Surgical Endoscopy (2022) 36:7225–7232
https://doi.org/10.1007/s00464-022-09088-y

Prevention of incisional hernia after single-port sleeve gastrectomy (PRISM): a prospective non-randomized controlled study

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Received: 18 October 2021 / Accepted: 29 January 2022 / Published online: 10 February 2022

Abstract

Background SPSG carries a risk of incisional hernia, particularly in patients with high body mass index. Prophylactic mesh placement with either permanent or absorbable mesh could decrease the occurrence of incisional hernia, with uncertainty on other postoperative parietal complications.

Methods This is a non-randomized monocentric single-blinded prospective study. High-risk patients (body mass index ≥ 45 kg/m^2) underwent either 3 strategies of parietal closure (suture with or without permanent or absorbable mesh) during SPSG. The primary outcome was the occurrence of radiologically defined incisional hernia during the first postoperative year. Secondary outcomes included surgical site infection rates and postoperative pain.

Results Between November 2018 and November 2019, 255 patients were included (85 in each group). All patients reached one-year postoperative follow-up. Significantly more incisional hernias were observed in the no mesh group in comparison with permanent and absorbable mesh groups, respectively (20% vs. 7.1% vs. 5.1%, $P=0.005$). No difference was observed in mesh groups. No difference was observed regarding other parietal complications. One patient in the absorbable mesh group presented a superficial surgical site infection and required surgical drainage without mesh removal and one patient in the permanent mesh group presented a parietal hematoma and required surgical drainage with mesh removal. Twenty-six (92.8%) asymptomatic patients presented incisional hernia discovered on the one-year CT-scan.

Conclusions Prophylactic mesh placement during SPSG decreases the occurrence of postoperative incisional hernia. Routine permanent mesh placement could be proposed in high-risk patients.

Keywords Obesity · Morbid · Bariatric surgery · Incisional Hernia · Surgical mesh · Prospective study

Abbreviations

BMI	Body mass index
CI	Confidence interval
IQR	Interquartile range
OR	Odds ratio
SG	Sleeve gastrectomy
SILS	Single-incision laparoscopic surgery
SPSG	Single-port sleeve gastrectomy

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Sleeve gastrectomy (SG) has become the most frequently performed bariatric procedure [1]. Considering that SG is performed in one abdominal quadrant with limited range of movements and requires extraction of a specimen, it is potentially an excellent candidate for single-incision laparoscopic surgery (SILS).

The expected advantages of SILS over conventional laparoscopy are linked to the potential reduced parietal aggression and include less postoperative pain, shorter hospital stay, faster return to normal activity, and of course a better cosmetic result. However, the SILS approach could be associated with a paradoxical increased risk of incisional hernia,

particularly when the trocar is placed around the umbilicus [2]. Indeed, a unique but consequent parietal incision, required for the correct placement of the single-port and specimen extraction, might promote postoperative parietal weakness.

A standardized and reproducible technique of single-port sleeve gastrectomy (SPSG) was designed in the authors' institution [3]. Since 2010, this approach is routinely used in all patients and more than 2500 SPSG were performed. The single port is placed in the left hypochondrium, allowing a direct access to the stomach with an optimal axis for the instrument [4]. Besides, the placement of the single-port in a 3-cm transverse incision through the rectus abdominis muscle allows the closure of both abdominal aponeurosis with a good exposition at the end of the surgical procedure [5], and can be used to place a retromuscular mesh in order to prevent the occurrence of incisional hernia.

Efficient prophylactic mesh placement has been reported after abdominal surgery, including gastrointestinal surgery [6, 7]. The choice of either permanent or absorbable mesh can be discussed in the context of a clean-contaminated surgery which carries a superior risk of local postoperative infection, seroma development and pain [8]. Since SILS carries an independent risk factor of incisional hernia, several surgeons in our team have tried to routinely reinforce with a mesh (permanent or absorbable) the parietal incision at the end of SPSG in patients with high body mass index (BMI), who are particularly at risk [9].

