



Impact of Routine 12 mm Epigastric Trocar Site Closure on Incisional Hernia After Sleeve Gastrectomy: a Prospective Before/After Study

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Abstract

Background Recent studies have reported trocar site hernia (TSH) rates after bariatric surgery ranging from 0 to 45.2% based on imaging assessment. The objective of this study was to evaluate the TSH rate after sleeve gastrectomy (SG) comprising routine 12 mm epigastric trocar site closure (TSC).

Material Prospective observational study with retrospective control cohort of a group of patients undergoing primary SG with routine 12 mm epigastric TSC. The “before” group (control group) was a previously published group of patients without 12 mm epigastric TSC and the “after” group (closure group) concerned patients with routine 12 mm epigastric TSC. Primary endpoint was the TSH rate after routine epigastric TSC. Secondary endpoints were comparison of the TSH rate, TSC feasibility and causes of failure, TSC-related morbidity, evaluation of TSC time and its course, and identification of risk factors for TSH.

Results One hundred twenty-three patients were analyzed during the study period. Feasibility of epigastric TSC was 97.3% without related morbidity. Mean epigastric TSC time was 44.2 s (18–150). Epigastric TSC time was always less than 60 s after 10–15 procedures. At 1 year, 10 patients presented TSH (8.1%): epigastric in 6.5% ($n = 8$) cases and after open laparoscopy in 1.6% ($n = 2$) cases. Comparison of the two groups revealed a lower TSH rate in the closure group (8.1% vs. 17.0%; $p = 0.02$), due to a lower epigastric TSH rate (6.5% vs. 14.8%; $p = 0.02$). Routine epigastric TSC was a protective factor for TSH ($p = 0.03$; relative risk of 0.43).

Conclusion Routine epigastric TSC during SG is rapid and provides effective prevention of TSH.

Keywords Sleeve gastrectomy · Abdominal CT scan · Trocar site hernia · Open laparoscopy · Trocar site closure

Abbreviations

SG Laparoscopic sleeve gastrectomy
TSH Trocar site hernia
OSA Obstructive sleep apnea
BMI Body mass index

CT Computed tomography
RYGB Roux-en-Y gastric bypass

Introduction

Several series have reported trocar site hernia (TSH) rates ranging from 0 to 0.7% after bariatric surgery, but the diagnosis of TSH was based exclusively on clinical evaluation in every case [1, 2]. Clinical evaluation of incisional hernia in obese patients is known to be difficult, even following significant weight loss after bariatric surgery due to the appearance of an abdominal apron. Pilone et al. [3] recently published their experience of TSH in a series of 624 patients undergoing bariatric surgery in the absence of trocar site closure (TSC). In their series, TSC was not performed because of the difficulty of the procedure, the TSC operating time and the risk of injury to adjacent organs. In their series, also based on clinical

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evaluation, the authors reported a low TSH rate of 1.5% with a mean follow-up of 54 months.

Scozzari et al. [4] reported a TSH rate, based on abdominal ultrasound evaluation, between 0 and 45.2% following laparoscopic Roux-en-Y gastric bypass (RYGB) with a higher TSH rate at the epigastric trocar site (ranging from 26.2 to 37.9%). Recent studies have reported similar results, with a 17% TSH rate in the absence of 12 mm epigastric TSC based on CT scan evaluation [5].

Tabone [6] recently suggested that routine epigastric TSC may not be as effective as lateralizing the position of the trocar site relative to the linea alba. However, changing the site of this trocar would introduce an additional technical difficulty when performing SG either requiring a change of axis for stapling or inducing conflict between instruments when performing SG [7]. The argument that TSC is a time-consuming procedure is also no longer valid, as Del Junco et al. [8] have shown that TSC using an appropriate device is feasible and not time-consuming with a mean TSC time ranging from 98 to 133 s depending on the type of device used. No series have evaluated the results of routine TSC after bariatric surgery.

The objective of the present prospective study was to evaluate the results of routine epigastric TSC on the 1-year TSH rate after SG.

