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ORIGINAL CONTRIBUTIONS

Impact of Pyloric Injection of Magnesium Sulfate-Lidocaine Mixture on Postoperative Nausea and Vomiting After Laparoscopic Sleeve Gastrectomy: a Randomized-Controlled Trial

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Abstract

Background One of the most common adverse effects of laparoscopic sleeve gastrectomy (LSG) is postoperative nausea and vomiting (PONV). The present study aimed to assess the impact of local injection of a mixture of magnesium sulfate and lidocaine into the pylorus on gastric intraluminal pressure (ILP) and PONV after LSG.

Methods Patients with morbid obesity who underwent LSG were randomly allocated to one of two equal groups: treatment group (pyloric injection of a mixture of magnesium sulfate and lidocaine) and control group (pyloric injection of normal saline). PONV and antiemetic requirements were recorded at 6 and 24 h postoperatively.

Results Seventy patients (63 female) with a mean age of 34.6 ± 9.9 years were included. The mean preoperative and postoperative gastric ILP was comparable in the two groups. The pyloric injection of magnesium sulfate-lidocaine mixture resulted in 31% reduction in the mean gastric ILP (19.4 ± 4.7 mmHg before injection to 13.4 ± 4.1 mmHg after injection, $p < 0.0001$). Pyloric injection of saline did not result in significant change in ILP (19.9 ± 4.9 vs 20.3 ± 5.1 mmHg). Of the treatment group patients, 17.1% had significant PONV at 6 h compared to 91.4% of control group patients ($p < 0.0001$). At 24 h, none of the treatment group patients had significant PONV versus 40% of the control group patients ($p < 0.0001$).

Conclusion Pyloric injection of magnesium sulfate-lidocaine mixture during LSG resulted in lower incidence of PONV and less use of antiemetic medications in the first 24 h after LSG without being associated with higher complication rate.

Keywords Sleeve gastrectomy · Pyloric injection · Magnesium sulfate, lidocaine · Early outcome · Randomized trial

Introduction

Laparoscopic sleeve gastrectomy (LSG) is considered one of the most popular procedures for the treatment of morbid obesity. The increasing popularity of LSG is attributed to its technical feasibility, satisfactory outcomes in terms of weight loss and improvement in comorbidities, and high safety profile [1, 2]. Despite the multiple advantages of LSG, a number of postoperative morbidities have been recognized including staple line leakage, hemorrhage, gastroesophageal reflux

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disease (GERD), and postoperative nausea and vomiting (PONV) [3].

PONV may be considered the most common adverse effect of LSG with variable incidence that can be as high as 80% in patients without antiemetic prophylaxis [4]. The risk of PONV after bariatric surgery can be estimated before surgery using Apfel score [5] which comprises female gender, history of motion sickness or PONV, non-smoking, and postoperative use of opioids. On the other hand, the actual PONV is assessed postoperatively using PONV impact scale score [6].

PONV after LSG may be explained by higher gastric intraluminal pressure (ILP) that results from decreasing the distensibility and compliance of the postopertaive gastric pouch compared to that of the whole stomach preopertaively [7]. Therefore, it may be logical that any intervention that reduces the gastric ILP may interfere with this mechanism and results in a lower incidence of PONV after LSG.

Although many measures were devised for the prevention of PONV after LSG including the reduction of opioid consumption, use of supplemental oxygen, and preoperative intravenous fluid administration [4], none of these measures aimed to reduce the gastric ILP.

The present study aimed to assess the impact of local injection of a mixture of magnesium sulfate and lidocaine into the pylorus on the gastric ILP and PONV after LSG. We postulated that the injection of this mixture may help relax the pyloric sphincter ring and canal, lowering the gastric ILP, and conferring a lower incidence of PONV.

Patients and Methods

Study Design, Setting, and Registration

This was a single-center, randomized, controlled, double-blind trial on patients with morbid obesity who underwent LSG in the General Surgery Department, Mansoura University Hospital, in the period of July 2017 to July 2018. Morbid obesity was defined as body mass index (BMI) ≥ 40 kg/m^2 or BMI ≥ 35 kg/m^2 associated with at least one obesity-related comorbidity. Ethical approval for the study was obtained form the Institutional Review Board (IRB) of Faculty of Medicine, Mansoura University. The trial registration number in www.clinicaltrials.gov is NCT03729505.

Eligibility Criteria

Patients included to the trial were adult patients with morbid obesity below 65 years, with ASA class I-III, who failed to achieve and maintain a clinically significant weight loss through supervised non-surgical methods for at least 6 months. We excluded the following patients:

- Obesity secondary to endocrine disorders.
- History of previous bariatric procedure.
- Impaired intellectual capacity or major psyciatric disorder.
- Lack of willingness and motivation to embrace postoperative lifestyle changes.
- Substance abuse.
- Pregnancy or expected pregnancy in the following 12 to 18 months.
- Severe GERD as assessed clinically.

Random Sequence Generation and Blinding

Patients were randomly allocated to one of two equal groups: group I (treatment group) in which patients underwent LSG and injection of magnesium sulfate and lidocaine mixture into the pyloric sphincter muscle and group II (control group) in which patients underwent LSG and injection of normal saline into the pyloric sphincter muscle.

Randomization was conducted by an online random-number generator software (www.randomization.com). Allocation concealment was undertaken by sealed envelope method. Randomly generated treatment allocations were placed in sealed envelopes. Upon completion of sleeve gastrectomy, the envelope was opened in the operation theater by the circulating nurse and the patient was then assigned to one of the study groups.