A non-randomized single-blinded prospective study was therefore designed in our department to compare the different proposed strategies of parietal closure (suture with or without permanent or absorbable mesh) during SPSG in high-risk patients (BMI $\geq$ 45 kg/m^2).

Methods

This study was designed as a non-randomized patient-blinded prospective controlled study at a single institution. In view of its observational design, approval by local ethics committee was considered sufficient. Written informed consent was obtained from all subjects. The study (PRISM) was registered at ISRCTN as ISRCTN 52,462,725. Starting from November 2018, all consecutive patients who underwent SPSG in the digestive surgery department of our hospital were considered for the study.

Patients were freely addressed to one of three teams of surgeons in the department, who adopted and routinely performed exclusively one of three parietal closure strategies: suture without mesh (ID, PL), suture with permanent mesh placement (NS, MG), suture with absorbable mesh placement (HT, CD). All surgeons had carried out more than 150 procedures before participating in the study. Each surgeon performed equal numbers of procedures. Inclusion criteria were: age at least 18 years; indication for bariatric surgery according to French guidelines [10]; sleeve gastrectomy as a primary bariatric procedure; BMI $\geq$ 45 kg/m^2. Exclusion criteria were: previous upper abdominal surgery (laparoscopic cholecystectomy excepted); patients under guardianship and trusteeship; patients with known allergy to mesh component. Inclusions were stopped in each group as soon as the planned number of patients was reached.

Perioperative management and surgical procedure

Before surgery, all patients underwent meticulous evaluation by a multidisciplinary team consisting of an endocrinologist, a gastroenterologist, a psychiatrist, a nutritionist, an anesthesiologist, and a surgeon. Standard investigations were carried out during preoperative follow-up, including esophagogastroduodenoscopy, upper gastrointestinal series, abdominal ultrasonography, polysomnography, and endocrinologic and nutritional evaluations. The indication for SG was validated during a multidisciplinary staff meeting 1 month before surgery.

SPSG was performed as previously described [3–5]. A multiport single-access device (QuadPort +, Olympus Medical, Nagano, Japan, or Octoport, Landanger, Chaumont, France) is introduced through a 2–4 cm transversal incision, starting 2 fingers left of the midline and 4 fingers below the costal margin (Fig. 1a). The single-port device allows the introduction of 5-mm, 10-mm and 12-mm instruments. To avoid conflict between instruments, only 3 ports are simultaneously used during the procedure. A 10-mm flexible tip laparoscope (Endoeye Flex HD, Olympus) is used. A double-curved grasper and a thermofusion device (LigaSure, Covidien, Élancourt, France) are used for dissection of gastrocolic ligament and gastroepiploic vessels. Transection of the stomach is done using a 60-mm endoscopic stapler (Endo-GIA Tri-Staple with purple cartridge, Medtronic or Echelon Flex Powered with gold cartridge, Ethicon, Issy-Les-Moulineaux, France) after placement of a 36-Fr orogastric calibration tube. The excised gastric specimen is easily removed through the single-port access without the need for trocar-site enlargement, the trocar's protective skirt preventing parietal contamination. Abdominal or parietal drainage is not used routinely.

At the end of the procedure, the rectus fascia was closed in 2 layers using absorbable multifilament polyglactin 910 (Vicryl 0, Ethicon, Issy-les-Moulineaux, France) small bites running sutures, and subcuticular suturing is used for skin closure. Vicryl 0 was used instead of monofilament suture materials because of the availability of 5/8 circle needles that allow the closure of the aponeurosis through a small incision in patients with significant cutaneous fat. In case of mesh reinforcement, placement of a 6 × 3 cm