Material and Methods

Population

This was a prospective observational study with retrospective control cohort group of patients (before/after study) undergoing primary SG with routine 12 mm TSC between January 2016 and February 2017. The “before” (control) group was composed of a previously published series of patients without 12 mm epigastric TSC during SG [5]. The “after” (closure) group corresponded to prospectively included patients undergoing routine 12 mm epigastric TSC. This study was part of a local research protocol registered as “Impact of the Systematic Closure of the Epigastric Trocar on Postoperative Incisional Hernia After Sleeve Gastrectomy Rate of First Intention. Monocentric Study, Before/After Prospective (TROCSLEEVE) ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02973009) identifier: NCT02973009).” This study was approved by the local institutional review board (*Comité de Protection des Personnes Nord Ouest II*). During a preoperative visit, patients were provided with a study information sheet and all patients provided their written informed consent to participate in the study.

Surgical Technique

We have previously described our primary SG technique [9]. SG was performed using four trocars (COVIDEN France SAS, Elancourt, France). The open laparoscopy trocar site was routinely closed contrary to the epigastric trocar site that was not closed at the end of SG in our previous study (“before group”) [5]. The open laparoscopy trocar site and epigastric trocar site were routinely closed at the end of SG concerning patients in the “after group.”

An open laparoscopy technique was systematically used for supramesocolic surgery in all obese patients, as previously described [10]. A Veress needle was never used to establish pneumoperitoneum. Open laparoscopy was performed using two absorbable sutures on the anterior rectus abdominis fascia and two absorbable sutures on the posterior rectus abdominis fascia (e.g., Vicryl 0, Ethicon France SAS, Issy Les Moulineaux, France). A 15-mm bladeless trocar was inserted into the abdomen via the open laparoscopy (15 mm Versaport™ Plus). This technique allows easier and more rapid routine closure of the abdominal wall at the open laparoscopy site at the end of the surgical procedure.

Two bladed 5-mm trocars (one right subcostal margin and one left subcostal margin) were then used (5 mm long Versaport™ Plus V²). Five-millimeter trocar sites were not closed at the end of SG.

Finally, one 12-mm bladed trocar was used at the epigastric site (12 mm long Versaport™ Plus V² with fixation). The epigastric trocar site was closed at the end of the procedure using Weck® EFX Shield™ (Teleflex Medical SAS, F-31460 Le Faget, France) and absorbable suture material (e.g., Vicryl 0, Ethicon France SAS, Issy Les Moulineaux, France) (Fig. 1, Video in the Electronic Supplementary Material). The first three cases in which the device was used (training in use of the device) were not taken into account in the analysis of the results.

At the end of the surgical procedure, a suture was placed laparoscopically on one edge of the resected stomach allowing exposure of one edge of the stomach for easy extraction of the specimen without further opening of the fascia. Routine



Fig. 1 12 mm epigastric trocar site closure

drainage was not performed. Routine upper gastrointestinal contrast study was not performed, and oral refeeding was initiated on the day of SG.

Concerning material used and size of trocars used in our technique of SG, only the left subcostal margin was changed (previously 12-mm diameter in the “before group”) to a 5-mm trocars diameter (in the “after group”) (Fig. 2).

Trocar Site Hernia Evaluation

TSHs were systematically evaluated by abdominal CT scan performed 1 year after surgery and was defined as a gap in the abdominal wall with a bulge in the vicinity of a postoperative scar. All abdominal CT scans were evaluated on a single-blind basis by one radiologist experienced in the postoperative assessment of bariatric surgery. Abdominal CT scan was performed without oral contrast with difference of abdominal CT performed on the historical cohort [5].

Inclusion Criteria

Patients included in the study had to meet all of the following inclusion criteria: patient undergoing primary SG, abdominal CT scan performed 12 months after SG. Patients requiring conversion to laparotomy or laparotomy for postoperative complications, patients undergoing surgical procedures other than primary SG (history of gastric banding, RYGB, or others), abdominal CT scan performed for assessment of complications after SG (gastric leaks, bleeding, etc.) due to the risk

of increased abdominal pressure that may increase the risk of TSH, patients with a history of abdominal surgery such as cholecystectomy, patients undergoing laparoscopy or laparotomy for abdominal disease before the abdominal CT scan (for example, gallbladder disease) were excluded from the study.

