

# Comparison of Early Results and Complications between Multi-and Single-Port Sleeve Gastrectomy: A Randomized Clinical Study

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## What's Known

- In recent years, laparoscopic sleeve gastrectomy (LSG) has become more acceptable for obese patients.
- Single-port sleeve gastrectomy is more popular since each abdominal incision carries the risks of bleeding, hernia, and internal organ injury as well as exponentially affecting cosmesis.

## What's New

- Complication differences between the groups were not statistically significant.
- Single-port sleeve gastrectomy seems to be safe and has similar major post-operation complications as multiport sleeve gastrectomy. Thus, it allows surgeons to choose either approach.

## Abstract

**Background:** In recent years, laparoscopic sleeve gastrectomy (LSG) has become more acceptable for obese patients. Single-port sleeve gastrectomy (SPSG) is more popular since each abdominal incision carries the risk of bleeding, hernia, and internal organ injury as well as exponentially affecting cosmesis. This cross-sectional study aimed at comparing multi-port sleeve gastrectomy (MPSG) and SPSG in terms of their early results and complications.

**Methods:** Out of 129 obese patients candidate for LSG, 102 patients were assigned to 2 groups of SPSG and MPSG. Complications and demographic data such as body mass index (BMI), age, gender, operation time, and hospital stay were measured. All surgeries were carried out between 2013 and 2015 in Shiraz, Iran. Data analysis was performed using SPSS, version 16 for Windows (SPSS Inc., Chicago, IL). The continuous and categorical variables were compared using the Student *t*-test and the Chi-square test or the Fisher exact test, respectively.

**Results:** The patients' data from both groups were similar in terms of age, intraoperative and postoperative bleeding volume, and length of hospital stay. Mean BMI was  $42.8 \pm 0.7$  in the SPSG group and  $45.3 \pm 1.2$  in the MPSG group. Duration of surgery was significantly lower in the SPSG group ( $P < 0.001$ ). Only 1 patient from the SPSG group and 5 patients from the MPSG group had bleeding as an early complication.

**Conclusion:** The differences in each complication between the groups were not statistically significant. SPSG seems to be safe and is the same as MPSG in terms of major postoperative complications.

**Trial Registration Number:** IRCT201512229936N12

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**Keywords** • Complications • Bariatric surgery • Gastrectomy • Bariatric surgery • Single port

## Introduction

Obesity is a common disorder and it seems to have been on the increase in recent years in Iran.<sup>1</sup> For the treatment of obesity,

there are many nonsurgical suggestions such as special diets, exercise, and lifestyle modification, which can decrease weight but only 3% to 8% of patients are cured through these measures.<sup>2</sup> Bariatric surgery is currently known as the most effective treatment for morbid obesity, and it offers greater improvement in weight loss outcomes. Bariatric surgery accounted for 95.7% of all worldwide laparoscopic surgeries in 2013,<sup>3</sup> with the highest number of such surgeries having been performed in North America. Laparoscopic sleeve gastrectomy (LSG) constituted 37% of these surgeries, with the most significant increase in prevalence between 2003 and 2013. It is currently the most frequently performed surgery in North America, Canada, and Asia-Pacific regions. It is ranked second to Roux-en-Y gastric bypass (RYGB) surgery in Europe and Latin America.<sup>3</sup>

LSG has proven effective in providing significant weight loss, correction of obesity-related comorbidities, and excellent short- and long-term results, thereby improving survival and reducing mortality attributable to the disease.<sup>4</sup> In patients with body mass index (BMI) >40 or BMI >35 with metabolic disorders such as diabetes, hypertension, sleep apnea, or fatty liver, restrictive LSG is recommended.<sup>5</sup> The procedure has attracted the attention of many surgeons as it does not require gastrointestinal anastomosis or intestinal bypass. Furthermore, there is no dumping since the preservation of the pylorus and the resection of the stomach minimize the risk of gastric ulcer and cancer.<sup>6</sup> It also confers, in addition to its restrictive effect, hormonal regulation of appetite due to reduced levels of ghrelin, a hormone produced by cells in the gastric fundus that stimulates hunger.<sup>5</sup>

In 2008, single-incision surgery was introduced.<sup>7,8</sup> Whereas multi-port sleeve gastrectomy (MPSG) is done via 3 to 6 ports in the abdominal cavity, single-port sleeve gastrectomy (SPSG) reduces incisional complications and postoperative scar and pain.<sup>9-13</sup> Patients undergoing these operations are usually followed up closely to monitor their weight-loss status. The rates of complications such as bleeding, visceral injury, hematoma, and incisional hernia seem to be different between these methods. Accordingly, the present study was carried out in order to compare the early results between MPSG and SPSG in respect to the incidence of early complications.

