

Single Port Sleeve Gastrectomy as Safe Procedure in the Treatment of Morbidly Obese Patients

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Background: Laparoscopic sleeve gastrectomy had gained popularity and acceptance among bariatric surgeons, mainly as a result of its low morbidity and mortality. Single-incision laparoscopic surgery (SILS), the most recent development in minimally invasive surgery, allows operations to be carried out through, only a single incision. The aim of our study was to evaluate the efficacy and safety of a laparoscopic single-incision sleeve gastrectomy for morbid obesity in comparison with multiport laparoscopic sleeve gastrectomy.

Patients and methods: This is a prospective comparative study conducted between June 2012 to November 2015, which included 35 morbidly obese patients, divided into 2 groups. Group (A) included 18 patients who underwent multiport laparoscopic sleeve gastrectomy and group (B) included 17 patients who underwent single-incision laparoscopic sleeve gastrectomy.

Conclusion: Laparoscopic single-incision sleeve gastrectomy seems to be safe and effective as same as conventional multiport sleeve gastrectomy. However, additional work must be carried out before these techniques achieve the level of standardization.

Key words: Sleeve gastrectomy, single port, laparoscopy.

Introduction

Morbid obesity increases the risk for many associated diseases including hypertension, type II diabetes, cardiac diseases, and sleep apnea.^{1,2} Bariatric surgery should be considered as a treatment option for patients with BMI of 40kg/m² or greater who instituted but failed on adequate exercise and diet program, and for patients with BMI of 35kg/m² who present with obesity-related co-morbid conditions such as hypertension, diabetes, hyperlipidemia and obstructive sleep apnea.³ Bariatric surgery has quickly become one of the fastest growing fields of medicine. The demands for less-invasive bariatric procedures are gaining more popularity and, as a result, bariatric procedures have become no exception to the ever-advancing pursuit of minimally invasive surgery.^{3,4} Laparoscopic Sleeve Gastrectomy progressively emerged as a standalone procedure in the treatment of morbid obesity. Benefits of LSG include a low rate of complications, maintenance of gastrointestinal continuity, and absence of malabsorption.^{5,6} Furthermore, there is no dumping syndrome because of preservation of the pylorus and resection of the stomach minimizes the risk of gastric ulcer and cancer. It also yields, in addition to the restrictive effect, hormonal regulation of appetite, because of reduced levels of ghrelin, a hormone produced by cells in the gastric fundus that stimulates hunger.^{7,8} Currently single-incision laparoscopic surgery (SILS) is considered to be a bridging technique to natural orifice transluminal endoscopic surgery (NOTES).⁹ Applications of SILS have expanded rapidly, and

various procedures including bariatric surgery have been carried out with this technique.^{9,10} Laparoscopic sleeve gastrectomy owing to its pure resection in nature, and the need of one slightly enlarged surgical wound for specimen retrieval, has been regarded as an ideal field of application for Single Port techniques.^{11,12} This is a prospective comparative study that aimed to assess safety and efficacy of laparoscopic single incision sleeve gastrectomy in the treatment of morbidly obese patients in comparison to multiport sleeve gastrectomy.

Patients and methods

This was a prospective comparative study performed at Ain Shams University hospitals and KSA private hospital after approval from the ethical committee. From June 2012 to November 2016, thirty-five morbidly obese patients with comparable demographic characteristics were divided into 2 groups. Group (A) included 18 patients (10 females and 8 males) who underwent multiport sleeve gastrectomy (MPSG). and group (B) included 17 patients (11 females and 6 males) who underwent single port sleeve gastrectomy (SPSG). An informed consent was taken from all patients before enrollment in the study. Morbidly obese patients with BMI higher than 40kg/m² or BMI over 35kg/m² with at least one co-morbidity were included. Exclusion criteria included pregnancy, lactation, moderate to severe gastroesophageal reflux disease, severe cardiopulmonary diseases, presence of liver cirrhosis or portal hypertension, heavy sweat-eaters, patients with prior upper

abdominal surgery or previous bariatric surgery or prior umbilical hernia repair with mesh, patients with psychiatric disorders and patients with extreme of age. We excluded patients with BMI > 50kg/m² from both groups. All patients involved in this study underwent a multidisciplinary evaluation by cardiologist, endocrinologist, psychologist, nutritionist and anesthesiologist.

