

Intraperitoneal Bupivacaine with Dexamethasone versus Bupivacaine Alone for Pain Relief after Laparoscopic Bariatric Surgeries: A Randomized Controlled Trial

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ABSTRACT

Background: Pain after laparoscopic bariatric surgeries has negative effects on patients' recovery.

Objective: To evaluate efficacy and safety of adding intraperitoneal dexamethasone to bupivacaine for postoperative pain relief after laparoscopic bariatric surgeries.

Patients and Methods: Sixty patients were randomly allocated into 3 groups as follows: Group B (n=20): bupivacaine 100 ml 0.25% + 5 ml normal saline. Group BD4 (n=20): bupivacaine 100 ml 0.25% + 4 mg dexamethasone (1 ml) + saline 4 ml, and Group BD8: (n=20) bupivacaine 100 ml 0.25% + 8 mg dexamethasone (2 ml) + saline 3 ml. Postoperatively ketorolac IV 30 mg/6 hours + Paracetamol IV 1 g/8 hours were given± nalbuphine.

Results: Pain was lower in Group BD8. Sedation was deeper in Group B. Time to first supplementary analgesia was longer in Group BD8 than Groups B or BD4, and longer in Group BD4 compared to Group B. Patients requiring supplementary analgesia were less in Group BD8 than Groups B or BD4. Total postoperative consumption of nalbuphine in the first postoperative day (POD 1) was less in Group BD8 than Groups B or BD4, and less in Group BD4 than Group B. Time for independent ambulation was shorter in Group BD8 than Groups B or BD4, and shorter in Group BD4 than Group B. Postoperative nausea and vomiting (PONV) was higher in Group B compared to other groups.

Conclusion: Intraperitoneal administration of either 4 mg or 8 mg dexamethasone to bupivacaine (0.25%) resulted in better recovery and pain relief after bariatric surgeries. Dexamethasone 8 mg is superior to 4 mg.

Keywords: Bariatric surgery, Dexamethasone, Intraperitoneal bupivacaine.

INTRODUCTION

Morbid obesity is a growing health problem with significant complications and increased risk of potentially associated diseases as type II diabetes mellitus, hypertension, coronary heart disease, and obstructive sleep apnea (OSA) ⁽¹⁾. Laparoscopic bariatric surgery is an effective treatment for morbid obesity ^(2,3). However, serious perioperative challenges do exist ⁽⁴⁾. Although laparoscopic surgeries are accompanied by less postoperative pain than open surgeries ⁽⁵⁾, postoperative pain after laparoscopic bariatric surgery may be significant and has negative effect on patients' recovery and regaining of physiological functions including respiration, hemodynamics, ambulation, gastric motility, and total time of hospital stay ⁽⁶⁾. Opioids in morbidly obese patients are accompanied by serious unwanted effects as postoperative nausea and vomiting (PONV), respiratory depression, ileus, sedation, delayed ambulation and higher rates of mortality ⁽⁷⁾. These potential complications are added to the pre-existing problems of as OSA or cardio- and/or respiratory impairment ^(8,9). Some studies used low-opioid ⁽¹⁰⁾ or non-opioid-based ⁽¹¹⁾ multimodal analgesic regimens for postoperative pain management after bariatric surgeries.

Chronic postsurgical pain (CPSP) is pain persisting for more than 3 months after the expected healing time ⁽¹²⁾. In some cases of bariatric surgeries, CPSP extended to one year of postoperative suffering⁽¹³⁾. Prevention of acute postoperative pain reduces the incidence of CPSP after bariatric surgeries ⁽¹⁴⁾.

