	NL - S less than 120 and D less than 80	27(67.5%)	16(40%)	7.147	0.067	<0.05
	ELEVATED - S 120-129 and D less than 80	8(20%)	13(32.5%)			N.S
	STAGE 1 - S 130-139 and D 80-89	5(12.5%)	9(22.5%)			N.S
	stage 2 - S 140 or higher and D 90 or higher	0(0%)	2(5%)			N.S
BP after 24 hr	NL - S less than 120 and D less than 80	28(70%)	23(57.5%)	4.321	0.229	N.S
	ELEVATED - S 120-129 and D less than 80	10(25%)	9(22.5%)			N.S
	STAGE 1 - S 130-139 and D 80-89	2(5%)	7(17.5%)			N.S
	stage 2 - S 140 or higher and D 90 or higher	0(0%)	1(2.5%)			N.S
BP Total	NL - S less than 120 and D less than 80	16(40%)	10(25%)	2.718	0.437	N.S
	ELEVATED - S 120-129 and D less than 80	13(32.5%)	13(32.5%)			N.S
	STAGE 1 - S 130-139 and D 80-89	8(20%)	13(32.5%)			N.S
	stage 2 - S 140 or higher and D 90 or higher	3(7.5%)	4(10%)			N.S

*N.S: Not Significant S: Systolic D: Diastolic

The results in the table (9) above show that there are significant differences in blood pressure after 4 hr (S less 120 and D less 80) between the two experimental groups (P-value of the post hoc Multiple comparison test <0.05), the results exhibited that number of patients whose blood pressure after 4 hr (S less 120 and D less 80) in Mg group(N(%)=8(20%)) is significantly less than that in Bup group (N(%)=17(42.5%)).

The results in the table (9) above show that there are significant differences in blood pressure after 8 hr (Stage 2 - S 140 or higher and D 90 or higher) between the two experimental groups(P-value of the post hoc Multiple comparison test <0.05), the results exhibited that number of patients whose blood pressure after 8 hr (Stage 2 - S 140 or higher and D 90 or higher) in Mg group (N(%)=10(25%)) is significantly higher than that in Bup group (N(%)=3(7.5%)).

The results in the table (9) above show that there are significant differences in blood pressure after 12 hr(STAGE 1 - S 130-139 and D 80-89) between the two experimental groups (P-value of the post hoc Multiple comparison test <0.05), the results exhibited that number of patients whose blood pressure after 12 hr (STAGE 1 - S 130-139 and D 80-89) in Mg group(N(%)=13(32.5%)) is significantly higher than that in Bup group(N(%)=5(12.5%)).

The results in the table (9) above show also that there are significant differences in blood pressure after 16 hr (NL - less S 120 and D less 80) between the two experimental groups (P-value of the post hoc Multiple

comparison test <0.05), the results exhibited that number of patients whose blood pressure after 16 hr(NL - less S 120 and D less 80) in Mg group (N(%)=16(40%)) is significantly less than that in Bup group (N(%)=27(67.5%)).

Table (10): Frequencies, Percentages and Chi-square test results for differences between the two groups of types of infiltration and Post-Operative Nausea and Vomiting.

Post-Operative Nausea and Vomiting	TYPE OF INFILTRATION		Chi-square	P-value
	Bup n(%)	Mg n(%)		
Complete response (no nausea, no vomiting , no rescue medication)	27(67.5%)	14(35%)	8.455	0.004*
Nausea only	9(22.5%)	22(55%)	8.901	0.003*
Vomiting only	4(10%)	4(10%)	0.000	1.000

The results in the table (10) above show that there are significant differences in complete response (no nausea, no vomiting, no rescue medication) between the two experimental groups (P-value =0.004<0.05), the results exhibited that number of patients with complete response in Mg group (N(%)=14(35%)) is significantly less than that in Bup group (N(%)=27(67.5%)).The results indicate that fewer patients in the Bup group had PONV.

On the other hand, the results in the table (10) above show that there are significant differences in nausea between the two experimental groups(P-value =0.003<0.05), the results exhibited that number of patients who had nausea in Mg group (N(%)=22(55%)) is significantly higher than that in Bup group (N(%)=9(22.5%)). And the results show that there are no

significant differences in vomiting between the two experimental groups (P-value =1.000>0.05).

Discussion

Pain is described as “an undesirable sensual and affectionate experience combined with substantial or possible tissue deterioration, or described in terms of such damage” (Macintyre, et al., 2010). Efficient control and organization of postoperative pain is certainly of main involvement to the patient and also of emphasis to the surgeon due to potentiality of adverse effects of the physiological concession to pain from surgery. Deficient therapy of postoperative pain is still a dominant clinical problem, outstanding not only to impoverished outcomes during the prompt postoperative period but also to an increment risk of long-term pain after surgery. Rebellious post-surgical pain, pain everlasting longer than the exemplary healing period of 1 to 2 months, has turned into progressively perceived as a crucial issue after surgery and can outpaced30% after specific surgeries, exclusively amputations, thoracotomy, mastectomy, and inguinal hernia repairs. This trial produces comparison between two groups of magnesium and bupivacaine infiltration in the subcutaneous tissue at the surgical site of inguinal hernia repair prior the end of surgery to decrease pain incidence and intensity after surgery, analgesic rescue medication and to increase time for first analgesic dose request. Eighty patients were randomly recruited and classified into two groups: Forty participants were randomized into Bup group given five milliliter Bupivacaine 0.5% was mixed with five milliliter NaCl filtered S.C. and 40 participants in Mg group given 10 ml magnesium sulfate 20% infiltrated subcutaneously.

