

# Laparoscopic Sleeve Gastrectomy—A Novel Surgical Tool for Weight Loss in morbidly Obese Patients: A Prospective Cohort Study

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## ABSTRACT

**Introduction:** Obesity has reached epidemic proportions worldwide. India ranks 3rd after the United States and China. The health consequences range from increased risk of premature death due to serious chronic illness like hypertension and diabetes mellitus (DM) which reduces the overall quality of life. Laparoscopic sleeve gastrectomy (LSG) produces long-lasting control of obesity as well as associated comorbidities.

**Materials and methods:** A prospective cohort study was conducted between the period of January 2015 and March 2016. The criteria for selection were Body mass index (BMI)  $\geq 40$  kg/m<sup>2</sup> or BMI  $\geq 35$  kg/m<sup>2</sup> with comorbidities. All the patients were screened by a multidisciplinary team. All the patients were operated by the same surgeon to avoid any procedural biasness. Follow-up visit as per our study protocol were evaluated.

**Results:** Out of 60 patients operated for morbid obesity, the weight loss is substantial and statistically significant. Excess weight loss (EWL) (in %) were 4.31, 8.14, 16.28, and 30.61% at subsequent visits at 1st, 2nd, 4th, and 12th week respectively. Except for a few minor complications which were managed conservatively, the procedure was uneventful.

**Conclusion:** Laparoscopic sleeve gastrectomy is simple, effective, and reproducible surgical method to treat morbid obesity.

**Keywords:** Excess weight loss, Laparoscopic sleeve gastrectomy, Morbid obesity.

**How to cite this article:** Kumar S, Ansari AM Md, Verma U, Kumar N. Laparoscopic Sleeve Gastrectomy—A Novel Surgical Tool for Weight Loss in morbidly Obese Patients: A Prospective Cohort Study. *World J Lap Surg* 2016;9(3):107-113.

**Source of support:** Nil

**Conflict of interest:** None

## INTRODUCTION

World Health Organization (WHO) defines obesity as a chronic multisystem disease resulting from complex

interaction between the human genotype and the environment.<sup>1</sup> It has reached epidemic proportion worldwide. The worldwide prevalence of obesity more than doubled between 1980 and 2014. There are over 600 million adults are obese globally. According to WHO Report 2014, about 13% of the world's adult population were obese of which 11% are men and 15% are women. There is dramatic increases in the prevalence of both overweight and obesity in Canada over the last 15 years, and the problem is particularly pronounced among children.<sup>1</sup> The obesity rate has increased dramatically in the last 15 years from 2 to 10% among boys and from 2 to 9% among girls.<sup>2,3</sup> Interestingly, there has been a 14 times increase of the number of bariatric surgeries in Canada in the last 2 years.<sup>3,4</sup> According to the WHO's World Health Statistics Report 2012, globally one in six adults is obese and nearly 2.8 million individuals die each year due to overweight or obesity.

Obesity involves a complex interaction of metabolic, genetic, psychological, and social issues and has become the second leading cause of preventable death in developed countries after smoking. Body mass index (BMI) is a simple index that is used to classify obesity in adult population. Body mass index is calculated by the following method: BMI = kg/m<sup>2</sup>. Obesity is defined as BMI > 25 kg/m<sup>2</sup>. Morbid obesity is defined as BMI > 40 kg/m<sup>2</sup> or > 35 kg/m<sup>2</sup> with associated comorbidities like diabetes mellitus (DM) and hypertension.

Obesity has reached an epidemic proportion in India. India is currently facing double burden of disease as malnutrition due to poverty now being rapidly replaced by obesity associated with affluence.<sup>5</sup> Industrialization and urbanization are playing a big role in increased prevalence of obesity. The changing lifestyle of the rural dwellers is an upcoming contributory factor for the rising rates of obesity and associated metabolic diseases, such as diabetes.<sup>6</sup> Studies from different parts of India have provided evidence of the rising prevalence of obesity.<sup>5,7-9</sup>

Mechanization of rural and urban areas is an important cause of the increasing prevalence of obesity. For example, two-wheeler sales have increased from 5,076,551 in 2002 to 8,418,626 in 2009.<sup>10</sup> The figures state that there is an increasing use of automobiles to commute, with

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obviously negative implications on exercise and energy expenditure at the biological level. Apart from that medical care, food habits, educational status, and family income have dramatically improved, which, along with easy access to city and television watching, result in unwanted changes in lifestyle. These have eventually led to significant increase in BMI.

