

Intraperitoneal Local Instillation of Levo-Bupivacaine versus Magnesium Sulfate versus Levobupivacaine Plus Magnesium Sulfate for Postoperative Pain Relief after Laparoscopic Sleeve Gastrectomy: Prospective Randomized Clinical Trial

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Abstract

Background: Laparoscopic sleeve gastrectomy is the gold standard option for the management of morbid obesity, it is a less invasive procedure with better cosmetic results and shorter operative time and hospital stay. Moreover, the current body of evidence shows that laparoscopic interventions are generally associated with less post-operative pain and analgesic requirements.

Aim of Study: To compare the efficacy and safety of intraperitoneal levobupivacaine, and/or magnesium sulphate in different combinations for post-operative pain relief in patients undergoing laparoscopic sleeve gastrectomy.

Methods: This is double blind prospective randomized clinical trial set at Ain Shams University Hospitals over a period of 7 months from February to September 2020 on 60 patients who were scheduled to undergo laparoscopic sleeve gastrectomy at Ain Shams University Hospitals. 60 patients were divided into three groups: Group A included patients received intraperitoneal instillation of 30ml of 0.25% Levobupivacaine alone, group B included patients received intraperitoneal instillation of 30ml Magnesium Sulphate 10% alone and Group C included patients received intraperitoneal instillation of 15ml Magnesium Sulfate 10% plus 15ml of 0.25% Levobupivacaine to a total volume of 30ml.

Results: The average Time to 1st dose of post-operative analgesia demand was also the longest in LevMg group compared to Mg group and Lev group (8.75 ± 4.51 hours compared to 1.40 ± 0.50 hours and 4.95 ± 1.76 hours respectively) which was also highly significant. When total analgesia consumption in 24 hours was analysed, LevMg group had 35.00 ± 26.66 mg, Mg group had 136.50 ± 19.27 mg and Lev group 87.00 ± 33.73 mg of Pethidine consumption which was highly significant Bupivacaine group had mild to moderate pain and most of the patients in bupivacaine plus magnesium sulphate group had mild pain in first 24 hours of surgery.

Conclusion: Intraperitoneal combination of levobupivacaine and magnesium sulphate is more effective than levobupivacaine or magnesium sulphate alone for post-operative pain after laparoscopic sleeve gastrectomy.

vacaine or magnesium sulphate alone for post-operative pain after laparoscopic sleeve gastrectomy.

Key Words: Levo-Bupivacaine – Levobupivacaine – Laparoscopic Sleeve Gastrectomy – Magnesium Sulfate.

Introduction

CURRENTLY, laparoscopic sleeve gastrectomy is the gold standard option for the management of morbid obesity [1]. Laparoscopy offers many advantages over laparotomy, it is a less invasive procedure with better cosmetic results and shorter operative time and hospital stay [2]. Moreover, the current body of evidence shows that laparoscopic interventions are generally associated with less post-operative pain and analgesic requirements [3].

On the other hand, laparoscopic procedures are associated with variable degrees of early post-operative pain; post-laparoscopic abdominal pain, mainly visceral, is proposed as a consequence of abdominal incision, tissue injuries, and pneumoperitoneum with subsequent peritoneal stretch [4]. Moreover, concurrent shoulder tip pain may occur as a result of peritoneal irritation by carbon dioxide and phrenic nerve irritation by diaphragmatic muscle fibers stretch [5].

Inadequate management of acute post-laparoscopic pain can significantly affect patient satisfaction, prolong hospitalization, and increase the risk of morbidities and development of chronic pain [6]. Previous reports have shown that the post-laparoscopic pain is inadequately treated in approximately one-half of all surgical procedures [7].

Thus, effective analgesia through a multimodal approach can modify these consequences and im-

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prove patient recovery and quality of life [8]. Different multimodal approaches including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), opioids and local wound infiltration have been described [9]. However, NSAIDs may precipitate ischemic renal insufficiency and coagulopathy. Opioids are associated with respiratory depression, Post-Operative Nausea and Vomiting (PONV), and dependence [10,11].