Using local anesthetics for attenuation of pain following bariatric surgery have been discussed in previous studies aiming to reduce or avoid postoperative opioid consumption ^(6, 15). Bupivacaine has a good role in reducing postoperative pain ⁽¹⁶⁾, and adding steroids is thought to be an advantageous step ⁽¹⁷⁾. Dexamethasone is a glucocorticoid that has a beneficial analgesic and anti-emetic effect with a single perioperative dose that might extend up to 2-3 days ⁽¹⁸⁾. The analgesic effect of steroids was attributed to various mechanisms including suppressing bradykinin and releasing neuropeptides at nerve terminals, and decreasing prostaglandin synthesis through suppressing the formation of cyclooxygenase in both peripheral tissues and central nervous system. Moreover, steroids inhibit inflammatory mediators of hyperalgesia as tumor necrosis factor- α , interleukin-17b, and interleukin-6 ⁽¹⁹⁾. It was hypothesized in the current study that postoperative pain in bariatric surgery would be reduced by intraperitoneal instillation of bupivacaine with dexamethasone more than intraperitoneal instillation of bupivacaine alone.

The aim of the present study was to evaluate efficacy and safety of adding two different doses of intraperitoneal dexamethasone (4 mg or 8 mg) to bupivacaine (0.25%) versus intraperitoneal bupivacaine (0.25%) alone for postoperative analgesia after laparoscopic bariatric surgeries.

PATIENTS AND METHODS

This was a double-blind, prospective, randomized controlled trial conducted at Zagazig University Hospitals from June to December 2019. 60 adult (aged

between 21-65 years), American Society of Anesthesiology (ASA) II-III⁽²⁰⁾ patients of either males or females who were posted for a laparoscopic bariatric surgery [Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG)] were enrolled in the current study.

Ethical consent:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee (IRB number: ZU-IRB #5903/22-5-2019). Every patient signed an informed written consent for acceptance of participation in the study. Perioperative procedures and pain management were discussed and explained to all patients before obtaining the informed consent. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria: Body mass index (BMI) ≥ 35 kg/m² in association with one or more comorbid disease (e.g. hypertension, diabetes mellitus or OSA having an Apnea Hypopnea Index (AHI) score < 30) or BMI ≥ 40 kg/m² without any comorbid disease.

Exclusion criteria:

Patients with sleep apnea having an AHI score > 30 , which is a sign for potential rapid desaturation during induction of anesthesia⁽²¹⁾, anemia (hemoglobin < 9 g/l), cardiac, hepatic or renal impairment (creatinine > 1.5 mg/dl), pregnancy or presence of a contraindication for a laparoscopic surgery based upon upper endoscopy findings. Patients were also excluded if they had history of drug or alcohol abuse, consumption of a non-steroidal anti-inflammatory drug (NSAID) within a week before surgery, or hypersensitivity to any agent used in the study.

Thirty minutes before surgery, all patients were premedicated with IV ranitidine hydrochloride (Zantac) 50 mg (2 mL) diluted to 20 mL in 0.9% saline and given slowly over a duration of 5 min, (to reduce the risk of aspiration during induction of anesthesia and endotracheal tube insertion). Ondansetron 8 mg IV was given to guard against PONV. Patients also received single dose of antibiotic. Moreover, subcutaneous heparin (5000 units SQ) was given as prophylaxis against deep vein thrombosis (DVT).

Patients were examined for predictive signs of potential difficult airways and the equipment necessary for emergency airway management including supraglottic airways and a fiberoptic bronchoscope were available.

Patients were closely monitored using electrocardiography, sphygmomanometer cuff, capnograph, pulse oximetry and peripheral nerve stimulator placed over the ulnar nerve for monitoring train of four (TOF) response.

Before induction, all patients laid down in ramped position (elevating the upper part of the body to the level at which the external auditory meatus becomes at the

same horizontal plane with the sternal notch)⁽²²⁾. All doses were calculated based upon ideal body weight (IBW). Preoxygenation was started with fraction of inspired oxygen (FiO₂) 100% and positive end expiratory pressure (PEEP) 10 cm H₂O for 5 minutes. Induction of anesthesia was done using 1 μ g/kg fentanyl, propofol 1.5-2 mg/kg, and 1-2 mg/kg succinylcholine to facilitate endotracheal tube insertion. Anesthesia was maintained using 1 MAC sevoflurane, fentanyl 1 μ g/kg/hours, and rocuronium 0.1-0.2 mg/kg IV (subsequent doses of 0.01 mg/kg were given if needed according to TOF response). Patients were then positioned in reversed Trendelenburg position. Just before reversal of muscle relaxation, ondansetron 4 mg IV was given. Reversal of muscle relaxant was done using neostigmine 0.04–0.07 mg/kg + 0.01-0.02 mg/kg atropine sulphate. Patients voided before surgery, and no Foley's catheters were used intraoperatively.

