



Randomised Controlled Trial

Cruroplasty added to laparoscopic sleeve gastrectomy; does it decrease postoperative incidence of de-novo acid reflux?: A randomised controlled trial

Masoud Sayadi Shahraki^a, Mohsen Mahmoudieh Dehkordi^a, Mahmoud Heydari^{a,*}, Shahab Shahabi Shahmiri^a, Maryam Soheilipour^b, Abbas Hajian^c

^a Department of General Surgery, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran

^b Department of Gastroenterology and Hepatology, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran

^c Department of General Surgery, School of Medicine, Kashan University of Medical Sciences, Kashan, Iran



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ABSTRACT

Background: Laparoscopic sleeve gastrectomy (LSG) is the most popular bariatric surgery worldwide. Postoperative de-novo acid reflux is one of the major common complications of the procedure. Different additive anti-reflux surgical techniques have been tried to decrease the complication although no favorable outcome is obtained. This study was conducted to evaluate effects of concurrent cruroplasty during LSG on postoperative de-novo acid reflux incidence rate.

Methods: In current participant-blinded randomised controlled trial total of 80 subjects who were candidate for LSG were enrolled from the September 2018 to the December 2019. Following matching patients by gender and age, simple randomization method was held to allocate participants to LSG alone and LSG + cruroplasty groups with equal 40 members in each. Demographic data, length of hospital stay, and operation time was registered. Presence of acid reflux was looked by using gastroesophageal reflux disease-health related quality of life (GERD-HRQL) questionnaire prior and 6 months after surgery in follow-up visit.

Results: Finally 12/28 and 14/26 male/females with 38.5 ± 10.7 and 39.7 ± 8.2 years of age were recruited in LSG alone and LSG + cruroplasty, respectively. ($p > 0.05$) The length of operative time was significantly shorter in LSG alone ($p < 0.01$) although no obvious difference was existed in length of hospital stay between groups. ($p = 0.7$) Postoperative de-novo acid reflux also was not considerably lesser after cruroplasty compared with controls. ($p = 0.1$) The GERD-HRQL scores were not remarkable between subjects of study groups. ($p > 0.05$).

Conclusion: Equipping LSG with concurrent cruroplasty to diminish postoperative de-novo gastroesophageal acid reflux is not effective and not recommended in absence of other indications.

1. Introduction

In 2008, the World Health Organization (WHO) represented in its report that about 1.5 and 0.5 billion of 20 years or older people worldwide suffered from overweighting (body mass index (BMI) ≥ 25 and < 30 kg/m²) and obesity (BMI ≥ 30 kg/m²) respectively [1]. The WHO has estimated that by the year 2045 the number of overweight and obese people will reach to 2.3 and 0.7 billion respectively [2]. A doubled increase in prevalence of whether being overweight or obese has globally occurred since 1980. Namely today near one third of the world general

population is considered as whether overweight or obese. Iran was not excepted from the latter issue and national evaluations have showed a relatively rapid increase in obesity among both genders recently [3]. Following to increase in obesity bariatric surgery performance rate and most commonly laparoscopic sleeve gastrectomy (LSG) has extended in parallel [4]. As for any other surgical procedure LSG isn't an exception for postoperative complication. Bleeding, anastomosis leakage, infection, dyspepsia, bile and/or acid reflux are some examples that occasionally need reoperation to fix the problem [4,5]. Although evidences implied on that LSG could improve, exacerbate, or be neutral on

* Corresponding author. Department of General Surgery, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran.

E-mail addresses: Drsayadi@yahoo.com (M.S. Shahraki), Mahmoudieh46@gmail.com (M.M. Dehkordi), Dr.m.heydari1365@gmail.com (M. Heydari), Shshahabi@yahoo.com (S.S. Shahmiri), M_soheilip@yahoo.com (M. Soheilipour), Abbashajian@ymail.com (A. Hajian).

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preoperatively confirmed acid reflux in 10, 40, and 50% of candidates it could be unfortunately a reason for postoperative de-novo gastroesophageal reflux disease (GERD) in 30–40% of patients [6,7]. Therefore case selection for LSG operation is fundamental and the procedure regarding to some authors' opinion is contraindicated for obese patients with preoperatively established reflux disease [7]. To prevent postoperative de-novo generation of GERD after LSG several surgical methods have been presented. Cruroplasty or cardiac reconstruction is one of these techniques that considered to be preventive whether from generation or exacerbation of postoperative GERD [8,9]. The method is concentrated on reinforcement of diaphragmatic crura by using surgical stich to make the diaphragmatic esophageal ring enough narrow which expected to prevent reflux at the level of the lower esophageal sphincter (LES). Nonetheless findings following cruroplasty for GERD prevention are varied. Although some authors considered no advantage for the technique in preventing postoperative GERD the other showed cruroplasty was even effective in long-term when an absorbable synthetic mesh was also loaded [10,11].

