Evaluating the Impact of Intraoperative Leak Testing on Postoperative Complications in Sleeve Gastrectomy: A Retrospective Comparative Study

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Introduction: During sleeve gastrectomy (SG), intraoperative leak testing (IOLT) is often done to detect problems with the staple lines before the surgery is finished. Despite being widely used, there is still only limited and uneven evidence to support its ability to predict or stop surgical gastric leak (GL).

Aim of work: The aim of this study was to find out if there was a link between IOLT and GL after surgery in people who were having SG.

Patients and methods: This retrospective comparative study was conducted on 400 patients, both sexes, aged 18-65 years, body mass index (BMI ≥ 40 kg/m2) or with obesity-related comorbidities), and Scheduled for SG. Patients were divided into two equal groups: Group I underwent IOLT with SG, while Group II underwent SG without IOLT. Data were collected from surgical databases and medical records.

Results: IOLT was negative in all patients in Group I. No significant differences were found in postoperative leak rates at 2 weeks, 30 days, or 3 months ((1.5% vs 0.5%, 0 vs 0 and 0 vs 0, respectively, $P > 0.05$). IOLT showed 0% sensitivity and 98.5% specificity, with 0% positive predictive value and 100% negative predictive value. No significant differences were observed in operative time, hospital stay, complications, or readmission.

Conclusions: IOLT showed no added benefit in reducing postoperative complications after SG and failed to detect cases of leak, demonstrating zero sensitivity despite high specificity. These findings suggest that routine IOLT offers limited clinical value in SG and may be unnecessary in standard, uncomplicated cases.

Key words: Sleeve gastrectomy, intraoperative leak testing, gastric leak, bariatric surgery, complications.

Introduction

Bariatric surgery (BS) is currently considered the most effective treatment for individuals with severe obesity[1,2] Studies have demonstrated that patients undergoing BS experience significant weight loss and improvement in obesity-related metabolic diseases, like type 2 diabetes mellitus (T2DM), dyslipidaemia, and high blood pressure.[3,4]

Among the various bariatric procedures, sleeve gastrectomy (SG) is currently the most commonly performed. During the surgery, the stomach size is decreased by about 80%, leaving behind a tube-shaped stomach that helps control hunger and decrease appetite.[5] SG is widely accepted as a safe and effective intervention to treat sever obesity and its comorbidities. However, like all surgical procedures, SG carries potential risks, particularly in high-risk patient populations.[6]

one of the most serious complications after SG is gastric leak (GL).[7] even though it doesn't happen very often (1.1% to 5.3% of cases) GL is the second most common cause of death after SG, It has an average mortality rate of about 0.4%.[5]

A mechanical or an ischaemic cause can lead to GL.[8] Incorrect use of stapling device or direct injury to the gastric wal during surgery are examples of mechanical causes. Ischaemia near the gastro-esophageal junction (GEJ) which is a place that may have poor blood supply makes it more possible for leaks to happen.[9] The intragastric pressure can also rise if the distal gastric exit is blocked whether structural or functional.[10]

Gastric leaks (GLs) are associated with serious complications, including sepsis, haemodynamic instability, multi-organ failure, and potentially death. Early evaluation and treatment are critical to improving patient outcomes, but most leaks don't show up until days or weeks after surgery, which makes early diagnosis particularly challenging.[11]

To detect leaks during surgery, many surgeons utilize intraoperative leak testing (IOLT), which typically involves injecting methylene blue dye or insufflating air through a nasogastric tube or an upper gastrointestinal endoscope.[12]

ntraoperative leak testing (IOLT) is a commonly utilized intraoperative measure for the identification of staple line disruptions, leaks, hemorrhage, structural defects, and strictures. A positive test finding enables immediate surgical correction, which may contribute to the prevention of postoperative morbidity.[13] However, the efficacy of intraoperative leak testing (IOLT) in sleeve gastrectomy (SG)

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remains controversial, as current literature provides limited high-quality evidence to support its routine use.[14]

Randomised controlled trials (RCTs) evaluating the effectiveness of intraoperative leak testing (IOLT) are limited due to the high costs and logistical challenges associated with conducting them. This is primarily because gastric leaks are relatively rare postoperative complications. The results of observational studies have been mixed. Some showed that there was no statistically significant link between IOLT and a lower rate of GL,[15,16] while others showed that patients who were getting IOLT were more likely to get GL.[17,18] Furthermore, the role of IOLT in revision bariatric surgery (RBS) remains poorly understood and under-investigated.[19]

Because RBS treatments are being done more often, it's more important than ever to understand how IOLT can be used in this situation.