Patients were randomly allocated using computer generated randomization tables into 3 equal groups:

Group B (n=20): bupivacaine 100 ml 0.25% + 5 ml normal saline. **Group BD4 (n=20):** bupivacaine 100 ml 0.25% + 4 mg dexamethasone (1 ml) + saline 4 ml, and **Group BD8: (n=20)** bupivacaine 100 ml 0.25% + 8 mg dexamethasone (2 ml) + saline 3 ml. Postoperatively ketorolac IV 30 mg/6 hours + Paracetamol IV 1 g/8 hours were given \pm nalbuphine.

Study drugs were prepared by an anesthesiologist who was not involved in the study. Before withdrawal of trocars, the surgeon performed all injections of the study solution under vision to ensure adequate anesthesia of the peritoneum. Patients' position was maintained as reversed Trendelenburg for 2 min then changed to Trendelenburg, left then right lateral positions (for 2 min each). Finally, patients were maintained on supine position. The physician who observed the patient and collected the postoperative data were blinded to the study protocol.

Postoperatively, all patients were admitted to post-anesthesia care unit (PACU) for at least 1 hour. Then, patients were transferred to surgical intensive care unit (SICU) for the first postoperative day (POD 1) before being transferred to the ward. All patients were encouraged to mobilize with assistance within 2 hours after surgery. Postoperative nasogastric tubes were used.

The following postoperative analgesic plan was applied for all patients:

- Ketorolac 30 mg IV every 6 hours (with maximum dose of 120 mg/day).
- Paracetamol IV 1 g every 8 hours.
- Supplementary analgesia was given if VAS ≥ 4 using nalbuphine starting with 5 mg IV. If VAS remained ≥ 4 after 15 min, another 5 mg IV was given. Nalbuphine regimen was repeated after 6 hours as needed.

The degree of pain was assessed according to visual analogue scale (VAS) score⁽²³⁾ where 0 is no pain

and 10 is the worst possible pain. VAS ≥ 4 was defined as inadequate pain relief.

Collected data in the first postoperative day (POD 1):

- 1- Degree of postoperative pain was evaluated and recorded using a paper with standard 10-cm lineal visual analogue scale (VAS) score ⁽²³⁾ during rest and during mobilization at these times of postoperative period: 0, 2, 4, 6, 12 and 24 hours; where time 0 corresponds to the time of patient arrival to PACU. Mobilization at time 0 was defined as ability to sit in bed.
- 2- Levels of sedation using Ramsay sedation scale (RSS)⁽²⁴⁾ (Table 1) were evaluated and recorded at the following postoperative times: 0, 3, 6, 12 and 24 hours; where time 0 corresponds to the time of patient arrival to PACU.
- 3- Number of patients requiring supplementary analgesia in each group.
- 4- Time to first dose of supplementary analgesia if VAS ≥ 4 using nalbuphine was recorded in each group.
- 5- Total postoperative consumption of nalbuphine after 24 hours was recorded in each group.
- 6- Times for the patient to be able to ambulate independently.
- 7- Complications were recorded and managed if occurred including: (a) Hypotension: (systolic blood pressure below 85 mmHg) and was planned to be managed with IV fluid infusion and IV ephedrine 0.1 mg/kg and check the cause. (b) Bradycardia: (heart rate < 60 b/min) was planned to be managed by atropine sulphate 0.01 mg/kg. (c) Tachycardia: (HR>110 b/min) was planned to be dealt with according to the cause. Respiratory rate (RR): bradypnea (RR < 12 breath/min) was managed by non-invasive mechanical ventilation. (b) Hypoxemia (decreased oxygen saturation (SPO₂) below 91% on room air) was planned to be managed by applying O₂ nasal cannula 3 L/min or continuous positive airway pressure CPAP in resistant cases. (e) PONV was treated by IV 8 mg ondansetron. (f) Any other unanticipated complication were dealt with.
- 8- Patient satisfaction in regards to postoperative pain relief was done by the end of the first postoperative day using a scale of 1-10: where one as unsatisfied and 10 as mostly satisfied.