Considering above, current study was designed in a controlled trial method to evaluate that if cruroplasty concurrent with LSG is preventive for postoperative de-novo GERD or not?

2. Materials and method

Ethical committee approval to perform current randomised participant-blinded controlled clinical trial study was obtained from the University of Medical Sciences with reference code IR.MUI.MED.REC.1399.037 and with clinical trial registration code IRCT201807131102N4 which is available at www.irct.ir. Data was extracted from the September 2018 to the December 2019. Consent written form was signed by every participant. Obese patient with $35 \leq \text{BMI} < 50 \text{ kg/m}^2$ who was between 18 and 60 years of age was included. Positive history of whether current or in recent 6 months of GERD, pregnancy for females, chronic disease under treatment like hypertension, diabetes mellitus, lung, heart, thyroid or inflammatory disease, confirmed psychiatric disorder, regular consumption of medications specially corticosteroids, NSAIDs, H2 blockers, and proton pump inhibitors, alcohol drink, smoking, and being candidate for any other concurrent operation were exclusion criteria. Demographic data including gender, age, weight, height, BMI, and race were recorded in primary visit by a senior resident of surgery.

To discover reflux disorder without imposing patient to upper esophageal endoscopy or LES pH-metry procedure, gastroesophageal reflux disease-health related quality of life (GERD-HRQL) questionnaire was used [12,13]. The Persian-translated version of this subjective questionnaire based on Likert's scoring system was previously assigned valid and reliable. It consists of 12 questions searching for symptoms of retrosternal heartburn, swallowing dysfunction, and sour taste feeling relative to GERD (regurgitation) [14]. Each question could score from zero to 5 and a completely filled questionnaire scores 0–60. The greater the final score resembles for the presence of more severe reflux disorder. If patient scored from GERD-HRQL equal or greater than 24 in first visit he/she then was excluded from the study because of presence of preoperative reflux disorder.

Because no other local study with identical topic was found, we needed at least 30 participants for the study. According to the study criteria 80 eligible patients through a stratified four blocks randomization based on participants' age and gender were allocated in to two groups; LSG alone and LSG plus cruroplasty. Patients then were allocated to two groups each contained equal 40 members by a computer analytic software. Participants were blind to their groups. Preoperative patient's preparation was in lined with current scientific instructions and included biochemical measurement, anesthesiologist, gastroenterologist, and psychiatrist consults. If any remarkable finding was appeared patient then was excluded from trial. It should be mentioned that either medical or surgical team members were common for every

patient in whole study time. Surgical team was consisted of an attending professor, two fellow of laparoscopy, one senior resident of surgery, and one technician aid.

In operating room, after induction of general anesthesia, in suitable reverse Trendelenberg's position, the closed method for inserting the first of five laparoscopic trocars by using the Veress' needle (150 mm) was applied. Intra-abdominal pressure with carbon dioxide inflation remained between 13 and 15 mmHg during surgery. Sleeve gastrectomy was initiated for all patients through omentolysis in greater curvature of stomach (2–4 cm proximal to pylorus) toward the adjacent site of the angle of the His, continued with resection parallel to greater curvature border to near abdominal esophagogastric junction (1–2 cm distal to LES) under guidance of 36 Fr inserted bougie, and completed by making a new stomach with estimated 15–20 cc volume using EndoGIA™ stapler (3–4 mm, Covidien, Medtronic Co, USA). Stapling line was reinforced with hand sutures using 2.0 Prolene (Kollcut, USA) thread. The operation was as mentioned above for all participants. For patients in LSG plus cruroplasty group additional procedure was performed as cruroplasty. For the latter bilateral diaphragmatic crura were explored following by insertion of a 56 Fr intra-esophageal bougie, and making a figure of 8 surgical stich with hand to approximate crura and narrow esophageal ring of diaphragm.

After the surgery was accomplished, patient was referred to the surgical ward and underwent intravenous pantoprazole 40 mg every 24 hours during admission. Following to successful oral intake and favorable mobilization he/she discharged with tablet of pantoprazole 40 mg to use every 12 hours for next 2 months. Either the operation or the hospital admission time was recorded. Postoperative follow up visits were performed in 2 and 6 months after surgery respectively. To evaluate de-novo reflux disorder history and physical exam were taken and the GERD-HRQL questionnaire also was filled in 6 months follow up session. All study data was reported in lined with the CONSORT criteria [15].

