OBES SURG (2011) 21:1664–1670
DOI 10.1007/s11695-011-0478-y

NEW CONCEPTS

Single-Incision Sleeve Gastrectomy Versus Conventional Laparoscopic Sleeve Gastrectomy—a Randomised Pilot Study

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Published online: 26 July 2011
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Abstract
Background This is a prospective pilot study done to evaluate the feasibility and to assess the outcomes and complication rates of the single-incision sleeve gastrectomy versus the conventional five-port laparoscopic sleeve gastrectomy.
Methods A prospective comparative analysis was done of 50 patients in each arm who underwent laparoscopic sleeve gastrectomy and single-incision sleeve gastrectomy from September 2009 until April 2010. Both groups were matched for age, gender and BMI and were then randomly assigned to either group. Postoperative pain scoring was done using the visual analogue scale. Postoperative outcomes in terms of pain scores, excess weight loss, resolution of comorbidities and complication rates were compared in both groups, at the end of 6 months.
Results Operating times in both groups were comparable with experience. Intraoperative blood loss was similar in both groups. VAS scoring revealed lesser postoperative pain after the first 8 h in the single-incision group as compared to the laparoscopy group—$P<0.0001$. At 6 months, excess weight loss and resolution of comorbidities were comparable in both groups. There were no major complications or mortalities in either group.
Conclusions Single-incision laparoscopic sleeve gastrectomy is a feasible surgical procedure for morbid obesity in selected individuals. When compared to conventional laparoscopic sleeve gastrectomy, it has equally effective weight loss and resolution of comorbidities. It also has the added benefits of little or no visible scarring and reduced postoperative pain.

Keywords Laparoscopic sleeve gastrectomy · Bariatric surgery · Single-incision sleeve gastrectomy · Visual analogue scale · SILS™

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Introduction

"*These are exciting times to be a surgeon*"—words of Lord Joseph Lister said more than a hundred years ago remain true even today. The science and art of surgery has come a long way in the last millennium.

The last decade witnessed some of the most spectacular innovations in the field of surgery. The motto has been to deliver *more* through *less*. The basic idea behind every new development has been reduction of pain, better cosmetic results and reduction in the hospital stay whilst having comparable results and complication rates as the conventionally accepted procedures.

Surgery has evolved from the era of big incisions used in open surgery to multiple tiny incisions in laparoscopy to surgery done through one small single incision to end with no incision surgery (NOTES). Scarless surgery is the natural and logical culmination of minimally invasive surgery.

The gynaecologists paved the road for single-incision surgery as in laparoscopic surgery. Early reports of single-incision surgery date back to 1972 when Wheeless C R performed tubal ligations through a single 1-cm infraumbilical incision [1]. In 1992, Pelosi et al. reported laparoscopic supracervical hysterectomy through a single umbilical incision [2]. In the late 1990s, the scope of single-incision surgery expanded to general surgical procedures. Espocito C. reported the use of single-incision technique for appendicectomy in the paediatric population [3]. Navarra et al. reported the first single-incision cholecystectomy in 1997 [4]. Subsequently surgeries like nephrectomy and hemicolectomy were reported using single-incision approach [5, 6]. In the year 2008, the gamut of single-incision surgery was broadened to include bariatric surgery, and a few early case reports of adjustable gastric banding and single-incision sleeve gastrectomy were published [7, 8]. In December 2009, Saber et al. from the USA and Huang et al. from Taiwan reported the first single-access Roux-en-Y gastric bypass [9, 10].

At the Center for Obesity and Diabetes Support, Saifee Hospital, we started performing the "single incision sleeve gastrectomy (SISG)" from September 2009 onwards. This study was done to evaluate feasibility and gauge the limitations of SISG when compared to LSG at our centre. At 6 months, results were compared in terms of postoperative pain, excess weight loss, resolution of comorbidities and complication rates.

Methods

Study Design

Data of 100 patients who underwent sleeve gastrectomy commencing from September 2009 to April 2010 were collected prospectively. Fifty patients underwent SISG, and 50 underwent LSG. All patients were operated upon by a single surgical team. Preoperative evaluation of anthropometric and biochemical parameters was done in all patients. Patients in both groups were matched in terms of age, gender and body mass index (BMI) and were assigned randomly to each group. Exclusion criteria from this study were:

Previous major abdominal surgery with excessive scarring
Age less than 18 years or more than 65 years
Patients with BMI ≥60 kg/m^2
History of substance abuse by the patient

Pain scoring was done using the "visual analogue scale" in both groups postoperatively at 4, 8, 12 and 24 h and on the 7th day. The patients followed up at 3 and 6 months when the anthropometric measures were taken and investigations done. Postoperative outcomes in terms of excess weight loss, resolution of comorbidities and complication rates were compared at the end of 6 months.