Obesity is one of the major risk factors for diabetes, yet there has been little research focusing on this risk factor across India.<sup>11</sup> Therapeutic interventions for the treatment of obesity range from lifestyle and diet modifications to pharmacologic and surgical therapy.<sup>12</sup> Studies showed that the nonoperative interventions for sustained weight loss usually fail to provide real benefits and are usually insufficient and not sustainable.<sup>13,14</sup> Bariatric surgery is an evidence-based treatment of morbid obesity with proven, sustained weight loss and improvement in comorbidities.<sup>15-17</sup>

The limited and nonsustainable success of behavioral, lifestyle modification and drug therapies in morbidly obese patients has led to a increase interest in bariatric surgery in Canada.<sup>6</sup> A variety of surgical procedures are available, and currently it is difficult to identify the most effective option based on patient characteristics and comorbidities. Furthermore, little is known regarding the effect of the various surgical procedures on glycemic control and on Type 2 diabetes mellitus (T2DM) remission.<sup>18-21</sup>

Laparoscopic sleeve gastrectomy (LSG), a single-stage procedure, is a relatively new and effective surgical option for morbid obesity.<sup>22</sup> Although LSG functions as a restrictive procedure, it may also cause early satiety by removing the ghrelin-producing portion of the stomach.<sup>23</sup>

## MATERIALS AND METHODS

The prospective cohort study was conducted at the Dr. Ram Manohar Lohia Hospital and Post Graduate Institute of Medical Education and Research, New Delhi, India, between January 2015 and March 2016. Patients included were of either sex of age 18 to 60 years who had tried for weight loss for at least 6 months by dietary restriction and lifestyle modification, but failed to maintain sustained weight loss. The criteria for selection were BMI  $\geq 40$  kg/m<sup>2</sup> or BMI  $\geq 35$  kg/m<sup>2</sup> with comorbidity. All the patients were screened by a multidisciplinary team consisted of a surgeon, a nutritionist, a cardiologist, an endocrinologist, a chest physician, and a psychologist. All the patients were thoroughly evaluated and an informed consent in detail was taken.

The percentage of excess weight loss (EWL) was measured on each follow-up visit. The BMI up to 25 was taken as the normal, and weight beyond that were taken as the excess weight.

## Preoperative Preparation

All routine investigations including upper gastrointestinal endoscopy, echocardiography, and psychological assessment for conducting LSG were done on every patient. All patients were instructed to start chest physiotherapy using incentive spirometry and liver shrinkage diet 1 week prior to surgery. Deep venous thrombosis (DVT) prophylaxis with DVT pump during surgery and subcutaneous low-molecular-weight heparin were given to all patients 12 hours before and continued for 7 to 10 days after the surgery.

## SURGICAL METHOD

A procedure of LSG was performed using classical five ports under general anesthesia. The patients were in antitrendelenburg position with legs apart to facilitate the small intestine to remain out of field of surgery. The surgeon stood between the legs. Pneumoperitoneum was achieved using a closed technique with a Veress needle, placed in supraumbilical area just left to the midline. The xiphisternum was taken as the reference point. Three ports of size 12 mm were placed from the reference point at 15 to 18 cm at right mid-clavicular line (left working port), 2 to 3 left to mid-line (optical port), and left mid-clavicular line (right working port) respectively. The 4th port of 5 mm (assistant port) were inserted at left anterior axillary line below the costal margin. The epigastric port of 5 mm was inserted to retract the left lobe of liver. All surgeries were done by the same surgeon to minimize the biasness (Figs 1 to 3).

The stomach was decompressed by placing an orogastric tube. The operating surgeon stood in between the legs of the patient with the first and second assistant standing to the patient's right and left side respectively. Omentolysis was started about 3 to 5 cm proximal to the