Aim of work: The aim of this study was to evaluate the association between intraoperative leak testing (IOLT) and the incidence of gastric leak (GL) following sleeve gastrectomy (SG).

Patients and methods

In this retrospective analysis, 400 patients aged between 18 and 65 years—both male and female—with a body mass index (BMI) of 40 kg/m² or higher, or with obesity-related comorbidities, were selected for sleeve gastrectomy (SG). The patients were split into two equal groups. Group I had IOLT with SG, and Group II had SG without IOLT. The operations were done in Mansoura University General Surgery Departments (Group 1) and Mansoura University Gastrointestinal Surgery Center (Group 2).

The research was conducted between January 2016 to December 2024, following the approval from Mansoura University ethical committee (IRB code: R.25.04.3138). The patients provided informed written consent.

Patients were excluded from the study if they had a history of previous bariatric surgeries (e.g., gastric bypass or adjustable gastric banding), severe cardiopulmonary disease, malignancy, or uncontrolled psychiatric disorders. These exclusion criteria aimed to minimize confounding factors and ensure a uniform study population.

Data were collected from hospital records and surgical databases. Variables assessed included patient age, sex, comorbidities, operative duration, intraoperative complications, results of intraoperative leak testing (IOLT) when performed, and the patients' hospital stays, reoperations, and readmission rates after the surgery.

Prior to surgery, all patients underwent preoperative evaluation, including a comprehensive medical history, demographic assessment, and screening for obesity-related comorbidities such as diabetes mellitus, hypertension, and obstructive sleep apnoea (OSA). Routine laboratory investigations were reviewed to assess surgical fitness and identify any clinically significant abnormalities.

Surgical procedure

All of the surgeries were done by general surgery doctors with a lot of experience. All operations were performed by experienced consultants of general surgery. Pneumoperitoneum was done using either the open technique with an optical trocar or the closed technique with a Veress needle, depending on the clinical context. Entry points included the umbilicus or Palmer's point. A five-port laparoscopic technique was used: A 10 mm camera port was inserted left of the midline approximately 20 cm below the xiphisternum; two working ports were placed in the mid-clavicular lines 5 cm below the costal margin on each side; an assistant port was inserted in the left anterior axillary line; and a liver retraction port was positioned in the midline, 2 cm below the xiphisternum.

Any hiatal hernia identified intraoperatively was repaired during the same session. SG was initiated approximately 5 cm from the pylorus using a linear stapler. Bougie size ranged from 36 to 40 French (Fr), selected at the surgeon's discretion. Hemostasis along the staple line was achieved with laparoscopic clips applied to bleeding points.

In Group I patients, intraoperative leak testing (IOLT) was conducted using methylene blue (MB). After completion of the sleeve gastrectomy, 100–150 mL of MB solution was instilled into the gastric sleeve while manual occlusion of the distal duodenum was performed. The presence of dye leakage into the operative field was considered indicative of a positive test. The solution was subsequently aspirated to reduce the risk of contamination

Postoperative management and follow-up

All patients received standard postoperative care, included intravenous fluids, prophylactic antibiotics, analgesia, proton pump inhibitors (PPIs), and low-molecular-weight heparin (LMWH). Patients were discharged between postoperative days 2 and 4, based on criteria including vital stability, oral intake tolerance, mobilization, and adequate pain control with oral medications. Follow-up was conducted at 2 weeks, 30 days, and 3 months postoperatively to monitor for complications.

Outcomes

The primary outcome of the study was the incidence of postoperative complications, specifically gastric leak and bleeding, in patients undergoing SG with or without IOLT. Secondary outcomes included the diagnostic accuracy of IOLT specifically its sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) as well as total operative time and hospital readmission rates.

Sample size calculation

The EpI-Info 2002 statistical package, which was made by the World Health Organisation (WHO) and the Centres for Disease Control and Prevention (CDC), was used to figure out the sample size. The sample size was found by taking into account the following: A previous study,[15] said that the rate of leaks was 8.7%, and the confidence level was set at 95%. To make the estimate more accurate, a ±2.8% confidence limit was added. Because of this, a sample size of about 390 cases was needed. Seven more cases were added to account for possible failure. So, there had to be at least 397 cases.