## Patients and Methods

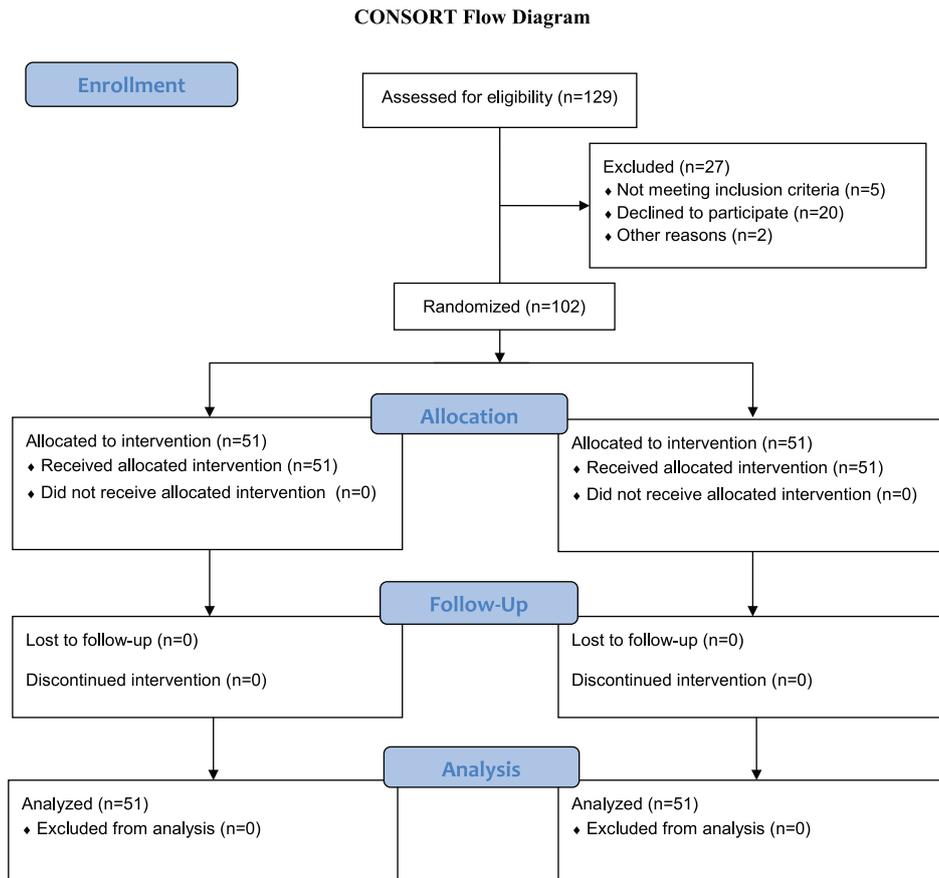
### Patients

This is a randomized clinical trial study of 2 groups of obese patients registered

as IRCT201512229936N12 in the RCT registration in Iran. Before decision was made to perform surgery, the patients were admitted to a multidisciplinary team clinic encompassing internal medicine specialists, surgeons, psychiatrists, nutritionist, sports medicine specialists, and nursing staff. The patients' conditions were discussed by the team, and the results were explained to the patients. Next, the patients provided written informed consent after having received detailed explanations regarding the risks and benefits. Patients with previous upper abdominal surgery, pregnancy, addiction to opium or alcohol, major depression, and bipolar disorder were excluded. Via a simple random method, the study population was assigned to 2 groups such that the first 5 patients who underwent SPSG were entered in the study, followed by the next 5 patients who underwent MPSG. The SPSG and MPSG groups each comprised 51 patients. Figure 1 depicts the Consort flowchart of the 2 groups. The sample size was calculated according to comparisons between 2 mean values and data from other similar studies on this new method of surgery. With power of 85% and alpha of 0.05 in each group, there should be a minimum of 33 patients; to ensure more precision, we assigned 51 patients to each group. BMI, gender, age, operation type, operation time in minutes, length of hospital stay in days, intraoperative blood volume loss, intraoperative and early postoperative complications, and comorbidities were measured and evaluated. This is a single-blind study, and the individual who gathered the data from the patients was blinded to their group allocation.

