



Single-Incision Sleeve Gastrectomy Versus Laparoscopic Sleeve Gastrectomy. A 2-Year Comparative Analysis of 600 Patients

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Abstract

Background This is a 2-year study to evaluate the feasibility; outcomes in terms of postoperative pain, weight loss, and complication rates; and cosmesis of the single-incision sleeve gastrectomy versus the conventional multiport sleeve gastrectomy.

Methods A prospective comparative analysis was done in 300 patients in each arm who underwent laparoscopic sleeve gastrectomy and single-incision sleeve gastrectomy from September 2009 till January 2012. Both groups were matched for age and BMI. Postoperative pain scoring was done using visual analogue scale. Outcomes in terms of pain score, scar satisfaction score, excess weight loss, resolution of co-morbidities, and complications were compared in both groups at the end of 6 months, 1 year, and 2 years.

Results Female patients preferred to undergo single-incision sleeve gastrectomy. Operating time and intraoperative blood loss were comparable in both groups. Visual analogue scale (VAS) scoring revealed lesser postoperative pain in the single-incision group. Excess weight loss and resolution of co-morbidities were also comparable in both groups at 6 months, 1 year, and 2 years. Incisional hernia was seen in 3 patients (1 %) in the single-incision group. Leak rate

was comparable. Cosmetic satisfaction was superior in patients who underwent single-incision surgery.

Conclusions Surgical outcomes are comparable in both groups at the end of 2 years. The myth of high long-term incisional hernia rate after single-incision surgery has been dispelled. Single-incision surgery is less painful with better cosmesis. It has come of age and should no longer be considered as an experimental procedure.

Keywords Single-incision sleeve gastrectomy · SILS · Multiport · Visual analogue scale · Scar satisfaction index

Introduction

Single-incision surgery had a humble start. In its infancy, simple gynecological procedures such as tubal ligations were tried [1]. It gained momentum in the late 1990s with procedures like hysterectomy, appendectomy, cholecystectomy, nephrectomy, hemicolectomy, and adrenalectomy being performed by this approach [2–6]. Over the last decade, the near-scarless approach of the single-incision laparoscopic surgery (SILS) has changed how patients perceive surgery.

The SILS approach was not attempted in bariatric surgery considering the large patient size, higher intra-abdominal fat content, big fatty livers, and the inherent complexity of the bariatric procedure in itself. The first reports of SILS bariatric surgery appeared in 2008 [7–9]. Adjustable gastric banding (AGB), sleeve gastrectomy (SG), and Roux-en-Y gastric bypass (RYGB) were then successfully performed by the SILS technique [8–10].

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Very soon, more reports on comparative studies emerged to establish efficacy and feasibility of this approach versus the conventional approach, and SILS was deemed as safe as conventional laparoscopic sleeve gastrectomy in the short term [11]. At our center, we started performing SILS sleeve gastrectomy in September 2009 and published short-term results comparing SILS technique to conventional laparoscopic technique in the year 2011 [12]. The present study is a continuation of our previous study, and we now present the 2-year comparative results of SILS sleeve gastrectomy versus laparoscopic sleeve gastrectomy (LSG) in terms of efficacy of weight loss, resolution of comorbidities, complications, cosmetic scoring, and pain scoring between the two groups.

Methods

Study Design

Data of 600 patients who underwent sleeve gastrectomy commencing from September 2009 until January 2012 was collected prospectively. Patients of 300 had conventional laparoscopic sleeve gastrectomy, and 300 patients had SILS sleeve gastrectomy. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All patients were operated by a single surgical team at the Center for Obesity and Digestive Surgery, Saifee Hospital, Mumbai. Informed consent was taken from all individual participants included in the study. Patients in both the groups were matched for age and BMI. Pre-operative evaluation of anthropometry, existing co-morbidities, and biochemical parameters was done. Excess weight loss (EWL), remission of co-morbidities, and short- and long-term complications were listed in the follow-up periods of 6 months, 1 year, and 2 years. Pain scoring was done with the visual analogue scale (VAS), and the cosmetic score was compared using the scar satisfaction index. Follow-up visits were scheduled at 7 days, 1 month, 3 months, 6 months, 1 year, and once every year thereafter.