The main advantage of this method is that systemic effects with central neural blocks, such as motor blocks, delayed ambulation and urinary retention are repulsive. In addition, robust narcotic drugs also ward off or reduce their dose in this way during the rapid postoperative period, which will lead to a reduction in their systemic effects, which may also be deferred rehabilitation (Quresh, et al 2016).

The incidence and intensity of moderate to severe postoperative pain amidst MgSO4 and bup groups in clients go through herniorrhaphy operation:

The outcomes of this trial determine the supremacy of the bupivacaine group over the magnesium group in diminishing the incidence and severity of pain after surgery, expenditures of the rescue medication morphine and to increment time for first analgesic dose needed through the total period of 24 hours after surgery. This trial result displayed that there are significant differences between two groups in pain (VAS) all along the total period of 24 hours after surgery. In Bup group, the mean of overall VAS (0.98) was less than mean of overall VAS in Mg (1.88) which means that the participants in Bup group unquestionably had lower severity of pain than participants in the MgSO4 group (P = 0.000). It indicates that bupivacaine is more efficient in decreasing the severity of pain after surgery than MgSO4. Justification for determining subcutaneous infiltration of the inguinal region is to block the visceral afferent signal and probably adapt visceral nociception. Local anesthetics prohibit nociception by stirring

nerve membrane combined proteins and by prohibiting the discharge and response of prostaglandins and other agents that sensitize or trigger nociceptors and devote to inflammation (Liu & Hodgson, 2001). Yet, saturation from large peritoneal surface can likewise happen, which may be a farther mechanism of analgesia. The mechanism of action of bupivacaine is endorse to be the same as for other local anesthetics. Prevailing local anesthesia theory prosed that these amalgamation avert the internal flow of sodium ions through nerve membrane and so prohibits the procreation of action potential (de Jong, 1974). Competing bounden to calcium sites is presupposed to happen in the outer lipid layer of nerve membranes with culminating secondary interference of mobile phosphate groups. Passage of sodium ions are closed off by preventing molecular membranes reconfiguration from the dormant (sodium-permeable) to the active (sodium permeable) state. Bupivacaine was elected in the present study as a result of its long-term efficacy. The half-life of bupivacaine is between 5 and 16 hours. The heightened duration of action of bupivacaine is characterized to its affinity for nerve tissue (Moore, et al., 2014).

The outcomes of this trial are promoted likewise by the trial performed by Razavi, et al. displayed that the inclusion of five milliliter bupivacaine 0.5% plus five milliliter NaCl infiltration s.c is more effective than 10 ml magnesium sulfate filtration to decrease pain after inguinal hernia surgery (*Razavi,* et al., 2015). The authors were displayed that postoperative pain results at diversity of times were related betwixt the two trial groups. Pain character after one and three hours didn’t vary unquestionably amidst

bupivacaine and MgSO4. Nonetheless, at 6 and 24 hours postoperatively, pain value was unquestionably less in the Bup group.

Further the outcomes of this trial is in consonance with Wallace, et al (1978) and Hashemi & Middleton (1983),results of these studies were suggested that, the use of subcutaneous bupivacaine for pain after herniorrhaphy verified to be efficient and secure, but unsatisfactory side effects or local complications. The method used contributes efficient and long-lasting local analgesia.

In a randomized controlled trial performed by O'Riordain (1998) , the authors correlated preperitoneal instillation of 40 ml 0.25% bupivacaine and adrenaline with NaCl. 54 participants were recruited in the trial, who were all men and went through laparoscopic totally extraperitoneal inguinal hernia repairs as ambulatory surgery. The diminished of pain after surgery is up to twelve hours, rapid rehabilitation to sufficient movement plain and greater gratification rate in participants obtaining bupivacaine. The researchers proposed that preperitoneal space was admirably appropriate for distillation of local anesthesia in comparison to peritoneal spatial distillation in cholecystectomy performed by laparoscopy, where dispersion of anesthesia may have been reasonably matter of deficiency to alleviate pain after surgery (O'Riordain, et al 1998).Nonetheless, Hon et al (2009) in a randomized controlled trial of ninety participants expressed powerful diminish in pain rates when 0.5% bupivacaine was pervade in a defending aspect (prior skin incisions and subsequently the initiation of the first

working gate and before farther dissection) during the first twenty four hours ensuing laparoscopic TEP hernioplasty. Another trial has declined to display one effect of preperitoneal bupivacaine instillation on pain after surgery (Saff et al, 1998). Saff, et al made a comparison between employment of Bup versus NaCl in preperitoneal space in TEP in a double-blind randomized study and launched no variations in scores of surgical pain or accession of pain killer demands (Saff et al, 1998). Ina different trial Participant were obtaining bupivacaine at the trocar site had clinically lower pain ($p < 0.001$ for all four sites) at both 4 and 24 hours after surgery. The participants in the experimental group consumed lower mepiridine and prometzin than the control group ($p = 0.001$ and 0.002, respectively) after surgery. Extensively, participants with local anesthesia had less postoperative pain and less antiemetic medication than participants in control group ($p = 0.02$). (Hasaniya, et al 2001).