All the procedures were performed between 2013 and 2015 in the Surgery and Colorectal Department of Shahid Faghihi Hospital and Mother and Childs' Hospital in Shiraz, Iran. The Ethics Committee of Shiraz University of Medical Sciences approved the study (#7510). As a standard procedure, the same surgeon and medical team performed all the surgeries. After surgery, the patients were invited to participate in our study and they filled the consent form based on information collected during a 6-month postoperative period.

According to the National Institutes of Health Consensus Conference (1991) on gastrointestinal surgery for severe obesity, patients with BMI ≥40 are candidates for this surgery and those between 35 and 40 are considered if they have a life-threatening comorbidity such as hypertension, sleep apnea, or diabetes.<sup>14-17</sup> The procedure can be used as metabolic surgery. LSG was performed on



**Figure 1:** Consort flow diagram shows the allocation of the study groups.

129 patients, 27 of whom were excluded because they had a history of upper abdominal operation or were pregnant or declined to participate during the follow-up. Evaluation was done in the 2 groups with respect to complications such as bleeding volume during surgery, number of patients that had bleeding after surgery, leakage from anastomosis parts, and wound infection.

#### *Surgical Technique*

There is diversity in the single-incision in terms of size, shape, and location that should not compromise safety and cosmetic outcomes. However, in the current study, the single-port device, Quad Port (Unimax, China), was placed through a 3.5-cm incision 4 cm lateral to the midline in the left upper quadrant area between the xiphisternum and the umbilicus. A curved grasper was employed, and LigaSure<sup>®</sup> was drawn upon as the energy source. Approximately, 75% of the stomach was excised with an Endo GIA<sup>™</sup> stapler. In MPSSG, for telescope, a 10-mm port was inserted 4–6 cm above the umbilicus to the left of the midline. Another 10-mm port, which was subsequently substituted with a 12-mm port, was inserted parallel to the first port at the midclavicular point. A third 10-mm port was

thereafter inserted parallel to the second one at the anterior axillary line. Afterward, a 5-mm port was inserted at the midline epigastric region for liver retraction using either the Nathanson retractor or a 5-mm grasper. The operative procedure included the sleeve technique involving the insertion of a 36-F blunt tip bougie orally up to the pylorus. Special attention was paid to avoid tightness at the incisura and the angle of His.

The procedure was started from 4–6 cm proximal to the pylorus with a 10-mm LigaSure<sup>®</sup> device (Covidien) with complete dissection to the left crus of the diaphragm to avoid leaving a pouch of fundus. All patients were tested intraoperatively by methylene blue injection through the bougie and then upper gastrointestinal study or methylene blue injection. A leak test was done on the first postoperative day before discharge on the second day.

#### *Statistical Analysis*

All data analyses were performed using SPSS, version 16 for Windows (SPSS Inc., Chicago, IL). The continuous and categorical variables were compared using the Student *t* test and the  $\chi^2$  test or the Fisher exact test,

respectively. According to the data distribution, nonparametric tests were used. A  $P < 0.05$  was considered statistically significant.

## Results

The SPSG group was comprised of 5 male and 46 female patients, and the MPSG group consisted of 16 male and 35 female patients. The patient demographics of both groups were similar and homogenized regarding age (16–59 y), BMI (35–68), comorbidities, and postoperative outcomes in terms of length of stay and weight loss.

Leakage and bleeding are the most serious surgical complications and sometimes require invasive intervention and conversion in the surgery method. Obstruction after laparoscopy, with a reported incidence rate of approximately 1%, is relatively uncommon. Wound infection and other complications accounted for 4.9% of our surgeries. In our experience, we did not find incisional hernia or symptoms created from adhesion bond or obstruction during our follow-ups. In the SPSG group, only 1 patient had bleeding as an early complication, and 3 patients developed leakage. One patient had obstruction after surgery. In the MPSG group, 5 patients had bleeding. No one had deep vein thrombosis in the groups, and 2 patients from each group required reoperation.