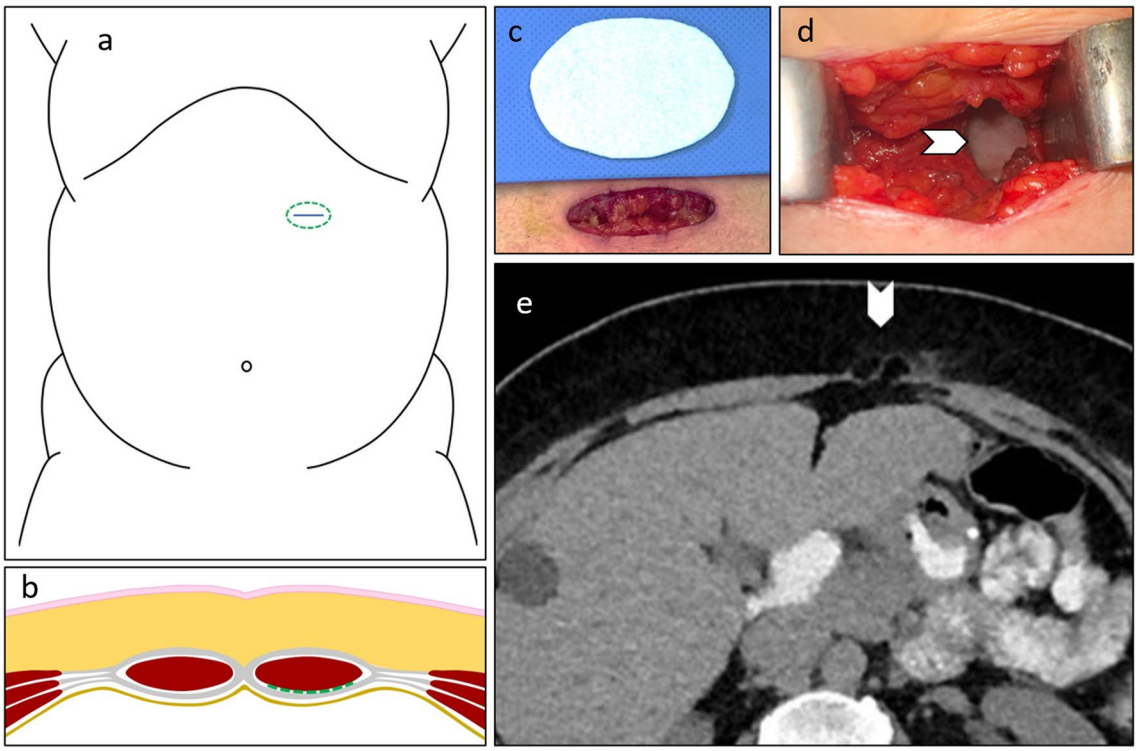

Fig. 1 **a** Position of the multiport single-access device in the left hypochondrium. **b** Position of the mesh patch in the retromuscular plane. **c** Operative view of incision site and absorbable mesh patch. **d** Operative view of incision site with placement of retromuscular mesh patch (arrow). **e** Representative computed tomography axial image taken at the L2 level showing a complete discontinuation of both aponeuroses with protrusion of peritoneum and abdominal fat defined as incisional hernia (arrow)

retromuscular mesh patch of either permanent medium-weight polypropylene mesh (Bard, Voisins-le-Bretonneux, France) or absorbable biosynthetic mesh (BioA, Gore Medical, Paris, France) (Fig. 1b). When used, the mesh was expanded to fully cover the aponeurotic incision with a 1,5-cm overlap, and no fixation with neither adhesive, fibrin glue or suture because of the limited dissection plan (Fig. 1c and d).

Patients were allowed free liquid intake and placed on a semiliquid diet 2 days after surgery and solid intake was allowed gradually during the first 3 weeks after operation. Postoperative antithrombotic prophylaxis was prescribed for 2 weeks and a proton pump inhibitor for at least 1 month. Patients were trained to use appropriate movements for rising and leaning and were requested to abstain from abdominal wall contraction activities during the first 2 months after surgery. Progressive return to physical activities was supervised by the institution's sports coach.