The present trial outcomes promoted by the trial results when utilized 20 ml of 0.25% standard bupivacaine infiltration at the time of wound closure. Results displayed that this approach significantly decreased postoperative pain and diminished the use of rescue analgesia in the first four hours after surgery (Qureshim et al, 2016).

As well as the present trial is not at the time line with trial results performed by Abbas, et al (2010). The authors displayed no significant variations in pain after surgery or participants' contentment with pain management with bupivacaine, distilled in preperitoneal space and distilled

into the port of incision, when correlated with placebo in clients underwent planned laparoscopic TEP repair of unilateral inguinal hernias. Bar- Dayan et al (2004) in correspondingly conducted prospects randomized trial stated debilitate pain for up to four hours after surgery in participants obtaining eighty milligram bupivacaine in preperitoneal space correlated to placebo. Nonetheless, the trial was insufficient due to inadequacy of standardization of anesthesia, many surgeons and assessors included in evaluation of pain after surgery, and non-protocol use of pre- and intraoperative narcotics pain killer endorse by the researchers of the trial.

In the present study, in PACU, the results displayed that there are significant differences in occurrence of moderate to severe pain between the two experimental groups at 0.5 hr, 1hr, 4 hr, 8 hr, and after 12 hr (P-values <0.05). The results respecting the occurrence of moderate to severe pain in the total period of 24 hr are displayed that there are significant differences in incidence of moderate to severe pain between the two experimental groups. the results displayed that the number of participants who had incidence of moderate to severe pain in Mg group (n(%)=38(95%)) is significantly greater than that in bupivacaine group (n(%)=18(45%)), p=0.000.These results are persistent with the results of prior studies illuminated to accomplish minimum pain rate after inguinal hernia surgery with local wound infiltration over long-term local anesthesia (Pettersson et al., 1999; Vintar et al., 2002). In regard to local wound infiltration of bupivacaine after open inguinal hernia surgery, which is advantageous to diminish opioid expenditures and increment the

introductory time to utilize rescue analgesia, as exhibited by earlier trials (Hadj et al., 2012; El-Radaideh et al., 2006). The present study results are likewise uniform with the trial results from Lau et al., Who exhibited that wound infiltration with bupivacaine 0.5% after surgery had a superior analgesic effect compared to the use of single oral analgesics (Lau et al., 2003).

The results of the present trial expressed that magnesium sulfate is less convenient than bupivacaine for the management of pain after surgery. Earlier studies exhibited when utilizing magnesium parenteral as a systemic ancillary is more efficient in decreasing pain (Telci et al., 2002). To reasonable assert the analgesic influence of magnesium parenteral utilized is more favored than topical. And it has greater central amplifications than local anti-nociceptive amplifications. Magnesium is N-methyl-D-aspartic (NMDA) receptor antagonist / blocker of the nociceptive pathway in the spinal cord that obtained analgesic attributes. It also proved its role in the increments in narcotic analgesia. Apparently by preventing NMDA mediators from simplify the path (Richebe et al., 2005). Remarkably diminishing of pain results (VAS score) after surgery exhibited with MgSO4 influence on pain. Pastore et al. proposed that, MgSO4 has analgesic attributes that endorse its use as a reciprocal analgesic and these attributes come from its action on NMDA receptor as a non-competitive antagonist and calcium channel blocker, these attributes prohibit the workings of central sensitization connected to nociceptive pain triggered by peripheral nerves (Pastore et al., 2013).

The usage of magnesium to obtain an impact as a local anesthetic impact is quietness argumentative. It can block morphine and other opioid receptors through NMDA antagonism if MgSO4insufficiencyhappens, which endorses sensitization of nociceptive pathways in the spinal cord that contain NMDA and non-NMDA receptors (Begon et al., 2001). Albrecht et al. was declared that magnesium i.v. before operation can decrease opioid usage, reduce intensity of pain after operation all along the first 24 hours after operation (Albrecht et al., 2013). Koinig et al (1998), in a randomized, double-blind study with two alongside groups, evaluated the analgesic efficiency of perioperative magnesium sulfate disposition in physical ASA I or II went through arthroscopic knee surgery with total IV anesthesia launched a significant diminishing in serum magnesium levels intraoperative in the control group. This reduction in serum magnesium levels may farther illustrate the increments in analgesic needs in the control group. As for the observation that there is an converse relationship between the severity of pain (Weissberg, et al 1991) and serum magnesium levels in females during labor force and in patients with different medical status, such as myocardial infarction or pancreatitis, control of perioperative magnesium levels in serum and the prevention of hypomagnesaemia should be treated conscientiously.