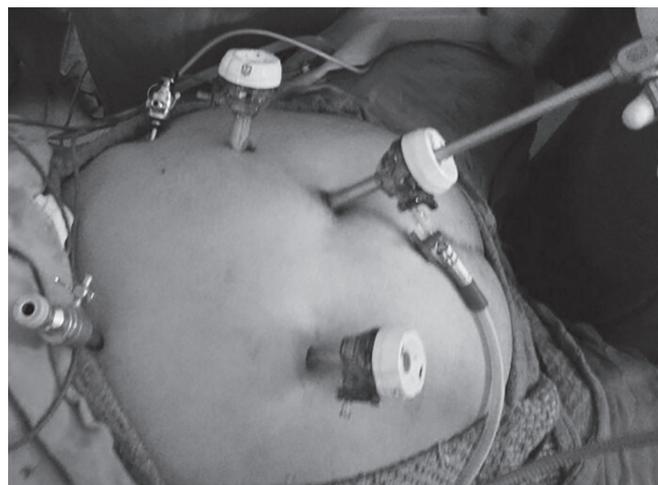
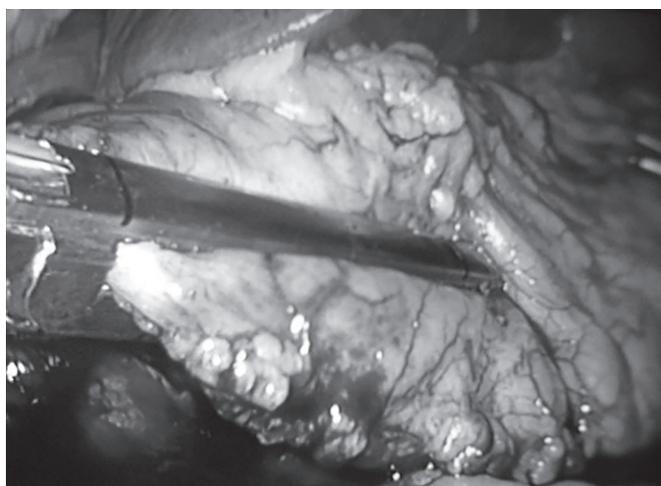


Fig. 1: Port placement



**Fig. 2:** Starting point of sleeve gastrectomy after omentolysis using 1st green fire (Endo GIA)



**Fig. 3:** Resected specimen

pylorus up to the gastroesophageal junction using the harmonic scalpel. The orogastric tube was then removed and replaced by a 38-French (Fr) gastric calibration tube placed in the stomach by the anesthesiologist and guided laparoscopically to sit on the lesser curvature of the stomach up to the pylorus. The first two 60 mm green cartridge (Endo GIA Stappler) was used to divide the stomach starting 3 to 5 cm proximal to the pylorus. Next 60 mm blue cartridges were used to complete the division of the remainder of the stomach. The specimen was then taken out of the abdominal cavity through the 12 mm port. The bougie was then removed, and leak test was performed with by air insufflations test. We routinely performed transfascial closure our all 12 mm ports. We routinely put 24 Fr abdominal drain along the sleeve.

### Postoperative Period

Patients were observed in the high-dependency unit for the first night after the procedure. Patients were encouraged to sit out of bed and chest physiotherapy using incentive spirometry on the evening after surgery in order to minimize postoperative atelectasis. No leak test was done postoperatively. Patients were allowed clear liquid on postoperative day 1 along with maintenance intravenous fluid. Antibiotic and prokinetics/antiemetic were continued for a period of 5 days and 14 days respectively. Patients were discharged and followed up at 1st, 2nd, 4th, and 12th weeks. At each follow-up visit, weight loss was evaluated.

### STATISTICAL ANALYSIS

Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean  $\pm$  SD and median. Statistical tests were applied as follows:

- Quantitative variables were compared using unpaired t test/Mann–Whitney test (when the datasets were not normally distributed) between the two groups.
- Qualitative variables were correlated using chi-square test/Fisher's exact test. The p-value of  $<0.05$  was considered statistically significant.

The data was entered in MS EXCEL spreadsheet, and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. All of the results are presented as two-tailed values with statistical significance defined as  $p < 0.05$ .

### RESULTS AND OBSERVATIONS

A total of 60 patients were operated for morbid obesity of the age from 27 to 55 years with a mean of  $41.53 \pm 8.89$  years, and the male-to-female ratio is 3:7. The patients were selected randomly who came to our OutPatient Department (OPD). All patients were thoroughly investigated for any reversible causes of obesity as well as any psychiatric, cardiac, and respiratory problems including obstructive sleep apnea syndrome.

Postoperatively all patients were strictly followed up as per the research protocol, that is, at 1st, 2nd, 4th, and 12th weeks and were given same diet plan for the first three months of the follow-up.

The mean weight of the all morbidly obese patients preoperatively was  $111.03 \pm 8.78$  kg (100–130) and the mean height was 1.6 gm (1.5–1.73). On follow-up, the mean weight at 1st, 2nd, 4th, and 12th weeks reduced to  $109 \pm 8.23$ ,  $107.2 \pm 7.88$ ,  $103.37 \pm 7.81$ , and  $96.63 \pm 7.06$  kg respectively. On statistical analysis it was found to be significant ( $p$ -value  $< 0.05$ ).