The study was double-blind as the patients and the operating surgeons were unaware of the nature of the substance injected in the pylorus intraoperatively. The early postoperative outcome was also assessed by assessors who were unaware of the allocation of the study groups.

Preoperative Assessment

Patients were assessed carefully before surgery by taking detailed history of the onset and duration of obesity, associated medical comorbidities, and previous treatments for morbid obesity, in addition to detailed dietary history. Using a simplified risk score [5], the risk of PONV and the predicted postoperative antiemetic requirements were estimated in all patients.

Thorough clinical examination was done to exclude patients with secondary obesity and to assess for coexisting abdominal hernias or organomegally. All patients had ultrasound examination, electrocardiography, and pulmonary function tests as a part of comprehensive clinical assessment. Measures against thromboembolism were taken including wearing elastic stockings after admission and subcutaneous administration of low molecular weight heparin (Enoxaparin, 40 IU) 12 h prior to surgery.

Surgery

Written informed consents to participate in the trial were obtained from the patients after explaining the nature of the study and the potential benefits and harms in each group. One gram of cefotaxime was given on induction as prophylactic antibiotic. The procedures were done under opioid-free general anesthesia by consultants of general and laparoscopic surgery.

A three-port technique was used. Devascularization of the greater curvature of the stomach started 4 cm proximal to the pylorus using a 5-mm sealing device (HARMONIC ACE®+ Shears). A 36-French bougie was inserted into the stomach then gastric transection started 4 cm proximal to the pylorus using long 60-mm endo-stapler (ECHELON FLEX™ ENDOPATH®).

Upon completion of LSG, a mixture of 100 mg/2 ml magnesium sulfate (Magnesium Sulfate®) and 5 ml of 2% lidocaine (Lidocaine®) was injected into the pylorus in the treatment group whereas normal saline was injected into the pylorus in the control group.

Pyloric injection was achieved using a line extension set introduced through the 12-mm working port. A 28-gauge needle (insulin needle), about 0.5 an inch in length, was used to inject 2 ml (of a total of 7 ml mixture) at a single point into the pyloric ring and canal proximal to the prepyloric vein of Mayo.

Measurement of Gastric Volume and ILP

We measured the gastric volume and ILP using the revised semi-continuous method as previously described [7, 8]. A Sengstaken-Blakemore tube, used as a pressure-measuring tube, was introduced into the stomach. The gastric balloon was connected to 3 ml syringe and a pressure transducer using a three-way stopcock. To secure the stomach, mechanical compression was applied just distal to the pylorus using non-traumatic intestinal clamp and occlusion of gastroesophageal junction was achieved by inflation of the esophageal balloon (Fig. 1).

The stomach was decompressed and 1 to 2 ml of air was injected into the gastric balloon and the pressure was recorded. Then, the stomach was inflated using methylene blue colored saline until full distension detected by sharp elevation of pressure or when the instilled saline volume reached 2000 ml and the distended stomach blocked the operative field, then the pressure was recorded. Afterwards, the stomach was deflated and the tube was withdrawn.

Gastric volume and ILP were measured in the empty and distended stomach states at three time points: before sleeve gastrectomy, after sleeve gastrectomy and before pyloric injection, and after pyloric injection with either magnesium sulfate-lidocaine mixture or normal saline.

Postoperative Care and Assessment

Patients were monitored in the general ward. Vital signs were assessed on regular basis and patients were observed for early postoperative complications. Adequate analgesia was achieved using intravenous acetaminophen infusion. Early ambulation was advised for the patients and liberal intake of low-sugar clear oral fluids was encouraged in the same operative day as tolerated by the patient.

PONV was assessed with PONV impact scale [6] at 6 and 24 h postoperatively.

Antiemetic medications used to control PONV included a single dose of intravenous (IV) 4 mg ondansetron (Zofran®) as first-line treatment. Other antiemetic drugs were added sequentially according to patients' need including a single dose of IV 4 mg dexamethasone (Epidron®), then a single dose of 50 mg meclizine (Navoproxin®) suppository and as a last measure 20 mg of IV metoclopramide (Primperan®) was used, maximally for 48 h. The number of different antiemetic agents used was recorded and compared with the estimated number preoperatively according to the Apfel score.

Follow-up

Follow-up was scheduled at 1, 2, 4, and 6 weeks following surgery. During follow-up visits, patients were examined for detection of any postoperative complications, PONV, symptoms or signs of gastric leakage, healing of the wounds, surgical site infection (SSI), improvement in comorbidities, assessing compliance to diet regimen and adoption of lifestyle modifications, and measuring the percentage of excess weight loss (%EWL) at 6 weeks.

Outcomes of the Study

The primary outcome of the study was PONV score at 6 and 24 h postoperatively and the number of antiemetic agents required postoperatively compared to that estimated before surgery.

Secondary outcomes included the need for antiemetic medications, postoperative complications including gastric leakage, operation time, gastric volume and ILP before and after LSG and after pyloric injection in both groups, and %EWL at 6 weeks.

Sample Size Calculation

Based on the primary outcome of the study (PONV), and in light of previous literature [4], we assumed that the percent of patients with significant PONV in the treatment group would be 45% compared to 80% in the control group.