The demographic characteristics of both groups were as follows: The median age of patients in the SISG group was 26 years (18 to 50 years) versus 28 years (18 to 54 years) in the LSG group. There were 40 females and 10 male patients in the SISG group versus 39 females and 11 male patients in the LSG group. Median BMI in the SISG group was 41 kg/m^2 (32 to 58 kg/m^2) versus 43 kg/m^2 (34 to 59 kg/m^2) in the LSG group. Table 1 depicts the incidence of comorbidities in both the groups.

Study Intervention

Patients were put on a strict high protein, low fat and low carbohydrate diet for a minimum of 7 days prior to surgery. Prophylaxis for deep vein thrombosis was given to all patients in the form of DVT stockings, intraoperative calf pumps and low molecular weight heparin injections 12 h prior to surgery. Informed consent pertaining to SISG or LSG was taken from all patients prior to the procedure. Patients were given an option to opt out of the study if they chose a technique of surgery over the one randomly assigned to them.

Technique of Surgery for Conventional Laparoscopic Sleeve Gastrectomy

Five-port technique was used.

(a) 12 mm supra-umbilical under vision trocar
(b) 12-mm trocar in the right midclavicular line (Vertical distance from the subcostal margin is variable depending upon the xiphisternoumbilical span of the patient.)
(c) 12-mm trocar just lateral to the left midclavicular line (Vertical distance from the subcostal margin is variable depending upon the xiphisternoumbilical span of the patient.)

Table 1 Number of patients with comorbidities in both groups

Comorbidity	SISG	LSG
Type 2 diabetes mellitus	6	8
Hypertension	7	5
Sleep apnoea	7	6
Dyslipidaemia	7	5
Joint pains	6	8
PCOD	4	3
Cholelithiasis	2	0
GERD	8	10

(d) 5-mm trocar in the epigastrium
(e) 5-mm trocar in the left anterior axillary line, just below the costal margin

The gastrosplenic as well as gastrocolic omentum was divided from the greater curvature close to the stomach wall using Harmonic Scalpel™ or a Ligasure™ device. Either of the two devices was used for conventional laparoscopy. The left crus was dissected and the angle of His delineated. Laxity of the crura was looked for and repaired if very wide. Posterior adhesions to the pancreas were lysed. The sleeve of the stomach was created over a 36-F bougie. First firing of the linear stapler was done using a green load with a height of 3.5 mm at a distance of 4 to 5 cm from the pylorus, and subsequently, blue loads with a height of 2.5 mm were used. We routinely do not oversew or use any kind of reinforcing material over the staple line. Staple line was oversewed whenever there was bleeding from the staple line, if the patient had severe sleep apnoea and was on bi-pap or if the last fire was too close to the oesophagus.

Methylene blue leak test was performed in all cases. The specimen of the stomach was removed from the left subcostal port. We do not use an endobag routinely. The left subcostal port was closed with a 2-0 absorbable polyfilament suture with the help of a port closure needle.

Technique of Surgery for Single-Incision Sleeve Gastrectomy

A 2- to 2.5-cm vertical transumbilical skin incision was made by everting the umbilicus, and the abdominal cavity was entered with the open Hasson's technique. Multichannel SILS™ port from Covidien was used in all cases. Three 5-mm ports were then inserted through the SILS™ port. A 5-mm 30° telescope and conventional straight instruments were used in all cases. The rest of the steps for SISG were essentially the same as in conventional LSG. We preferred to use the 5-mm blunt tip Ligasure™ device for dissection in single-incision surgery as the particulate matter that clogs the view of the endoscope is considerably less with a Ligasure™ when compared to a Harmonic scalpel™.

Whenever we encountered a large overhanging left lobe of liver, we retracted the liver using a monofilament suture with two straight needles and a pledget to lift the liver towards the anterior abdominal wall (Fig. 1). One needle was inserted through the left lobe of the liver near the hiatus and brought out vertically through the skin in the epigastric region. The other needle was inserted through the left lobe of the liver closer to the falciform ligament and brought out through the skin. Both ends were then tied on the skin over a gauze. This helped to retract the liver. In our experience, no arterial bleeding or biliary leak was noticed in any of the cases. Minor oozing of blood from the surface of the liver was controlled with compression. There never was any need for further management in any of the cases.

