International Journal of Surgery Open 32 (2021) 100337

Contents lists available at ScienceDirect

International Journal of Surgery Open

journal homepage: www.elsevier.com/locate/ijso

Case Series

Clinical outcomes of pre-attached reinforced stapler reloads in bariatric surgery: A prospective case series

Ahmed Ahmed [a,*], Salvador Morales-Conde [b], Marc Legrand [c], Simon Nienhuijs [d], Jacques Himpens [e], Long R. Jiao [f], Olivier Facy [g]

[a] Imperial College Healthcare NHS Trust, London, England, United Kingdom
[b] Unit of Innovation in Minimally Invasive Surgery, Department of General and Digestive Surgery, University Hospital "Virgen Del Rocío", Sevilla, Spain
[c] Chirurgie Abdominale, CHR de Huy, Huy, Belgium
[d] Catharina Ziekenhuis, Eindhoven, the Netherlands
[e] Service de Chirurgie Abdominale, Edith Cavell Hospital, Bruxelles, Belgium
[f] Department of Surgery & Cancer, Hammersmith Hospital, London, United Kingdom
[g] CHU Dijon, Dijon, France

ARTICLE INFO

Article history:
Received 3 March 2021
Received in revised form
23 March 2021
Accepted 24 March 2021
Available online 31 March 2021

Keywords:
Surgical stapling
Staple line reinforcement
Roux-en-Y gastric Bypass
Laparoscopic sleeve gastrectomy
Adverse events
Case series

ABSTRACT

Background: Staple line reinforcement during surgery may decrease morbidity or reduce the risk of staple line leaks and bleeding. There is debate regarding the benefit, safety, and best form of reinforcement. This case series characterizes the safety of a stapler with a pre-attached buttress in bariatric surgeries.

Methods: This prospective, multicenter, post-market study examined the use of stapler reloads with built in reinforcement material. The primary endpoint is the incidence of reported device-related adverse events up to 30 days after laparoscopic Roux-en-Y gastric bypass (RYGB) and laparoscopic sleeve gastrectomy (SG) surgeries. Specific outcomes included bleeding (≥50 mL), leaks, and 30-day readmissions.

Outcomes: A total of 51 patients (19 RYGB, 32 SG) were assessed after exclusion criteria were applied. Intraoperatively, no leaks or bleeding related to the staple line occurred. Four patients (8% overall, 3 RYGB, 1 SG) experienced bleeding unrelated to the staple line and staple line intervention, in these cases, was not required. Four subjects (8%, all SG) required readmission and each were attributed as unrelated to the investigational device. No unanticipated device-related events were observed. Two adverse events (bleeding) occurred post-operatively that were attributed as possibly related to the device; both were endoscopically managed.

Conclusions: This study demonstrates that there were no serious safety concerns from the AEs observed related to reinforced reload use during or in the 30-day course after 51 common bariatric procedures in a multicenter setting.

Trial registration: The study was registered with clinicaltrials.gov (NCT02500537). Thoracic subjects from this study are described in a separate manuscript.

1. Background

Surgical staplers represent a critical tool for surgeons to efficiently enable tissue resection, approximation, and anastomosis. In bariatric surgery procedures, including laparoscopic Roux-en-Y gastric bypass (RYGB) and laparoscopic sleeve gastrectomy (SG), stapling can be applied to the creation of anastomoses, closing of the stomach pouch, and creation of gastric sleeves [1]. As with any closure method, the integrity of the staple line is key to its function. Failure of the staple line can lead to severe complications including death [1–3].

Leaks and bleeding are among the most common staple line complications [3]. Complication rates differ by procedure and complication type. Leaks have been reported to occur at about 1–3% (up to 8%) after SG [1,3,4–6] and 1–4% (up to 6%) after RYGB [3,5,7]. Typical bleeding rates have been reported of 1–2% after SG [8,9] and 1–3% after RYGB [1], but rates of up to 4.3% (SG) [10] and 9.4% (RYGB)

* Corresponding author. St. Mary's Hospital, Imperial College Healthcare NHS Trust, Imperial College Healthcare, Room 35, 4th floor, Salton House, Praed St., London, W2 1NY, United Kingdom. Fax: +44 20 3311 1757.
E-mail address: ahmed.ahmed4@nhs.net (A. Ahmed).

https://doi.org/10.1016/j.ijso.2021.100337

[11] have been reported. The economic burden from complications can be considerable. Leaks post-SG have been associated with extra care costs of over €9000 per patient in the Netherlands [8] and extra outpatient costs of over €41,000 in France [2].