Our results is not in accordance with trial results in regards to effectiveness of MgSO4 in decreasing postoperative pain that performed by Koinig, et al (1998), The participants obtained each of twoMgSO4 50 mg / kg before operation and 8mg/kg/h intra-operatively or the equal amount of isotonic

NaCl solution i.v. It was exhibited that participants in magnesium group needed significantly lower fentanyl than those in control group for intraoperative and respective postoperative course. The authors concluded that in a clinical context with approximately compatible levels of surgery stimulant, IV magnesium sulfate decreases intraoperative and postoperative analgesic demands in comparison to isotonic sodium chloride solution. Ramification of this trial that the perioperative management of IV magnesium sulfate reduces intra- and postoperative analgesic demand in patients with approximately compatible levels of surgical stimulant. The authors proposed that magnesium can be an impetus to perioperative analgesic handling. The combative results may be that magnesium in the present trial was infiltrated at the surgical site at the end of surgery and in Koinig et al magnesium was given I.V. prior and intra-operatively. It could be divergence in route have divergence results.

The difference in the requirement for analgesic rescue medication between MgSO4 and bupivacaine in clients underwent herniorrhaphy surgery:

The outcome of the present trial is clarified that there is a significant variations of using of rescue analgesia between two groups, the total number of clients who required rescue analgesia in bupivacaine group (N=17) with percent (42.5%) but in magnesium group the total number of participants who required rescue analgesia (N=38) with percent (95%). Which indicates that the bupivacaine is superior to magnesium in decreasing rescue analgesia expenditures. These outcomes are

commensurate to a previous study executed by Razavi, et al. (2015). There correlation of number of participants required somewhat 1 dose of rescue morphine was achieved between the two groups. In the MgSO4 group required somewhat 36 patients 1 dose of morphine and in the bupivacaine group 22 patients required rescue pain killer medication, which was significantly less in bupivacaine group). The present trial outcomes are likewise in the same timeline in a trial implemented by Derkering et al. determined the effect of wound infiltration on morphine request during the first 24 hours and launched a decrement in morphine demands (Dierking, 1994).

Adverse effects (nausea, vomiting) amidstMgSO4 and bupivacaine in patients underwent herniorrhaphy surgery:

In regard to side effects, there are significant variations between two experimental groups as regards to complete response (no nausea, no vomiting, and no rescue anti-emetic medication) (P value < 0.05). But there is no significant variations between two experimental groups in regard to the postoperative vomiting only (P value > 0.05). There are significantly greater number of complete response in the bupivacaine group 27/40 (67.5%) compared with the Mg group 14/40 (35%) (P = 0.004). In regards to nausea, it is significantly lower in bupivacaine group 9/40 (22.5%) in comparison to the MgSO4 group 22/40 (55%) (P = 0.003). As well as the percentage of participant s who had nausea in the MgSO4 group more than the percentage of participants who had nausea in the bupivacaine group,

also the percentage of total rescue analgesic demand in Mg group was greater than the percentage of total rescue analgesic demand in bupivacaine group that presumably clarified the relationship between rescue analgesia "morphine" and nausea. The present outcomes are not persistent with the results of Razavi et al (2015) study when nausea and vomiting after surgery were compared between bupivacaine and magnesium sulfate groups and 9 (22.5%) patients in bupivacaine and 15 patients (37.5%) in MgSO4 group had PONV, which was not significantly vary (P = 0.143).

Hemodynamic

There were significant variance between the two groups regarding BP and respiration at different times but it was not clinically significant.

Limitation

There are certain limitations in our trial. We did not see at the time of discharge from the hospital or patient satisfaction, which could have provided additional information.

Recommendation

This approach of providing postoperative analgesics should be further expanded to substitute or somewhat supplement the extensive use of drugs. Pain is an imminent aftereffect of all surgical operations and appropriate attention to pain origin and its handling will obtain significant benefits to the participants and those responsible for its handling.

The use of bupivacaine infiltration in the repair of inguinal hernia is more efficient than magnesium sulfate and it is endorsed to use the drug to diminish postoperative pain and adverse effects.

Nurse anesthesia implications

Wound instillation with local anesthetics is an uncomplicated, efficient and economical approach to obtain good painkillers for patients following inguinal hernia operation without any major side effects. Local anesthetics are broadly well countenance. This approach for obtaining postoperative analgesia can be involved in the reciprocal of multimodal analgesia.

Conclusion

Bupivacaine infiltration of wounds at the operation location was more efficient than Mg SO_4 filtration in reducing incidence and intensity of pain after surgery, reduce opioid expenditures, and increment introductory time to require postoperative rescue analgesics in patients undergoing inguinal hernia surgery.