Table (1): Ramsay sedation scale ⁽²⁴⁾

Score	Response
1	Anxious or restless or both
2	Cooperative, oriented and tranquil (calm)
3	Responding to command
4	Brisk (quick) response to stimulus
5	Sluggish (slow moving) response to stimulus
6	No response to stimulus

Primary outcome: Degree of postoperative pain in the first postoperative day.

Secondary outcomes: (1) Sedation level in the first postoperative day. (2) Time to first dose of supplementary analgesia. (3) Total postoperative consumption of nalbuphine after 24 hours. (4) Times for independent patient ambulation. (5) Complications if occurred. (5) Patient satisfaction.

Statistical Analysis

For software data analysis, Statistical Package for the Social Sciences (SPSS version 20.0) was applied. Number and percentage were used to express qualitative data, while, mean \pm standard deviation (SD) or median and range were used to express quantitative data. Statistical tests including Chi square test (X²), ANOVA or Kruskal Wallis test were used when appropriate. P value of <0.05 was considered a significant result and <0.001 as a highly significant result.

RESULTS

Comparing patients and operative data in this study, statistically significant differences were not detected between the study groups (Table 2).

Table (2): Patients and operative data of the three groups of the study

Variable	Group B (n=20)	Group BD4 (n=20)	Group BD8 (n=20)	P value
Age (yr.)	37.7 \pm 2.3	39.2 \pm 1.9	38.4 \pm 2.7	0.133
BMI (kg/m ²)	40.3 \pm 1.1	41.1 \pm 2.8	40.6 \pm 1.9	0.466
Sex (Male/Female) (n)	9/11	8/12	7/13	0.812
ASA classification II/III (n)	8/12	9/11	8/12	0.934
Surgical data				
Duration of surgery (minutes)	213 \pm 21	208 \pm 27	212 \pm 23	0.782
Type of surgery				
Sleeve gastrectomy (n)	13 (65%)	15 (75%)	14 (70%)	0.788
Roux-en-Y gastric bypass (n)	7 (35%)	5 (25%)	6 (30%)	

Data were represented as mean \pm SD or number (percent). BMI: body mass index. ASA: American Society of Anesthesiologists.

The degree of pain during rest and during mobilization was statistically significantly lower in Group BD8 compared to group B and group BD4 as shown in table 3 and table 4 respectively. Sedation levels were statistically significantly deeper in Group B than Group BD4 and Group BD8 after 6 and 12 hours during the first postoperative day as shown in (Figure 1).

Table (3): Degrees of pain during rest in different times of the study

Variable	Group B (n=20)	Group BD4 (n=20)	Group BD8 (n=20)	P value
VAS 0	2 (0-2)	1 (0-2)	0 (0-1) *	0.007
VAS 2	3 (1-4)	2 (0-3)	0 (0-1) **	<0.001
VAS 4	3 (2-4)	2 (1-3)	1 (0-2) **	<0.001
VAS 6	4 (2-4)	3 (2-4)	2 (1-2) **	<0.001
VAS 12	4 (3-5)	3 (2-4)	2 (1-3) **	<0.001
VAS 24	5 (4-5)	4 (2-4)	2 (1-4) **	<0.001

Data were represented as median and (range).
 * Statistically significant as compared to the other groups.
 ** Statistically highly significant as compared to the other groups.

VAS: visual analogue scale.
Group B: Bupivacaine group.
Group BD4: Bupivacaine+ 4 mg dexamethasone group.
Group BD8: Bupivacaine+ 8 mg dexamethasone group.