Reinforcement of the staple line has emerged as a key strategy to minimize staple line failures and complications and includes running sutures/over-sewing; fibrin or synthetic glue; or buttress reinforcement with biological (e.g., bovine pericardial strips) or synthetic materials (e.g., expanded polytetrafluoroethylene sleeves [ePTFE]) [12–16]. Each method of reinforcement may provide varying degrees of efficacy and for different outcomes. The type of reinforcement used has shown different effects on leak versus bleeding rates [1,4], and it can also have differing effects on total operative time, with some resulting in increased duration [17,18]. Results vary by study, but meta-analyses comprising large numbers of patients have shown the use of buttressing materials to be associated with lower rates of complications after bariatric surgeries compared to non-reinforcement [1,4,19].

Current buttressing techniques require surgeons to manually apply the material prior to staple firing [18]. To address this issue, stapler cartridges pre-loaded with buttress material may improve operating room efficiency and reduce the risk of handling errors while also providing the benefits associated with staple line reinforcement. This case series presents prospectively collected procedure outcomes following the routine clinical use of an available stapler reload with pre-attached reinforcement (reinforced reloads) in bariatric surgeries. The aim of this study was to collect evidence on the safety of the pre-attached reinforced stapler reload across a range of surgeons and locations focused on bariatric procedures and enable surgeons with additional information when planning their reinforcement strategy.

2. Methods

2.1. Study design

This case series was designed as a prospective, multi-center, non-comparative trial on safety in the use of a surgical stapler with buttressing material integrated into the reload cartridge for a regulatory body submission. It was conducted by surgeons in 12 different European academic hospitals from May 2015 to May 2016 which was intended to characterize the safety of this stapler by tracking adverse events (AEs) in the hands of expert surgeons and different applications. Written informed consent was obtained from all study patients, and the study was approved by the Institutional Review Boards of each of the participating institutions. The study was registered with clinicaltrials.gov (NCT02500537, https://clinicaltrials.gov/ct2/show/NCT02500537?term=NCT02500537&draw=2&rank=1); this work is reported in line with PROCESS 2020 guidelines [20].

The primary study outcome is the incidence of device-related AEs, particularly regarding bleeding (per protocol defined as total estimated blood loss $\geq$ 50 mL) and leaks. Secondary outcomes were intraoperative incidence and duration of leak, index hospital stay duration, incidence of infections, as well as any reinterventions to address staple line failures, 30-day postoperative hospital readmissions, and postoperative complications.

2.2. Protocol deviation

The original protocol called for patients in two groups, abdominal and thoracic surgeries, with target enrollment of 60 and 40 patients, respectively. To better assess outcomes in the different types of surgeries, the decision was taken to focus presentation by reporting separately the results for abdominal and thoracic procedures. Among the abdominal procedures included in this study, counts were too low for non-bariatric procedures (3 colonic, 2 hepatic and 1 pancreatic resection) to enable any conclusions to be drawn. Bariatric procedures made up the vast majority of abdominal patients in the current study, therefore this case series presents bariatric surgeries (RYGB and SG) only. A separate manuscript reports results of the thoracic data.

The protocol definition of infections was to count those related to the staple line. The infection data recorded referred primarily to the surgical incision site, and no association to the staple line can be inferred. The outcome is reported as surgical site infection (SSI), but these rates do not relate to use of the device.

2.3. Device

The device used in this study is the Endo GIA™ Tri-Staple™ technology with Reinforced Reload (Covidien, Mansfield, MA). This Tri-Staple™ reload, which fires a triple-staggered row of titanium staples, is preloaded with buttress material. This material is a layer of NEOVEIL™ Reinforcement Staple Line Material, an absorbable polyglycolic acid (PGA) porous mesh developed by GUNZE (Osaka, Japan) and is secured with an anchoring suture to the anvil and cartridge of the stapler reloads. After firing, the reinforcement material remains in the tissue after staples are secured on either side of the cut line. Cartridge size and quantity were determined by the on-site surgeon at the time of the procedure.