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Appendixes

Appendix A

Assign subjects to groups

A: Bupivacaine

B: Magnesium Sulfate

Subject #	Group Assigned
1	B
2	A
3	A
4	A
5	A
6	A
7	B
8	B
9	A
10	A
11	B
12	B
13	A
14	B
15	B
16	B
17	B
18	B
19	A
20	B
21	A
22	A
23	A
24	B
25	A
26	A
27	A
28	A
29	B

30	B
31	A
32	A
33	B
34	A
35	A
36	B
37	B
38	B
39	B
40	A
41	A
42	B
43	A
44	A
45	A
46	A
47	A
48	A
49	B
50	B
51	B
52	B
53	A
54	A
55	A
56	B
57	A
58	B
59	B
60	A
61	A
62	A
63	B
64	A
65	B
66	A
67	B
68	B
69	A

70	B
71	B
72	A
73	B
74	B
75	A
76	B
77	B
78	B
79	B
80	B

Appendix B

Data Collection Form

Analgesic Effect of local wound infiltration with magnesium sulfate versus Bupivacaine in reducing postoperative pain in patients undergoing inguinal hernia repair surgery

Age: _____ Gender: Male □ Female □

Current Admission Date: __ /__ /__

Operation Date: __ /__ /__

ASA:____

Pre-operative data

Weight:----------

Height----------

- Body mass index (BMI):
- 2. Elective □ Acute □
- 3. Past medical and surgical history……
- type of Infiltration : group A □ group B □

Follow up of the patient

(VAS-0 with end-point labeled "no pain" and 10 to "worst conceivable pain"). The degree of postoperative pain.

VAS score degree	0 Hr	1/2 Hr	1 hr	4 Hr	8 hr	12 Hr	16 hr	24 hr

Morphine 2 mg I.V. , as rescue analgesia, will be administered on in the recovery room and in the ward if needed. The number of patients requiring rescue analgesia will be recorded in each group.

Dose of rescue analgesic in PACU and in the surgical ward as continuous variable.

rescue analgesia	zero hr	1/2 Hr	1 hr	4 Hr	8 hr	12 hr	16 hr	24 Hr
Morphine Dose								

Postoperative hemodynamic in PACU and in the surgical ward as continuous variable.

Hemodynamic	zero hr	1/2 Hr	1 Hr	4 Hr	8 Hr	12 hr	16 hr	24 Hr
blood pressure								
heart rate								
Respiration								

- Postoperative complications :

nausea□ vomiting□ drowsiness□ dizziness □others , mention

If frequency of vomiting is two times and above, it is an indication for giving antiemetic (Pramine10mg i.v.)and it will be evaluated by a Lickert-type scale.

Lickert-type scale:

MANE* Score	None	Very mild	Mild	Moderate	Severe	Very severe	Intolerable

* MANE (Morrow Assessment of Nausea and Emesis*)*

- Duration of Surgery: _____ (*in minutes*)
- Duration of anesthesia:----------(*in minutes*)

Appendix C

INFORMED CONSENT

You have been invited, because you recently had surgery hernia repair, to participate in a research project being conducted in the Department of Operation, Your participation is entirely voluntary. It is up to you to decide whether or not to take part in this study.

Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done and the possible benefits, risks and discomforts.

If you wish to participate, you will be asked to sign this form. If you decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision. You will not lose the benefit of any medical care to which you are entitled or are presently receiving Please read this form carefully and feel free to discuss it with your family, friends and doctor before you decide

Benefits

There will be direct benefits to you for participating in this study. Postoperative pain after hernia repair surgery hopefully will be reduced. Also we hope that the information gained from this study can be used in the

future to benefit other people with a similar condition.

Risks and discomforts

There are no physical risks associated with this study.

Costs and reimbursements

There is no cost to you for participating in this study. You will not be paid for your participation.

Who to contact for questions about this study

If you have any questions about this study, you can contact The Principal Investigators,

Yahya Sleet (0595123520)

Consent:

I, _____, have read and understand the above information and agree to participate in the study entitled:

Analgesic Effect of local wound infiltration with magnesium sulfate versus Bupivacaine in reducing postoperative pain in patients undergoing inguinal hernia repair surgery

I understand that my participation is voluntary and that all the information collected will be kept confidential and used only for scientific objectives.

I am not waiving any of my legal rights by signing this consent form. I freely consent to participate in this study,

Signature_____

Date_____

نموذج موافقة

لقد تمت دعوتك للمشاركة في البحث كونك ستقوم بعملية جراحية–الفتاق، بحيث ستكون مشاركتك في البحث الذي سيقام في قسم العمليات الجراحية، وهذه المشاركة تعتبر طواعية ولك الحق في القبول أو الرفض، وقبل أن تقرر المشاركة في البحث يجب أن تدرك مضمون هذا البحث.

نموذج الموافقة هذا سيوضح لك أهمية إجراء البحث وما هي المنافع المنتظرة وهل سيكون هناك خطورة أو أي إزعاج يترتب على مشاركتك.