Exclusion Criteria

Patients with a BMI >60 kg/m², previous major abdominal surgeries with excessive scarring of the anterior abdominal wall, patients with large ventral hernias, those with large hiatus hernia/gastro-esophageal reflux, and those with a history of substance abuse were excluded from this study.

Demographics

The demographic characteristics of both the study groups are listed in Table 1, and the pre-operative incidence of comorbidities in both the groups was as shown in Table 2.

Study Intervention

All 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 compression stockings, intraoperative calf pumps, and low-molecular-weight heparin injections 12 h prior to surgery and for 7 days postoperatively. Informed consent pertaining to SILS sleeve gastrectomy or LSG was taken from all patients prior to the procedure.

Technique of Surgery for Conventional Laparoscopic Sleeve Gastrectomy

Five-port technique was used.

1. 12-mm under-vision trocar in the right mid-clavicular line (vertical distance from the subcostal margin is variable depending upon the xiphisterno-umbilical span of the patient)
2. 12 mm supra-umbilical trocar
3. 5 mm trocar just lateral to the left mid-clavicular line (vertical distance from the subcostal margin is variable depending upon the xiphisterno-umbilical span of the patient)
4. 5-mm trocar in the epigastrium
5. 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 a Harmonic scalpel™, Thunderbeat™, Enseal™, or

Table 1 Demographic characteristics of both study groups

Parameters	SILS sleeve gastrectomy	Laparoscopic sleeve gastrectomy
Number of cases	300	300
Mean age (years)	35.5±9.7	35.5±7.8
BMI (kg/m ²)	39.9±5.2	39.9±5.1
M:F	1:13	1:1
Mean EBW (kg)	42±12.8	45.2±15.1
Mean WC (cm)	114.6±10.8	121.3±15.4
Mean HC (cm)	130.5±10.9	127.3±12

BMI body mass index, *M* male, *F* female, *EBW* excess body weight, *WC* waist circumference, *HC* hip circumference

Table 2 Pre-operative incidence of co-morbidities in both study groups

Co-morbidities	SILS sleeve gastrectomy (%)	Laparoscopic sleeve gastrectomy (%)
Type 2 diabetes mellitus	15	14
Hypertension	21	35
Dyslipidemia	13	11
Gout	16	25
Joint pains	34	29

LigaSure™ device. Either of these 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 the crural gap was 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/purple load at a distance of 3 to 4 cm from the pylorus, and subsequently, blue/purple loads were used. We routinely over-sew the staple line in all patients. Methylene blue leak test was performed in all cases. The specimen of the stomach was removed from the right subcostal port. The right subcostal port was closed with a 2-0 absorbable polyfilament suture with the help of a port closure needle. We do not insert a drain routinely.

Technique of Surgery for Single-Incision Sleeve Gastrectomy

A 2- to 2.5-cm vertical trans-umbilical skin incision was made by everting the umbilicus, and the abdominal cavity was entered with the open Hasson's technique. Multichannel SILS™ port 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™ or an Enseal™ device for dissection in single-incision surgery as the particulate matter that clogs the view of the endoscope is considerably less with these devices when compared to a Harmonic scalpel™. Initially, in the first 100 cases, whenever we encountered a large overhanging left lobe of the liver, we retracted the liver using the Huang's technique where a monofilament suture with two straight needles and a pledget is used to lift the liver toward the anterior abdominal wall. In the last 200 cases, we started using a 2.5-mm needlescopic instrument to retract the liver (Figs. 1 and 2). It was inserted directly through the anterior abdominal wall in the epigastric region. There was no need to make an incision and it left almost no visible scar later.

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. The staple line was over-sewed in all patients using 2-0 monofilament

**Fig. 1** Use of a 2.5-mm needlescopic instrument in retracting the liver

absorbable suture materials. Hemostasis was achieved using either hemoclips or biosurgical products such as fibrillar or glue. 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 non-absorbable 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 on the same evening.

