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Frequency of Leakage after Surgery Following Leak Test during Laparoscopic Sleeve Gastrectomy

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Abstract **Original Research Article**

***Background*:** Leakage after laparoscopic sleeve gastrectomy is a serious hazard, recorded in 0-8% of patients. Leak test during surgery with methylene blue seeks to decrease postsurgical leakage. ***Aim*:** To evaluate the effect of MB leak test to recognize leakage following LSG. ***Methods*:** Our prospective, double-blinded, randomized investigation enrolled 400 participants, aged 27-39 years, of both sexes, with BMI of 38-46 kg/m^2, scheduled for LSG in Jordan during the period Jan 2021-Jan 2022. Participants were randomly divided into Group A (n=200) without LTDS, and group B (n=200) with MB LTDS. Group B participants had pylorus laparoscopically closed with a bowel clamp, and the stomach was filled with 50 ml of MB, administered via the orogastric bougie. Postsurgical leakage for both groups was determined by the presence of MB at staple line during surgery, radiologically spotted with contrasting extravasation from the staple line after surgery, and the presence of saliva in the drain. Categorical parameters between groups were analyzed using Pearson's Chi-square test, and discrepancies between groups in non-normally continuous parameters were analyzed using the Mann-Whitney U-test. ***Results*:** The groups had the same leakage frequency (1.5%, P>0.05). Group A had leakage in 3 participants (1.5%) in the fundus; Group B had leakage in 3 participants (1.5%) in the fundus (n=1) and antrum (n=2). ***Conclusion*:** The use of LTDS did not decrease the frequency of postsurgical leakage, undermining universal applicability.

Keywords: Laparoscopic sleeve gastrectomy, surgery leak test, Stapler leakage.

INTRODUCTION

More bariatric surgery procedures are being performed worldwide due to universally increasing rates of obesity. There are various bariatric surgical techniques, of which the most frequent is sleeve gastrectomy, a restrictive technique that is efficient in the management of obesity and obesity-correlated co-diseases [1]. However, sleeve gastrectomy surgery is associated with numerous technical problems and risks, including hazardous postsurgical leakage, for which leak test during surgery (LTDS) offers a problematic potential solution to enable earlier (potentially instant) and more effective leakage management. There is no standard protocol for the use of LTDS, the type of test, or the timing of the test. The use of LTDS in colorectal surgery and gastric bypass is known to be efficient, but this has not been demonstrated in the case of sleeve gastrectomy [2]. Consequently, this study aims to evaluate the effect of leak test using methylene blue (MB) to recognize leakage following laparoscopic sleeve gastrectomy (LSG).

METHODS

This prospective, double-blinded, randomized investigation enrolled 400 participants, aged 27-39 years, of both sexes, with BMI of 38-46 kg/m^2, scheduled for LSG at King Hussein Hospital, King Hussein Medical City, Amman, Jordan, during the period Jan 2021-Jan 2022. Fieldwork was conducted after obtaining written informed consent from all participants and approval from our local ethical and research board, the Review Committee of the Jordanian Royal Medical Services. Participants with re-sleeve gastrectomy were ruled out.

Participants were randomly divided into two groups. Group A (n=200) did not receive LTDS, while Group B participants (n=200) had MB LTDS. Leakage after surgery was assessed between both groups. All participants had LSG using the same operative method. Following insertion of 38French gastric calibration bougie, the staplers were located 1 - 2 cm from the

calibration bougie in the direction of the gastroesophageal junction. Bleeding points were secured using 10 mm endoclips. For participants in Group B, the pylorus was laparoscopically closed with a bowel clamp, and the stomach was filled with 50 ml of MB, administered via the orogastric bougie, and the leak from the staple line was studied. The drain was located next to the staple line in both groups. Radiological or CT scans after surgery for spotting of leak were not used in all patients. A clear liquid diet was initiated for all subjects on day one after surgery. The drains were discontinued on day 3 after surgery, and follow-up was performed on day 7, and on 1 and 6 months after surgery.

The primary outcome was postsurgical leakage. The presence of MB at staple line during surgery, radiologically spotted contrast extravasation from staple line after surgery, and presence of saliva in the drain were labelled as leaks. Categorical parameters between groups were analyzed using the Pearson's Chi-square test. Discrepancies between groups in non-normally continuous parameters were analyzed using the Mann-Whitney U-test. A P-value of less than 0.05 was considered statistically significant.

RESULTS

Group A included 160 (80%) women and 40 (20%) men; Group B included 155 (77.5) women and 45 (22.5%) men. There were no differences between the two groups regarding the characteristics of the participants (Table I). In group A, leakage after surgery was recorded in 3 (1.5%) patients. All leakages were in the fundus. Leakage was reported after surgery on day 7 and 25. In group B, leakage after surgery was found in 3 (1.5%) patients at day 3 after surgery. One leakage was in the fundus, and the others were in the antrum. The leakage frequency was the same between the two groups (P>0.05) (Table II).

Table I: Participant characteristics

	GA	GB	P
No.	200	200	
Age (yrs.) mean	29.5 (27-32)	34 (29-39)	0.341
Gender (No., %) F M	 160(80) 40(20)	 155(75.5) 45(22.5)	0.513
BMI (kg/m^2) mean	40 (38-42)	41 (36-46)	0.311

Table II: Effect of leak test during surgery to anticipate leakage after surgery

		Leakage after surgery		Overall
		+ ve	-ve	
Leak test	+VE	0	0	0
During surgery	-VE	3	197	200
Overall		3	197	200

DISCUSSION

Leakage after LSG is recorded in 0-8% of patients, causing lengthened admission, infection, long standing fistula, multi-organ failure [3]. To decrease the frequency of leakage after surgery, LTDS can be undertaken with MB, or by air insufflation [4]. Most leakages are reported days following operation, as in this investigation [2]. LTDS is not efficient for spotting of leakage occurring days following operation. LTDS is handful for spotting of leakages because of defects in operative techniques.

In LSG, the complete stapler line made by linear staplers and the anterior or posterior stapler lines may be assessed optically. Gastrojejunostomy in Roux-en-Y gastric bypass, colonic anastomosis, or esophagojejunostomy are made by circular stapler, and the posterior part of anastomosis might not be assessed optically. LTDS is helpful for assessing the posterior part of anastomosis for leakage [5]. Leak test during LSG might not attain any extra data if the stapler line is optically strong, and it must not be done always but for chosen patients. Indeed, there is no agreement for the use of LTDS in LSG [6]. In 2012, the International Sleeve Gastrectomy Expert Panel Consensus Statement did not give a final recommendation for LTDS, but 48% of the participants advised the use of LTDS [6].

In this investigation, there were two patients with leakages, but there was no positive LTDS for 226 patients. There was no leakage during surgery, but leakage was recorded in 15 patients after surgery and despite leakage, LTDS was negative at re-surgery of two patients [7]. Leakage was found in 3 of 224 patients assigned for LSG, but none of them experienced leakage during LTDS [8]. LTDS did not influence leakage spotting percentage [9].

LTDS with MB could have some negative effects, including induced leakage, whereby inflating the stomach with MB can induce tension in the new staple line, disturb healing, and increase leakage [10]. LTDS increases surgical duration and the cost of

surgical operations, and MB might lead to anaphylaxis [11-13].

CONCLUSION

LTDS is not correlated with reduction in the frequency of leakage following LSG. Leakage during surgery was not reported in any patient with LTDS using MB; but leakage was spotted later after surgery. LTDS should not be a standard treatment, although it may be advisable for particular patients. The most important limitation of this study was that minor leakage of no clinical importance was not considered.

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