Intraperitoneal instillation of drugs has been proposed as an effective option for postlaparoscopic pain management. According to a previous meta-analysis by Marks et al., [12], intraperitoneally instilled agents can potentially block the visceral afferent signalling and inhibit the release and action of prostaglandins. Moreover, after systemic absorption from through the large peritoneal surface, they may further modulate peritoneal and visceral signalling to the brain, thereby attenuating the metabolic impact of visceral manipulations.

The current body of evidence shows that the intraperitoneal local anesthetics led to lower post-operative pain scores and rare serious adverse effects among patients who underwent laparoscopic surgeries, regardless of the instillation time which may be pre-pneumoperitoneum or near the end of surgery [13,14].

In addition, different types of drugs were proposed for intraperitoneal instillation, including bupivacaine, magnesium, and cortisosteroids. Over the past decades, a growing body of evidence has suggested a significant role of glutamate receptors on peripheral nociceptive sensation; thus, an effective blockade of glutamate receptors, such as N-Methyl-D-Aspartate (NMDA) receptor, can alleviate different type of pain including post-operative pain [15]. Intraperitoneal magnesium has emerged as an effective, adjuvant, local and systemic analgesic due to its effective blockade of NMDA receptors and calcium channels after systemic absorption through the large peritoneal surface [16]. It also increases the number of nerve fibers affected by bupivacaine and therefore potentiates its conduction block [17].

However, there is a scarcity in the published literature, which evaluates the efficacy of different types of drugs in the management of post-operative pain following laparoscopic sleeve gastrectomy. Therefore, the aim of the present trial is to compare the efficacy of intraperitoneal levobupivacaine, and/or magnesium sulphate in different combinations for post-operative pain relief in patients undergoing laparoscopic sleeve gastrectomy.

Aim of the work:

The aim of the present trial is to compare the efficacy and safety of intraperitoneal levobupivacaine, and/or magnesium sulphate in different combinations for post-operative pain relief in patients undergoing laparoscopic sleeve gastrectomy.

Patients and Methods

This is double blind prospective randomized clinical trial set at Ain Shams University Hospitals over a period of 7 months from February to September 2020 on 60 patients who were scheduled to undergo laparoscopic sleeve gastrectomy at Ain Shams University Hospitals. The patients were divided into three groups Group A included patients received intraperitoneal instillation of 30ml of 0.25% Levobupivacaine alone, group B included patients received intraperitoneal instillation of 30 ml Magnesium Sulphate 10% alone and Group C included patients received intraperitoneal instillation of 15ml Magnesium Sulfate 10% plus 15ml of 0.25% Levobupivacaine to a total volume of 30ml. Our inclusion criteria were patients between 18 to 65 years old with American Society of Anaesthesiologists (ASA) Physical Status Classification II and with BMI from 30 to 45 who were scheduled to undergo laparoscopic sleeve gastrectomy. Patients with one or more of these criteria were excluded: Patient refusal, patients with cardiac, pulmonary or renal diseases, patients with chronic abdominal or pelvic pain syndrome where pain evaluation will be unreliable due to neurological disease or treatment with steroids prior to surgery, patients with allergy to any of the study drugs, patient with known hypermagnesemia, patients with history of chronic use of analgesics, or with 24 pre-operative use of opioids, patients who were unable to understand the Visual Analogue Scale (VAS) and patients who needed a surgical drain at the end of surgery.

Sampling method: Non-probability consecutive sample size using PASS 11 Program for sample size calculation and assuming VAS score after 2 hours in the 3 study groups = 2, 3 and 4. With SD of 1, sample size of 20 patients in each group can detect this difference with power = 80%, and α -error = 0.05.