Patients took part in a standard follow-up bariatric program including 4 visits to the outpatient clinic during the first postoperative year (at 6 weeks, 3 months, 6 months, and 1 year), with clinical examination of the surgical wound and of the parietal wall. Systematic CT-scan without contrast injection was performed in all patients one year after surgery. The assessment of trocar-site hernia was performed by two operators, not aware of the specific closure procedure.

Primary outcome

The primary outcome measure was the occurrence of incisional hernia during one year of follow-up, assessed by imaging with or without clinical suspicion. Incisional hernia was defined as any abdominal wall gap with or without bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging, as determined by the European Hernia Society [11] (Fig. 1e).

Secondary endpoints

Secondary endpoints included operative duration, intraoperative difficulties, hospital stay, global postoperative (< 90 days) morbidity according to Dindo−Clavien classification [12] and time interval between SPSG and incisional hernia discovery. Incidence of surgical site infection according to CDC criteria (superficial, deep or organ space) [13] was recorded, as the incidence of hematoma and seroma. Actions for wound events were categorized as follows: antibiotics only, bedside wound intervention, radiological

percutaneous drainage, or surgical debridement with or without mesh removal. The need for pain medication after 6 postoperative weeks (at the first postoperative outpatient visit) was monitored. Time to return to free physical activity was also recorded.

Statistical analysis

The sample size for this study was calculated considering a tomographic incisional hernia rate one year after surgery of 18% (after SPSG) based on previous literature [14, 15] and a preliminary retrospective assessment performed in the authors' institution (data not shown). A two-third decrease was expected after prophylactic mesh placement. Considering a unilateral alpha risk of 5% and a power of 80%, it was calculated that 85 patients were needed in each group.

All analyses followed the intention-to-treat principle. Demographic data were collected in a prospective electronic database. Quantitative variables are expressed as median and interquartile range (IQR) and were compared using the Kruskal–Wallis test. Qualitative variables were expressed as frequencies (percentages) and were compared using the X^2 test. A multivariate analysis using binary logistic regression was performed to determine the main independent risk factors for incisional hernia. All variables achieving statistical significance were considered for the multivariate analysis. Odds ratio (OR) with 95% confidence intervals (CI) were given. Values of $P < 0.05$ were considered statistically significant. Statistical analysis was carried out with SPSS software (IBM Company, New York, USA).

Results

Characteristics of patients

All inclusions were completed by November 2019 with 85 patients included in each group (255 patients). All patients reached one-year follow-up. There were 200 women (78.4%) and 55 men (21.6%), and more men were included in the permanent mesh group (32.9%, $P = 0.006$). The median age of the study population was 40 years [28–50] and median BMI was 49.4 kg/m2 [46.6–52.7]. Co-morbidities were equally distributed among the groups. Tobacco use was globally rare, but more frequently reported in the no mesh group (10.6%, $P = 0.018$). No patient presented either abdominal aortic aneurysm, corticosteroid use or chronic respiratory disease. Characteristics of patients are summarized in Table 1.

Intraoperative data

Operative duration was increased in permanent and absorbable mesh groups, respectively (81 [75–110] vs. 85 [72–107] vs. 70 [64–95], $P = 0.045$). Five patients required 1 or 2 additional trocars placement to complete the procedure to expose the left liver lobe. No conversion to laparotomy or particular intraoperative difficulties were reported. Specifically, mesh positioning was easily performed in all cases. No abdominal or parietal drainage was left in place at the end of the procedure. Operative outcomes are detailed in Table 2.