Statistical analysis was performed under the SPSS version 21. Parametric factors were addressed by mean and standard deviation. Non-parametric variables were presented by numbers and percent. To compare means the independent t, paired t-test, and the ANOVA were used. Analysis of parametric variables was performed through the chi-squared exam. Significant level of analysis was considered as the $p < 0.05$.

3. Results

Total 12/28 and 14/26 male/females ($p = 0.4$) with mean age of 38.5 ± 10.7 and 39.7 ± 8.2 ($p = 0.5$) years were recruited in LSG alone and LSG plus cruroplasty respectively. All of patients had similar race, therefore the variable was omitted from analysis. Table 1 shows preoperative demographic data and GERD-HRQL questionnaire scores of

Table 1
Preoperative demographic data and GERD-HRQL questionnaire results of study.

Variable	Unit	LSG [1](n = 40)	LSG + C [2](n = 40)	p	
Gender	male	N(%)	12(30)	14(35)	0.4
	female		28(70)	26(65)	
Age	years		38.5 ± 10.7^9	39.7 ± 8.2	0.5
Weight	kg		114.1 ± 20.0	112.2 ± 14.1	0.6
BMI ³	kg.m ⁻²		43.5 ± 3.8	42.7 ± 3.0	0.3
EWG [4]	kg		73.7 ± 2.4	74.2 ± 2.1	0.3
GERD-HRQL [5]	Total	N	1.1 ± 1.0	1.4 ± 1.3	0.2
	HB [6]		0.6 ± 0.4	0.7 ± 0.6	0.4
	SD [7]		0.3 ± 0.3	0.4 ± 0.4	0.5
	RE [8]		0.2 ± 0.3	0.3 ± 0.3	0.3

1 Laparoscopic sleeve gastrectomy 2 Cruroplasty 3 Body mass index 4 Excess weight gain 5 Gastroesophageal reflux disease-health related quality of life 6 Heartburn 7 Swallowing dysfunction 8 Regurgitation 9 mean \pm SD.

study subjects.

According to Table 1, no significant difference was obtained considering table variables. Operation was performed according to study design for each patient and accomplished with no acute intra-operative complication and no need to change laparoscopy to open surgery. There were three patients in LSG plus cruroplasty group that had mild to moderate hiatal hernia which was not diagnosed preoperatively. For those cruroplasty was performed following hernia reduction. Postoperative follow up was initiated from the hospital and elongated for 6 months. One of patients in LSG alone group faced with disturbing acid reflux which was intractable to medication, needed reoperation and therefore omitted from the study. Table 2 illustrates study findings during postoperative time.

Considering Table 2 there was no obvious difference between types of surgery and postoperative amount of weight loss, BMI, length of hospital stay, and GERD-HRQL score after 6 months of operating time. Namely, adding cruroplasty to basic LSG didn't influence on incidence of postoperative de-novo reflux disorder. However, adding cruroplasty to previously performed LSG led to increase in mean of operating time significantly ($p < 0.01$).

Paired analysis showed significant postoperative decrease in weight ($p < 0.01$) and BMI ($p < 0.01$) for every participant although GERD-HRQL score didn't manifest remarkable change between groups. ($p = 0.5$ and 0.3 for LSG alone and LSG plus cruroplasty groups, respectively).

Postoperative complications through 6 months follow up period including of bleeding, anastomosis leakage, infection, dysphagia, and death were unremarkable to report.

4. Discussion

Bariatric surgery and most commonly the LSG operation concurrent to obesity extension have increased worldwide recently [1–3]. Like every other surgical procedure LSG isn't an exception for postoperative complication. De-novo reflux disorder after LSG is one of its common, disturbing, and hazardous side effects because of the following association to esophageal malignant degeneration [4–6]. Therefore reoperation after LSG procedure is occasionally indicated if risk of chronic reflux remains. Prior researches have tried to find whether medical or surgical novel methods to conclude in reflux prevention or cessation. Despite, the incidence rate of de-novo reflux generation after LSG is still high and reaches to 30–40% among patients [7]. Hence it is important for either physician or patient to make solution for the problem. Current study was designed to investigate effects of adding concurrent cruroplasty to basic performed sleeve gastrectomy. For the latter through this participant-blind control trial study patients randomly underwent LSG alone or LSG plus cruroplasty in which after sleeve gastrectomy reinforcement of diaphragmatic crura was developed and patient then was