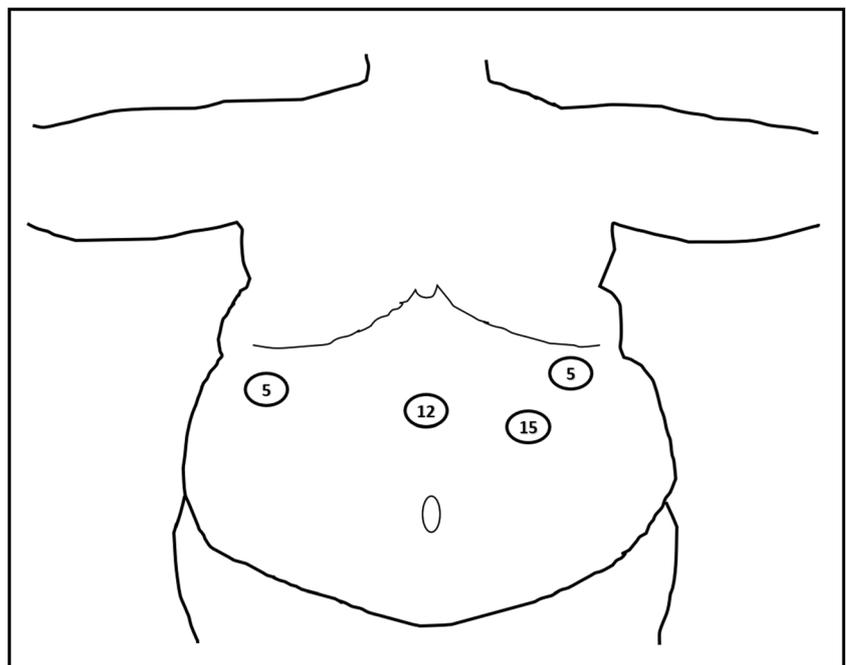
Endpoints and Collected Data

The primary endpoint of this study was the 1-year TSH rate after SG with routine 12 mm epigastric TSC. The secondary endpoints were comparison of TSH rates between the control and closure groups, the feasibility of the closure device and the causes of failure, epigastric TSC-related morbidity (organ injury, local hematoma, surgical site infection), evaluation of the TSC time and its course during the study, and identification of risk factors for TSH by analyzing data of the previous published series and the current prospective study.

The following study parameters were collected:

- Preoperative data: age, gender, body mass index (BMI), type 2 diabetes (T2D), dyslipidemia, hypertension, obstructive sleep apnea syndrome.
- Intraoperative data: overall operating time, Weck® EFX Shield™ device time, adverse events related to use of the device (organ injuries, local infection, and hematoma)
- Postoperative complications: complication rate and types of complications according to the Clavien-Dindo classification [11] (secondary exclusion).

Fig. 2 Positioning and size of the trocar site during SG in the after group



- Abdominal CT scan data: TSH rate and site, interval between abdominal CT scan and primary SG.
- Follow-up: course of TSC time during the study (learning curve), trocar site events during follow-up (proportion of patients with painful TSH symptoms, strangulated TSH rate).
- Risk factors for TSH based on data from the prospective study and the previous published series by analyzing preoperative data, operative data, and use of the epigastric TSC device.

Statistical Analysis and Sample Size Calculation

The control group population consisted of 223 of the 228 patients from our previous published series [5] for whom the 12-month TSH rate after SG was available. The expected results for the closure group were based on extrapolation of the results obtained after conventional open laparoscopy site closure (open laparoscopy site TSH rate of 1.8%).

To validate the hypothesis that routine epigastric TSC could reduce the TSH rate from 17 to 4% (with a limit of significance of 5% and a power of at least 80%), 87 patients had to be included in the closure group. Allowing for a typical loss-to-follow-up of 30% at 12 months follow-up (37 patients), we estimated that 124 patients had to be included in the study.

Baseline patient characteristics are expressed as mean \pm standard deviation (SD) and median (interquartile range) for quantitative data according to their distribution and as number (frequency) for qualitative data. Univariate analysis for quantitative data and qualitative data was performed by a Student's *t* test and chi-square test, respectively. The limit for statistical significance was set at $p < 0.05$. Risk factors for TSH were identified using univariate and bivariate analyses with backward stepwise selection. Potential risk factors considered were demographic variables and intraoperative data (operating time). Variables with a *p* value < 0.15 were included in a multivariate regression model.