A written informed consent obtained from all participants prior to screening and enrolment. Benefits from participation in the research were explained to all patients. The study's protocol gained the ethical approval of the Ethics Committee

of Ain Shams University Hospital. All participants underwent:

Full history taking, clinical examination, routine investigations including CBC, liver function tests, renal function tests and serum electrolytes. Intra-operative monitors including Electrocardiogram (ECG), Non-Invasive Blood Pressure (NIBP), oxygen saturation (Sa O₂), and end-tidal Carbone dioxide pressure (ETCO₂). VAS, at rest (VASstatic) and during cough while assuming an upright position (VASdynamic), 5 minutes after the arrival of the patient to the PACU and then every 2 hours till the end of the study (24 hours post-operatively). VAS was represented as a horizontal line of 10 centimeters length; in which a score of 0 means "no pain" and score of 10 means "worst imaginable pain" [18].

Randomization was done through opaque and well-sealed envelopes. The sequence generation was done with a computer. The number was printed on envelopes and the group was written on the card together with the serial number.

Patients were instructed how to use a 10cm VAS (VAS-0 with end-point labelled "no pain" and 10 to "worst conceivable pain").

When the patient arrived the envelope was open to see the group that would be assigned. A drug solution was prepared by a doctor who would not participate in the study, and drugs were filled in pre-coded syringes and given to the surgeon. Patients were also blinded for the administered drug.

Patients were monitored for (ECG), (Sa O₂), Non-Invasive Blood Pressure (NIBP) and end-tidal CO₂ (ETCO₂). Wide bore intravenous cannula was inserted into a suitable vein.

The induction protocol was standard for all patients. All patients received ringer lactate according to the fluid chart. Patients were pre-oxygenated at 5 liters/min 100% O₂ for 3 to 5 minutes. Anaesthesia was induced by intravenous administration of fentanyl (2 g g/kg), propofol (2mg/kg) and to facilitate the endotracheal intubation atracurium (0.5mg/kg) to a maximum 50mg.

Anaesthesia was maintained with a mixture of oxygen and air 50%/50%, isoflurane 1.5%-2.5% and atracurium supplementation was 10mg/20 minutes or when needed. The ventilation was adjusted to maintain ETCO₂ between 35mmHg and 40mmHg. Patients were placed in reverse trendelenburg position during laparoscopy, intra-abdominal pressure was maintained between 12mmHg and 15mmHg. Standard laparoscopic

sleeve gastrectomy with 4-port technique was performed. All operations were performed by a team of surgeons experienced in laparoscopic surgery.

The prepared drugs were delivered in the same size syringe and the same colour by the surgeon and instilled at the site of surgery via the navel port with patient in a Trendelenburg position (after peritoneal washing and suction).

- (Group A) Lev. group: 30ml 0.25% Levobupivacaine.
- (Group B) Mg group: 30ml Mg Sulphate 10% Group.
- (Group C) LevMg group: 15ml 0.25% levobupivacaine and 15ml of magnesium sulphate 10%.

Co₂ was then evacuated from the peritoneal cavity and skin incision was sutured, when Muscle relaxant was reversed with intravenous (i.v.) neostigmine 0.05mg/kg and atropine 0.02mg/kg. No analgesics were given to patients before recovery. After the surgery, patients were taken to Post Anesthesia Care Unit (PACU). Nurse who was not aware of the study protocol were evaluating patients for parameters in the Post-Anaesthesia Care Unit (PACU). Usually the cut off value of VAS is 4 for rescue medication indication. When VAS ≥4 rescue analgesic was administered as 20mg of pethidine I.V. in the recovery room and 50mg intramuscularly in the ward. The number of patients requiring were recorded in each group. The post-operative pain score was reported at 0 and 30minutes, then at 1, 2, 4, 8, 12, and 16 and 24 hours using the VAS score, The time of arrival in the post-operative recovery room was defined as zero hr. post-operatively. Post-operative monitoring includes also HR, NIBP, and SaO₂ were recorded. Any expected Side effects were recorded which included.