In addition, 4 of the SPSG operations were switched to MPSG due to the lack of exposure and bleeding. The median follow-up was 6 months. We found that the patients' age, BMI, operation type, and degree of postoperative weight loss were not associated with the occurrence of hernia or adhesion. Two patients were converted to open surgery to control their bleeding (1 patient of each group). Three patients had cholecystectomy, and the patients with fatty liver before surgery became approximately normal after surgery (table 1).

## Discussion

Minimally invasive surgeries are new techniques for obese patients with fewer side effects than open surgeries.<sup>18</sup> Of total laparoscopy bariatric surgeries in 2013, LSG was performed at a rate of 43% in North America, 37% in Europe, 24.7% in Latin America, and 49% in Asia-Pacific regions.<sup>3</sup> This technique has become popular, especially over the past 10 years.<sup>2</sup> The simplicity of this surgical technique compared with RYGB and short-term weight loss outcomes has made this surgery the treatment of first choice for patients. Some long-term studies have already

been conducted worldwide, but they are still limited to small sample sizes.

SPSG is popular since each abdominal incision carries the risk of bleeding, hernia, and internal organ injury as well as exponentially affecting cosmesis.<sup>13</sup> An appropriate surgical candidate selection is of prime importance for the success of SPSG.<sup>19</sup> In one study, the median operating time was 66 minutes and the median hospital stay was 3 days. Twenty patients showed 70.6% excess weight loss (the average weight decrease=40.3 kg) after 1 year. Therefore, SPSG appears to be safe and effective in the short term in severely obese adolescents.<sup>19</sup> In our study, weight loss after 1 month was  $11.4 \pm 1.0$  kg in the SPSG group and  $13.1 \pm 0.5$  kg in the MPSG group, with the difference not constituting statistical significance. In addition, after 6 months, the SPSG group lost  $29.6 \pm 1.6$  kg and the MPSG group lost  $33.1 \pm 2.9$  kg, again with no significant difference between the 2 groups. The median duration of surgery was significantly lower in the SPSG group, and the median hospital stay was slightly lower than that in the MPSG group ( $P < 0.001$ ).

Based on a systematic review on 15 randomized clinical trials, the reported incidence of bleeding after laparoscopy was low and comparable to the rates reported in those associated with RYGB. Furthermore, the complications in LSG comprised leakage, bleeding, stricture, and reoperation, which occurred at rates of 0.9%, 3.3%, 0%, and 2.1%, respectively.<sup>20</sup> In a recent study, the incidence of bleeding after primary LSG was 2.6% and staple-line leakage was reported in 2.3% of the patients. Additionally, 8.2% of the study population had a revision of the LSG on a pooled analysis of 1041 patients.<sup>21</sup>

Some risk factors have been proposed with respect to the increased risk of hernia, including patient age, obesity, wound infection, and closed entry into the abdomen. In a laparoscopic study by Sucher et al.,<sup>22</sup> the complication rates were leakage (2.5% in the SPSG group and 0% in the MPSG group), bleeding (2.5% in the SPSG group and 2.5% in the MPSG group), and trocar-site hernia (0% in both groups). According to our results, leakage occurred at a rate of 2.9% in the SPSG group and bleeding at a rate of 2% in the SPSG group and 9.8% in the MPSG group; there was no hernia in either group. However, different bariatric procedures may carry different risks of complications. Complications including leak, wound infection, and conversion were observed in 9 patients in the SPSG compared with 3 in the MPSG group. Some randomized trials have demonstrated the safety and efficacy

**Table 1:** Comparison between the patients who underwent SPSG and MPSG bariatric operations (means±SEMs) and numbers (%)