Table (4): Degrees of pain during mobilization different times of the study

Variable	Group B (n=20)	Group BD4 (n=20)	Group BD8 (n=20)	P value
VAS 0	3 (1-3)	2 (1-2)	1 (1-2) *	0.012
VAS 2	4 (3-4)	3 (1-4)	1 (1-2) **	<0.001
VAS 4	4 (2-4)	2 (1-4)	2 (0-2) **	<0.001
VAS 6	5 (2-5)	3 (3-4)	2 (1-3) **	<0.001
VAS 12	5 (3-6)	3 (3-4)	2 (2-3) **	<0.001
VAS 24	5 (4-6)	4 (3-4)	2 (2-4) **	<0.001

Data were represented as median and (range).
 * Statistically significant as compared to the other groups.
 ** Statistically highly significant as compared to the other groups.

VAS: visual analogue scale.
Group B: Bupivacaine group.
Group BD4: Bupivacaine+ 4 mg dexamethasone group.
Group BD8: Bupivacaine+ 8 mg dexamethasone group.

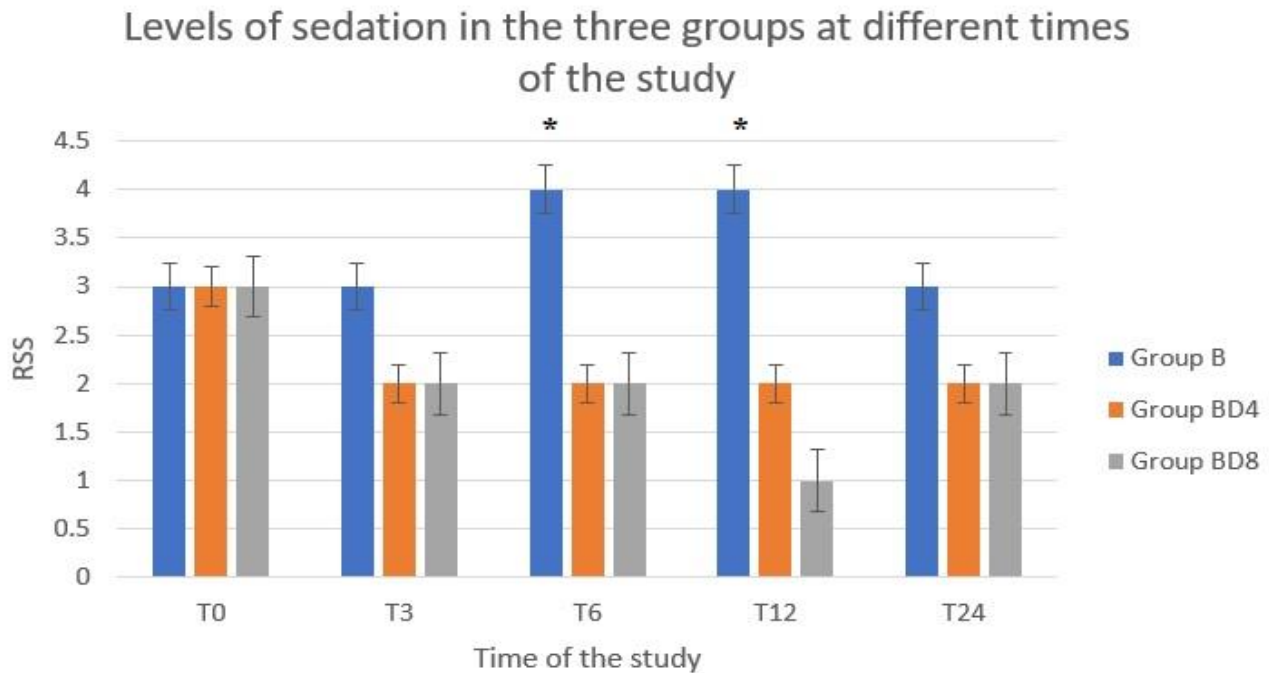


Fig. (1): Levels of sedation according to Ramsay sedation scale (RSS) in the three groups of the study during the first 24 h of postoperative time.

T0= time of admission to PACU. Data were presented as median and range.
 * Statistically significant as compared to the other groups.