Preoperatively, all patients underwent pelviabdominal ultrasound for gall stones, upper GIT endoscopy to exclude gastritis or reflux disease, esophageal manometry, 24-h pH monitoring and pulmonary function studies. Routine preoperative laboratory investigations were done (blood tests, including complete blood picture, coagulation profile, liver function tests, renal function tests and ECG). Follow up for all cases were recorded at 1, 3, 6, and 12 months.

Operative details

All procedures were performed under general anesthesia in the supine reverse Trendelenburg position with the legs apart after the patient was positioned on the table with a belt and application of compression bandage around both legs up to the mid thigh. The main surgeon stood between the patient's legs, with assistants standing on both sides. A monitor was located at the head of the patient. Elastic and intermittent pneumatic compressing stockings were applied. In group (A), pneumoperitoneum was achieved using a Veress needle placed in the left mid-clavicle sub-costal region. A five-port technique was employed: first trocar (10 mm) was placed 15 cm below the xiphoid process slightly left to the patient's mid-line (telescope trocar); second trocar (12 mm) was placed at the location of the Veress needle in the left upper quadrant (surgeon's right hand); 3rd one (10 mm) was placed in the right upper quadrant (surgeon's left hand); 4th one (5 mm) was placed high epigastric in the mid-line (flexible liver retractor); and 5th one (5 mm) was placed in the lateral left abdomen (assistant's 5-mm Babcock). Nasogastric tube to decompress the stomach was placed first, followed by gastrolysis using the Harmonic Scalpel which started at the middle of the greater curvature then up to the angle of His and left crus of the diaphragm and down to 4 cm from the pylorus. Then by using the Endo-GIA linear cutter tri-stapler (by Covidien), division of the stomach alongside a bougie (36 French) which was fitted to the lesser curvature was done. The bougie was then removed and the specimen was taken out of the abdominal cavity through the 12 mm port. Inflating the gastric pouch by Methylene blue to examine the integrity of stapler line was done as a last step of the procedure. In group (B), three cm curvilinear incision was made at the superior aspect of the umbilicus. This incision

was performed to introduce the multichannel port using a Kocher clamp. We used a special single-port silicon device that had two 5 mm and one 12 mm trocars in addition to insufflation channel. The port was flexible and reusable.



Fig 1: Single port device used in our study.

The operative steps were similar to those of a conventional laparoscopic sleeve gastrectomy. Starting from decompression of the stomach to gastrolysis of the greater curvature 4 cm from pylorus to angle of His using the Harmonic Scalpel by the same manner as MPSG (**Figure 2**).



Fig 2: Reticulating instrument with starting dissection of greater curvature of stomach.

We used the shaft of a flexible grasper to retract the liver anterolaterally (**Figure 3A**). However, we also used laparoscopic Babcock (**Figure 3B**) which was introduced through the same fascial opening for liver retraction if needed in some cases.



Fig 3: Retraction of liver, A: via flexible grasper, B: via Babcock.

Retro gastric adhesions were taken down to allow complete mobilization of the stomach. Gastric transection was then started at a point 3-4 cm proximal to the pylorus using an articulating long laparoscopic stapler with 60 mm loads (by Covidien) (**Figure 4**), and division of the stomach occurred alongside a bougie (36 French) which was fitted to the lesser curvature.

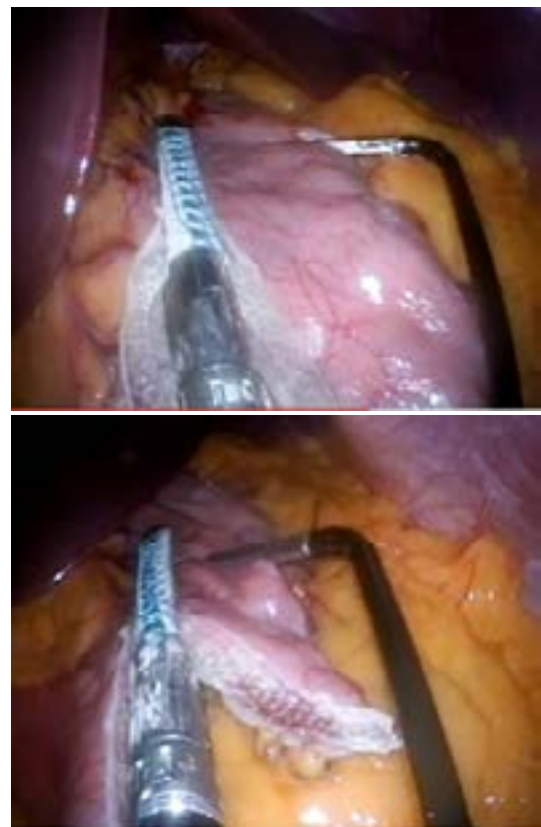


Fig 4: Gastric division by tri-stapler close to the bougie.