Using sample size calculation software (www.clincalc.com), a minimum of 58 patients, equally divided into two

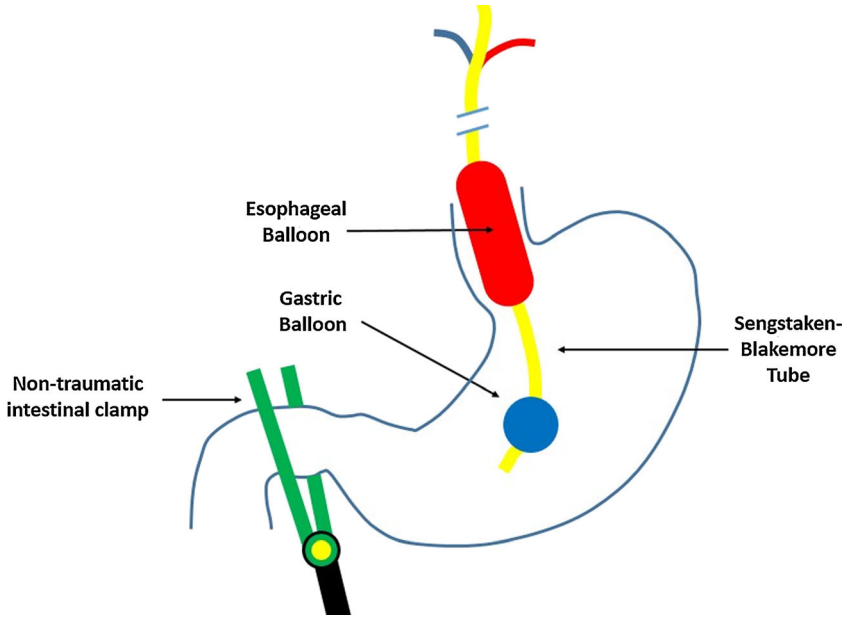

Fig. 1 Measurement of gastric intraluminal pressure using revised semi-continuous method

groups, was needed to achieve a study power of 80% with alpha set at 5%. Therefore, a total of 64 patients were ultimately included to the trial.

Statistical Analysis

Statistical analysis of the data was performed using SPSS software, version 17 (IBM Corp., Chicago, USA). For continuous variables, descriptive statistics were calculated and described as mean ± standard deviation (SD). Categorical variables were reported using percentages. Student's *t* test for paired samples was used to detect differences in the means of continuous variables and Fisher exact test or Chi-square test was used for categorical variables. p values < 0.05 were considered to be significant.

Results

Patients' Characteristics

Eighty-three patients were initially assessed, 13 of whom were excluded and 70 were ultimately included to the study as shown in the Consort flow chart (Fig. 2).

Patients were 63 female (90%) and 7 male (10%). The mean age of patients was 34.6 ± 9.9 years, ranging from 24 to 56 years. The mean weight of patients was 130 ± 15.3 kg, ranging from 98 to 175 kg. The mean BMI was 49 ± 5.2 kg/m^2, ranging 40.8 to 62 kg/m^2.

There were 14 (20%) patients with obesity-related comorbidities (type II diabetes mellitus = 10, hypertension = 4) and 4 patients (5.7%) with asymptomatic cholelithiasis. There were no significant differences between the two groups regarding age, gender, weight, height, BMI, and obesity-related comorbidities as shown in Table 1.

Risk of PONV

The mean risk of PONV as evaluated according to Apfel score was 46 ± 12.2% in the treatment group vs 46 ± 11% in the control group ($p = 0.71$). The number of antiemetic agents estimated to be required in both groups ranged from two to four agents (Table 2).

Gastric Volume and ILP Before and After LSG

The mean preoperative gastric volume in both groups was comparable with no significant differences (1318.6 ± 225 ml in the treatment group vs 1347.1 ± 191 ml in the control group, $p = 0.57$).

The mean postoperative gastric volume was also comparable in both groups (133.1 ± 20 ml in the treatment group vs 127.7 ± 20.5 ml in the control group, $p = 0.27$). There were no significant differences in preoperative and postoperative gastric volumes between the two groups as shown in Table 3.

Preoperative Gastric ILP

The mean preoperative gastric ILP was comparable in the two groups in both empty and distended stomach states (Table 3).

The mean preoperative gastric ILP in the distended state was significantly ($p < 0.0001$) higher than the empty state in both groups [28.4 ± 5.1 vs 17.3 ± 3.5 mmHg in the treatment group; 29.7 ± 5.6 vs 17.6 ± 3.5 mmHg in the control group] (Tables 4 and 5).