Fig. 1 Use of monofilament suture with pledget for liver retraction

Once the dissection was completed, one of the 5-mm trocars from the SILS™ port was replaced by a 12/15-mm trocar for facilitating the insertion of a stapler gun. Staple line haemostasis was achieved using either haemoclips or biosurgical products such as fibrillar or glue routinely and rarely by oversewing the entire staple line. A haemoclip was used whenever there were one or two localized spurters from the staple line. In case of generalized oozing of blood with no active spurting from the staple line, we used glue or preferred to suture in hypertensive patients. Suturing was also done for patients who had severe sleep apnoea and were on bi-pap.

We did not use reinforcing material, but it could be useful in SISG cases. A methylene blue leak test was routinely done in all cases. Drains were not inserted in any patient. The specimen was removed from the umbilical incision, and proper closure of the sheath was done with a nonabsorbable suture material to decrease the chances of an incisional hernia in the future.

A gastrograffin swallow was routinely done in both groups of patients on the first postoperative day to check for a leak. All patients were started on clear liquids after the gastrograffin study and discharged the same evening.

Results

Single-incision sleeve gastrectomy was successfully performed in 50 patients. None of these patients were converted to a standard five-port laparoscopic sleeve gastrectomy or open surgery. Median operative time was 50 min (range 35–120 min) in SISG group and 45 min (range 25–72 min) in the LSG group. The first few cases done by the single-incision technique took 90 to 120 min with subsequent decrease in the operating time with experience. The median intraoperative blood loss in the

SISG group was 20 ml (range 15–75 cc) and 28 cc (range 15–80 cc) in the LSG group. There were no intraoperative complications in either group.

Postoperative pain scores were compared between the two groups using the visual analogue scale (VAS). Pain medication was standardized in the intra- and postoperative periods. The following medications were used intraoperatively in both the groups: fentanyl 1 mics/kg, tramadol 2 mg/kg, paracetamol 1 g, dexmedotemidine 0.4 mic/kg/h and diclofenac suppository 2 mg/kg. Postoperative pain scoring was done on a scale of 1 to 5 for the first 24 h and on the 7th postoperative day. For VAS more than 4, diclofenac was used as the first line of medication, paracetamol as second line and tramadol as third line. Pain charting was done at 4, 8, 12 and 24 h and then on the 7th postoperative day. Pain charting in both the groups for the first 24 h is shown below in Fig. 2.

There was no significant difference in the pain scores for the first 4 h postoperatively in both the groups. A paired *t* test was used to compare the pain scores between the two groups after the first 8 h, with significance set at $P<0.05$. Thirty five out of 50 patients in the SISG group did not require any pain medication after the first 8 h postoperatively. No patient needed painkillers on discharge, and all of them were pain free on the 7th postoperative day.

Amongst the LSG patients, 12 patients needed painkillers even after the first 24 h until the 7th postoperative day ($P<0.0001$, CI −1.37 to 0.67). Most patients complained of pain at the port site from where the specimen was removed.

Median hospital stay for SISG patients was 48 h (range 36–72 h) which was comparable to that for LSG. Table 2 shows the median percent excess weight loss in the two groups at the end of 3 and 6 months.

Resolution of type 2 diabetes was taken as HbA1c levels below 7 and fasting blood sugar levels below 100 mg/dl without medication. In the SISG group, type 2 diabetes

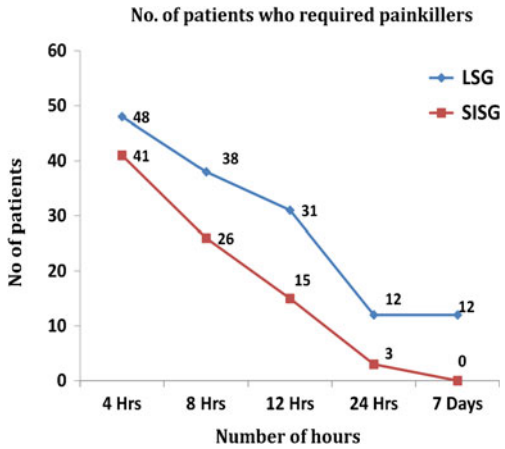

Fig. 2 VAS scoring for the first 24 h ($P<0.0001$)

Table 2 Median percent excess weight loss in the two groups at 3 and 6 months

Duration (months)	SISG	LSG
3	33.4% (18–45.7%)	32.6% (16–48%)
6	52% (39–68%)	50.8% (27–70%)

resolved in five patients and improved in one patient by the end of 6 months, and hypertension resolved in four and improved in three patients. Sleep apnoea improved in all seven patients. In the LSG group, type 2 diabetes resolved in six patients and improved in two, hypertension resolved in three patients and improved in two. Sleep apnoea improved in all six patients. Improvement in other comorbidities was also comparable. All patients were routinely prescribed proton pump inhibitors for the first 6 months; hence, no significant difference in postoperative GERD was seen. In the SISG group, we performed concomitant cholecystectomy in two patients. All patients in the SISG group were happy with the visible scar and hence with the cosmetic results as compared to LSG. There were no major intraoperative or postoperative complications in either group. There was no mortality in either group.