Similarly, the mean BMI of all the patients was  $43.68 \pm 3.75$  kg/m<sup>2</sup> (37.63–56.44). Preoperatively and on follow-up the mean BMI reduced to  $42.9 \pm 3.52$ ,  $42.09 \pm 3.26$ ,  $40.55 \pm 3.14$ , and  $38.01 \pm 2.31$  kg/m<sup>2</sup> at 1st, 2nd, 4th, and

12th weeks respectively. All these observations were analyzed and found statistically significant ( $p < 0.05$ ) (Table 1 and Graph 1).

**DISCUSSION**

World Health Organization reveals in its report that obesity is one of the most common, yet among the most neglected public health problems in both developed and developing countries.<sup>17</sup> Obesity is strongly associated with other comorbidity including diabetes, hypertension, dyslipidemia, cardiovascular disease, and some cancers.<sup>24</sup>

There is a growing consensus that bariatric surgery is the predominant treatment option available for the management of morbid obesity and its associated comorbidities. Diet therapy, medical treatment, exercise, and yogas are relatively ineffective in treating morbid obesity in the long term.<sup>25</sup> Recently, the LSG has emerged as a stand-alone procedure for the treatment of morbid obesity, and unlike the Roux-en-Y gastric bypass (RYGB), the LSG does not bypass the foregut.<sup>26,27</sup>

The mechanisms of action of LSG are probably mechanical restriction and hormonal modulation. It reduces the size of the gastric reservoir to 60 to 100 mL, permitting the intake of only small amounts of food and imparting a

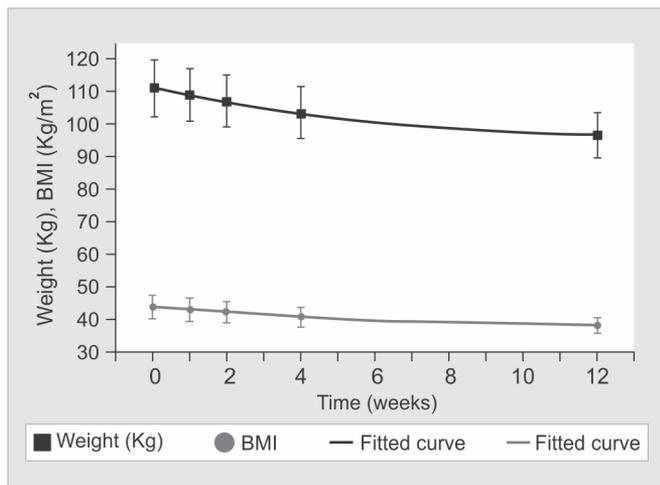
feeling of satiety earlier. Ghrelin, a hunger-regulating peptide hormone, produced by P/D1 cells that are found mainly in the fundus of the stomach are removed, thus reducing plasma ghrelin levels and, subsequently, the feeling of hunger. Ghrelin regulation is also disturbed following the sleeve gastrectomy. In a prospective study of 20 patients, the effects of LSG on immediate and 6-month postoperative ghrelin levels were compared with those of laparoscopic adjustable gastric banding.<sup>28</sup> The LSG patients showed a significant decrease in plasma ghrelin levels on day 1, which remained low throughout 6 months. In a prospective double-blind study of 32 patients, LSG resulted in a marked reduction in fasting ghrelin levels and significant suppression after a meal, which was not seen after RYGB.<sup>29</sup> Furthermore, appetite was also reduced to a greater extent after LSG.<sup>29</sup> Laparoscopic sleeve gastrectomy was also reported to have a hindgut effect with increasing levels of glucagon-like peptide-1 and peptide YY due to the increased transit time after LSG.<sup>30</sup>