Table 1 Baseline characteristics of patients

Characteristic	No mesh group ($n = 85$)	Permanent mesh group ($n = 85$)	Absorbable mesh group ($n = 85$)	P
Gender (female/male)	73/12	57/28	70/15	0.006*
Age, y, median (IQR)	39 (27–46)	45 (27–51)	39 (30–51)	0.297[a]
Weight, kg, median (IQR)	133 (123–150)	134 (120–147)	136 (124–149)	0.772[a]
BMI, kg/m^2, median (IQR)	48.8 (47.3—52.3)	48.4 (45.7–52.6)	49.6 (46.5–60.2)	0.609[a]
Co-morbidities				
Diabetes, n (%)	16 (18.8)	17 (20.0)	27 (31.8)	0.089*
Hypertension, n (%)	29 (34.1)	33 (38.8)	23 (27.1)	0.261*
Dyslipidemia, n (%)	9 (10.6)	13 (15.3)	16 (18.8)	0.318*
OSAS, n (%)	53 (62.3)	54 (63.5)	50 (58.8)	0.806*
Cardiovascular disease, n (%)	6 (7.1)	6 (7.1)	5 (5.9)	0.918*
Fatty liver disease, n (%)	50 (58.8)	57 (67.1)	49 (57.6)	0.390*
Antiplatelet and/or anticoagulant therapy, n (%)	3 (3.5)	9 (10.6)	4 (4.7)	0.126*
Tobacco use, n (%)	9 (10.6)	2 (2.3)	2 (2.3)	0.018*

IQR Interquartile range, *BMI* Body mass index, *OSAS* Obstructive sleep apnea syndrome

*χ^2 test

[a]Kruskal–Wallis test

Table 2 Operative and postoperative outcomes of patients

Characteristic	No mesh group ($n=85$)	Permanent mesh group ($n=85$)	Absorbable mesh group ($n=85$)	P
Operative time, min, median (IQR)	70 (64–95)	81 (75–110)	85 (72–107)	0.045[a]
No additional extraport, n (%)	3 (3.5)	2 (2.3)	0 (0.0)	0.240*
90-day postoperative complications, n (%)	6 (7.1)	4 (4.7)	11 (12.9)	0.132*
Bleeding (intraabdominal or intraluminal), n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
Staple-line leak, n (%)	3 (3.5)	0 (0.0)	1 (1.2)	–
Dindo−Clavien Grade ≥ IIIa, n (%)	3 (3.5)	1 (1.2)	5 (5.9)	–
Surgical site infection	0 (0.0)	0 (0.0)	1 (1.2)	–
Parietal hematoma/seroma	0 (0.0)	1 (1.2)	0 (0.0)	–
Length of stay, day, median (IQR)	3 (2–3)	3 (3–3)	3 (3–3)	0.427[a]
Pain medication requirement > 6 weeks, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	–
Incisional hernia, n (%)	17 (20.0)	6 (7.1)	5 (5.9)	0.005*
Clinical discovery, n (%)	0 (0.0)	1 (1.2)	1 (1.2)	–
CT-scan discovery, n (%)	17 (20.0)	5 (5.9)	4 (4.7)	–
Return to free physical activity ≤ 12 weeks, n (%)	85 (100.0)	83 (97.6)	83 (97.6)	0.362*

IQR interquartile range

*χ^2 test

[a]Kruskal−Wallis test

Postoperative course

Global morbidity was 8.2% ($n=21$), including 4 patients that presented a postoperative gastric leak (1.6%). Two patients in the no mesh group required a relaparoscopy to evacuate and drain a peri-gastric abscess with subsequent endoscopic drainage. Exclusive endoscopic management was sufficient in the remaining 2 cases. One patient in the absorbable mesh group presented a superficial surgical site infection and required surgical drainage without mesh exposition, which was finally conserved. One patient in the permanent mesh group presented a parietal hematoma and required surgical drainage with mesh removal. No patient required a specific pain medication 6 weeks after surgery.

Twenty-eight (11%) patients presented incisional hernia during the first postoperative year. Two incisional hernias were discovered during the first year of postoperative course in permanent and absorbable mesh groups, at 4 and 10 months after SG, and were treated by elective surgery with redo permanent mesh placement. Twenty-six (92.8%) asymptomatic patients presented incisional hernia discovered on the one-year CT-scan. Median size of abdominal wall defect was 27 (24–31) mm.