Hypotension is defined as BP that is 20 to 30% less than his baseline BP, local anaesthetic systemic toxicities are numbness in tongue or lips, irritability, dysrhythmias, and convulsions.

The following parameters were evaluated in all study groups for 24 hours post-operative:

The incidence and severity of post-operative pain for 24hrs using VAS pain score, post-operative hemodynamics (HR, BP). All adverse effects including nausea vomiting and dizziness were recorded during 24 hours post-operatively total dose of analgesia. The primary outcome in the present study was the severity of post-operative abdominal and shoulder pain by static and dynamic VAS score. The secondary outcomes included time of first

post-operative analgesic requirement, and total post-operative analgesic consumption during the first 24 post-operative hours. The Mean Arterial Pressure (MAP) and Heart Rate (HR) after instillation of the study drugs and through the first 24 post-operative hours; and the incidence of adverse events including local anaesthetic systemic toxicities (numbness in tongue or lips, irritability, dysrhythmias, and convulsions), sedation, shivering, respiratory depression, and PONV.

Statistical analysis:

Data were analysed using IBM® SPSS® Statistics version 22 (IBM® Corp., Armonk, NY). Normally distributed numerical data were presented

as mean \pm SD, and skewed data as median and interquartile range. Qualitative data were number and percentage. Comparison of normally distributed numerical data were done using the unpaired *t*-test. Skewed data were compared using the Mann-Whitney test. Categorical data were compared using the Pearson chi-squared test or Fisher's exact test, if appropriate. A two-sided *p*-value <0.05 were considered statistically significant.

Results

All the three groups were non-significant in comparison to age, weight, height, BMI and sex.

Table (1): Comparison between the studied groups regarding the study parameters.

| | Group A No.=20 | Group B No.=20 | Group C No.=20 | Test value | <i>P</i> - value | Sig. |
|-------------------------------|--------------------|--------------------|--------------------|---------------|---------------------|------|
| Age: | | | | | | |
| Mean \pm SD | 42.10 \pm 9.19 | 38.75 \pm 6.21 | 40.85 \pm 9.90 | 0.777• | 0.464 | NS |
| Range | 30-56 | 30-49 | 30-65 | | | |
| Sex: | | | | | | |
| Female | 12 (60.0%) | 11 (55.0%) | 14 (70.0%) | 0.987* | 0.610 | NS |
| Male | 8 (40.0%) | 9 (45.0%) | 6 (30.0%) | | | |
| Weight: | | | | | | |
| Mean \pm SD | 121.55 \pm 11.87 | 125.10 \pm 14.59 | 120.90 \pm 14.08 | 0.555• | 0.577 | NS |
| Range | 95-150 | 95-155 | 100-155 | | | |
| Height: | | | | | | |
| Mean \pm SD | 168.55 \pm 6.61 | 169.15 \pm 7.71 | 166.40 \pm 8.00 | 0.751• | 0.476 | NS |
| Range | 159-186 | 155-186 | 155-185 | | | |
| Medical problems: | | | | | | |
| No | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | – | – | – |
| Yes | 20 (100.0%) | 20 (100.0%) | 20 (100.0%) | | | |
| History of anesthesia: | | | | | | |
| No | 12 (60.0%) | 13 (65.0%) | 11 (55.0%) | 0.417* | 0.812 | NS |
| Yes | 8 (40.0%) | 7 (35.0%) | 9 (45.0%) | | | |
| Allergy to drugs: | | | | | | |
| No | 20 (100.0%) | 20 (100.0%) | 20 (100.0%) | – | – | – |
| Yes | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | | | |
| ASA class: | | | | | | |
| 2 | 20 (100.0%) | 20 (100.0%) | 20 (100.0%) | – | – | – |
| Mallampati score: | | | | | | |
| 2 | 6 (30.0%) | 4 (20.0%) | 8 (40.0%) | 1.905* | 0.386 | NS |
| 3 | 14 (70.0%) | 16 (80.0%) | 12 (60.0%) | | | |
| Operation: | | | | | | |
| Sleeve | 20 (100.0%) | 20 (100.0%) | 20 (100.0%) | – | – | – |

