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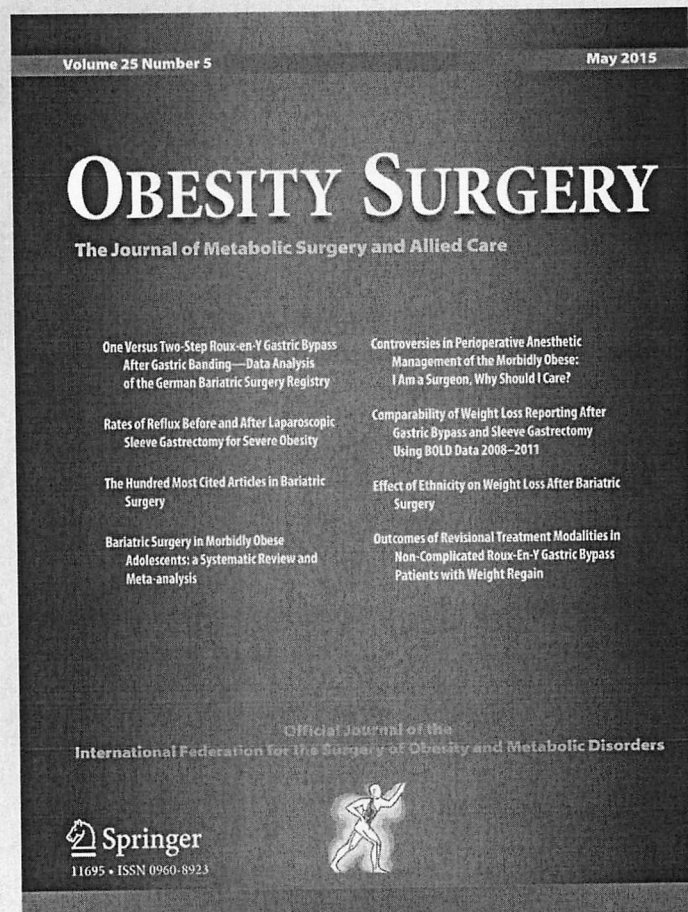
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Abstract

Background Currently, there is a debate whether the laparoscopic gastric imbrication (LGI) offers similar weight loss when compared to the laparoscopic sleeve gastrectomy (LSG). On the surface, they seem to offer similar-sized stomachs after the procedures are performed. We chose to perform a randomized double-blinded trial to see if similar-sized pouches result in similar types of weight loss. Our belief was that sleeve gastrectomy would offer at least a 10 % better weight loss over a 3-year period.

Methods Thirty patients were randomized to one of two arms. The patients and the third party administrator following the patients were blinded as to which procedure was chosen. The surgeon had full knowledge of the patients' surgery throughout the treatment. The decision of which arm to place them was made by a single employee of the third party administrator and not shared with the employees following the patients. Patients were then followed for 3 years.

Results There were no differences in weight, age, or BMI preoperatively. There were no differences between the two groups at any follow-up time point from 6 months to 3 years. Follow-up was 100 %.

Conclusion Due to the large standard deviations present in both groups, there was no statistical difference between either of the groups in terms of weight loss.

Keywords Sleeve gastrectomy · Gastric imbrication · Weight loss surgery · Randomized trial

Introduction

Recently, the laparoscopic gastric imbrication (LGI) has been gaining prominence around the world as an operation that is simple to understand and inexpensive to perform. Yet, its acceptance as a bariatric surgical treatment of choice has been hampered by the lack of comparative trials between it and the standard bariatric surgical treatments. We believe that the laparoscopic sleeve gastrectomy (LSG) is the most similar to the LGI in its restrictive function. Therefore, we elected to perform a randomized double-blinded trial of LGI compared to the LSG laparoscopic sleeve gastrectomy for weight loss outcomes in single surgical center with Indian patients believing that the sleeve gastrectomy would add at least 10 % better EWL over a 3-year period.

Methods

This trial is an individually randomized two-group parallel trial with 30 patients randomized equally to one of two arms. The recruited patients all needed to meet the NIH criteria for bariatric surgery (BMI over 40 or greater than 35 with at least one comorbidity). Patients were only excluded if they planned

All works and patients recruitment were done in Ahmedabad, India.

S. Sharma
Department of Surgery, University of Florida Health at Jacksonville,
655 West 8th Street, Jacksonville, FL 32209, USA
e-mail: Sunil.Sharma@jax.ufl.edu

M. Narwaria
Asian Bariatrics & Cosmetics, Silver Point, Patel Park Society,
Navarangpura, Ahmedabad 380009, India
e-mail: Narwaria@yahoo.com

D. R. Cottam (✉) · S. Cottam
Bariatric Medicine Institute, 1046 East First South, Salt Lake City,
UT 84102, USA
e-mail: drdanielcottam@yahoo.com

S. Cottam
e-mail: samuelcottam@yahoo.com

on becoming pregnant within the 3-year time period that the patients were to be followed. There were no changes to the protocol for the duration of the study.