Discussion

Whenever a new technology rolls in, questions about its feasibility, safety, efficacy and reproducibility are raised. The risk versus benefit ratio of any new procedure must be weighed before it can be promoted as a standard procedure that can stand the test of time.

Morbid obesity was initially considered as a detractor to single-incision surgery. Increasing BMI with very high intraabdominal fat content and large fatty livers when added to the inherent difficulty of single-incision surgery proved to be stumbling blocks for the application of this technique to bariatric surgery. Case selection for SISG thus holds paramount importance especially in the first few cases.

Patients between the age group of 18 to 65 years were included in this study. We believe in doing only reversible procedures for adolescents less than 18 years of age. Sleeve gastrectomy is not routinely recommended to this age group at our centre. Patients more than 65 years of age are usually high risk, and we kept them out of the study group till we established the safety protocol for single-incision surgery at our centre.

In one of the first case reports in 2008, Nguyen et al. successfully performed a single-incision surgery on a 54-year-old male patient with a BMI of 38 kg/m^2. They suggested that without any kind of liver retraction, the use

of single-incision surgery in bariatric surgery will be limited only to patients with lower BMI [7]. In the same year, Saber et al. reported a series of seven single-access laparoscopic sleeve gastrectomy patients. The mean BMI in their series was 53.5 kg/m^2 (range 42–68). Although the BMI range was wide, they used an additional Nathanson's liver retractor through a small subxiphoid incision in all patients [8]. In 2010, Saber et al. extended the use of this technique to include super super obese patients and performed single-incision surgery in four super super obese with a mean BMI of 62.5 kg/m^2 [11].

In obese patients, enlarged livers pose the biggest difficulty during single-incision surgery, and liver retraction remains to be a challenge. P. Gentileschi et al. reported the use of a laparoscope for liver retraction in their series of eight patients who underwent single-incision sleeve gastrectomy. The mean BMI in their series was 52.6 kg/m^2 (range 44.2–66.2). They did not make use of another trocar in their series [12]. At our centre, we retracted the liver using monofilament sutures on straight needles with a pledget to retract the liver to the anterior abdominal wall. This technique was first described by Huang et al. in 2009 [13]. With the help of this technique, we observed a marked improvement in the visibility in the region of the first short gastric vessel as well as the left crus of the diaphragm. This helped us in adequate dissection and complete removal of the fundus in all cases. We did not need to use an extra 5-mm trocar in any of our SISG cases.

Distance between the xiphisternum and umbilicus was another difficulty that was encountered in taller patients. Long-length instruments were a must in tall patients to enable us to reach the left crus from the umbilicus.

Previous abdominal surgery with dense intraabdominal adhesions is another deterrent for single-incision surgery. P. Gentileschi et al. also excluded patients with previous major abdominal surgery in their series like we did in our study [12].

In the first two reports of single-incision sleeve gastrectomy, multiple conventional ports were used through one incision [7, 8]. Saber et al. used three trocars from the same umbilical skin incision along with a 5-mm epigastric incision for liver retraction [8]. Nguyen et al. used a 4-cm transverse skin incision in the epigastric region and inserted three trocars through separate fascial entries [7]. With increasing popularity of single-incision surgery, various devices like the SILS™, R port™, Tri Port™, Gel port™ etc. have been developed for gaining intraabdominal access. In our series, we have used the SILS™ device (Covidien) through a single transumbilical incision in all cases.

When compared to conventional laparoscopic surgery, single-incision surgery defies the standard surgical principles of traction and counter traction. Shortcomings of the SISG as compared to LSG are: (1) clashing of instruments, (2) crossing of hands during surgery, (3) difficulty in reaching up to the fundus from the umbilicus, especially in taller patients, (4) difficulty in repairing the hiatal defects and (5) oversewing the staple line is technically very demanding.