When we analysed the VAS score nine times in 24 hours; at zero and after one, two, four, six, eight, twelve, sixteen and twenty four hours of surgery; the cumulative mean pain score was less in LevMg group compared to Lev group and Mg group and the difference was statistically significant ($p < 0.05$). In first hour the Lev group had

VAS pain score of 3.05 ± 0.22 , Mg group had 4.30 ± 1.69 and the levMg group had 2.75 ± 0.64 . Similarly the LevMg group had the least VAS pain score in 2-24 hours compared to Mg group and Lev group (3.15 ± 0.81 - 3.20 ± 0.41 , 4.55 ± 0.89 - 3.25 ± 0.55 and 3.30 ± 1.13 - 3.35 ± 0.49 respectively) Fig. (1).

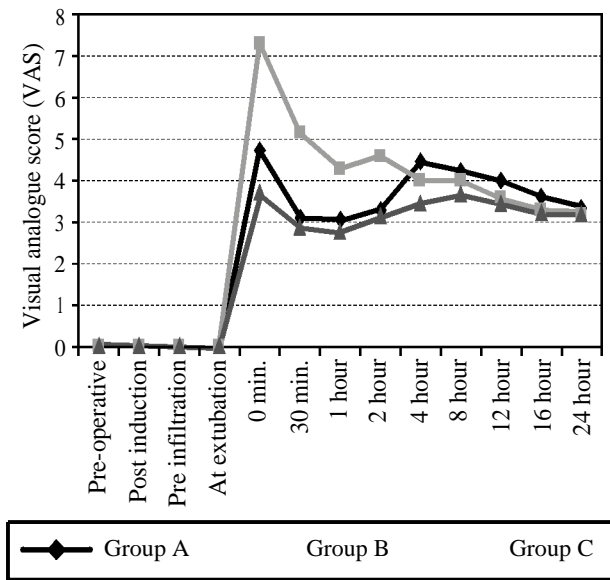


Fig. (1): Comparison between the studied groups regarding VAS

The average time to 1st dose of post-operative analgesia demand was also the longest in LevMg group compared to Mg group and Lev group (8.75 ± 4.51 hours compared to 1.40 ± 0.50 hours and 4.95 ± 1.76 hours respectively) which was also highly significant Fig. (2).

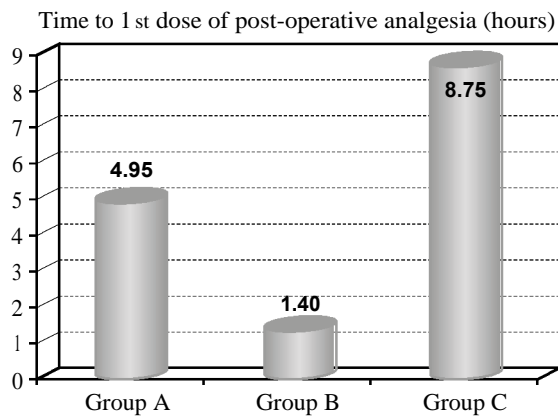


Fig. (2): Comparison between the studied groups regarding time to 1st dose of post-operative analgesia.

When total analgesia consumption in 24 hours was analysed, LevMg group had 35.00 ± 26.66 mg, Mg group had 136.50 ± 19.27 mg and Lev group 87.00 ± 33.73 mg of Pethidine consumption which was highly significant Bupivacaine group had mild to moderate pain and most of the patients in bupivacaine plus magnesium sulphate group had mild pain in first 24 hours of surgery Fig. (3).

Regarding the comparison of the heart rate in the three groups it was highly significant starting from 30min-24 hours post-operative as the least

heart in LevMg group 86.90 ± 15.11 - 84.00 ± 10.91 BPM to the Mg group 103.40 ± 11.82 - 97.75 ± 7.87 BPM and Lev group 95.95 ± 14.12 - 96.90 ± 9.99 BPM Fig. (4).