The bougie was then removed and the specimen was taken out of the abdominal cavity through the 12 mm port. The staple line was then carefully inspected for bleeding and examined for integrity with methylene blue. Then, an intra-abdominal drain was inserted in the left hypochondrium and the stomach remnant was exteriorized from the same fascial incision. The defect was then carefully closed with a nonabsorbable suture to prevent an incisional hernia.

Patients were monitored for postoperative complications (reactionary hemorrhage, leakage, infection, deep venous thrombosis, and vomiting). Routine postoperative care was performed for all patients group (A) and group (B), in form of prophylactic dose intravenous anticoagulant injection on the night of the operation and routine gastrographin imaging for gastric remnant at second post-operative day before starting oral fluids. All patients received intravenous antibiotics, one dose at time of induction of anesthesia, and then post operatively for the first 24 hours. Patients were kept on intravenous fluids for 12 to 24 hours until the patients tolerated oral intake without vomiting. After that, patients were discharged from the hospital. Analgesics, antiemetic, and antispasmodics were given for the first week. Proton pump inhibitors were taken for one or two months depending on the patient's symptoms. At home, patients were allowed to take liquid

diet for two weeks, blended diet for the next two weeks, and semi-solid diet for another two weeks. After that patients returned gradually to normal diet according to the patient's compliance and acceptance. Operative times in minutes, hospital stay in days, post operative complications were recorded for both groups. Postoperatively follow up visit after 7 days was scheduled for removal of stitches. Then follow-up data for all cases were recorded at 1, 3, 6, and 12 months for both groups.

The following data of all the patients were prospectively collected and maintained in a database: age, gender, weight, height, BMI, surgical approach (SPSG or MPSG), operative time, intra- and post operative complications, length of hospital stay, pain assessment scores, patient-assessed cosmesis scores, and patient satisfaction scores. Primary and secondary end points of the study were identified and compared between the two groups. Postoperative pain, surgical complications and estimated weight loss (EWL) were defined as primary endpoints. The secondary end points were patient-assessed cosmesis scores, patient satisfaction scores, and operating time. Post operative pain was assessed by using visual analog scale (VAS) score on day 0 (at 6 h postoperatively) and postoperative day 1 (at 24 h postoperatively) of surgery and by the number of doses of analgesics administered for breakthrough pain. As a routine pain management protocol, all patients received injection paracetamol 1 g every 8 hours and diclofenac 50 mg every 12 h for the first 24 h after surgery. The patients who required analgesia for breakthrough pain were administered pethidine IM injection of 50/100 mg. VAS is a means of measuring subjective characteristics that cannot be directly measured. We used the VAS score in the form of questionnaires handed over to patients for scoring pain, cosmesis, and overall satisfaction with the surgical procedure. Cosmesis was assessed in patients at their first follow-up when dressing was removed on postoperative day 7 (**Figure 5**).



Fig 5: 7 days post operative of SPSG.

Patients in both groups were shown the same photograph of an abdomen with a surgical scar of midline incision of open sleeve gastrectomy. This scar was rated 0 on the VAS scale. Patients were asked to rate cosmesis assessment of their own surgical scar (0–10) on a VAS scoring chart after comparing their postoperative scar to the scar on the photograph. The scale was calibrated from 0 to 10, 10 being the highest and 0 the lowest score for a given attribute. Complications were recorded as intraoperative and postoperative. Patient satisfaction scores were also determined using the VAS score on postoperative day 7.

Statistical analysis

Demographic, clinical, morbidity and weight loss data were collected, recorded, coded, revised, and entered into the statistical package for social science, version 20 (IBM, Armonk, New York, USA). The data was presented as number and percentages for the qualitative data and mean with ranges for the quantitative data. Categorical variables were analyzed using chi-square, and continuous variables were analyzed using Mann–Whitney U test (Wilcoxon rank test). A P value of less than 0.05 was considered significant.

Results

Thirty-five morbidly obese patients were included in the study. These patients were divided into 2 groups, group (A) included 18 patients (10 females and 8 males) who underwent MPSG and group (B) included 17 patients (11 females and 6 males) who underwent single-incision laparoscopic sleeve gastrectomy (SPSG).