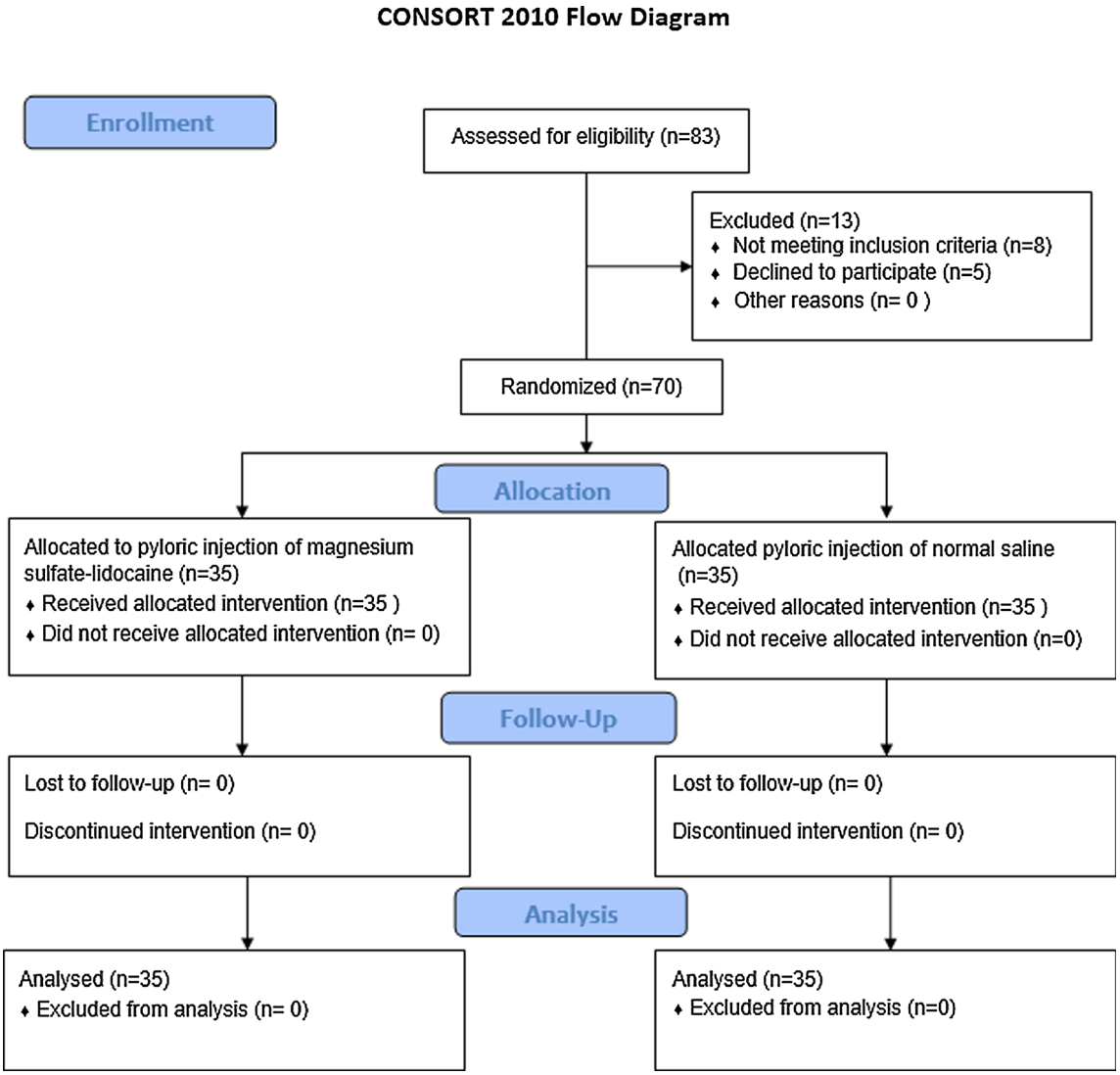

Fig. 2 Consort flow chart for selection of patients included to the study

Postoperative Gastric ILP

The mean postoperative gastric ILP was comparable in the two groups after LSG in both empty and distended stomach states (Table 3).

The mean postoperative gastric ILP in the distended state was significantly ($p < 0.0001$) higher than the empty state in both groups [42.3 ± 7 vs 19.4 ± 4.7 mmHg in the treatment group; 43.1 ± 6 vs 19.9 ± 4.9 mmHg in the control group] (Tables 4 and 5).

Comparing Gastric ILP Before LSG, After LSG, and After Pyloric Injection

Gatric ILP showed a significant increase after LSG compared to before LSG in both empty and distended stomach states as shown in Tables 4 and 5.

In the treatment group, the mean gastric ILP after pyloric injection of magnesium sulfate-lidocaine mixture was significantly lower than before injection in both empty and distended states ($p < 0.0001$) (Table 4).

In the control group, there were no significant differences in the gastric ILP before and after pyloric injection of saline in both empty and distended states (Table 5).

Moreover, there were significant differences between postoperative ILP in the treatment and control groups after pyloric injection in both empty and distended states of the stomach as shown in Table 6.

Postoperative Nausea and Vomiting

The median PONV score at 6 h postoperatively was 4 (range, 2–5) in the treatment group vs 5 (range, 4–6) in the control group. The median PONV score at 24 h

Table 1 Baseline characteristics of patients in both groups

Variable	Treatment group ($n = 35$)	Control group ($n = 35$)	p value
Mean age in years	35.8 ± 8.4	33.5 ± 5.7	0.18
Male/female	5/30	2/33	0.43
Mean weight in kilograms	132.4 ± 14.3	127.6 ± 16	0.19
Mean height in meters	1.6 ± 0.1	1.6 ± 0.1	1
Mean BMI in kg/m^2	49.8 ± 5.2	48.2 ± 5.2	0.2
Comorbidities (%)	9 (25.7)	5 (14.3)	0.23

postoperatively was 1 (0–4) in the treatment group vs 4 (2–6) in the control group.

The number of patients with significant PONV score at 6 h was 6 (17.1%) in the treatment group compared to 32 (91.4%) in the control group. The number of patients with significant PONV score at 24 h dropped to 0 and 14 (40%) in the treatment and control groups, respectively. There were significant differences between both groups regarding PONV impact scale score and the number of patients with significant PONV score at 6 and 24 h postoperatively as shown in Table 7.