Results

SILS sleeve gastrectomy was performed successfully in all 300 patients with no conversions to either conventional laparoscopy or open surgery. Additional trocars were not inserted in any of the patients who underwent SILS sleeve gastrectomy. LSG was also successfully completed in all 300 patients with no conversions to open surgery. In the first 45 to 50 cases, it took up to 120 min in some cases to complete the procedure from skin to skin. However, as our technique became more standardized, the mean operating time became shorter. After the first 100 cases of SILS sleeve gastrectomy, the operating

**Fig. 2** Retraction of the liver using a 2.5-mm needlescopic instrument

time decreased to 45 ± 20.5 min. The operating time for LSG was 42 ± 18.2 min. The blood loss in both groups was comparable and was less than 30–50 ml in all cases. There were no intraoperative complications in either group. Follow-up rate was 100 % in both the groups at 6 months and 1 year. At 2 years, 98 % of patients followed up in the SILS group and 96 % in the LSG group.

Postoperative Pain Scoring

Postoperative pain scores were compared between the two groups using the visual analogue scale (VAS). Pain medication was standardized in the intraoperative and postoperative periods. The following medications were used intraoperatively in both the groups: fentanyl 1 mic/kg, tramadol 2 mg/kg, paracetamol 1 g, dexmedetomidine 0.4 mic/kg/h, and diclofenac suppository 2 mg/kg. Postoperative pain scoring was done on a scale of 1 to 5. For VAS of more than 4, diclofenac was used as the first line of medication, paracetamol as second line, and tramadol as third line. In both groups, pain charting was done on the visual analogue scale at 4, 8, 12, and 24 h and then on the 7th postoperative day. Pain medication was administered to the patients only on demand. In the first 4 h, patients in both the groups complained of pain in the epigastric region and needed similar doses of pain killer medication.

Of the SILS patients, 30 % needed painkillers between 4 and 8 h. None of them required painkillers on discharge, and all remained pain free on the 7th postoperative day.

Of the LSG patients, 76 % needed painkillers between 4 and 8 h. Of the patients, 24 % needed pain medication on discharge and continued to complain of pain on the 7th postoperative day ($p < 0.0001$). The most common site for pain was at the right subcostal port site from where the specimen was removed, and a stitch was taken to close the sheath.

Excess Weight Loss

EWL% in both the groups was comparable at 6 months, 1 year, and 2 years (Table 3). Both the groups showed similar decrease in BMI at 6 months, 1 year, and 2 years (Fig. 3).

Table 3 EWL% in both groups at 6 months, 1 year, and 2 years

Duration	Mean EWL%		<i>p</i> value
	SILS	LSG	
6 months	59.7 ± 19.7	58.6 ± 22.3	0.78 (NS)
1 year	69.2 ± 22.8	68.3 ± 24	0.93 (NS)
2 years	65.4 ± 29.6	69.1 ± 26.3	0.47 (NS)

EWL% excess weight loss percent, NS not significant, SILS single-incision laparoscopic surgery, LSG laparoscopic sleeve gastrectomy

Resolution of Co-morbidities

The resolution of co-morbidities was comparable in both the groups. Remission of type 2 diabetes mellitus (T2DM) was defined as the achievement of the ADA criteria without any medication for a continuous minimum period of 6 months. At the end of 1 year, T2DM resolved in 98 % patients who underwent LSG as compared to that in 97.5 % who underwent SILS. Hypertension resolved in 91 % who underwent LSG as compared to that in 92 % of those who underwent SILS. Dyslipidemia resolved in 75 % of LSG patients as compared to that in 73 % SILS patients. Resolution of joint pains was comparable in both groups. New-onset GERD was observed in 5 % of patients in both groups at the end of 1 year.