Significantly more incisional hernias were observed in the no mesh group in comparison with permanent and absorbable mesh groups, respectively (20% vs. 7.1% vs. 5.1%, $P=0.005$). No difference was observed in mesh groups. No incisional hernia was observed in the 5 patients requiring additional trocars placement. Return to free physical activity was possible in the vast majority of patients (98.4%) 12 weeks after surgery. Postoperative outcomes are detailed in Table 2.

Three factors were considered for multivariate analysis: gender, tobacco use and mesh placement. The only independent risk factor for incisional hernia was the absence of mesh placement (OR = 3.802 [1.633–8.849], $P=0.002$). The full model is provided in Table 3.

Weight loss and resolution of co-morbidities

Median percentage of total weight loss at 1 year was 28.8% [22.4–36.3]. Median percentage of excess weight loss at 1 year was 59.5% [44.0–73.7]. Weight loss and co-morbidities resolution at 1 year after SG were globally similar in the three groups (data not shown).

Table 3 Multivariate analysis on the main independent risk factors for incisional hernia

Factor	Odd ratio	95%IC	P
Male	8.695	[0.831–5.464]	0.115
Tobacco use	2.985	[0.118–2.066]	0.335
Absence of mesh placement	3.802	[1.633–8.849]	0.002

IC Confidence interval

Discussion

This non-randomized prospective study suggests that the placement of a retromuscular mesh patch at the end of SPSG allows to decrease the occurrence of postoperative incisional hernia, without negative impact on postoperative outcomes. No difference was observed between permanent and absorbable mesh groups concerning the rate of incisional hernia, but also regarding other parietal complications.

The 20% rate of CT-scan discovered incisional hernia in the no mesh group is consistent with the 18% rate observed in our global cohort of SPSG (data not shown). This rate is high but must be analyzed in view of the results of laparoscopic bariatric surgery. Indeed, recent data support that incisional hernias are highly underestimated in patients with obesity undergoing laparoscopy. Numerous studies report a near 3% rate of incisional hernia following laparoscopic bariatric surgery [14], which is close to the rate observed after most laparoscopic procedures [16], some studies reporting even lower rates of port-site herniation after bariatric surgery in comparison with colorectal procedures [17]. These results are particularly surprising since obesity is a well-known major risk factor for incisional hernia [18]. One possible explanation for this underestimation is the limited number of studies specifically focusing on trocar-site hernia after bariatric surgery [14]. Moreover, clinical examination of trocar wounds has proven to be unreliable for the evaluation of trocar-site hernias in patients with obesity [19]. Recent studies based on imaging have demonstrated more significant rates of incisional hernia, reaching 24.5% [14], which is consistent with the reported incisional hernia rate in the no mesh group in our series. Karampinis et al. even reported a 37% prevalence of trocar hernias detected by ultrasonography within 9 months after the bariatric procedure, despite systematic fascial closure of > 5-mm trocars [20]. It is our belief that the technique of parietal closure after SPSG through a small transverse incision is at least not inferior to conventional laparoscopic SG in terms of trocar-site hernia, which is a reason to promote the adoption of the left hypochondrium rather than the umbilicus as a preferential site for SPSG. One could argue that not-clinically palpable and asymptomatic CT-diagnosed incisional hernias are not significant. However, at 1 year evaluation, an important number of patients still present excess weight to lose. These patients (as all patients undergoing bariatric surgery) will have to practice an intense and regular sports activity. Therefore, those early diagnosed incisional hernias could become symptomatic in the future, particularly considering the young age of patients undergoing bariatric surgery. Future studies assessing the long-term evolution of these CT-diagnosed incisional hernias are required.