The number of antiemetic agents used after surgery ranged from one to two agents in the treatment group vs two to four agents in the control group. Unlike the control group, there was a significant difference ($p < 0.0001$) between the estimated number of antiemetic agents depending on Apfel score and the actual number of antiemetic agents used after surgey in the treatment group as shown in Table 8.

Technical Details

One patient (2.9%) in the treatment group and three patients (8.6%) in the control group underwent additional cholecystectomy. The operation time of both groups ranged from 60 to 125 min and did not show any significant difference (87.6 ± 18.7 min in the treatment group vs 92.1 ± 15.7 min in the control group, $p = 0.28$). There were no significant differences between the two groups regarding hospital stay (2.6 ± 1.4 in treatment group vs 2.7 ± 1.7 in the control group, $p = 0.79$).

Postoperative Complications

Four (5.7%) patients experinced early postoperative complications. Complciations included hospital-acquired pneumonia ($n = 2$) that was treated with antibiotics and physiotherapy; hypertensive crisis in one patient in the control group who required ICU admission and IV antihypertensive agents; and reactionary hemorrhage ($n = 1$) that required laparoscopic intervention to control bleeding points at staple line.

On folow-up, eight patients (11.4%) developed complications which included surgical site infection ($n = 4$) that were treated with wound drainage and antibiotics; and GERD ($n = 4$) that was treated with proton pump inhibitors and prokinetic agents. There were no recorded cases of gastric leak in both groups as assessed by clinical and radiological assessment. Also, there were no recorded cases of pyloric wall hematoma or leakage at the site of injection or allergic reaction to magnesium sulfate-lidocaine mixture. There were no significant differences between the two groups regarding postoperative complications (14.3 vs 20%, $p = 0.75$).

Discussion

PONV is a common, yet an unpleasent, sequel of sleeve gastrectomy. It has been estimated that around 60–80% of patients may experience PONV after sleeve gastrectomy [4]. Predisposing factors for PONV are female gender, history of motion sickness, use of opioids, duration of surgery, induced

Table 2 Estimated risk of PONV

Variable		Treatment group	Control group	p value
Apfel score (%)	1	2 (5.7)	1 (2.9)	0.71
	2	19 (54.3)	22 (62.9)	
	3	14 (40)	12 (34.3)	
	4	0 (0.0)	0 (0.0)	
Mean risk for PONV		46 ± 12.2	46 ± 11	1
Estimated postoperative antiemetic agents	1	0 (0.0)	0 (0.0)	0.71
	2	2 (5.7)	1 (2.9)	
	3	19 (54.3)	22 (62.9)	
	4	14 (40)	12 (34.3)	

PONV postoperative nausea and vomiting

Table 3 Preoperative and postoperative gastric volume and ILP in both empty and distended stomach

Variable	Treatment group	Control group	*p* value
Mean preoperative gastric volume in ml	1318.6 ± 225	1347.1 ± 191	0.57
Mean postoperative gastric volume in ml	133.1 ± 20	127.7 ± 20.5	0.27
p value	< 0.0001	< 0.0001	
Mean preoperative ILP in empty stomach in mmHg	17.3 ± 3.5	17.6 ± 3.5	0.72
Mean preoperative ILP in distended stomach in mmHg	28.4 ± 5.1	29.7 ± 5.6	0.31
Mean postoperative ILP in empty stomach in mmHg	19.4 ± 4.7	19.9 ± 4.9	0.66
Mean postoperative ILP in distended stomach in mmHg	42.3 ± 7	43.1 ± 6	0.61

ILP intraluminal pressure

pneumoperitoneum, distance of a point from the pylorus at which the transection of greater curvature begins, and dilated proximal pouch [5, 9–11].

The present study aimed to investigate the impact of injection of magnesium sulfate-lidocaine mixture in the pylorus on PONV after LSG. Magnesium sulfate is a calcium channel antagonist and vascular smooth muscle relaxant that has been used in management of wide spectrum of diseases including preeclampsia, convulsions, tetanus, and acute asthma [12, 13]. Lidocaine is a potent sodium-channel blocker, smooth muscle relaxant, and cholinergic antagonist that is used as local anesthetic and for prevention of bronchospasm and decreasing the frequency of rebound spasm during colonoscopy [14–16]. We opted to use a mixture of both agents as the combination of magnesium sulfate and lidocaine has been proved to confer a longer duration of action and more potent sensory and motor blocking action [17].

We included 70 patients with morbid obesity in the present study, around 90% of whom were female in concordance with the female predominance of obesity described in the literature [1, 18]. The mean age of patients was approximately 35 years in line with the middle age distribution of patients undergoing bariatric surgery [1]. There were no significant differences between the two study group in terms of baseline and demographic characteristics which reflects absence of selection bias, most probably due to proper randomization of patients to the study groups.

On assessment of the primary outcome of the study using PONV impact scale at 6 h postoperatively, we observed a significantly lower incidence of patients with significant PONV in the treatment group compared to the control group (17.1 vs 91.4%). Halliday et al. [19] reported a lower incidence of significant PONV after LSG (64%) than that of the control group in our study which can be explained by the fact that Halliday and colleagues used prophylactic antiemetic medications before LSG while we did not employ antiemetic prophylaxis in the present study. At 24 h postoperatively and after the use of antiemetic medications to control PONV, the incidence of significant PONV dropped to zero in the treatment group and 40% in the control group.