2.4. Study population

Patients were required to be 18–80 years of age and undergoing RYGB or SG for obesity with or without comorbidities. Only primary surgery (not revision or reoperation) procedures were included. Pregnancy and concurrent enrollment in other drug or device research studies were additional exclusion criteria. Surgeons experienced in the procedure performed each procedure using Standard of Care practice at their facility.

2.5. Assessment of adverse events (AEs)

Occurrence of AEs was tracked based on changes to the subject physical examination, laboratory results, and/or signs and symptoms excluding conditions requiring preplanned procedures, as well as symptoms relating to preexisting conditions found because of the screening unless either of these exclusions has worsened since screening. Monitoring occurred from the start of the procedure until the 30-day follow-up visit was completed. AEs were assessed for severity, duration, and relationship to the investigational device. An adverse device event was defined as an occurrence relating to or caused by the investigational device.

2.6. Intraoperative measures

The staple line was assessed intraoperatively, including incidence of staple line bleeding, incidence of leakage, leak site origin in relation to buttress material, and interventions needed to treat staple-line failure. Additionally, estimated total blood loss and incidence of blood transfusion were noted. Device deficiencies and AEs were recorded.

2.7. Postoperative measures

Prior to discharge, information on vital signs, surgical site and infection assessment, incidence and cause of reoperations, incidence of post-operative bleeding, estimated blood loss, requirement of blood transfusions, length of hospital stay, length of intensive care unit stay (if applicable), AEs, and treatment for AEs were collected.

A 30-day follow-up examination was also performed, which included collection of vital signs and performance of a physical exam. Incidence and cause of hospital readmissions or staple line reinterventions as well as AEs and their treatment were again collected. An eCRF was used and source data were monitored.

2.8. Statistics

Endpoint analysis was summarized with descriptive statistics as counts and percentages, mean ± standard deviation (SD), and median with interquartile range (IQR) as appropriate. No comparative tests yielding p-values were performed. Analyses were performed using SAS® Version 8.0 or higher (SAS Inc., Cary, NC).

3. Results

3.1. Patient demographics

Initially, 53 patients were screened for bariatric procedures. One patient withdrew from the study and one patient was excluded for not matching surgical criteria (overweight but not obese and no indication of obesity-related comorbidity). There remained 19 RYGB and 32 SG patients for analysis who completed the study. Patient demographics are shown in Table 1. Patient characteristics were similar between the groups, with the majority of patients female (RYGB 72%, SG 63%) and on average with class III obesity with median body mass index (BMI) over 40 kg/m^2 (RYGB 42 kg/m^2, SG 43 kg/m^2). All included patients underwent surgery for an indication of obesity with or without comorbidities.

Table 1
Baseline demographics.

	RYGB (N = 19)	SG (N = 32)
Age, median [IQR], years	45 [40–51]	44 [33–52]
Female, n/N (%)	14/19 (74%)	20/32 (63%)
BMI, median [IQR], kg/m^2	42 [39–48]	43 [40–50]
ASA grade		
Grade 2, n/N (%)	9/19 (47%)	23/32 (72%)
Grade 3, n/N (%)	10/19 (53%)	9/32 (28%)
Regular alcohol use	5.3%	6.2%
Tobacco use		
Current smoker, n/N (%)	1/19 (5%)	5/32 (16%)
Former smoker, n/N (%)	9/19 (47%)	7/32 (22%)
Non-smoker, n/N (%)	9/19 (47%)	20/32 (62%)
Duration smoking,[a] median [IQR], years	15 [15–18]	19 [10–31]

[a] Duration of smoking only applies to former and current smokers. BMI, body mass index; RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; IQR: Interquartile Range; SD: standard deviation.

3.2. Intraoperative outcomes

Collected perioperative data are displayed in Table 2. Per protocol definition, bleeding incidence was counted for cases where estimated blood loss was at least 50 mL; four patients had such an intraoperative bleed (SG: 1 patient with 50 mL, RYGB: 1 patient 100 mL, 2 patients 200 mL). However, none of these four cases were related to the staple line as bleeding was not was observed at the staple line and no staple line intervention was performed for these patients.