إذا أحببت المشاركة سيكون أمامك المقدرة على ترك البحث والانسحاب في أي وقت ودون إبداء الأسباب، وفي حال انسحابك من المشاركة في البحث، لن تفقد أي رعاية طبية أو اهتمام.

رجاء اقرأ نموذج الموافقة هذا جيدا وبأريحية مطلقة، وناقش الأمر مع العائلة والأصدقاء أو الطبيب الخاص بك قبل اتخاذ القرار.

المنفعة من المشاركة في البحث

ليس هناك منفعة مرتقبة, وأنا أرجو أن تكون المعلومات المستفادة من البحث بعد إتمامه مفيدة لأشخاص آخرين سيخضعون لمثل هذه العملية الجراحية.

المخاطر

لا يوجد مخاطر أو مضاعفات مرتبطة بهذه الدراسة.

التكلفة

لا يوجد تكلفه مترتبة على المشاركة في البحث.

جهة الاتصال عند الحاجة

عند وجود أي استفسار أو توضيح بالإمكان الاتصال مباشرة بالباحث الرئيسي في البحث (يحيى سليط) على الرقم 0569901049.

نموذج الموافقة

أنا _____ قرأت وفهمت كل ما جاء من معلومات وأوافق على المشاركة في البحث، وقد فهمت أن مشاركتي في البحث بإرادتي وجميع المعلومات التي أصرح بها والتي يتم جمعها سيتم الاحتفاظ بسريتها، واستعمالها للأهداف العلمية فقط، وعليه أوقع.

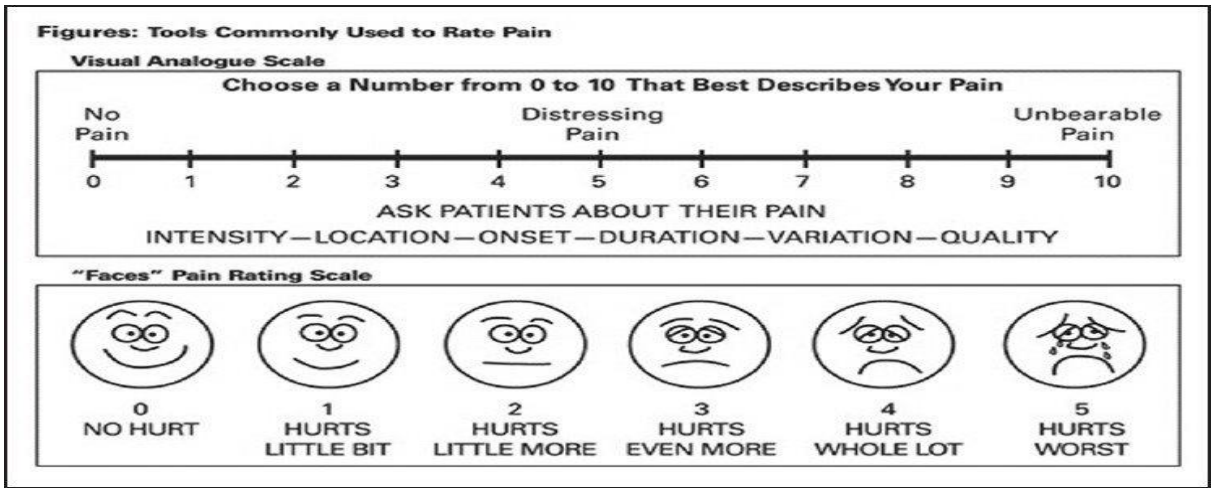
توقيع المريض: _____ التاريخ:_____

Appendix E

Table (1) ASA Classification:

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A Patient with mild system disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (<3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are begin removed for donor purposes	

Table (2) VAS scale :



جامعة النجاح الوطنية

كلية الدراسات العليا

تأثير التسكين لسلفات المغنيسيوم مقارنة بالبوبيفكائين عن طريق الترشيح الموضعي لجرح العملية للحد من ألم ما بعد الجراحة في المرضى الذين يخضعون الى جراحة اصلاح الفتق الاربي: دراسة عشوائية مزدوجة التعمية

إعداد

يحيى محمد محمود سليط

إشراف

د. عائدة القيسي

د. ظافر معالي

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

2020

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اعداد

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اشراف

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الملخص

المقدمة

يعد ألم ما بعد الجراحة من أكثر المشاكل شيوعًا بعد عملية إصلاح الفتق الإربي. فالحد من الألم بعد الجراحة يؤدي إلى تسريع التعافي الوظيفي، ويقلل من مدة الإقامة في المستشفى والمراضة بعد الجراحة. يوصى بترشيح الجرح باستخدام التخدير الموضعي لتقليل استهلاك المواد الأفيونية قبل الجراحة وآلام ما بعد الجراحة. هدفت هذه الدراسة إلى تقييم فعالية البوبيفاكايين مقابل كبريتات المغنيسيوم في جراحات إصلاح الفتق الإربي وذلك بحقن الجرح قبل إغلاقه، لتقليل حدوث وشدة الألم بعد العملية الجراحية، واستهلاك المسكنات وزيادة وقت طلب الجرعة الأولى المسكنة.