All statistical tests were performed with PASW software (version 18.0 for Windows, SPSS Inc., Chicago, IL, USA).

Role of the Funding Source

The present study was sponsored and funded by the Weck® EFX Shield™ device manufacturer (Teleflex Inc.). The sponsor was not involved in the study design, data collection, statistical analysis, or formulation of the results.

However, the manufacturer provided training in the use of the device, with three procedures performed by the surgeon before inclusion in the study.

Results

Population

A total of 332 patients underwent bariatric surgery in our institution during the study period, 146 patients were included in the study (closure group) on the basis of preoperative exclusion criteria, and, after exclusion of patients with intraoperative and postoperative events and patients lost to follow-up, 123 patients were finally analyzed (Fig. 3).

The study population comprised 123 patients (33 men (26.8%)) with a mean age of 40.6 ± 11.9 (19–72) and a mean BMI of 45.4 ± 5.8 kg/m² (35.1–58.5). Twenty-eight patients (22.7%) had a BMI ≥ 50 kg/m². Comorbidities consisted of T2D (31.7%, $n = 39$), hypertension (34.1%, $n = 42$), dyslipidemia (17.9%, $n = 22$), obstructive sleep apnea syndrome (39.8%, $n = 49$), and metabolic syndrome (9%, $n = 11$).

Operative Data

The mean operating time was 58 ± 13 min (35–100). Open laparoscopy was performed in all cases (100%) and was associated with no morbidity (no injury to intraperitoneal organs). Intraoperative conversion to laparotomy was never required. Four patients required abdominal drainage (2.7%, secondary exclusion). Epigastric TSC was performed in all but four cases (secondary exclusion), representing a closure rate of 97.3%.

Data Concerning the TSC Device

No events were related to use of the specific epigastric TSC device. The four cases of closure device failure were due to insufficient length of the device related to excessively tangential insertion of the trocar relative to the abdominal wall. Epigastric TSC time using the device is described in Fig. 4. The mean epigastric TSC time was 44.2 s (18–150) and the epigastric TSC time was almost always less than 60 s after performing between 10 and 15 procedures.

Early Outcomes

Four postoperative complications were observed in this series of 146 patients (2.7%), consisting of two grade 3A complications due to postoperative hematoma adjacent to the gastric staple line for which endoscopy was performed to eliminate a gastric leak (secondary exclusion criteria). Two other patients experienced grade 2 complications: dehydration in one patient and open laparoscopy trocar site wound infection requiring local wound care in another patient (not excluded).