Group B: Bupivacaine group.
Group BD4: Bupivacaine+ 4 mg dexamethasone group.
Group BD8: Bupivacaine+ 8 mg dexamethasone group.

Table 5 shows that the time to first supplementary analgesic requirement (nalbuphine) was highly statistically significantly longer in Group BD8 than Group B or Group BD4. The time to first supplementary analgesic requirement was also high statistically significantly longer in Group BD4 than Group B. The number of patients requiring supplementary analgesia was statistically significantly lower in Group BD8 than Group B or Group BD4. The total postoperative consumption of nalbuphine in first postoperative day was less in Group BD8 as shown by the high statistical difference than Group B or Group BD4. The total postoperative consumption of nalbuphine in first postoperative day was also statistically significantly less in Group BD4 than Group B.

Table (5): Analgesic performance in the three groups of the study

Variable	Group B (n=20)	Group BD4 (n=20)	Group BD8 (n=20)	P value
Time to first supplementary analgesic requirement (hours)	6.1 ± 0.19	7.4 ± 0.55 [¥]	9.2 ± 0.14 ^{**}	<0.001
Number of patients requiring supplementary analgesia (n)	13 (65%)	9 (45%)	5 (25%) [*]	0.039
Total postoperative consumption of nalbuphine in 24 hours (mg)	15.2 ± 7.5	11.1 ± 2.1 [¥]	3.4 ± 2.8 ^{**}	<0.001

Data were represented as mean ±SD or number and (percent).
 * Statistically significant as compared to the other groups.
 ** Statistically highly significant as compared to the other groups.

¥ Statistically significant as compared to Group B.

¥¥ Statistically highly significant as compared to Group B.

Group B: Bupivacaine group.

Group BD4: Bupivacaine+ 4 mg dexamethasone group.

Group BD8: Bupivacaine+ 8 mg dexamethasone group.

Table 6 shows that the time for independent ambulation, patients in Group BD8 showed highly significantly shorter time than those in either Group B or Group BD4. It was also highly significantly shorter in Group BD4 than Group B. The incidence of PONV was statistically significantly higher in Group B compared to Group BD4 and Group BD8. Patients' satisfaction was statistically significantly lower in in Group B than Group BD4 and Group BD8.

Table (6): Time for independent ambulation and incidence of complications and patients' satisfaction in the three groups of the study

Variable	Group B (n=20)	Group BD4 (n=20)	Group BD8 (n=20)	P value
Time for independent ambulation (hours)	20.3 ± 1.8	14.6 ± 1.2 ^{¥¥}	8.7 ± 3.3 ^{**}	<0.001
PONV (n)	9 (45%) [*]	3 (15%)	1 (5%)	0.006
Patients' satisfaction	7 (6-8) [*]	8 (7-8)	8 (7-9)	0.001

Data were represented as mean ±SD, number and (percent) or median and (range).

p value was considered statistically significant when <0.05 and highly significant when P<0.001.

* Statistically significant as compared to the other groups.

** Statistically highly significant as compared to the other groups

¥ Statistically significant as compared to Group B.

¥¥ Statistically highly significant as compared to Group B.

Group B: Bupivacaine group.

Group BD4: Bupivacaine+ 4 mg dexamethasone group.

Group BD8: Bupivacaine+ 8 mg dexamethasone group.

Patients in all groups were hemodynamically stable with no significant differences in pulse rate or blood pressure during different times of the study between the studied groups. Respiratory parameters including rate and arterial oxygen saturation were comparable as well among the three groups and within normal ranges during different times of the study. No interventions were needed to stabilize hemodynamic or ventilation parameters of patients in the current study.

DISCUSSION

The results encountered in this study showed that VAS was not reduced by adding 4 mg of dexamethasone while adding 8 mg dexamethasone to intraperitoneal bupivacaine significantly reduced postoperative pain. Yet, both doses of dexamethasone lengthened the duration of performance of bupivacaine as shown by the significantly longer time to first dose of supplementary analgesia and lower consumption of nalbuphine. The higher doses of nalbuphine consumed by patients in bupivacaine group resulted in significantly deeper levels of sedation and delayed independent ambulation in that group. Incidence of PONV was higher and patients' satisfaction was lower when bupivacaine was used alone.