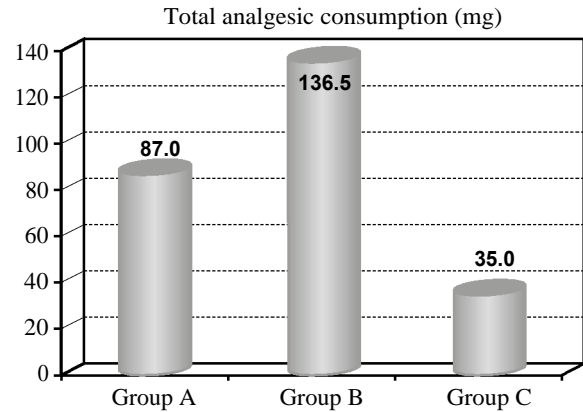


Fig. (3): Comparison between the studied groups regarding total analgesic consumption (mg).

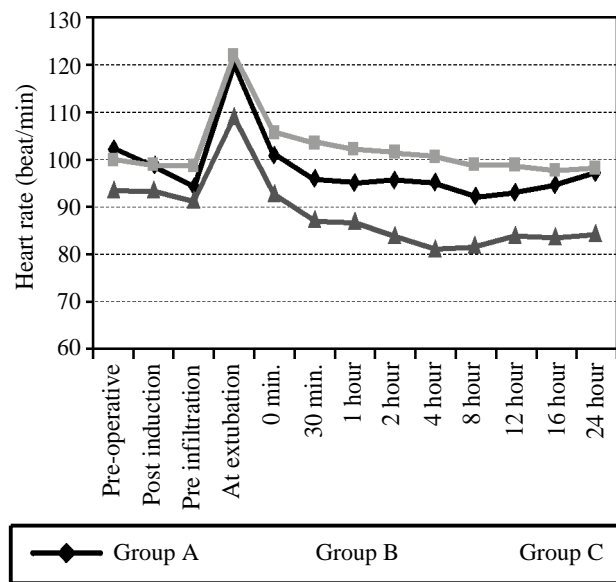


Fig. (4): Comparison between the studied groups regarding heart rate.

There were no remarkable side effects recorded in all of the three groups.

Discussion

In this study, we analysed the analgesic effect of intraperitoneal instillation of Levobupivacaine and Magnesium Sulfate in patients undergoing laparoscopic sleeve gastrectomy. Our results showed that addition of magnesium sulphate to Levobupivacaine decreases post-operative pain and analgesic consumption in first 24 hours after surgery along with longer pain free period compared to patients who were given sole Levobupi-

vacaine or Manesium sulphate after laparoscopic sleeve gastrectomy. Longer pain free period and less analgesic requirements may be due to blockage of both somatic and visceral pain fibres. As magnesium decreases intracellular calcium influx and also antagonizes NMDA receptor thereby decreasing post-operative pain, it is useful for decreasing somatic and visceral pain. It can be used parenterally as bolus and as continuous infusion for peri-operative pain management and to decrease the opioid analgesics requirements as well [19-21].

As pain after laparoscopic surgery is multifactorial and multimodal analgesia is necessary to counter this pain and parenteral as well as intraperitoneal magnesium sulphate may be useful in this regard [22-26].

Abdel Rouf and Amer [24] studied the post-operative analgesic effects of intraperitoneal NMDA receptor antagonist, magnesium sulphate and ketamine in patients undergoing laparoscopic cholecystectomy. They used 30mg/kg of magnesium sulphate in patients receiving intraperitoneal 0.25% bupivacaine and 1mg/kg of ketamine along with 0.25% bupivacaine and concluded that demand for first analgesia in NMDA receptor antagonist was around 130 minutes after surgery compared to control and bupivacaine group (15.30 minutes and 35.30 minutes respectively) [7]. Our study also shows 2-5 hours of less pain period in patients with intraperitoneal instillation of bupivacaine and magnesium sulphate.