Statistical analysis

IBM SPSS v27 (Armonk, NY, USA) was used for statistical research. Shapiro-Wilks and histograms were used to check if the data was normal. The mean and standard deviation of the numeric parameters were given, and the single student t-test was used to examine them. Qualitative factors were given as frequency and percentage, and Chi-square or Fisher's exact tests were used to look at them. Statistical methods were used to measure the IOLT's sensitivity and specificity. An important result was a two-tailed P value ≤0.05.

Results

There were no statistically significant differences between the two groups regarding demographic characteristics, comorbidities, or operative duration. All intraoperative leak tests performed in Group I showed negative results **(Table 1).**

The length of hospital stays, diagnosis of postoperative bleeding, complications at follow up at 2 weeks, one month and three months, and readmission were insignificantly different between both groups. No patient in both groups suffered from gastric sleeve stenosis or persistent vomiting during follow up. No patient in both groups suffered from leak at 30 days and 3 months postoperative **(Table 2).**

All patients diagnosed with a gastric leak were identified at or shortly after the 2-week follow-up visit. These patients were readmitted and required further intervention. In Group I, two patients (1%) underwent laparoscopic exploration with drainage and feeding jejunostomy, and one patient (0.5%) received an intragastric stent. One patient in Group II (0.5%) also required intragastric stenting. Postoperative bleeding was diagnosed based on hemodynamic instability, a drop-in hemoglobin levels, and pelvic-abdominal ultrasound findings. Bleeding occurred in four patients: One in Group I and three in Group II. All bleeding events were identified during the initial hospital stay (On postoperative days 1 or 2) and were successfully managed by laparoscopic re-exploration and hemostasis with 98.5% specificity, 0% PPV, 100% NPV, and 98.5% accuracy, the IOLT can't tell if there will be a leak after surgery **(Table 3).**

Table 1: Demographic data, duration of surgery and comorbidities of the studied groups

		Group I (n=200)	Group II (n=200)	P
Age (years)		42.24 ± 12.86	40.97 ± 13.46	0.333
Sex	Male	87 (43.5%)	103 (51.5%)	0.109
	Female	113 (56.5%)	97 (48.5%)	
Weight (kg)		123.97 ± 7.11	125.16 ± 7.47	0.103
Height (cm)		167.45 ± 5.59	168.51 ± 6.22	0.074
BMI (kg/m^2)		44.31 ± 3.25	44.17 ± 3.16	0.671
Duration of surgery (min)		66.93 ± 14.14	64.85 ± 13.77	0.138
Comorbidities	DM	61 (30.5%)	67 (33.5%)	0.520
	Hypertension	74 (37%)	67 (33.5%)	0.464
	Obstructive sleep apnea	23 (11.5%)	28 (14%)	0.454
Positive intraoperative leak test		0 (0%)	---	---

Data presented as mean ± SD or frequency (%). BMI: Body mass index, DM: Diabetes mellitus.

Table 2: Postoperative data of the studied groups

		Group I (n=200)	Group II (n=200)	P
Length of hospital stay (days)		2.11 ± 0.83	2.04 ± 0.83	0.365
Complications	Gastric sleeve stenosis	0 (0%)	0(0%)	1
Follow up of leak	2 weeks postoperative	3 (1.5%)	1 (0.5%)	0.623
	30 days postoperative	0 (0.0%)	0 (0%)	---
	3 months postoperative	0 (0.0%)	0 (0%)	---
Post-operative bleeding		1 (0.5%)	3 (1.5%)	0.623
Readmission		3 (1.5%)	1 (0.5%)	0.623

Data presented as mean ± SD or frequency (%). PONV: Postoperative nausea and vomiting.

Table 3: Role of IOLT in prediction of postoperative leak in group I

		IOLT		
		Yes	No	
Postoperative leak	Yes	0	3	
	No	0	197	
Sensitivity	Specificity	PPV	NPV	Accuracy
0 %	98.5%	0%	100%	98.5%

PPV: Positive predictive value, NPV: Negative predictive value, IOLT: Intraoperative leak testing.

Discussion

The main findings of this study indicate that IOLT failed to predict any postoperative leaks, showing a specificity of 98.5%, sensitivity 0%, PPV of 0%, NPV of 100%, and an overall accuracy of 98.5%. Demographic characteristics, operative duration, and comorbidity profiles were comparable between the SG with IOLT group and the SG without IOLT group. All IOLT results in the SG with IOLT group were negative. Postoperative outcomes, including duration of hospital stay, complication rates, leak incidence at the 2-week follow-up, in-hospital bleeding, and readmission rates, did not differ significantly between the two groups. No patients in either group developed gastric sleeve stenosis or experienced leaks at the 30-day or 3-month follow-ups. Postoperative interventions included laparoscopic exploration with drainage and feeding jejunostomy in 2 (1%) patients from the SG with IOLT group and endoscopic stenting in 1 (0.5%) patient in each group.