**Laparoscopic Sleeve Gastrectomy Efficacy Profile**

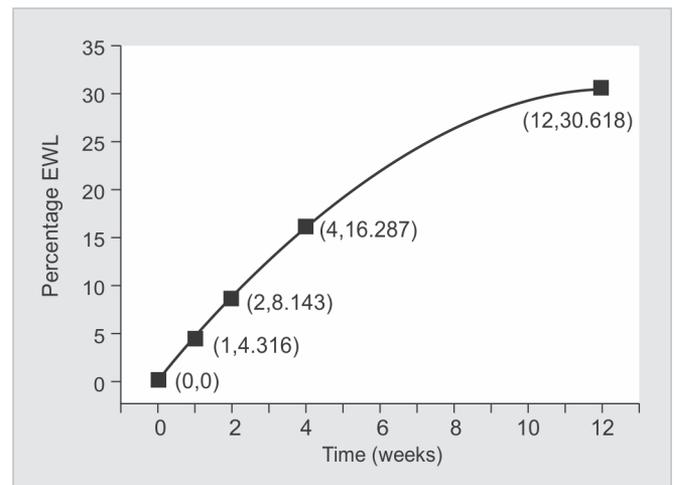
Early safety and efficacy of LSG was examined prospectively by Mognol and colleagues.<sup>31</sup> Mean operative time was 120 (90–150) minutes and the average length of stay

**Table 1:** Correlation of weight and BMI with postoperative period after LSG

Duration	Sample size	Parameter	Mean $\pm$ SD	Min–Max	p-value
0 Week	60	Weight (kg)	111.03 $\pm$ 8.78	100–130	
		BMI	43.68 $\pm$ 3.75	37.63–56.44	
1st Week	60	Weight (kg)	109 $\pm$ 8.23	98–126	<0.0005
		BMI	42.9 $\pm$ 3.52	37.63–55.55	<0.0005
2nd Week	60	Weight (kg)	107.2 $\pm$ 7.88	97–124	<0.0005
		BMI	42.09 $\pm$ 3.26	37.26–53.33	<0.0005
4th Week	60	Weight (kg)	103.37 $\pm$ 7.81	94–120	<0.0005
		BMI	40.55 $\pm$ 3.14	36.13–51.11	<0.0005
12th Week	60	Weight (kg)	96.63 $\pm$ 7.06	84–112	<0.0005
		BMI	38.01 $\pm$ 2.31	34.62–44.44	<0.0005



**Graph 1:** Weight and BMI trends following LSG



**Graph 2:** Percentage of EWL trend with postoperative period

in hospital was 7.2 days. No early mortalities or complications were reported. At 1 year after LSG, an EWL of 51% and a BMI decrease to 41 was reported in the 30% of patients who completed follow-up.

Similar results were demonstrated in a retrospective study by Baltasar et al,<sup>32</sup> involving 31 patients who had undergone LSG for various reason. There were no instances of deep vein thrombosis or pulmonary embolism, leak or pneumonia. However, there were two instances of trocar-related intraabdominal bleeding, with one leading to death. Mean EWL ranged from 56.1% (at 4–27 months) in the super-obese patients to 62.3% (3–27 months follow-up) in the lower BMI patients with significant comorbidities. Himpens et al<sup>33</sup> published a prospective randomized study involving 40 patients undergoing LSG. With a median initial BMI of 39 (30–53), their 3-year follow-up data found a median weight loss of 29.5 kg (1–48), median BMI decrease of 27.5 kg/m<sup>2</sup> (0–48), and a median percent of EWL of 66% (–3.1 to 152.4) after LSG.

Milone et al<sup>34</sup> retrospectively compared their experience with 20 LSG patients (BMI > 50) to that of 57 Bio-Enterics Intra-gastric Ballons. In LSG patients, the only complication was a trocar site infection. Laparoscopic sleeve gastrectomy not only produced significantly more weight loss but also had fewer complications in this limited study.

Laparoscopic sleeve gastrectomy as a sole weight loss procedure was also examined by Langer et al.<sup>35</sup> At 6 months, mean EWL among all 23 patients was 46%, and it was 56% at 1 year. Two patients required conversion to RYGB.

In our study the percentage of EWL was 4.31, 8.14, 16.28, and 30.61% at 1st, 2nd, 4th, and 12th weeks respectively, which is significant and in consistent with other studies. Similarly, the mean BMI also reduced substantially in accordance with the earlier studies. It is expected that the loss of excess weight may be even more if patients follow the nutritional guidelines strictly, which is high-protein low-calorie diet and regular exercise (Graph 2).