The entire surgery is performed without any counter traction. Loss of triangulation and frequent clashing of the instruments all inserted from a very small incision further increase the difficulty. In our series, we used standard straight instruments and a conventional 5-mm 30° telescope for all cases. Roticulating instruments may help to overcome the problem of triangulation. A coaxial camera with a flexible tip like the Endoeye™ can be helpful in preventing frequent clashing of the light cable of the telescope with the hand instruments. Haemostasis at the staple line can be achieved using clips or biosurgical products such as fibrillar or glue. Seamguards and Duet TRS™ may also be of help. Oversewing of the staple line, although difficult, is possible in cases which require the staple line to be sutured.

Operating time and blood loss for SISG was comparable to LSG in our series. In the initial few cases of SISG, the time taken was longer. Overall surgical time for SISG in our series ranged from 35 to 120 min with a median of 50 min. Operating time reported by Nguyen et al. for a single laparoscopic incision transabdominal sleeve gastrectomy was 120 min [7]. Saber et al. reported a mean surgical duration of 125 min in their series of seven cases of sleeve gastrectomy done through a single transumbilical incision [8]. The mean operative time reported by P. Gentileschi et al. was 128 min. The number of cases reported in all these studies was less than ten compared to 50 patients reported in our series. We believe that as the experience with SISG increases, the operative time proportionally decreases.

In our series, there were no intra- or postoperative complications in either group. We mainly looked at the following complications:

- Intraoperative: injury to adjacent viscera like liver, oesophagus and spleen
- Postoperative

  Early complications—leaks, DVT, wound infection
  Late complications—strictures, acid reflux and incisional hernia

There were no mortalities in either group. P. Gentileschi et al. reported postoperative wound infection in one patient in their series [12]. No complications occurred in the series reported by Saber et al. and Nguyen et al. [7, 8]. We believe that SISG requires a much higher level of skill and dexterity, and it must be performed by surgeons who have had adequate experience in performing LSG. The learning curve for single-incision sleeve gastrectomy is longer and

hence should preferably be carried out at high-volume centres.

Pain scoring was done using VAS in both groups. Our observation was that patients who underwent SISG had lesser pain after the first 8 h and required less pain medication as compared to the LSG group. Paired *t* test performed on both groups led to a *P* value <0.0001. In a report published in December 2010, Saber et al. also demonstrated statistically significant difference in the pain scores between 12 patients who underwent single-incision sleeve gastrectomy when compared to 14 of those who had laparoscopic sleeve gastrectomy [14].

Efficacy is a very important aspect of any new procedure. It must be implemented only if the results of the conventional procedure can be duplicated or made better. In our series, the median percent EWL at 6 months in the SISG group was 52% (39% to 68%) and that in the LSG group was 50.8% (27% to 70%). Not only was the percent EWL comparable in both groups, it was also comparable with other studies on LSG. Baltasar et al. have reported a mean percent EWL of 56.1% (46% to 66%) from 4 to 27 months after surgery [15]. Lakdawala et al. and Rosenthal et al. have also reported a mean percent EWL of 50.8% and 52.8% at the end of 6 months, respectively [16, 17].

The limitations of this pilot study were that these were short-term results in a small patient pool. We acknowledge that this is a pilot study, and the intention was to establish the feasibility and safety of this new single-incision technique as compared to the conventional laparoscopic technique. After determining the weight loss results and complication rates, we intend to extend this study into a randomised controlled trial with a larger number of patients comparing the results of single-incision sleeve gastrectomy to laparoscopic sleeve gastrectomy for a follow-up period of up to 5 years. Another limitation of our study was that the feeling of satisfaction pertaining to a superior cosmetic scar after SISG was a purely subjective feeling expressed in the opinion of most of our patients. We hope to record this on a validated patient outcome questionnaire in our future endeavour. The limitations of the technique remain that the benefits of this procedure may not extend to patients who are super super obese or have a scarred abdomen. Additionally, only long-term results will show if there is any merit to the risk of increased risk of incisional hernias through a relatively larger incision of 2 to 2.5 cm on the sheath in SISG.

Conclusion

Single-incision sleeve gastrectomy when compared to conventional laparoscopic sleeve gastrectomy has similar operating times, comparable blood loss, similar complication rates, leads to similar weight loss and has comparable resolution of comorbidities. Our data elucidate that SISG has a definite advantage over LSG in terms of lesser postoperative pain. Patients in the SISG group were happier with their postoperative scars. To conclude, in selected cases and after due experience, single-incision sleeve gastrectomy is as safe, feasible and as effective a procedure as the conventional laparoscopic sleeve gastrectomy and should be practised with regularity.

Disclosures Drs. Muffazal Lakdawala, Aparna Bhasker, Nor Hisham Bin Muda and Sunita Goel have no conflicts of interest or financial ties to disclose.

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