Table 1: Shows demographic data

	MPSG	SPSG
Age (in years)	37.5±8.6	33.6±7.5
Gender F/M	8-Oct	6-Nov
BMI (kg/m ²)	42.85	41.33

Table 2: Operative details

	MPSG	SPSG	P –value
Operative time (in minutes)	75.83	101.59	<0.0001
Hospital stay (in days)	3.9 ± 1.7	3.2 ± 2.3	0.0473

Table 3: Intraoperative and Post-Operative Complications

Variable	MPSG	SPSG
Nausea	5 patients (27.77%)	6 patients (35.29%)
Vomiting	4 patients (22.22%)	5 patients (29.41%)
Intraoperative bleeding	2 patients (11.11%)	3 patients (17.64%)
Conversion	No (0%)	4 patients (23.52%)
wound infection	1 (5.55%)	2 patients (11.76%)
Incisional hernia	0	3 patients (17.64%)

Intra operative complications included three cases (17.64%) of bleeding in group (B) which occurred during dissection. Two of them occurred during mobilization of stomach at short gastric vessels and one occurred as bleeding from gastric remnant edge that was controlled. In comparison to group (A) bleeding occurred in 2 patients (11.11%). Early postoperative complications included six cases of nausea (35.29%) in group (B) in comparison to 5 patients (27.77%) in group (A), starting in first day which was controlled by medications, five cases of vomiting (29.41%) in group (B) starting on second day which were controlled by medications and antiemetic drugs. However in group (A) vomiting occurred in four patients (22.22%). There were two cases (11.76%) of wound infection in fifth day in group (B) in comparison with one patient in group (A) (5.55%), which was managed by oral antibiotics and resolved. Incisional hernia occurred in three cases (17.64%) in group (B) that developed after 7, 8 and 12 months and needed surgical repair with mesh in comparison to zero in group (A) $P=0.0004$. The operating time was significantly higher in the SPSG group with mean (101.85) minutes, MPGS (75.3) min $P=0.0005$. In SPSG group the mean operative time in the first 9 cases was (118) min while it was (94.125) min in the following 8 cases $P=0.0003$.

In the SPSG group, conversion occurred in 4 of 17 patients. All of them were converted to MPSG, 3 of them due to bleeding and one due technical difficulties. Additional analgesia for severe pain was required in 5 patients of MPSG (23.5%) and 4 (27.8%) patients in SPSG which were statistically insignificant ($P=0.29$). The VAS scores for pain on day 0 in the MPSG and SPSG groups were 4.3 (0–9) and 3.1 (0–6), respectively ($P=0.005$). The VAS scores for pain on day 1 in the MPSG and SPSG groups were 3.7 (0–6) and 1.92 (0–8), respectively ($P=0.0005$), The mean VAS score for cosmesis was higher in the SPSG group. SPSG 8.1 (4–10), MPSG 6.8 (2–10), $P=0.003$. Thereby indicating that patients in the SPSG group were more satisfied with their cosmetic results. Patient satisfaction scores were also higher in the SPSG group. SPSG 8.7 (6–10), MPSG 7.2 (2–10), $P=0.004$. This suggested

that patients in the SPSG group were more satisfied with the surgery compared to those in the MPSG group.

There were no other early morbidities such as leakage and no mortality occurred in our study in both groups. The mean hospital stay was 3.2 ± 2.3 days in group (B) in comparison to (3.9 ± 1.7) in group (A). Mean %EWL was measured at 1, 3, 6, and 12 months in group (A) MPSG and group (B) SPSG. 1 month % EWL was (19.7%) and (18.8%), at 3 months, %EWL was (31.1%) and (30.5%), whereas at 6 months, %EWL was (47.5%) and (46.8%), reaching (58.8%) and (57.9%) by the end of the 12th month respectively (Statistically insignificant).

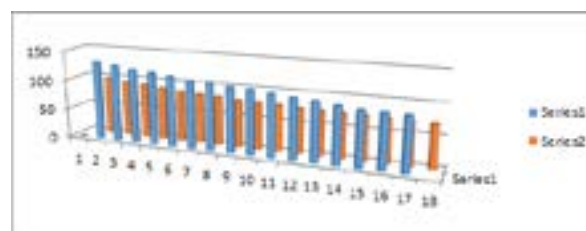


Fig 6: Shows comparison between operative time in minutes in consecutive operations.