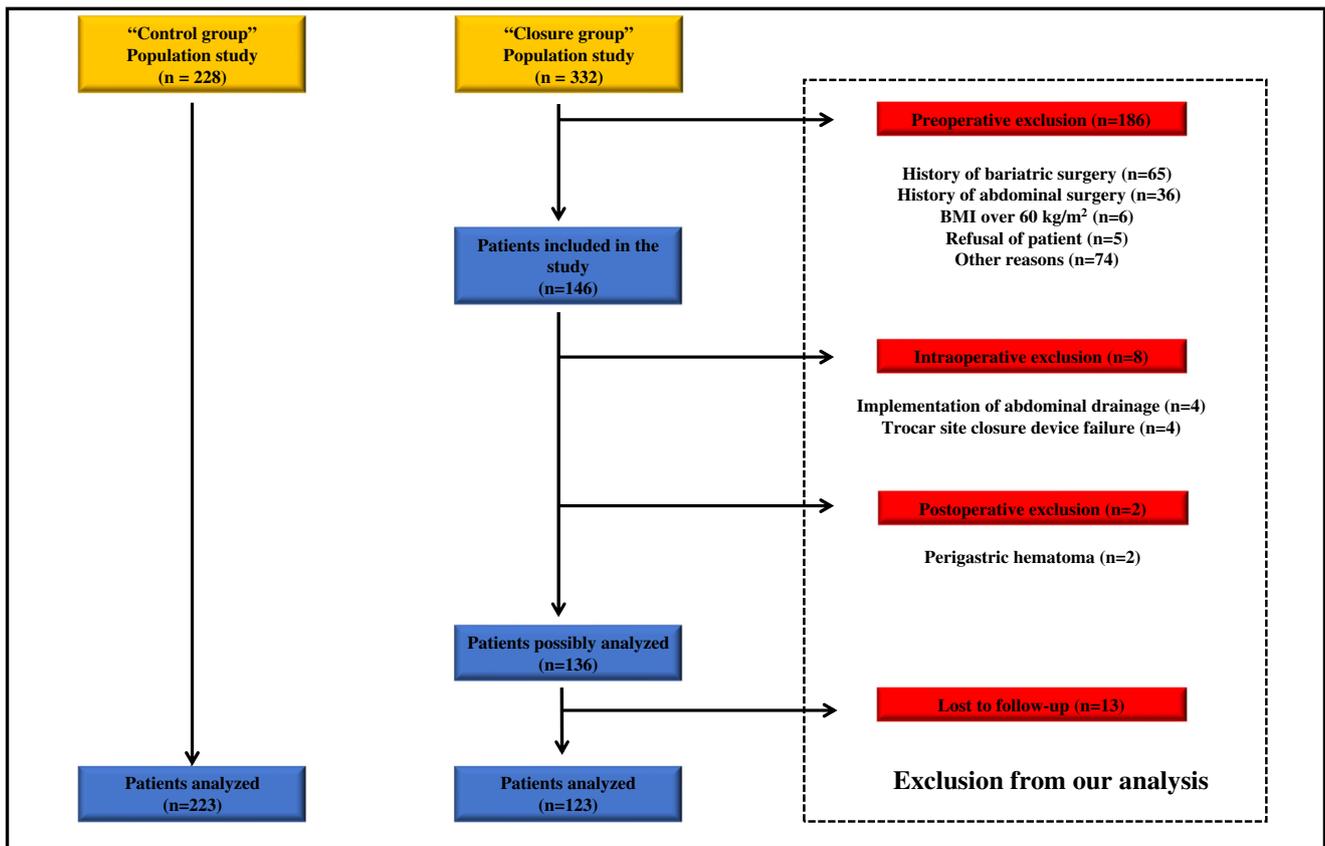


Fig. 3 Study flow chart

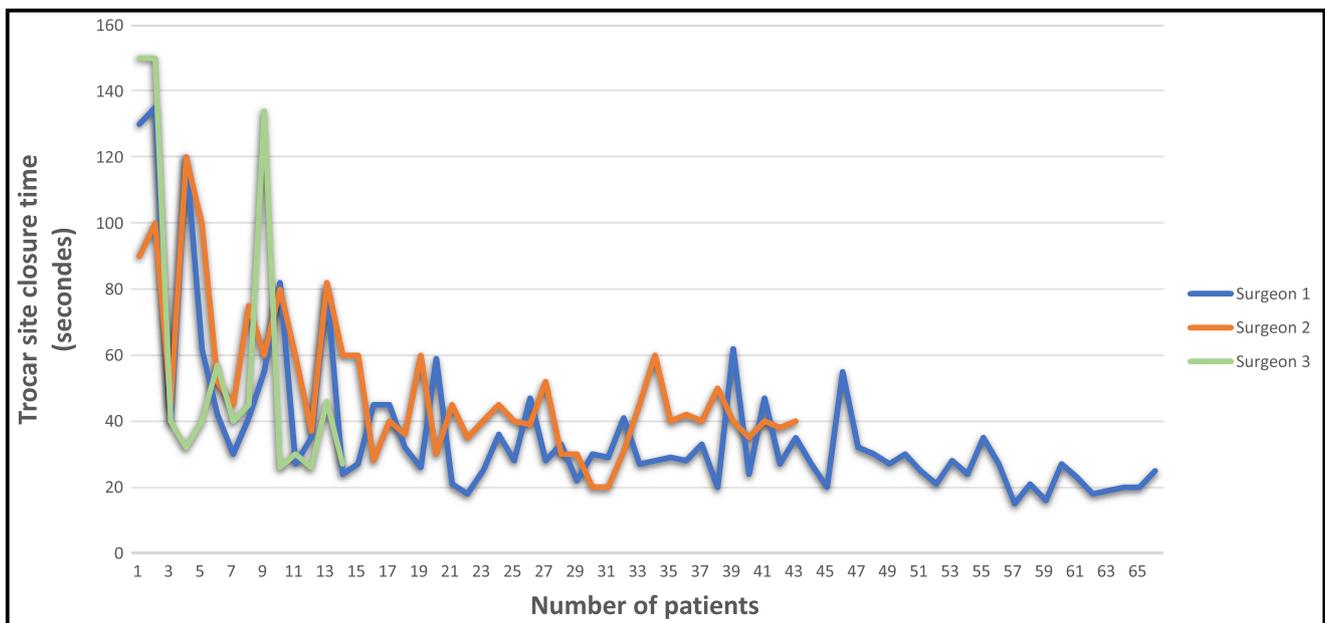


Fig. 4 Epigastric trocar site closure time and its course during the study for the various surgeons

Data at 1-Year Follow-up

Thirteen (9.6%) of the 136 patients were lost to follow-up at 1 year. At 1-year follow-up, mean BMI was $31 \pm 5.7 \text{ kg/m}^2$ (22–48), representing a mean excess weight loss of 68% (24–114) and a mean percentage weight loss of 31% (11–56). The median time interval between SG and CT scan was 13 months (range, 12–15). Ten patients developed TSH (8.1%) on abdominal CT scan, but none of these patients were symptomatic requiring TSH repair. TSH sites were as follows: epigastric TSH in 6.5% of cases ($n = 8$), open laparoscopy TSH in 1.6% of cases ($n = 2$), with no left or right subcostal margin TSH.

Comparison Between Control and Closure Groups

Comparison of the two groups showed that the control group was significantly older (45 years vs. 40.6 years; $p = 0.001$), with a higher BMI (47.6 kg/m^2 vs. 45.4 kg/m^2 ; $p = 0.003$), and higher rates of T2D (42.6% vs. 31.7%; $p = 0.05$) and dyslipidemia (31.3% vs. 17.8%; $p = 0.007$) than the closure group. The operating time was also longer in the control group compared to the closure group (90.2 min vs. 58 min, respectively; $p < 0.001$) (Table 1).

Analysis of TSH rates revealed a significantly lower TSH rate in the closure group compared to the control group for all trocar sites (8.1% vs. 17.0%, respectively; $p = 0.02$), and for the epigastric trocar site (6.5% vs. 14.8%, respectively; $p = 0.02$) (Table 1).

Risk Factors for TSH

No risk factors for TSH after SG were identified in the patients of the control and closure groups (346 patients). Routine

epigastric TSC was considered to be a protective factor for TSH in our univariate and multivariate analysis ($p = 0.03$; relative risk of 0.43).

Discussion

The TSH rate after bariatric surgery is underestimated according to most publications on this topic. Most published series of TSH after bariatric surgery were based on clinical evaluation of TSH, while only two series evaluated the postoperative TSH rate by postoperative imaging. In these series, the TSH rate ranged from 0 to 45.2% with higher rates when the trocar site was located on the linea alba (ranging from 17 to 38%) [4, 5]. Karampinis et al. [12] in their recent systematic literature review found that studies dedicated to detection of TSH reported a pooled incidence of 24.5% and specific TSH examination using imaging modalities were associated with a significantly higher incidence of TSH. The major limitation of this review was that most studies included in this analysis were not dedicated to detecting TSH explaining why so many series have low rate of TSH after bariatric surgery. This also explain why surprisingly, routine closure of the fascia in this review was associated with a significantly higher incidence of TSH compared to studies without fascia closure. No study evaluates routine closure of trocar site using imaging.