Lee and Kwon [20] reported that incisional and intraperitoneal bupivacaine is effective in decreasing somatic pain during first three post-operative hours [10]. Hernandez et al., investigated the intraperitoneal application of bupivacaine plus morphine for pain relief after laparoscopic surgery and reported that combination is effective in decreasing pain during first 6 hours. Our study also shows bupivacaine and magnesium sulphate renders patients pain free period of 2-5 hours and tramadol consumption is also less compared to solebupivacaine group.

We didn't study the blood magnesium sulphate level and sedation score in post-operative ward to conclude the safe level of blood magnesium sulphate level after peritoneal instillation. We only studied the VAS pain score but not shoulder tip pain and other effects like nausea and vomiting. We didn't observe any unwanted effects of study drugs like anaphylaxis, nausea, vomiting and hypotension in the studied patients. Further large scale study is needed to draw definitive conclusion

after the use of the safest more doses intraperitoneally for pain management after laparoscopic sleeve gastrectomy, moreover we didn't notice a complication like nausea and vomiting due to the routine prescribed antiemetic drugs.

Conclusion:

Intraperitoneal combination of levobupivacaine and magnesium sulphate is more effective than levobupivacaine or magnesium sulphate alone for post-operative pain after laparoscopic sleeve gastrectomy.

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مقارنة بين الحقن داخل التجويف البريتوني لعقار الليفوبابافكين وسلفات الماغنسيوم أحدهما أو كلاهما معاً لتخفيف الألم في عملية تكميم المعدة بالمنظار

مقدمة: تكميم المعدة بالمنظار هو الخيار العلاجي الذهبي لمرض السمنة المفرطة، وهو إجراء أقل توغلاً مع نتائج تجميلية أفضل ووقت أقصر للجراحة وإقامة في المستشفى علاوة على ذلك، تُظهر مجموعة الأدلة الحالية أن التدخلات بالمنظار ترتبط عموماً بدرجة أقل من آلام ما بعد الجراحة والإحتياج للمسكنات.

الهدف من العمل: مقارنة فعالية وسلامة الليفوبيفاكين داخل البريتون مع/أو سلفات الماغنسيوم في تركيبات مختلفة لتخفيف الآلام بعد الجراحة في المرضى الذين يخضعون لعملية تكميم المعدة بالمنظار.

المرضى وطرق البحث: تشمل الدراسة ٦٠ مريضاً إلى ثلاث مجموعات حيث المجموعة (أ) تلقى المرضى الذين شملتهم حقناً داخل البريتون بحجم ٣٠ مل من ليفوبيفاكين بتركيز ٠.٢٥٪. المجموعة (ب) تلقى المرضى الذين شملتهم حقناً داخل البريتون ٣٠ مل من كبريتات الماغنسيوم ١٠٪. المجموعة (ج) تلقى المرضى الذين شملتهم حقناً داخل البريتون من ١٥ مل من كبريتات الماغنسيوم ١٠٪ بالإضافة إلى ١٥ مل من الليفوبيفاكين بتركيز ٠.٢٥٪ ليصل الحجم الإجمالي ٣٠ مل.

النتائج: فيما يتعلق بمقارنة معدل ضربات القلب في المجموعات الثلاث، كان ذلك مهماً للغاية بدءاً من ٣٠ دقيقة إلى ٢٤ ساعة بعد الجراحة كأقل معدل في مجموعة الليفوبيفاكين مع سلفات الماغنسيوم مقارنة بمجموعات سلفات الماغنسيوم ومجموعة الليفوبيفاكين.

الخلاصة: أن حقن مزيج عقار الليفوبابافكين وعقار سلفات الماغنسيوم داخل التجويف البريتوني أكثر فاعلية من عقار الليفوبابافكين فقط أو عقار سلفات الماغنسيوم فقط لتخفيف الألم بعد عملية تكميم المعدة بالمنظار.