Complications

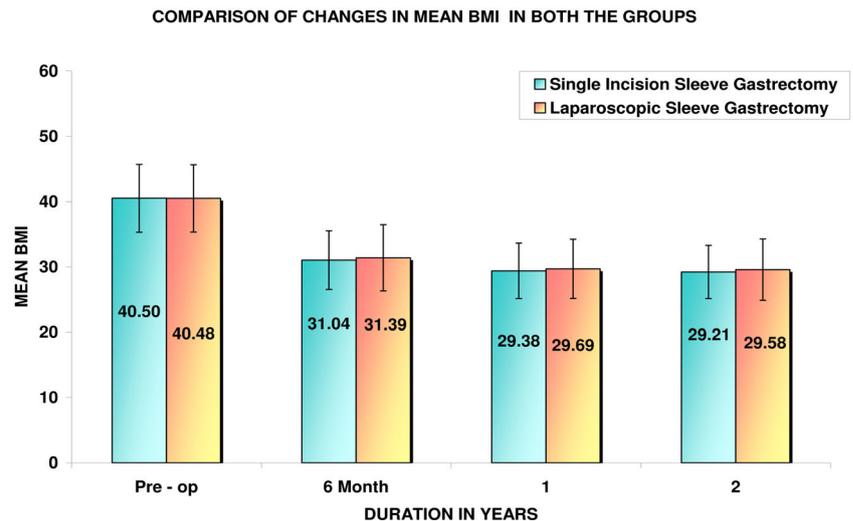
Wound infection was seen in 2 patients who underwent SILS. It was treated with antiseptic dressings. Delayed incisional hernia from the trocar site was seen in 3 patients (1 %) in the SILS group. None of the patients in the LSG group had an incisional hernia. There were two early leaks in the SILS group. These were seen in the first 50 patients where we did not over-sew the staple lines. There was one leak in the LSG group. We started over-sewing the staple lines in all patients since June 2010 and have not had any leaks since then in either of the two groups. There was no mortality in either group. On the whole, the complication rate in both the groups was comparable and did not show any significant difference.

Scar Satisfaction Score

A scar satisfaction index was used to objectively assess the cosmetic outcomes in both the groups. The following questions were posed to all patients at 6 months follow-up. The analysis of the answers is presented below:

1. Are you less satisfied with your body since the operation? Of the patients who underwent LSG, 21.7 % were not at all satisfied with their body after surgery as compared to that in 2.3 % of the patients in the SILS group ($p < 0.05$)
2. Do you think the operation has damaged your body? Of the LSG patients, 93.1 % did not think that the surgery had damaged their body as compared to that in 79 % of the patients in the SILS group ($p < 0.05$).
3. Do you feel less attractive as a result of your disease or its treatment? Of the patients in the SILS group, 95 % did not feel less attractive as a result of their disease or its treatment as compared to that in 73.3 % of the patients who underwent LSG ($p < 0.05$).
4. On a scale of 1 to 10, how satisfied are you with your surgical scar? Of the patients who underwent SILS,

Fig. 3 Decrease in BMI at 6 months, 1 year, and 2 years



60.5 % were very satisfied with their scar as compared to that in 51.7 % of the patients who underwent LSG ($p>0.05$).

5. Could you score your own incisional scar on a scale of 1 to 10? Of the SILS patients, 43 % rated their scar as 10 (beautiful) as compared to that in 26.4 % of the patients who underwent LSG ($p>0.05$). Mean score of the surgical scar in the SILS group was 8.2 which was comparable with a score of 7.7 in the LSG group ($p>0.05$).
6. The photograph is a picture of an open surgery scar (Fig. 4). Please rate the scar on a scale of 1 to 10. Of the SILS patients, 38.9 % rated the open surgery scar as “revolting” compared to that in 56.4 % of the LSG patients ($p>0.05$).
7. The photograph is a picture of a laparoscopic surgery (Fig. 4). Please rate the scars on a scale of 1 to 10. Only 8.1 % of the SILS patients rated the laparoscopic surgery scars as 10 (beautiful) as compared to that in 27.1 % of patients in the LSG group ($p<0.05$).
8. The photograph is a picture of a single-incision scar (Fig. 4). Please rate the scar on a scale of 1 to 10. Of the SILS patients, 41.9 % rated the single-incision surgery scar as 10 (beautiful) as compared to that in 49.1 % of the LSG patients ($p>0.05$).
9. Now, please score your scar again after seeing the pictures of the different kinds of scars for the same surgical

operation. Does your opinion about your scar change after seeing these pictures? After seeing the pictures of different kinds of scars for the same surgery, 48.8 % of the SILS patients rated their own scar again as 10 (beautiful) as compared to that in 21.6 % of the patients who underwent LSG ($p<0.05$). Mean score of the SILS scar was 8.73 as compared to 7.92 for LSG scars ($p<0.05$).