Patients were recruited after an IRB was submitted and approved by IBIOME Independent Ethics Committee (B501, Krishna Complex, Opp. Devashish School, Nr. Rajpath Club, S. G. Highway, Ahmedabd -380 054, Gujarat, India, tel. no. +91 79 4005; ibiomeiec@gmail.com. It is a registered company with office for Human Research Protections, US Dept. of Health and Human Services). All participants were patients of the ASIAN Surgical Center, Ahmedabad, India.

Informed consent was obtained from all individual participants included in the study, and it involved a written and oral presentation to each participant of the risk and benefits of LGI and LSG. Each patient had ample time to reflect on their decision prior to signing the informed consent. Patients were not required to pay for the LGI or the LSG or the complication of the LGI or LSG.

Our technique of LSG is one that has not been previously published by our group. Briefly, we use a four-trocar technique (three fives and one 12 mm trocar) to enter the abdomen and perform the LSG. Then the surgeon divides the vasculature between the gastric omentum and the greater curve of the stomach using a harmonic scalpel (Ethicon Endo-Surgery, Inc., Cincinnati, OH, USA). Then a 40-French bougie is placed in the mobilized stomach down to the antrum. A GIA stapler (Covidian, Mansfield, MA, USA) is fired along the bougie from 4 cm from the pylorus up to the angle of His. No buttressing or oversewing of the staple line is performed. The specimen is removed by removing the 12-mm trocar, dilating the tract, and grasping the specimen with a Kocher clamp and gently extracting it. An EGD was performed at the end of the case checking for bleeding, and an air leak test was performed checking for leaks.

The LGI was performed by using the same four-trocar technique as the LSG. Then the attachments and vasculature between the gastric omentum and the greater curve of the stomach are taken down using a harmonic scalpel. Then instead of transecting the greater curve of the stomach, we placed interrupted sutures along the greater curve of the stomach invaginating the greater curve using an endostitch suturing device (Covidian, Mansfield MA, USA) using a 2-0 Surgidac. The invagination was started 4 cm from the pylorus and done every 4 cm until the angle of HIS was reached. Next a running suture of 2-0 surgidac was started near the angle of HIS and the greater curve was further invaginated until the point 4 cm from the pylorus was reached. This gave the appearance of sleeve gastrectomy without any of the greater curve being resected. An EGD was performed at the end of the case checking for bleeding, and an air leak test was performed checking for leaks. All sutures were extramucosal.

The volume of the imbricated or sleeved stomach was checked for size after the surgeries were complete. This was done via the endoflip device (Croson Inc., Ireland) and measured between 18 and 25 cc. The endoflip device is a 20-cm-long balloon with bioimpedance markers every 1 cm. The balloon is pulled up to the hiatus, and it extends beyond the angularis incisura. The device then calculates the size by a predetermined algorithm.

Post operatively, all patients were treated the same and admitted to the ASIAN Surgical Center in Ahmadabad, India. Each group received Zofran 4 mg and Decadron 4 mg IV following surgery. They then received Zofran 4 mg or Phenergan 25 mg IV q6 prn for nausea or vomiting. The first day diet was clear liquids, and this was advanced as tolerated to full liquids. Patients were to remain on full liquids for 2 weeks and then soft food for 2 weeks and then regular diet from that point on. All patients received the same instruction on postoperative dietary guidance with special counsel to avoid refined food and sugary drinks. Patients were not discharged until they could tolerate liquids.

Follow-up time schedules were the same for each group. Each patient followed up at 1 week, 1 month, 3 months, 6 months, 9 months, and then yearly to 3 years. The primary outcome measure done at each time point for this study was weight loss.

At the end of the first year, the patients and the third party employee following the study patients were unblinded to the surgery that they had. The patient was given the opportunity to change from the LGI to the LSG if they so choose at the 1-year time point without having to pay for the second surgery or the complication of the second surgery if they happened.

Statistical analysis was done using Sigma Plot 11 software. Prior to the study, we performed a sample-size analysis and found with a power of .85 an expected difference of the means of 10- and 7-point standard deviation and an alpha of 0.05; we found that we needed 10 patients in each arm to show significant differences. We therefore enrolled 15 patients in each arm hoping to have at least 10 to complete the study. All postoperative data was compared, and the two groups with *T* Tests or rank-sum test where appropriate.