The efficacy of magnesium sulfate-lidocaine mixture in reducing the incidence and seveirty of PONV was also demonstrated by a noticeable decline in the use of postoperative antiemetic agents in the treatment group compared to the preoperative estimation based on Apfel score. On the other hand, the control group required a number of postoperative antiemetic medications similar to the number estimated before surgery.

Although both groups were comparable in regards the number of antiemetic medications estimated preoperatively to be required after surgery, the actual postoperative requirment of antiemetic medications was signifincatly lower in the treatment group than the control group.

The improvement in PONV in the tretament group may be attributed to the reduction in the gastric ILP. In order to

Table 4 Gastric ILP before LSG, after LSG, and after pyloric injection of magnesium sulfate-lidocaine mixture

Variable	Empty stomach	Distended stomach	*p* value
Mean ILP in mmHg before LSG	17.3 ± 3.5	28.4 ± 5.1	< 0.0001
Mean ILP in mmHg after LSG and before pyloric injection	19.4 ± 4.7	42.3 ± 7	< 0.0001
p value*	0.04	< 0.0001	
Mean ILP in mmHg after pyloric injection	13.4 ± 4.1	31.9 ± 6.8	< 0.0001
p value**	< 0.0001	< 0.0001	

ILP intraluminal pressure, *LSG* laparoscopic sleeve gastrectomy

*Comparing ILP before and after LSG (before pyloric injection)

**Comparing ILP before and after pyloric injection of magnesium sulfate-lidocaine mixture

Table 5 Gastric ILP before LSG, after LSG, and after pyloric injection of saline

Variable	Empty stomach	Distended stomach	*p* value
Mean ILP in mmHg before LSG	17.6 ± 3.5	29.7 ± 5.6	< 0.0001
Mean ILP in mmHg after LSG and before pyloric injection	19.9 ± 4.9	43.1 ± 6	< 0.0001
p value*	0.0270	< 0.0001	
Mean ILP in mmHg after pyloric injection	20.3 ± 5.1	43 ± 5.6	< 0.0001
p value**	0.7390	0.9427	

ILP intraluminal pressure, *LSG* laparoscopic sleeve gastrectomy

*Comparing ILP before and after LSG (before pyloric injection)

**Comparing ILP before and after pyloric injection of normal saline

confirm this theory, we measured gastric ILP in all patients at three time points: before LSG, after LSG and before pyloric injection of magnesium sulfate-lidocaine mixture or saline, and after pyloric injection in both empty and distended states of stomach.

It is known that the gastric fundus is the thinnest and most distensible part of the stomach that acts as a reservoir [20], and since the fundus is entirely removed in LSG, this results in loss of gastric dispensability and compliance. This was clearly shown in our study as the gastric ILP showed significant increase after LSG due to loss of the most distensible part of the stomach. In order to assess the effect of injection of magnesium sulfate-lidocaine mixture in the pylorus, we measured gastric ILP after pyloric injection to evaluate its change in both groups.

The mean volume of the stomach before and after LSG in both groups was comparable to another study [7] that measured gastric volume and pressure before and after LSG. Similarly, the gastric ILP before and after LSG in our study was comparable to the results reported by Yehoshua et al. [7].

Pyloric injection of magnesium sulfate-lidocaine mixture resulted in a significant decrease in gastric ILP in both empty and distended stomach states compared to the control group which did not show any significant change in ILP after saline injection. This observation confirms our theory that the use of magnesium sulfate-lidocaine mixture resulted in marked relaxation of the pyloric sphincter and canal with subsequent reduction in gastric ILP that was associated with lower rates of PONV.

Although PONV after LSG is usually managed with antiemetic medications, the efficacy of these medications is variable according to various patient and technical factors. In addition, another shortcoming of antiemetic medications is the adverse effects and increased costs associated with their use, especially with double or triple combination of these medications. While pyloric injection of magnesium sulfate-lidocaine mixture addresses the main cause of PONV after LSG which is increased gastric ILP, antiemetic drugs function through other unrelated mechanisms [21].

Increased gastric ILP may also factor in the development of staple line leak after LSG. None of the patients in the present study experienced gastric leak by clinical and radiological assessment. This could be attributed to the relatively small sample size included given the low incidence of staple line leak which is around 1% according to the International Sleeve Gastrectomy Expert Panel Consensus Statement 2011 [22], and can vary between 1 and 3% [23]. Absence of gastric leak in our study may be also attributed to the adoption of certain measures for prevention of gastric leak including gentle handling of tissues, avoiding distal stenosis, steady compression by the stapler before firing, and larger bougie size [24–27], in addition to the presumed effect of pyloric injection of magnesium sulfate-lidocaine mixture.

Another value of magnesium sulfate has been shown by Kizilcik and Koner [28] who reported that the perioperative use of intravenous magnesium sulfate reduced postoperative pain and opioid consumption in patients undergoing sleeve gastrectomy operations. However, our trial examined the effect of local delivery of magnesium sulfate into the pyloric sphincter and canal rather than its systemic application as followed in the other trial.