الأهداف

الهدف من هذه الدراسة هو تحديد التأثير المسكن لترشيح كبريتات المغنيسيوم مقابل البوبيفاكايين قبل إغلاق العملية الجراحية لإصلاح الفتق الاربي في تقليل حدوث وشدة الألم بعد الجراحة واستخدام المواد الأفيونية، لتقليل استهلاك المسكنات وزيادة وقت الجرعة الاولى للمسكنات.

تصميم الدراسة

في تجربة سريرية مزدوجة عمياء، تم تحديد المرضى المخطط لهم عملية إصلاح الفتق الإربي الاختيارية. بعد موافقة مجلس المراجعة المؤسسية والتوقيع على استمارات الموافقة على المشاركة

في الدراسة، يتم تقديم 80 مريضًا، من الحالة الجسدية الأولى والثانية حسب الجمعية الامريكية لأطباء التخدير، تتراوح أعمارهم بين 18 و70 عامًا، لإصلاح الفتق الإربي تحت التخدير العام الناتج عن إعطاء الفنتانيل، (2 ميكروغرام / كغ)، بروبوفول (2 ملغم / كغم) وروكورونيوم (0.6 ملغم / كغم) ويتم الحفاظ عليه بنسبة 70٪ / 30٪ من أكسيد النيتروز والأكسجين والأيزوفلورين بتركيز 0.5٪ إلى 1.5٪. بعد اجراء عملية التخدير، قسم المرضى عشوائياً إلى مجموعتين وقبل إغلاق الشق، تم ارشاح الجرح في مجموعة البوبيفاكائين ب 5 مل من بوبيفاكين 0.5٪ يضاف إلى 5 مل من محلول ملحي عادي يتم حقنها تحت الجلد وفي مجموعة المغنيسيوم 10 مل سلفات مغنيسيوم 20٪ تحقن تحت الجلد .تم استخدام المورفين 2 ملغ في الوريد كدواء إنقاذ. تم قياس قيم الألم باستخدام المقياس التناظري البصري (VAS) عند 0.5، 1، 2، 3، 6، 12، 18 و24 ساعة بعد الشفاء من التخدير. تم توثيق إجمالي استهلاك المورفين ووقت الطلب الأول لجرعة المورفين والآثار الجانبية لأدوية الدراسة.

النتائج

في هذه الدراسة، قارنا ارتشاح الجرح بحقن المغنيسيوم والبوبيفاكائين في موقع جراحة الفتق الإربي قبل الإغلاق للسيطرة على الألم بعد الجراحة. أظهرت نتائجنا تأثيرًا متفوقًا من مادة بوبيفاكايين مقارنةً بالمغنيسيوم في تقليل الألم وتقليل الأدوية المسكنة وزيادة وقت طلب الجرعة الأولى من المسكنات خلال 24 ساعة بعد العملية.

في هذه الدراسة، تم التحقق من تجانس المشاركين عن طريق اختبار ليفين، وكانت العينة متجانسة في العمر والوزن والطول (قيمة $P> 0.005$) مما يعني عدم وجود اختلاف كبير بين مجموعتين في البيانات الديموغرافية.

فيما يتعلق بمقياس التناظر البصري خلال الفترة الإجمالية البالغة 24 ساعة بعد الجراحة التي تعكس شدة الألم بعد الجراحة، أظهرت النتائج أن مقياس التناظر البصري في مجموعة المغنيسيوم (mean (SD) (1.88 ± 0.53) أعلى بكثير من مقياس التناظر البصري في مجموعة

البوبيفاكائين (mean (SD) = 0.98 ± 0.61)، وتشير النتائج إلى أن البوبيفاكائين أكثر فعالية في الحد من آلام ما بعد الجراحة من كبريتات المغنيسيوم.

أظهرت النتائج وجود فروق ذات دلالة إحصائية في نسبة حدوث الألم خلال الفترة الكلية البالغة 24 ساعة. بعد الجراحة بين المجموعتين التجريبيتين (P-value = 0.000 <0.05)، أظهرت النتائج أن عدد المرضى الذين يعانون من الألم في مجموعة كبريتات المغنيسيوم (n (%) = 38 ((95%) أعلى بكثير من مجموعة البوبيفاكائين (n (%) = 18 (45%)), (P = 0.000) تشير النتائج إلى أن البوبيفاكائين أكثر فعالية في الحد من حدوث آلام ما بعد الجراحة من كبريتات المغنيسيوم.

فيما يتعلق بطلب المورفين خلال الفترة الإجمالية البالغة 24 ساعة بعد الجراحة، أظهرت النتائج أن عدد المرضى الذين تناولوا المورفين (2 mg i.v.) في المجموعة كبريتات المغنيسيوم (n (%) = 38 (95%)) أعلى بكثير من مجموعة البوبيفاكين. (n (%) = 17 (42.5%)، (P = 0.000) النتيجة تشير إلى أن مجموعة البوبيفاكايين أكثر فعالية في تقليل استهلاك المواد الأفيونية من عقار المورفين من مجموعة كبريتات المغنيسيوم.