10. If you were to do the same surgery again, which approach would you prefer? Of the SILS patients, 90.5 % preferred doing a surgery by SILS approach again, whereas only 37.5 % of the LSG patients wanted to undergo the conventional multiport laparoscopy approach again ($p<0.05$).

Discussion

As with the introduction of any novel technique in surgery, the advent of single-incision surgery (SILS) was ridden with doubts and controversies. Most detractors of SILS did not see any added benefit to justify performing the same surgery by a more difficult technique. Questions were raised about safety, outcomes, and complication rates. In 2011, in a study

Fig. 4 Open surgery scar (a), laparoscopic (b), and single-incision scar (c)



done by us, we established the feasibility and safety of SILS vis-à-vis LSG in the short term [12]. With this study, it is our effort to establish the fact that SILS has firmly earned its place in the armamentarium of a bariatric practice.

Whenever a new technology emerges, the biggest concerns are around the safety of the procedure. In order to promote a new technique, the surgical steps must not be compromised. In SILS, all the instruments enter the abdomen through a single site. This restricts the range of movements and results in crossing over of the surgeon's hands, thus rendering the procedure to be considerably more difficult than conventional laparoscopy. Surgeons typically face difficulty in SILS in cases of a large overhanging liver that does not allow adequate visualization and makes crural dissection and over-sewing of the staple line difficult. In the early days, liver retraction was one of the biggest detractors for widespread application of SILS in bariatric surgery [7]. In 2008, Saber et al. reported the use of a Nathanson's liver retractor in 7 patients operated by him and later extended this technique to include even the super-super obese patients for SILS [8, 10]. At our center, in the initial few cases, we employed Huang's technique of using monofilament sutures on straight needles with a pledget to pull the liver up to the anterior abdominal wall [13]. We changed over from this technique and now use a 2.5-mm mini-laparoscopy instrument inserted directly in the epigastric region. This leaves no obvious scar. If one was to be rigid in the use of terminology, this could be called as a reduced port surgery rather than SILS. However, the mini-laparoscopy instrument is not only a good liver retractor but also doubles up as an able fundus retractor in difficult cases especially those with a patulous hiatus where a stitch has to be taken to approximate the crura. We aggressively dissect the left and right crus in all cases of LSG and SILS and concur with the concept of suturing the crura in case of a moderately patulous hiatus to reduce postoperative gastro-esophageal reflux [14]. This step may require a special skill set from the surgeon in case of SILS, and in difficult cases, there should be no hesitation to put an extra trocar to assist dissection and suturing. Lastly, leaks are the most dreaded complication after a sleeve gastrectomy. At our center, as a principle, we over-sew staple lines in all cases, be it LSG or SILS. Although there are numerous reports that have not shown any significant advantage of over-sewing the staple line, in our series, we did not have any leaks in either group after we started over-sewing the staple line [15, 16].

In terms of instrumentation, various devices like the R port™, Tri port™, Quad port™, Gel port™, X cone™, etc. are currently available for single-incision access. The limiting factor in these ports remains at the neck of the port which is at the level of the opening in the sheath. We used the SILS™ trocar from Covidien in all SILS cases as it allows for added flexibility in the area of the port above the skin and thus a wider lateral

spread of the surgeon's arms. Off late, some surgeons advocate robot-assisted SILS surgery. Spider® has also been advocated as a useful surgical platform for single-incision surgery as it allows the surgeon's arms to work at a distance from one another [17]. However, it is a relatively more expensive option and is yet to make inroads into regular practice. The third option is of doing a single-incision surgery through multiple facial openings close to one another with regular ports. This remains the cheapest option but closure of multiple fascial openings can be cumbersome and difficult in obese individuals and predispose to the risk of incisional hernias.