It is worthy to note that the local injection of magnesium sulfate in the pylorus may be associated with some complications including pyloric wall hematoma and leak which we did not encounter owing to the small caliber of the needle used for

Table 6 Postoperative gastric ILP after pyloric injection in both empty and distended stomach in the two groups

Variable	Treatment group	Control group	*p* value
Postoperative gastric ILP (mmHg) after pyloric injection in empty stomach	13.4 ± 4.1	20.3 ± 5.1	< 0.0001
Postoperative gastric ILP (mmHg) after pyloric injection in distended stomach	31.9 ± 6.8	43 ± 5.6	< 0.0001

ILP intraluminal pressure

Table 7 PONV impact scale score at 6 and 24 h postoperatively

Variable		Treatment group	Control group	*p* value
PONV score at 6 h (%)	0	0 (0)	0 (0)	< 0.0001
	1	0 (0)	0 (0)	
	2	4 (11.4)	0 (0)	
	3	10 (28.6)	0 (0)	
	4	15 (42.9)	3 (8.6)	
	5	6 (17.1)	16 (45.7)	
	6	0 (0)	16 (45.7)	
Patients with significant PONV (%)		6 (17.1)	32 (91.4)	< 0.0001
PONV score at 24 h (%)	0	7 (20)	0 (0)	< 0.0001
	1	12 (34.3)	0 (0)	
	2	10 (28.6)	3 (8.6)	
	3	5 (14.3)	4 (11.4)	
	4	1 (2.9)	14 (40)	
	5	0 (0)	13 (37.1)	
	6	0 (0)	1 (2.9)	
Patients with significant PONV (%)		0 (0)	14 (40)	< 0.0001

PONV postoperative nausea and vomiting

injection. Although not recorded in our trial, allergic reaction to the injected substance is another potential adverse effect that should be considered. The systemic absorption of locally injected magnesium sulfate was minimal and this is why it did not affect the blood pressure in any of the patients studied, even those who were on antihypertensive medications.

It could be arguable that pyloric injection of magnesium sulfate may increase the costs and operation time of LSG; however, the added costs of magnesium sulfate-lidocaine mixture (around 2 US dollars per patient) and time (average of 5 min) were not particularly significant.

Another effective strategy for management of PONV after bariatric surgery is the multimodal approach devised by recent guidelines [29]. The enhanced recovery after surgery (ERAS) protocol advocates a multimodal approach that includes using "Propofol for induction and maintenance of anesthesia, avoidance of volatile anesthetics, minimization of intra- and postoperative opioids and avoidance of fluid overload" [4]. Additionally, the use of a triple combination of haloperidol, dexamethasone, and ondansetron was proved superior over a single or double combination in control of PONV after LSG [30]. Given the positive impact of pyloric injection of magnesium sulfate on PONV as demonstrated by our trial, this method can be a part of the ERAS protocol to decrease PONV and antiemetic requirements after sleeve gastrectomy.

Limitations of the study include being a single center study, relatively small number of patients which was not able to detect significant differences between the groups in staple line leakage, and short follow-up. Endoscopic injection of magnesium sulfate-lidocaine mixture may be used as an alternative to the method we followed in the trial; however, intraoperative endoscopy was not freely available in our hospital at the period of the study.

Conclusion

The injection of magnesium sulfate-lidocaine mixture in the pylorus after LSG resulted in lower incidence of PONV and

Table 8 Comparison between estimated and actual need for postoperative antiemetic drugs

		Estimated PO antiemetic agents (%)	Actual PO antiemetic agents (%)	*p* value
Treatment group	1	0 (0.0)	29 (82.9)	< 0.0001
	2	2 (5.7)	6 (17.1)	
	3	19 (54.3)	0 (0.0)	
	4	14 (40)	0 (0.0)	
Control group	1	0 (0.0)	0 (0.0)	0.3
	2	1 (2.9)	4 (11.4)	
	3	22 (62.9)	23 (65.7.1)	
	4	12 (34.3)	8 (22.9)	
p value		0.71	< 0.0001	

PO postoperative

less use of antiemetic medications in the first 24 h after LSG without being associated with higher complication rate.

Authors' Contributions Hosam Elbanna and Mohammad Fathy designed the study. Mohammad Fathy, Mohamed Abdel-Razik, Ayman Elshobaky, and Hosam Elbanna performed the surgical procedures, followed the patients, and shared in data analysis and writing of the manuscript. Ghada El-Rahmawy and Ahmed Farid contributed to study design, collection and interpretation of data, and revising the manuscript. Sameh Emile contributed to data analysis and interpretation, writing and revising of the manuscript.

Compliance with Ethical Standards

Conflict of Interest No conflict of interests or financial ties to be declared by the authors.

Statement of Informed Consent Informed consent was obtained from all individual participants included in the study.

Statement of Human and Animal Rights This study was conducted in accordance with the declaration of Helsinki. Ethical approval for the study was obtained from the Institutional Review Board (IRB) of Mansoura Faculty of Medicine.