Parameters	SPSG (N=51)	MPSG (N=51)	P value
Age (mean)	34.7±1.2	34.4±1.2	0.875
Mean BMI (kg/m <sup>2</sup> )	42.8±0.7	45.3±1.2	0.055
Gender			
Male	5	16	0.007
Female	46	35	
DM (Yes)	4	1	0.167
Hypothyroidism (Yes)	3	2	0.645
Hyperthyroidism (Yes)	1	0	0.315
GBS (Yes)	1	2	0.557
Fatty liver grade before surgery (Yes)			
1	22	24	0.837
2	9	12	0.528
3	1	1	0.975
Cholecystectomy during surgery (Yes)	1	2	0.584
Bleeding during surgery (Yes)	3	9	0.075
Leakage (Yes)	3	0	0.072
Conversion rate	4	0	0.036
Wound infection (Yes)	2	3	0.682
GBS after 6 months (Yes)	3	0	0.072
Duration of surgery (min)	143.6±4.2	169.9±5.4	<0.001
Mean of intraoperative bleeding volume (cc)	159.0±44.1	141.9±29.6	0.738
Postoperative bleeding volume (cc)	83.5±17.8	57.4±8.0	0.188
Postoperative drainage volume (cc)	70.5±12.5	64.2±9.3	0.691
Mean length of hospital stay (d)	3.5±0.3	3.8±0.1	0.274
Weight loss after 1 month (kg)	11.4±1.0	13.1±0.5	0.149
Weight loss after 6 months (kg)	29.6±1.6	33.1±2.9	0.252

SPSG: Single-port sleeve gastrectomy; MPSG: Multi-port sleeve gastrectomy; BMI: Body mass index; DM: Diabetes mellitus; GBS: Gall bladder stone

of SPSG in comparison with MPSG for several types of procedures.<sup>23,24</sup> Nonetheless, whether or not SPSG increases the risk of leakage when used for bariatric procedures has yet to be fully elucidated. In the current study, 3 patients had leakage demonstrated by special dye the day after surgery; the problem was resolved shortly after we performed re-laparoscopy and sutured the leak area. Our data suggest that the use of SPSG in bariatric surgery did not increase the risk of bleeding. Nine patients had bleeding during MPSG, which may have been a result of hypertension of the patients or high blood pressure during surgery. We were, however, unable to find any convincing evidence. Additionally, in our study, patient age, BMI, and degree of postoperative weight loss were not associated with the occurrence of complications. We could not perform multivariate analysis for diabetes because none of the patients who developed complications was diabetic.

Some studies on LSG have reported beneficial effects besides weight loss such as beneficial effects on metabolic syndrome that could be made by insulin sensitivity. Also, circulating

plasma ghrelin levels can be affected by LSG.<sup>25</sup> Melissas et al.<sup>26</sup> showed that after LSG, the time required for stomach emptying of solid foods was shortened and also Rosenthal et al.<sup>27</sup> reported that the changes in gut hormone secretion after LSG could play a role in diabetes resolution. Lee et al.<sup>28</sup> reported that LSG resulted in remission up to 50% at 1 year's postoperative follow-up in their poorly controlled non-morbidly obese patients with diabetes mellitus type 2. The authors also claimed that the beneficial effect was related more to a decrease in insulin resistance rather than calorie restriction and weight loss alone. In addition, they demonstrated that C-peptide >3 ng/mL was the most important predictor of the remission of diabetes mellitus. More studies are required to demonstrate the mechanism of this effect through glucagon-like peptide-1 or gastric inhibitory polypeptide. It is necessary for the surgeon to know the various effects of weight loss that might help obese patients with various medical problems like hypertension, asthma, diabetes, infertility, irregular menstruation, thyroid disorders, hyperlipidemia, gallstone, fatty liver, cancer, pain, and even mental disorders.

We recommend that prospective randomized clinical trials be undertaken with longer study periods and larger sample sizes of obese patients with metabolic syndrome who undergo LSG. What is also necessary is an evaluation of the pathophysiology and mechanisms involved in the beneficial effects of LSG.

There are a few limitations in our study. We had no data available for analysis on some of our patients who might have been diagnosed with diabetes mellitus and not used any medication. Moreover, the fact that SPSG and MPSG are recently developed techniques meant that we could not find more patients in our setting. Another drawback of note is that we did not have newer EndoEYE® and SPIDER® devices for SPSG surgeries. Longer follow-ups, larger cohort studies, and/or systematic reviews will be necessary to assess the extent of the benefits and limitations of SPSG in bariatric surgery.

### Conclusion

Our data suggested that a low rate of bleeding could be achieved with the use of SPSG in bariatric surgery. According to these results, there was no statistical difference between the type of surgery and complications. SPSG seems to be safe and is the same as MPSG as regards their major postoperative complications.

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**Conflict of Interest:** None declared.

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