A recent survey conducted at the First International Consensus Summit for Sleeve Gastrectomy asked “Is LSG indicated as a primary procedure in patients with a BMI > 40 or BMI > 35 with comorbidities?” Of the respondents, 58% completely agreed, 19% somewhat agreed, 8% had no opinion, 14% somewhat disagreed, and 0% completely disagreed.<sup>36</sup>

## COMPLICATIONS

The risk of postoperative bleeding has been reported to be between 1 and 6% after LSG.<sup>37,38</sup> The bleeding may be intraluminal or extraluminal and are managed conservatively. The extraluminal bleeding may be from

gastric staple line, spleen, liver, or abdominal wall at the sites of trocar entry. A number of buttressing materials are commercially available to attempt to reduce the rate of bleeding from the staple line. Several authors have described oversewing the long staple line, whereas others have used buttressed staples (i.e., Gore Seamguard Bioabsorbable Staple Line Reinforcement) or fibrin glue as a sealant<sup>39</sup> and were able to demonstrate significantly less intraoperative blood loss in the buttressed staple line group (120 vs 210 mL,  $p < 0.05$ ). Albanopoulos and colleagues,<sup>29</sup> however, did not observe a significant difference in their rate of postoperative bleeding between patients with staple line suturing or buttressing with Gore Seamguard after LSG.

In our series, there were three cases of bleeding from the staple line of which two were managed with the titanium clips and one required staple line suturing. We routinely did not reinforce the suture line. The other minor bleeding from short gastric vessels (one case) and one from liver during retraction were managed conservatively. We did not encounter any case of intraluminal bleeding and any case of bleeding in the postoperative period.

Gastric leak is the most serious and dreaded complications of LSG. It occurs in up to 5% of patients following LSG.<sup>22,38</sup> An early leak is generally diagnosed within the first 3 days after surgery, whereas a delayed leak is usually diagnosed more than 8 days after surgery.<sup>40</sup>

In a study by Kolakowski et al,<sup>41</sup> a combination of clinical signs of fever, tachycardia, and tachypnea was found to be 58.33% sensitive and 99.75% specific for detection of anastomotic leaks clinically. In the presence of a leak, an abdominal washout laparoscopically with surgical repair of the leak (if technically feasible) and feeding jejunostomy should be performed.

Treatment of delayed gastric leak is more challenging and includes conservative or surgical management. This depends on the patient’s hemodynamic condition and on physical and radiological findings. In the absence of hemodynamic instability and physical findings suggestive of peritonitis, conservative management, including intraluminal stenting,<sup>42</sup> should be initiated. Himpens et al<sup>43</sup> reported their experience in the management of 29 patients with gastric leak after sleeve gastrectomy with stenting in which the stents were left *in situ* on average for 7 weeks. Immediate success was observed in 19 patients after placement of the first stent, whereas five patients required placement of a second stent. In a septic patient with radiological evidence of a leak with diffuse intraabdominal fluid collections, surgical drainage of the fluid collection is warranted.

## Abscess

Intraabdominal abscess is another known complication after LSG. In a series of 164 patients undergoing

LSG, Lalor et al<sup>44</sup> reported one patient with an abscess (0.7%). Treatment includes percutaneous drainage and antibiotics.

We did not encounter any staple line leak and intraabdominal abscess during the study.

Other chronic complications like stricture formation, kinking of the stomach, nutritional deficiencies, and gastroesophageal reflux disease (GERD) has been reported in different studies. The kinking of the stomach following LSG has been reported,<sup>45</sup> and the most common site of stenosis is at the incisura angularis<sup>46</sup> and is diagnosed by endoscopy. The treatment options include endoscopic dilations/seromyotomy/conversion to RYGB.

Nutritional deficiencies have been reported after LSG probably owing to impaired absorption and decreased oral intake. In a study by Gagner et al,<sup>26</sup> the prevalence of vitamin B12, vitamin D, folate, iron, and zinc deficiency was reported to be 3, 23, 3, 3, and 14% respectively after LSG. These deficiencies are less prevalent after LSG than RYGB. Folic acid deficiency was slightly more common after LSG than RYGB (22 vs 12%).<sup>48</sup>

Gastroesophageal reflux disease is also seen in the bariatric surgery population. Chiu et al,<sup>47</sup> found the data to be inconclusive with respect to the effect of LSG on GERD. Carter et al<sup>49</sup> performed a retrospective study on patients who underwent LSG and found 47% of their patients to have persistent (> 30 days) GERD symptoms and were treated with proton pump inhibitor.

## CONCLUSION

Laparoscopic sleeve gastrectomy is a simple and effective surgical treatment option for weight loss and should be considered as a definitive bariatric surgical management option. Long-term data for weight loss and other chronic complications of sleeve gastrectomy need to be studied further.

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