Each patient was randomized to the LGI or the LSG by a single employee of Investigators Forum (IFI): a healthcare research organization which assists researchers with project management and data collections (605, Sahajanand Shopping Center, Shahibaug, Ahmedabad 380 004, India, www.investigatrosforum.net). IFI randomized patients using dedicated software at the start of each case when the operating surgeon called IFI. Randomization was performed on the basis of age, BMI, and male to female ratio of the participant. A different employee of IFI performed all the

follow-up data collection (this person was a dedicated clinical research fellow) and was blinded to the operation for the first year following surgery. The third party followed the patients for an additional 2 years of collecting data on the patient's weight and comorbid conditions. When possible, follow-up was done by IFI at the ASIAN Surgical Center. When not possible, this was done by phone or email.

All postoperative data was analyzed using Sigma Plot 11 software to compare the two groups with *T* Tests or rank-sum test where appropriate.

Results

There were 30 patients recruited into the study, and they were randomized into two groups of 15. Each patient was followed for a period of 3 years.

Preoperatively, there was no statistical differences between the groups in terms of age, BMI, or male to female ratio (see Table 1). There were differences between the comorbidities between the groups preoperatively (see Table 1). There were 14 patients who completed the LSG study and 12 who completed the LGI study. Postoperatively, there also were no differences in BMI or EWL at 6 months, 12 months, and 3 years (see Tables 2 and 3).

In the sleeve group, there were no major complications. However, in both groups, there were patients who changed surgeries, crossed over, or dropped out of the study (See Chart 1).

There were two major complications in the LGI group. This included one leak and one gastric outlet obstruction from suturing the pouch to small. Both required reoperations. The gastric outlet obstruction required a removal of the sutures that were blocking the outflow of the pouch. The leak was reoperated quickly and converted to a sleeve gastrectomy, and patient suffered no further problems and was discharged 2 days later.

Table 1 Baseline demographic and clinical characteristics of each group

	LSG	LGI	<i>P</i> value
Age	39.9	40.5	0.8
BMI	44.0	44.7	.7998
Male/female ratio	9/6	9/6	
T2DM	8	3	
HTN	0	6	
Asthma	1	2	
Hypothyroid	3	2	

Table 2 BMI charted through time for the imbrication v the sleeve gastrectomy

	Pre	6 months	1 year	3 years
BMI sleeve	44.0±7.8	35.0±6.3	32.5±5.7	32.1±5.9
BMI imbrication	44.7±6.1	35.6±6.1	35.4±6.1	36.9±7.7
<i>P</i> value	.7998	.8076	.2448	.0931

Discussion

While we were able to complete a randomized double-blinded trial comparing LGI and LSG, this trial suffers from small sample size (therefore a high risk of type 2 error). We had 14 who completed the trial in the sleeve gastrectomy arm and twelve in the gastric imbrication arm. It would have been ideal to perform more procedures; but since the cost of these procedures and the follow-up by an outside consulting group was borne by the authors in this study, cost became the prohibiting factor in the recruitment of more patients. Yet, doubling or tripling the amount of procedures performed would not have altered the outcome of the trail, assuming the standard deviation stayed the same in the groups.

However, the study hypothesis was built on the belief that there would be a 10 % difference between the groups' EWL with smaller standard deviations than we experienced. Yet these large standard deviations are also seen in the most recent retrospective papers of both procedures [1, 2]. This makes our findings consistent with other large retrospective series of both LSG and LGI. Additionally, a recent case-controlled trial found that lap-banded gastric plication weight loss was similar to LSG at 3 years because of large standard deviations [3]. Both these procedures contrast greatly with the duodenal switch and gastric bypass procedures which have a very little standard deviation in the groups and between studies. This adds credence to the belief that malabsorption really does matter in obtaining consistent outcomes [2, 4, 5]. If we assume that the standard deviations are correct in both our paper and the retrospective analysis cited above, a surgeon wanting to prove the superiority of LSG over LGI would need at least 108 randomized blinded patients in each arm in order to prove a difference between the groups (sample size determination by

Table 3 EWL charted through time for the imbrication v the sleeve gastrectomy

	6 months	12 months	3 years
EWL sleeve	43.9±16.5	53.8±19.5	50.0±20.3
EWL imbrication	40.1±15.1	42.1±13.0	39.5±14.4
<i>P</i> value	.5458	.0817	.1380