Visceral pain caused by pneumoperitoneum is the main source of pain following laparoscopic surgeries as shown by results obtained by earlier studies (25,26). Improving postoperative analgesia after laparoscopic surgeries by intraperitoneal instillation of a local anesthetic has been widely investigated in previous studies (27-30). A study by **Symons et al.** (27) found that adding intraperitoneal bupivacaine reduced postoperative opioid consumption during the first postoperative day following laparoscopic gastric bypass. Another study by **Alkhamesi et al.** (28) showed a reduction in postoperative pain with the use of intraperitoneal bupivacaine in the same group of patients. Moreover, similar studies (29, 30) were conducted on pediatrics undergoing laparoscopic surgeries and concluded similar results.

To our knowledge the effect of intraperitoneal dexamethasone in addition to a local anesthetic on pain relief after bariatric surgeries has not been investigated before. **Sarvestani et al.** (31) in their study investigated the effect of intraperitoneal hydrocortisone for postoperative pain relief and its beneficial effects were concluded. Another study by **Sharma et al.** (17) administered intraperitoneal hydrocortisone plus bupivacaine and found that adding hydrocortisone improved postoperative pain relief compared to bupivacaine alone following laparoscopic cholecystectomy. **Asgari et al.** (32) investigated the postoperative analgesic effect of dexamethasone alone and found that instillation of single dose of dexamethasone (16 mg) in the peritoneal cavity

significantly reduced the pain severity after laparoscopy and decreased the need for postoperative opioids. They used this high single dose of dexamethasone based upon previous review literatures that did not record serious side effects as a result of using a single dose of corticosteroids (e.g. abdominal bleeding or delayed wound healing). In the current study, similar results were obtained with smaller doses of dexamethasone (4 or 8 mg) as they were used as adjuvants to bupivacaine not alone.

Non-steroidal anti-inflammatory drugs (NSAIDs) have been used following laparoscopic surgeries⁽²⁰⁾. **Ziemann-Gimmel and his colleagues**⁽¹¹⁾ studied paracetamol and ketorolac as a part of multimodal analgesia in patients undergoing laparoscopic gastric bypass in two different studies^(19,20). The first study by **Ziemann-Gimmel et al.**⁽¹¹⁾, reported decreased requirement of opioids for postoperative analgesia down to zero-postoperative-opioid use in few cases. In the current study, postoperative intravenous paracetamol and ketorolac were also a part of the designed multimodal analgesia. However, more patients reached zero-postoperative-opioid use when dexamethasone was administered.

In the second study by **Ziemann-Gimmel et al.**⁽³³⁾, reduction in PONV was reported with postoperative analgesia using intravenous paracetamol and ketorolac. All patients in the present study were given paracetamol and ketorolac, but incidence of PONV was significantly lowered when dexamethasone was used. In general, laparoscopy has been associated with high incidence of PONV. Minimizing the use of opioids can help reducing the incidence of PONV. Perioperative use of anti-emetics can also have a role⁽³⁴⁾.

LIMITATIONS AND RECOMMENDATIONS

(1) The study included two different types of bariatric surgeries (sleeve gastrectomy and Roux-en-Y gastric-bypass surgeries). Pain was expected to be similar since it has the same origin. It would be recommended to study each group separately in further studies. (2) Studies with larger sample size are recommended. (3) Studies with preplanned longer time are recommended to evaluate the effect of this regimen on the incidence of chronic postsurgical pain (CPSP).

CONCLUSION

Intraperitoneal administration of (dexamethasone either 4 mg or 8 mg) to bupivacaine (0.25%) reduced postoperative pain and postoperative consumption of opioids in addition to reduced incidence of postoperative nausea and vomiting following bariatric surgeries, with 8 mg being superior to 4 mg of dexamethasone with no added side effects.

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Author contribution: Authors contributed equally in the study.

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