followed for outcomes in a 6 months period. Finally study showed except for increasing in time of operation, cruroplasty had otherwise no further whether benefit or disadvantage during the study time. In lined with our findings, other author said adding cruroplasty to LSG made no significant superiority compared to LSG alone considering de-novo reflux disorder [16]. Other author showed that either LSG conducted alone or equipped with cruroplasty postoperative de-novo GERD was identical [17]. Opponents claimed that cruroplasty recovered GER symptoms in one third after operation although it was a trigger for generation of de-novo reflux postoperatively in over 15% of patients [18]. A systematic review in 2015 was implied on that the LSG could be a risk for whether reflux exacerbation or de-novo reflux generation. Although it has introduced cruroplasty might be preventive for GERD it didn't recommend adding the procedure to LSG [19]. Another novel review study which involved a great number of studies considered that cruroplasty might help prevention of de-novo reflux disorder although author was not clearly advised to set up the procedure with LSG [20]. Another study represented that inhibitory role of cruroplasty for de-novo GERD demonstrated at least after 12 months of surgery [21]. Diversity in findings could be due to several reasons including sample size and characteristics, presence of other simultaneous organ and field of surgery disorder like hiatal hernia, selected procedural technique details, expertise of surgical team, time of follow up, and also applied approach for diagnosis of GERD. Considering the latter, we used GERD-HRQL questionnaire while there also were more accurate approaches including direct upper gastroesophageal endoscopy or pH-metry at the level of LES. Since quality of the mentioned questionnaire was approved in other studies, we considered it for our patients to lessen medical expense [12–14]. Though the questionnaire was used previously in an identical study. The author manifested postoperative symptoms of basic GERD obviously improved after adding cruroplasty to LSG [22].

Although this study didn't support from additive cruroplasty to LSG for inhibiting de-novo reflux presentation postoperatively it seems even comprehensive reviews also didn't conclude in general consensus on cruroplasty approach as an inseparable component for LSG operation. However concentration to details of surgery, patients' characteristics, and follow up interval should be considered in further future studies to make a more clear answer for the study question. We highly recommend performing such studies.

4.1. Limitations

This study was conducted in a referral single medical center under observation of University of Medical Sciences. Sample size was not large enough and follow up period was limited to 6 months after surgery. Diagnostic approach for GERD was not objective and it was established by a questionnaire score although the quality of the latter was confirmed and it was used in an identical study previously.

5. Conclusion

Concurrent laparoscopic cruroplasty added to sleeve gastrectomy should not be expected to be preventive for postoperative de-novo gastroesophageal reflux generation. Although performing the procedure elongates operative time otherwise it is neither beneficial nor threatening for other postoperative factors including the length of hospital stay, complications, and de-novo reflux disorder. Therefore considering additional cruroplasty in absence of any clinical indication is not recommended during LSG operation.

Ethics approval and consent to participate

This study was performed under supervision of Isfahan University of Medical Sciences with reference code IR.MUI.MED.REC.1399.037 and with clinical trial registration code IRCT201807131102N4.

Table 2
Patients' postoperative data regarding study groups.

Variable	Unit	LSG [1](n = 39)	LSG + C [2](n = 40)	p
Weight	kg	80.7±12.5 ⁹	77.8 ± 10.4	0.2
BMI [3]	Kg. m ⁻²	30.8 ± 2.1	29.6 ± 2.3	0.09
Operation time	minute	73.7 ± 12.0	90.7 ± 13.7	<0.01
EWL [4]	%	64.8 ± 2.7	62.9 ± 3.6	0.8
Admission length	day	3.1 ± 0.5	3.1 ± 0.7	0.7
GERD-HRQL [5]	Total	1.4 ± 2.2	1.0 ± 1.0	0.1
	HB [6]	1.1 ± 1.5	0.7 ± 0.6	0.5
	SD [7]	0.2 ± 0.5	0.2 ± 0.3	0.3
	RE [8]	0.1 ± 0.2	0.1 ± 0.1	0.4

1 Laparoscopic sleeve gastrectomy 2 Cruroplasty 3 Body mass index 4 Excess weight loss 5 Gastroesophageal reflux disease-health related quality of life 6 Heartburn 7 Swallowing dysfunction 8 Regurgitation 9 mean ± SD.

Consent for publication

Informed consent was obtained from all individual participants for using their medical data in this study.

Availability of data and material

The surgical data used to support findings of this study is available in medical file archive unit of University of Medical Sciences, Isfahan, Iran.

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This study was conducted under order and supervision of Isfahan University of Medical Sciences and all advantages referred back to this university.

Author contribution

Masoud Sayadi Shahraki: study design, supervision, data collection, interpret results Mohsen Mahmoudieh Dehkordi: study design, supervision, data collection, interpret results Mahmoud Heydari: study design, data collection, data analysis Shahab Shahabi Shahmiri: study design, data collection, data analysis, Maryam Soheilipour: study design, supervision, data collection, GI consult, Abbas Hajian: Study design, interpret results, article draft.

Registration of research studies

This study was conducted under supervision of the Isfahan University of Medical Sciences.

Guarantor

Abbas Hajian.

Declaration of competing interest

The authors declared that they have no competing interests.

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