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References

1. Emile SH, Elfeki H, Elalfy K, et al. Laparoscopic sleeve gastrectomy then and now: an updated systematic review of the progress and short-term outcomes over the last 5 years. Surg Laparosc Endosc Percutan Tech. 2017;27(5):307–17.
2. Arterburn D, Gupta A. Comparing the outcomes of sleeve gastrectomy and Roux-en-Y gastric bypass for severe obesity. J Am Med Assoc. 2018;319(3):235–7.
3. Frezza EE, Reddy S, Gee LL. Complications after sleeve gastrectomy for morbid obesity. Obes Surg. 2009;19:684–7.
4. Gan TJ, Diemunsch P, Habib AS, et al. Consensus guidelines for the management of postoperative nausea and vomiting. Anesth Analg. 2014;118(1):85–113.
5. Apfel CC, Laara E, Koivuranta M, et al. A simplified risk score for predicting postoperative nausea and vomiting: conclusions from cross-validations between two centers. Anesthesiology. 1999;91:693–700.
6. Myles PS, Wengritzky R. Simplified postoperative nausea and vomiting impact scale for audit and post-discharge review. Br J Anaesth. 2012;108(3):423–9.
7. Yehoshua RT, Eidelman LA, Stein M, et al. Laparoscopic sleeve gastrectomy—volume and pressure assessment. Obes Surg. 2008;18:1083–8.
8. Malbrain ML. Different techniques to measure intra-abdominal pressure (IAP): time for a critical re-appraisal. In: Pinsky MR, Brochard L, Mancebo J, Antonelli M, editors. Applied physiology in intensive care medicine. 2nd ed. Berlin: Springer; 2012. p. 13–27.
9. Sinclair DR, Chung F, Mezei G. Can postoperative nausea and vomiting be predicted? Anesthesiology. 1999;91:109–18.
10. Fallatah B, Shehry A, Abdelsamad L, et al. Comparison study of gastric emptying after performing sleeve gastrectomy with two different techniques. Global Journal of Surgery. 2013;1(4):53–6.
11. Keidar A, Appelbaum L, Schweiger C, et al. Dilated upper sleeve can be associated with severe postoperative gastroesophageal dysmotility and reflux. Obes Surg. 2010;20(2):140–7.
12. Geiger H, Wanner C. Magnesium in disease. Clin Kidney J. 2012;5(1):i25–38.
13. El Hefnawy E, El Nakeeb A. Comparative study between magnesium sulphate and L-hyoscyamine on duodenal motility during ERCP under general anaesthesia: a prospective randomized study. Egyptian Journal of Anaesthesia. 2017;33(1):15–20.
14. Kao C, Chu Y, Wang H. Effects of lidocaine on rat's isolated tracheal smooth muscle. Eur Arch Otorhinolaryngol. 2010;267:817–20.
15. Khan T, Wani SQ, Ali Z, et al. Lidocaine nebulization in the treatment of acute severe refractory bronchial asthma. Journal of Case Reports. 2015;5(1):42–4.
16. Nemoto D, Utano K, Isohata N, et al. Topical lidocaine inhibits spasm during colonoscopy: a double-blind, randomized controlled trial (with video). Endosc Int Open. 2017;5(6):E402–7.
17. Li M, Jin S, Zhao X, et al. Does magnesium sulfate as an adjuvant of local anesthetics facilitate better effect of perineural nerve blocks? A meta-analysis of randomized controlled trials. Clin J Pain. 2016;32(12):1053–61.
18. Garawi F, Devries K, Thorogood N, et al. Global differences between women and men in the prevalence of obesity: is there an association with gender inequality? Eur J Clin Nutr. 2014;68:1101–6.
19. Halliday TA, Sundqvist Hultin JM, Walldén J. Post-operative nausea and vomiting in bariatric surgery patients: an observational study. Acta Anaesthesiol Scand. 2017;61:471–9.
20. Weiner RA, Weiner S, Pomhoff I, et al. Laparoscopic sleeve gastrectomy—influence of sleeve size and resected gastric volume. Obes Surg. 2007;17:1297–305.
21. Shaikh SI, Nagarekha D, Hegade G, et al. Postoperative nausea and vomiting: a simple yet complex problem. Anesth Essays Res. 2016;10(3):388–96.
22. Rosenthal RJ. International Sleeve Gastrectomy Expert Panel Consensus Statement: best practice guidelines based on experience of >12,000 cases. Surg Obes Relat Dis. 2012;8(1):8–19.
23. Fuks D, Verhaeghe P, Brehant O, et al. Results of laparoscopic sleeve gastrectomy: a prospective study in 135 patients with morbid obesity. Surgery. 2009;145:106–13.
24. Burgos AM, Braghetto I, Csendes A, et al. Gastric leak after laparoscopic-sleeve gastrectomy for obesity. Obes Surg. 2009;19:1672–7.
25. Baker RS, Foote J, Kemmeter P, et al. The science of stapling and leaks. Obes Surg. 2004;14(10):1290–8.
26. Sakran N, Goitein D, Raziel A, et al. Gastric leaks after sleeve gastrectomy: a multicenter experience with 2,834 patients. Surg Endosc. 2013;27:240–5.
27. de Aretxabala X, Leon J, Wiedmaier G, et al. Gastric leak after sleeve gastrectomy: analysis of its management. Obes Surg. 2011;21(8):1232–7.
28. Kizilcik N, Koner O. Magnesium sulfate reduced opioid consumption in obese patients undergoing sleeve gastrectomy: a prospective, randomized clinical trial. Obes Surg. 2018; https://doi.org/10.1007/s11695-018-3243-7.
29. Thorell A, MacCormick AD, Awad S, et al. Guidelines for perioperative care in bariatric surgery: enhanced recovery after surgery (ERAS) society recommendations. World J Surg. 2016;40:2065–83. https://doi.org/10.1007/s00268-016-3492-3.
30. Benevides ML, Oliveira SS, de Aguilar-Nascimento JE. The combination of haloperidol, dexamethasone, and ondansetron for prevention of postoperative nausea and vomiting in laparoscopic sleeve gastrectomy: a randomized double-blind trial. Obes Surg. 2013;23:1389–96.