توجد فروق ذات دلالة إحصائية في الاستجابة الكاملة (لا غثيان ولا قيء ولا دواء إنقاذ) بين المجموعتين التجريبيتين (قيمة P = 0.004 <0.05)، وأظهرت النتائج عدد المرضى الذين لديهم استجابة كاملة في مجموعة كبريتات المغنيسيوم (n (%) = 14 (35%)) أقل بكثير من مجموعة بوبيفاكائين (n (%) = 27 (67.5%))، (P = 0.004). تشير النتائج إلى أن عدد المرضى الذين يعانون من استجابة كاملة في مجموعة بوبيفاكايين أكثر من مجموعة كبريتات المغنيسيوم. كما توجد فروق ذات دلالة إحصائية في الغثيان بين المجموعتين التجريبيتين (P value = 0.003 <0.05)، وأظهرت النتائج أن عدد المرضى الذين عانوا من الغثيان في مجموعة كبريتات المغنيسيوم (n (%) = 22 (55%)) أعلى بكثير من واحد في مجموعة البوبيفاكائين (n (%) = 9 (22.5%)). وأظهرت النتائج عدم وجود فروق ذات دلالة إحصائية في القيء بين المجموعتين التجريبيتين. (P-value = 1,000> 0.05)

توجد فروق ذات دلالة إحصائية في ضغط الدم بعد مرور 4 ساعات (S less 120 and D less 80) بين المجموعتين التجريبيتين، (p-value of the post hoc Multiple comparison test <0.05)، وعدد المرضى الذين 0لديهم ضغط دم (S less 120 and D less 80) in في مجموعة كبريتات المغنيسيوم (N(%)=8(20%)) أقل بكثير من مجموعة البوبيفاكين (N(%)=17(42.5%)). تشير النتيجة إلى أن المزيد من المرضى في مجموعة البوبيفاكين كان لديهم ضغط دم أقل من 80/120 بعد 4 ساعات. توجد فروق ذات دلالة إحصائية في ضغط الدم بعد 16 ساعة. (S less than 120 and D less 80) بين المجموعتين التجريبيتين (P-value of the post hoc Multiple comparison test <0.05) ، عدد المرضى الذين لديهم ضغط دم بعد 16 ساعة (S less than 120 and D less 80) in MgSO4 لا group(N(%)=16(40%)) أقل بكثير من مجموعة (N(%)=27(67.5%)). تشير النتيجة إلى أن المزيد من المرضى في مجموعة البوبيفاكين لديهم ضغط دم أقل من 120 / 80 بعد 16 ساعة.

توجد فروق ذات دلالة إحصائية في ضغط الدم بعد مرور 8 ساعات (Stage 2 - S 140 or higher and D 90 or higher) بين المجموعتين التجريبيتين (P-value of the post hoc Multiple comparison test <0.05)، المرضى الذين لديهم ضغط دم بعد مرور 8 ساعات (Stage 2 - S 140 or higher and D 90 or higher) في مجموعة كبريتات المغنيسيوم (N(%)=10(25%)) أعلى بكثير من مجموعة البوبيفاكين (N(%)=3(7.5%)). تشير النتيجة إلى أن المزيد من المرضى في مجموعة كبريتات المغنيسيوم لديهم BP≥ 140/90. يمكن أن يكون نتيجة للألم. في الختام، تشير النتيجة إلى أن المزيد من المرضى في مجموعة البوبيفاكين لديهم ضغط دم أقل من 80/120 من مجموعة كبريتات المغنيسيوم (P-value=0.043<0.05).

توجد فروق ذات دلالة إحصائية في معدل التنفس الكلي بين المجموعتين ، وأظهرت النتائج أن معدل التنفس في مجموعة كبريتات المغنيسيوم (mean=16.88) أعلى بكثير من معدل التنفس في مجموعة البوبيفاكايين (mean=16.59). لكن الفرق ليس مهمًا من الناحية السريرية.

الاستنتاج

كان ترشيح بوبيفاكائين للجروح في موقع الجراحة أكثر فعالية من ترشيح كبريتات المغنيسيوم لتقليل حدوث الألم ما بعد الجراحة وشدته، وتقليل استهلاك المواد الأفيونية، وزيادة الوقت الأولي لطلب مسكنات الآلام بعد الجراحة في المرضى الذين يخضعون لجراحة الفتق الإربي.

توصية

في الدراسات المستقبلية، تناول المغنيسيوم كعامل مساعد وقياس مستويات المغنيسيوم في الدم قبل الجراحة وبعدها لتحقيق نتيجة مهمة. بناءً على النتائج، اتضح أن استخدام ترشيح بوبيفاكائين في إصلاح الفتق الإربي أكثر فعالية من كبريتات المغنيسيوم ويوصى باستخدام هذا الدواء لتقليل الألم بعد الجراحة والآثار الجانبية الطفيفة.