In agreement with our observations, Mayir,[20] conducted a cross-sectional comparative study in Turkey with 452 patients equally undergoing SG, with IOLT (MB test) and without. He reported an overall leakage rate of 1.6%. In the IOLT group, sensitivity and PPV were 0%, while NPV was 99.1%, leading him to conclude the routine use of IOLT did not reduce the incidence of postoperative leak.

A recent meta-analysis by Ma et al,[21] which included six studies encompassing a total of 469,588 patients, compared outcomes of sleeve gastrectomy (SG) performed with and without intraoperative leak testing (IOLT). The analysis revealed a significantly higher staple line leak rate in the IOLT group (0.38%) compared to the non-IOLT group (0.31%), with an odds ratio (OR) of 1.27 (95% CI: 1.14–1.42; P < 0.001). Conversely, the incidence of postoperative bleeding was lower in the IOLT group (OR = 0.79, 95% CI: 0.72–0.87; P < 0.001). These findings may reflect the influence of the meta-analysis's large pooled sample size and heterogeneous, multi-center design, which likely captured subtle differences not evident in individual studies.

Similarly, Yolsuriyanwong et al.[22] analyzed data from 265,309 bariatric surgery cases and found that intraoperative leak testing (IOLT), which was performed in 81.9% of procedures, had no significant impact on leak rates or hospital readmissions. Neither endoscopic nor non-endoscopic forms of IOLT were associated with a reduction in postoperative leaks. However, their analysis encompassed multiple types of bariatric procedures beyond sleeve gastrectomy, which may limit the applicability of their findings to SG specifically.

Aligning with our findings, Sethi and colleagues,[23] evaluated IOLT methods and reported the same postoperative leak rates (1%) between patients who underwent MB testing via naso/orogastric tube and those who received endoscopic air leak testing.

Liu et al.[24] analyzed data from 237,081 patients in the MBSAQIP database and reported that intraoperative leak testing (IOLT) was associated with a higher incidence of postoperative leak following sleeve gastrectomy (SG) (OR = 1.48) and a lower incidence of postoperative bleeding (OR = 0.76). Readmission rates were not significantly affected by the use of IOLT. These findings are consistent with our study regarding leak and readmission outcomes, as IOLT did not confer any benefit in reducing leak rates or readmissions. However, their observation of reduced bleeding contrasts with our results, which showed no statistically significant difference in bleeding between groups. This discrepancy may be attributed to the substantially larger sample size in their study, which likely allowed for the detection of small effect sizes not evident in our moderate-sized cohort.

Mangelli et al.[25] evaluated the use of indocyanine green (ICG) fluorescence angiography during revisional bariatric surgery and found that it did not lead to changes in intraoperative decision-making. There were no significant differences in postoperative complications, operative time, or length of hospital stay between the ICG and control groups. Consistent with our findings, their results suggest that intraoperative assessment tools have limited clinical utility in influencing surgical outcomes. However, a key distinction lies in the nature of the test and surgical setting: their study assessed vascular perfusion using ICG in revisional procedures, whereas our study focused on staple line integrity using IOLT in primary SG. This may explain the shared lack of clinical benefit, as ICG may fail to detect microvascular ischemia, while IOLT has limited sensitivity for identifying subclinical or ischemia-related leaks

Regarding the limitations of this study, this study was retrospective in nature, which may introduce selection and information biases. The low incidence of GL limited the ability to detect statistically significant differences between groups. Additionally, variability in surgical technique, including bougie size and surgeon experience, was not standardized or controlled. The reliance on MB alone as the IOLT method may also limit generalizability to other testing modalities. The study lacked randomization, which may have introduced selection bias and unequal distribution of confounding factors between groups. Moreover, the absence of blinding could have led to observer or performance bias in reporting postoperative outcomes.

Conclusion

IOLT showed no added benefit in reducing postoperative complications after SG and failed to detect cases of leak, demonstrating zero sensitivity despite high specificity. These findings suggest that routine IOLT offers limited clinical value in SG and may be unnecessary in standard, uncomplicated cases.

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