Table 4: The percentage of EWL during the follow up visits at 1, 3, 6 and 12 months

	MPSG	SPSG
1 Month	19.7 %	18.8 %
3 Month	31.1 %	30.5 %
6 Month	47.5 %	46.8%
12 Month	58.8 %	57.9 %

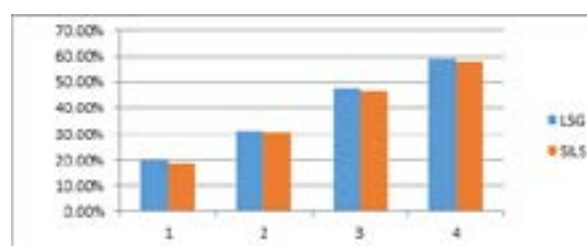


Fig 7: Shows % ewl during 12 months.

Discussion

Laparoscopic sleeve gastrectomy has surgical advantages because it does not require a gastrointestinal anastomosis or intestinal bypass and it is considered less surgically skill demanding than other bariatric operations.¹³ The conventional laparoscopic procedure is performed using 4 to 5 skin incisions for the placement of trocars. The relatively low complexity of this surgery, performed in only one abdominal quadrant with a limited range of movements, has made it a good candidate for the single-incision laparoscopic surgery (SILS).¹¹ Once a new technology is introduced, searching

for its feasibility, safety, and efficacy started before it can be promoted as a standard procedure that can stand for a long time.^{14,15}

In our study, the primary outcome measures were postoperative pain and surgical complications. The postoperative pain in the MSPSG and SPSG groups was compared using VAS scores and the number of patients (and doses) requiring analgesia for breakthrough pain. Analysis of these two parameters in both groups revealed more pain in the MSPSG group on the day of surgery and also post-operative day 1 which was statistically significant. Similar result were obtained by Maluenda et al¹⁶ who reported that patients who had undergone single-port sleeve gastrectomy had considerably less pain from the eighth hour after surgery, resulting in a decrease in the use of analgesics and also the study carried out by Lakdawala et al.¹⁷

As regards surgical complications, 3 cases of bleeding occurred in SPSG in comparison to 2 cases in MSPSG which were statistically insignificant. However, these 3 patients required conversion to MSPSG to control bleeding. This indicates that SPSG is a safe procedure in the hands of experienced surgeons with no serious complication. However, in our study, patients were carefully selected to ensure high BMI above 50 were excluded. In the series reported by Delgado et al,¹⁸ one case was converted (5%) (N=1/20 patients) because of technical problems with the length of the endo stapler and a large liver steatosis, rendering sleeve gastrectomy technically impossible. However, Maluenda et al¹⁶ and Gentileschi et al¹⁹ reported no conversions to open or conventional laparoscopic surgery. As regard, vomiting, nausea and wound infection the comparison between the two groups were statistically insignificant for all items. Most single-port surgery entails a fascial incision of at least 2.5 cm, moreover, there is a continuous stretching effect on the access wound due to the nature of the design of the single port. The umbilicus is an inherently anatomically weak area. It follows that an incision around the umbilical cicatrix would be prone to development of an incisional hernia in the postoperative period. A careful and meticulous closure of the fascial defect is mandatory.²⁰ Despite the meticulous closure, 3 patients in our study suffered from incisional hernia in SPSG group that developed after 7, 8 and 12 months and needed surgical repair with mesh in comparison to zero in group SPSG, P=0.0004. It was interesting that no early trocar site hernias were observed in MSPSG group. Many authors might consider higher BMI a risk factor for trocar-site hernias; however, to date only one study by Uslu et al.²¹ found a BMI of 28 kg/m² or higher to be a significant risk factor for

postoperative trocar site hernia development. In contrast, other studies did not reveal any association between trocar site hernias and BMI.²²

In the other hand Emmanuel et al²³ proved in his study that the development port site hernia is a major setback for a single port procedure that is popularized based on its cosmetic superiority. Sucher et al²⁴ demonstrated that he had no single case of incisional hernia in SPSG group in contrast to our study, mostly as we followed up patient for 12 months while mean follow-up period of Sucher was 6.6 months.

Finally as regards weight loss, as expected no difference was present in our series between the two groups, the median percent EWL at 6 months in the MPGS group was 47.5% and that in the SPSG group was 46.8% and at 12 months 58.5 and 57.9% respectively. Not only was the percent EWL comparable in both groups, but it was also comparable with other studies on MSPSG. Baltasar et al.²⁵ have reported a mean percent EWL of 56.1% (46% to 66%) from 4 to 27 months after surgery. Lakdawala et al¹⁷ and Baltasar et al²⁵ have also reported a mean percent EWL of 50.8% and 56.1% at the end of 6 months, respectively.