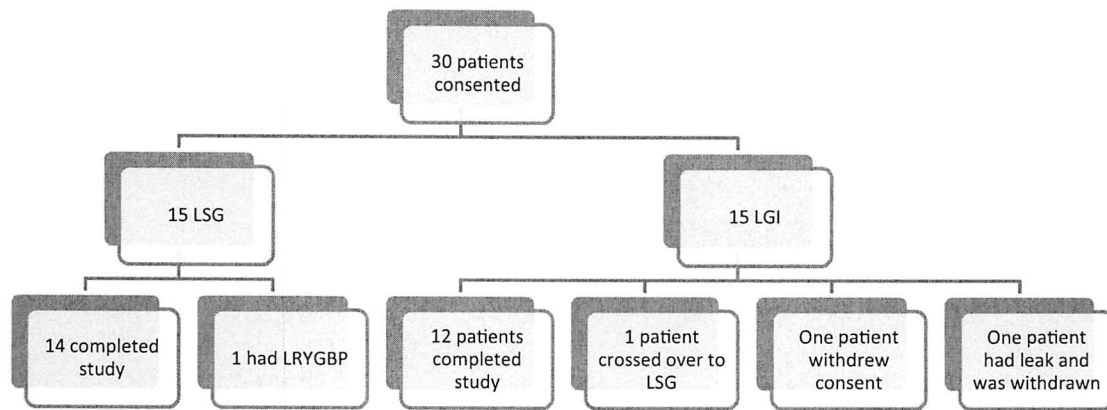


Chart 1 In the sleeve group, there were no major complications. However, in both groups, there were patients who changed surgeries, crossed over, or dropped out of the study

Sigma Stat Software based on BMI observations using differences in the means of 4.8, standard deviation of 9.7, desired power of 0.95, and alpha of 0.05).

Another limitation was the difference in the comorbidities between the two groups preoperatively specifically HTN and diabetes. This resulted from the fact that we did not include these comorbidities as part of the randomization process as this was not a primary or a secondary outcome. To what extent they impacted the randomization process is unknown.

The study also shows that both procedures will have failures of weight loss and will convert to another procedure. Both groups had one patient who failed weight loss with their assigned procedure and crossed over to another procedure. The literature is filled with examples of the LSG, LGI, LRYGBP failing weight loss and crossing over to another procedure.

Our groups were too small to draw conclusions about the safety or complications of either procedure. The one leak in our LGI group can be directly attributed to our lack of experience with the LGI. We are certain, if our study had been conducted by one of the prominent LGI groups around the world, the leak we experienced would have been avoided since it resulted from making the LGI too tight at the incisura [6–10].

Another problem with the study was the fact that the treating surgeons were never blinded. We do not feel that this issue influenced the outcomes of the study since all patients were treated the same with the same follow-up and dietary advice, it still is a source of weakness in the study.

Along the same lines was the fact that the third party administrator who followed the patients for weight loss outcomes also randomized the patients. We tried to account for this by having two different people perform each function and not having them communicate with one another about the study.

Conclusion

LGI and LSG offer similar weight loss at 3 years due to the large standard deviations present in both groups. The challenge for surgeons who perform LSG or LGI will be to decrease the standard deviations of both procedures to those seen in procedures like the LRYGBP or the DS.

Conflict of Interest The authors have no conflict of interest.

Ethical Standards All procedures performed in the studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

References

- Niazi M, Maleki AR, Talebpour M. Short term outcomes of laparoscopic gastric plication in morbidly obese patients: importance of postoperative follow-up. *Obes Surg.* 2013;23:87–92.
- Fischer L, Hildebrandt C, Bruckner T, et al. Excessive weight loss after sleeve gastrectomy: a systematic review. *Obes Surg.* 2012;22:721–31.
- Huang CK, Chhabra N, Goel R, et al. Laparoscopic adjustable gastric banded plication: a case-matched comparative study with laparoscopic sleeve gastrectomy. *Obes Surg.* 2013;23:1319–23.
- Topart P, Becouarn G, Ritz P. Laparoscopic biliopancreatic diversion with duodenal switch is a safe operation. *Surg Obes Relat Dis.* 2013;9:588.
- Pata G, Crea N, Di Betta E, et al. Biliopancreatic diversion with transient gastroplasty and duodenal switch: long-term results of a multicentric study. *Surgery.* 2013;153:413–22.
- Talebpour M, Motamedi SM, Talebpour A, et al. Twelve-year experience of laparoscopic gastric plication in morbid obesity: development of the technique and patient outcomes. *Ann Surg Innov Res.* 2012;6:7.

7. Fried M, Kozalova K, Sramkova P. Adjustable gastric banding outcomes with and without gastrogastic imbrication sutures: a randomized controlled trial. *Surg Obes Relat Dis.* 2011;7:23–32.
8. Ramos A, Galvao N, Galvao M, et al. Laparoscopic greater curvature placcation: initial results of an alternative restrictive bariatric procedure. *Obes Surg.* 2010;20:913–8.
9. Brethauer S, Jarris J, Kroh M, et al. Laparoscopic gastric plication for treatment of severe obesity. *Surg Obes Relat Dis.* 2011;7:15–22.
10. Huang CK, Lo CH, Shabbir A, et al. Novel bariatric technology: laparoscopic adjustable gastric banded placcation: technique and preliminary results. *Surg Obes Relat Dis.* 2012;8:41–5.