At our center, we use straight laparoscopy instruments for SILS along with a straight 5-mm 30° telescope. At times when the xiphisterno-umbilical distance is more as in the case of tall individuals, it may be difficult to reach the hiatus even with the extra-long instruments rendering the conventional laparoscopic approach better and safer in such cases.

EWL% is the best measure for the long-term efficacy of any bariatric procedure. In this study, the EWL% was comparable in both groups at 6 months, 1 year, and 2 years. At 2 years, an EWL% of 65.4±29.6 and 69.1±26.3 was seen in SILS and LSG patients, respectively. These results are comparable to those reported by us previously as well as by other groups [12, 18, 19]. Resolution of co-morbidities was also similar in both groups. If the right surgical candidates are picked and the sleeve is performed as per the accepted guidelines without any compromise, SILS technique is as effective as LSG at 2 years.

Complication rate was also comparable in both the groups. Initially, one of the biggest concerns after SILS has been the propensity for a higher incisional hernia rate. Incisional hernia rates as high as 5.8 % have been reported by studies on SILS cholecystectomy [20]. In our study, the incisional hernia rate was 1 %. We believe that incisional hernia rates in single-incision surgery can be brought down by proper closure of the sheath and giving due attention to this step in surgery. The surgeon must not neglect this and closure must be duly performed by the surgeon himself or by a well-trained, experienced colleague.

The leak rates were comparable in both groups. There was no mortality in either group.

Improved cosmesis remains one of the biggest advantages of single-incision surgery. In the early case reports on a single-incision approach to bariatric surgery, many a times the site of the incision was supra-umbilical and not necessarily buried in the umbilicus [21]. This took away the most major advantage of it being an almost scarless surgery. We believe that the trans-umbilical approach is most apt for SILS. We also believe that the nerve supply at the umbilicus makes the incision in

this area less painful than if placed elsewhere on the abdominal wall. This explains the VAS scoring that reveals lesser pain in patients in the SILS group.

Till date, cosmetic satisfaction after SILS has remained an unquantified entity. In an attempt to measure the scar satisfaction, we have used a scar satisfaction survey that was put forth to all patients at 6 months after surgery. The survey revealed that patients who had SILS were definitely more satisfied with the non-visibility of the scar as compared to those with visible scars. This becomes even more pertinent in case of patients with a tendency for a hypertrophic scar or a keloid formation.

The survey included immediate postoperative scar pictures after open surgery, multiport laparoscopic surgery, and single-incision surgery. They were also explained that these scars were immediately after surgery and would turn less visible over time. In the end, both the groups of patients were asked their preferred approach if they were to undergo surgery again. SILS patients of 90.5 % preferred the SILS approach again. Of the patients who underwent LSG, 62.5 % did not wish to have the laparoscopic approach again. This gives an important insight into the mindset of the patients. Given a choice, most patients would want to opt for the scarless approach over the conventional laparoscopic approach, more so in case of female patients.

Confidentiality is another major plus of the SILS approach. Greater loss of self-esteem and social anxiety has been observed in obese Indian women. Women tend to face greater discrimination at work and in interpersonal relationships due to obesity. In a country like India, bariatric surgery for morbid obesity especially in women is considered as a social taboo. The SILS approach helps them to get a second chance at life with an added advantage of complete confidentiality.

Conclusion

Initially, when SILS arrived on the surgical scene, it sparked off peoples' imagination, but there was no data to support its efficacy. Our data elucidates that surgical outcomes in terms of EWL% and remission of comorbidities are comparable in both groups at the end of 2 years. Complication rates are comparable in both groups, and the myth about a higher long-term incisional hernia rate has been dispelled. Additionally, SILS has proven to be less painful along with greater cosmetic results. It also has an added advantage of confidentiality. The only caveat is that it should be used in well-trained hands for selected patients. It must be

avoided in the super-super obese where the risks far outweigh the benefits.

SILS has come of age and should no longer be considered as an experimental procedure.

Conflict of Interest Authors Bhasker A G, Dhar S, Dhulla N, Agrawal A, and Lakdawala M have no conflict of interest or financial ties to disclose.

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