Our study, despite several limitations, shows that routine epigastric TSC after SG is feasible, with failure of the TSC device in only 4 out of 146 patients (2.7%). The 4 cases of failure of the closure device were related to excessively tangential trocar insertion early in our experience with this device. After several failures, epigastric trocar placement was modified to facilitate TSC at the end of the procedure. The

Table 1 Comparison of the 12-month TSH rate between the previous published series [5] and the present series

	Control group [5] ($n = 223$)	Closure group ($n = 123$)	p value
Male gender (%)	45 (20.1)	33 (26.8)	0.16
Age; range (years)	45.0 (18–68)	40.6 (19–72)	0.001
Preoperative BMI; range (kg/m^2)	47.6 (35–75.4)	45.4 (35.1–58.5)	0.003
BMI $\geq 50 \text{ kg/m}^2$ (%)	78 (35)	28 (22.7)	0.02
T2D (%)	95 (42.6)	39 (31.7)	0.05
Hypertension (%)	87 (39)	42 (34.1)	0.37
Dyslipidemia (%)	70 (31.3)	22 (17.8)	0.007
OSA (%)	81 (36.3)	49 (39.8)	0.52
Operating time; range (min)	90.2 (45–200)	58 (35–100)	<0.001
Routine epigastric trocar site closure (%)			
All trocar sites (%)	38 (17.0)	10 (8.1)	0.02
Epigastric trocar site (%)	33 (14.8)	8 (6.5)	0.02
Open trocar site (%)	4 (1.8)	2 (1.6)	0.91
Right subcostal margin (%)	1 (0.4)	0 (0)	0.46
Left subcostal margin (%)	0 (0)	0 (0)	0.99

BMI body mass index, OSA obstructive sleep apnea, T2D type 2 diabetes

TSC device is safe, as no device-related events, particularly no cases of organ injury, were observed during this study. Other devices are available, but we preferred to use the Weck® EFX Shield™ which comprises a shielded wing located at the end of the device allowing suture retrieval, avoiding the risk of organ perforation. During our study, we progressively used this device without direct vision due to the absence of risk of organ injury, allowing a reduction of the TSC time. In their experience of bariatric surgery without fascia closure, Pilone et al. [3] justified the absence of TSC by the risk of organ injury. The present study, although based on evaluation of the device in only 146 patients, shows that this argument is no longer valid.

Our study also shows that this epigastric TSC device is very easy to use. Pilone et al. [3] also considered that epigastric TSC could be time-consuming, while Del Junco et al. [8] showed that fascial closure using appropriate equipment was feasible and not time-consuming with a mean fascial closure time of 98 s and 133 s, respectively, according to the two types of device used. In our series, the device learning curve was about 10 to 15 cases, after which the TSC time was always less than 60 s with a mean TSC time of about 30 s (Fig. 4).

Our study shows that routine epigastric TSC after SG is effective to prevent TSH, as only 10 out of 123 patients with postoperative CT scan developed TSH (8.1%). This TSH rate was lower than the 17.0% TSH rate observed in the control group ($p = 0.02$). More detailed analysis of our results shows that the open laparoscopy trocar site TSH rate was similar between the two groups (1.6% in the closure group vs. 1.8% in the control group; $p = 0.91$) while the epigastric trocar site TSH rate was significantly lower in the closure group (6.5% in the closure group vs. 14.8% in the control group; $p = 0.02$). This study, based on a population of 346 patients, also showed that routine epigastric TSC was the only factor considered to have a protective effect on TSH on univariate and multivariate analysis ($p = 0.03$; relative risk of 0.43) (Table 2).

Routine epigastric TSC may have a positive clinical impact, as epigastric TSC needs to be performed in only 12

patients in order to avoid one TSH. In our study, routine TSC reduced the risk of TSH by more than 50%. The clinical impact of routine epigastric TSC could be even greater for certain types of surgical procedures. Although the risk of small-bowel incarceration at a trocar site is low in the context of SG (we have personally observed only two cases, detected immediately postoperatively in our institution), this closure device would be useful in the case of bariatric surgery involving small bowel, such as gastric bypass in which trocar sites are usually positioned lower on the abdominal wall. Postoperative bowel obstruction can be a very serious complication, with a risk of necrosis and also a risk of perforation of the excluded stomach and anastomosis leak depending on the site of obstruction and the time interval between surgery and bowel obstruction.

Other possibilities are available to decrease the TSH rate, for example, shifting the epigastric trocar site (on the linea alba) to the right rectus abdominis [6]. This modification of our technique could possibly decrease the TSH rate, but, in our experience, SG would be more difficult to perform and less ergonomic. In some patients with a thin rectus abdominis, more lateral trocar placement would not decrease the risk of hernia but would make the procedure technically more difficult with a possibly higher risk of complications.