The prophylactic placement of a retromuscular mesh patch significantly decreased the rate of incisional hernia, allowing more acceptable rates, close to those reported in the general population after laparoscopic abdominal surgery [16]. This is particularly interesting since mesh placement was always easily performed, only requiring approximately 10 min longer operative duration. Moreover, the use of the mesh did not increase postoperative morbidity. Only two Dindo−Clavien grade IIIb complications related to the mesh were observed: one patient required mesh removal during the management of a parietal hematoma, and one patient presented a superficial surgical site infection and required surgical drainage without mesh removal. Absorbable mesh doesn't seem to be superior to permanent mesh in the setting of this low contaminated surgery concerning the removal of a stapled gastric specimen through a wound protection, with very low rate of surgical site infection. Besides, the higher cost of the biosynthetic mesh is a limit to its systematic use, but could find a role in selected patients with increased risk of surgical site infection (diabetes, steroid use…). On the other hand, the cost of a 6 × 3 cm polypropylene mesh patch is approximately 50 euros, and its prophylactic use could be generalized to prevent incisional hernia after SPSG.

This study has several limitations that should be underlined. First of all, this study was undertaken by a team were SPSG is the standard for all patients undergoing SG, with more than 2500 procedures performed to date. Therefore, the results cannot be easily generalized. Particularly, the lack of a group of patients receiving conventional laparoscopic SG is debatable. Furthermore, these results were obtained in patients with high BMI (≥ 45 kg/m^2) and the interest of prophylactic mesh placement during SPSG has to be demonstrated in the general bariatric population. Several technical issues are debatable. First, aponeurosis closure was performed using Vicryl 0 in each group although slow absorbable monofilament suture materials are recommended for parietal closure of midline laparotomy [11]. However, no recommendation was published regarding transverse incisions. In fact, we decided to use Vicryl only because of the availability of 5/8 circle needles that allow to easily close the aponeurosis through a small incision in patients with important cutaneous fat. Secondly, the mesh was placed after closure of the deep layer of the rectus fascia in a retromuscular plane with a 1,5-cm overlap. Though a 3-cm overlap is generally used [21], it would require a more extensive dissection, which is difficult and time-consuming to perform through a 2–4 cm incision in patients with important cutaneous fat, and would be difficult to apply routinely. Besides, this study is exposed to confounding bias inherent to its non-randomized methodology. Particularly, tobacco use was more frequently reported in the no mesh group, which could have hampered the results in this group. However, at

multivariate analysis, the only independent risk factor for incisional hernia was the absence of mesh placement. A randomized trial was initially planned but abandoned since several surgeons in the team were somewhat reluctant to propose the use of a permanent mesh in this indication, but also because the development of a randomized controlled study can be challenging. Previous data concerning the use of prophylactic mesh in abdominal surgery (even for procedures at greater risk of complications like colorectal surgery) are in favor of mesh placement, therefore the interest of a randomized study for such a specific procedure as single-port sleeve gastrectomy is questionable. However, authors are currently discussing with their clinical research department the interest of performing such a randomized study. Indeed, those preliminary results could serve as a basis for a randomized trial assessing the interest of prophylactic permanent mesh placement. A cost-analysis is also lacking. We previously demonstrated that a limited but superior cost (+ 50 euros) was associated with SPSG in comparison with conventional laparoscopic SG, essentially related to a longer duration of surgery [5]. The use of a polypropylene mesh (approximately 50 euros) during a 10-min longer operative duration would inevitably induce superior cost, but has to be analyzed considering the potential savings of incisional hernia management costs. A more precise assessment of the impact of mesh placement on postoperative pain and quality of life could have been performed, however we chose to simplify the study monitoring based on our retrospective experience suggesting clinically irrelevant results.

Conclusion

This non-randomized prospective study suggests that the prophylactic placement of a retromuscular mesh patch during SPSG through the left hypochondrium decreases the occurrence of postoperative incisional hernia. Prophylactic retromuscular permanent mesh placement could be proposed in high-risk patients (BMI ≥ 45 kg/m^2). Randomized studies have to confirm these results.

Funding No funding was associated with this research.

Declarations

Disclosures Tranchart, Gaillard, Bekkhoucha, Dammaro, Schoucair, Lainas, Voican, Chague, Rocher and Dagher have no conflict of interest or financial ties to disclose.

Ethical approval All procedures performed in studies involving human participants 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.

Informed consent Informed consent was obtained from all individual participants included in the study.

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