The secondary outcome measures in our study were patient-assessed cosmesis scores, patient satisfaction scores, and operating time. Patient-assessed cosmesis scores were higher in the SPSG group. This indicates that patients in the SPSG group were more satisfied with their cosmetic results. A randomized trial comparing SPSG with MPGS showed that SPSG was superior to MPGS in terms of cosmesis.²⁶ Patient satisfaction scores were also higher in the SPSG group, thereby suggesting that patients in the SPSG group were more satisfied with the overall results of the procedure. In our study, on the basis of patients' own assessment, it is found that SPSG offers the advantages of better cosmesis and more patient satisfaction.

The operating time was significantly higher in the SPSG group 101.85 minute compared to 75.3 min in MSPSG with P=0.0004. Although, as the number of patients undergoing SPSG increased, there was a significant reduction in the operating time from 118 in the beginning of the study to 94.125. In our experience, operating time was significantly reduced after the first 8 SPSG procedures.

This corroborates with the reported "learning curve" in literature. The learning curve was identified as a significant factor in the quality and outcome of laparoscopic gastric sleeve. The single-port approach increases the technical complexity of the procedure and requires a new learning

phase. In this study, the learning curve was overcome with about 8 procedures, after which a flattening of the learning curve was observed. Another study comparing SPSG and MPSG showed that the operating time was higher in the SPSG group.²⁷

Our study was performed at tertiary care centers with expertise in minimal access surgery (MAS). Patients in both groups were matched for comparable demographic characteristics and were studied during the same period. However, there are several limitations in the study, patients were not randomized for procedure allocation as we believe that the true randomization is extremely difficult in the clinical setting of a large private hospital, the study design was created to study the patients in both arms (SPSG and MPSG) during the same study period. With this setting, it was not possible to have completely similar demographics in both groups. Patient-assessed cosmesis and satisfaction scores were obtained only once at 1 week postoperatively, the cost implications of SPSG have not been studied. During surgery, triangulation of instruments entails vision to be central and to have one working instrument on either side. Triangulation ensures the most comfortable working position for the surgeon ergonomically, triangulation is always present in conventional surgery and is most often possible in traditional MPSG. However, it is a struggle to achieve triangulation in SPSG. In SPSG, the optic and hand instruments are located in almost the same vertical plane.

There are several challenges inherent in performing SPSG with access from the umbilicus, there is likelihood of injury to the underlying bowel during introduction and placement of the access port. The placement of stay sutures and lifting up the abdominal wall while manipulating the port in place is essential to avoid injury. We use a pre-bent, curved, reticulating grasper to retract the liver in the left hand of the surgeon and a straight Harmonic scalpel in the right hand of the surgeon for well controlled and precise dissection.

It is expected that SILS shall be driven by patient demand and expectation and propelled by medical industry seeking to introduce new equipment and technology, with the development of a new technique, the accompanying learning curve may expose patients to risk.²⁸ It has been our experience that during SPSG, it is possible to always follow the rule for patient safety during the procedure. Moreover, in our experience, the learning curve for SPSG was short (approximately 8 patients), the safety of patients undergoing a new surgical technique should be paramount.

A new and innovative surgical technique normally involves added expenditure, as equipment become more sophisticated, they are more expensive as compared to standard laparoscopic instruments. Whether the increased cost translates into better outcomes for the patient in terms of faster and better recovery is yet to be determined.

SILS provides a means of minimizing access with equipment and hand instruments for surgical intervention. Further developments and advances shall most likely lead to providing a solution with the "best" access with minimal invasion. It seems reasonable to expect that once best access is achieved, we shall then think in terms of devising instruments that can comfortably perform the surgical procedure with the requisite optimal ergonomics. Further developments in robotics appear to be the next logical step forward. Today, SILS stands where MAS stood about two decades ago. It faces almost the same challenges and skepticism faced by the traditional laparoscopic surgery. With the ongoing changes and advances in the field of MAS, long-term follow-up and controlled trials are required to suggest if SILS is a meaningful and lasting technique or a stepping stone toward accomplishing a truly scarless intervention.²⁹

Conclusion

Single-incision laparoscopic sleeve gastrectomy is technically feasible, and safe alternative to conventional laparoscopic sleeve gastrectomy. Additional work must be carried out before these techniques can be standardized. The development of flexible articulating instruments, high-illumination, high-magnification, flexible endoscopes, and free-standing insertable retractors is needed.

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