Another interesting option would have been to use slowly absorbable sutures, as recommended for laparotomy [13]. For laparoscopy, we usually use rapidly absorbable sutures and, more recently, slowly absorbable sutures for closure of open laparoscopy sites. However, in the present study, slowly absorbable sutures would be too rigid and cannot be used to facilitate closure of epigastric trocar sites, which is why we used rapidly absorbable sutures. Prophylactic use of mesh would be useful, in view of the high risk of TSH without routine closure [4, 5]. The use of mesh for SG would not be associated with an increased risk of mesh infection, but would significantly increase the operating time and the cost of surgery. One of the strengths of our series is that our results can probably be transposed to gastric bypass or other more

Table 2 Risk factors for TSH in a study population of 346 patients

	Absence of TSH	Presence of TSH	Univariate analysis <i>p</i> value	Relative risk	Multivariate analysis <i>p</i> value	Relative risk
Male gender (%)	69 (23.2)	9 (18.8)	0.50	0.77 (0.35–1.66)	–	–
Age (years)	43 ± 12	44 ± 11	0.62	1.01 (0.98–1.03)	–	–
Preoperative BMI (kg/m ²)	46.7 ± 6.6	48.2 ± 7.9	0.16	1.03 (0.99–1.08)	–	–
BMI ≥ 50 kg/m ² (%)	89 (29.9)	17 (35.4)	0.44	1.29 (0.68–2.45)	–	–
T2D (%)	115 (38.6)	19 (39.6)	0.89	1.04 (0.56–1.95)	–	–
Hypertension (%)	111 (37.2)	18 (37.5)	0.97	1.01 (0.54–1.89)	–	–
Dyslipidemia (%)	76 (25.5)	16 (33.3)	0.26	1.46 (0.76–2.81)	–	–
OSA (%)	114 (38.3)	16 (33.3)	0.51	0.81 (0.42–1.54)	–	–
Metabolic syndrome (%)	61 (20.5)	13 (27.1)	0.30	1.44 (0.72–2.89)	–	–
Operating time (min)	79 ± 28	79 ± 29	0.93	1.0 (0.99–1.01)	–	–
Routine epigastric trocar site closure (%)	113 (37.9)	10 (20.8)	0.03	0.43 (0.21–0.89)	0.03	0.43 (0.21–0.89)

BMI body mass index, OSA obstructive sleep apnea, TSH trocar site hernia, T2D type 2 diabetes

complex bariatric procedures. Such options cannot be routinely in gastric bypass, as peritoneal fluid samples are positive in 15% of cases with a risk of mesh infection [14].

However, this study presents several limitations. Firstly, it was not a prospective randomized study. Our two study groups were quite different, as shown in Table 1, as the control group comprised older patients with higher BMI and more comorbidities (T2D and dyslipidemia), as no inclusion criteria were used to select the control group which was derived from retrospective analysis of all patients undergoing SG in our institution. The closure group was selected by clearly defined inclusion criteria, such as BMI over 60 kg/m² for example. The operating time was also different between the two groups due to the lower BMI in the closure group and more experienced surgeons in the SG technique in the closure group. Secondly, weight loss was not compared between the two groups and its impact on the TSH rate was not evaluated, although obesity is considered to be a risk factor for TSH after laparoscopy [15]. We are also unable to determine whether poor weight loss is a risk factor for TSH in our study. Lastly, no economic assessment was performed during our study, although use of this device could have a positive impact, as only 12 patients must be treated by routine epigastric TSC to avoid a subsequent surgical procedure for incisional hernia repair.

Conclusion

Routine epigastric TSC after SG using a specific device is feasible, rapid and provides effective prevention of TSH with a significant reduction of the TSH rate. In our study, routine epigastric TSC reduced the risk of TSH by 52.4% compared to the control group without TSC. Prospective randomized studies including economic assessment would be of interest to confirm our results and analyze the economic impact of this technique.

Acknowledgments We thank Delphine Lignier for her valuable help with this work.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflicts of interest.

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 by all individual participants included in the study.

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