Overall, no patient required intraoperative transfusion. Any other bleeding associated with the visualization of the staple line was minor (< 50 mL). Average total estimated blood loss was 38 ± 63 mL for RYGB and 3 ± 10 mL for SG patients. Intraoperative staple line interventions were electrocautery (n = 3, all SG patients, bleeding < 5 mL) and the rest were managed with clips (n = 2 RYGB, n = 3 SG, blood loss 1–20 mL, average 10 mL).

No intraoperative leak was identified in either surgical group. No clinical evidence (signs or symptoms) of leak was reported during the index hospital admission or 30-day postoperative follow-up period.

3.3. Postoperative outcomes

The length of stay (mean ± SD) from surgery to discharge was 4 ± 2 days and 2 ± 1 days for RYGB and SG procedures respectively (Table 3). Two patients (both having undergone RYGB, 7% overall incidence) experienced intraluminal bleeding. Neither of these endoluminal bleeds was from the staple line on endoscopy. One of

Table 2
Perioperative data.

	RYGB (N = 19)	SG (N = 32)	Overall (N = 51)
Operative time, mean ± SD, minutes	96 ± 48	50 ± 18	67 ± 39
Operative time, median [IQR], minutes	75 [68–115]	48 [41–60]	60 [45–72]
SSI class			
Class I, n/N (%)	8/19 (42%)	13/32 (41%)	
Class II, n/N (%)	11/19 (58%)	19/32 (59%)	
Leaks detected, n/N (%)	0/19 (0%)	0/32 (0%)	0/51 (0%)
Hemostasis			
Estimated total blood loss, mean ± SD, mL	38 ± 63	3 ± 10	16 ± 42
Estimated total blood loss, median [IQR], mL	10 [0–44]	0 [0–0]	0 [0–10]
Bleeding estimated > 50 mL, n/N (%)	3/19 (16%)	1/32 (3%)	4/51 (8%)
Bleeding requiring staple line intervention, n/N (%)	0/19 (0%)	0/32 (0%)	0/51 (0%)
Transfusion required, n/N (%)	0/19 (0%)	0/32 (0%)	0/51 (0%)
Staple line			
Staple line visualized, n/N (%)	19/19 (100%)	32/32 (100%)	51/51 (100%)
Buttress visualized in place, n/N (%)	19/19 (100%)	32/32 (100%)	51/51 (100%)
Perioperative intervention (minor bleed), n/N (%)	2/19 (11%)	6/32 (19%)	8/51 (16%)
Pre-discharge reintervention, n/N (%)	2/19 (11%)	0/32 (0%)	2/51 (4%)
Postoperative (30 day) reintervention, n/N (%)	0/19 (%)	0/32 (0%)	0/51 (0%)

ASA, American Society of Anesthesiologists; IQR, interquartile range; SD, standard deviation; SSI, surgical site infection.

Table 3
Postoperative outcomes.

Parameter	RYGB (N = 19)	SG (N = 32)	Overall (N = 51)
Length of stay, mean ± SD, days	4 ± 2	2 ± 1	3 ± 1
Length of stay, median [IQR], days	4 [2–4]	2 [2–3]	2 [2–3]
Postoperative blood loss > 50 mL, n/N (%)	2/19 (11%)	0/32 (0%)	2/51 (4%)
Estimated postoperative blood loss, mean ± SD, mL	64 ± 227	0 ± 0	24 ± 140
Estimated postoperative blood loss, median [IQR], mL	0 [0–28]	0 [0–0]	0 [0–0]
Readmission (any), n/N (%)	0/19 (0%)	4/32 (12%)	4/51 (8%)
Readmission (possible device), n/N (%)	0/19 (0%)	1/32 (3%)	1/51 (2%)

IQR, interquartile range; SD, standard deviation.

these patients experienced hemorrhaging (estimated blood loss 1000 mL) that required a postoperative blood transfusion; no evidence of bleeding via laparoscopy was observed but some haematoma was documented via endoscopy. The other patient had blood loss of 50 mL and the bleeding resolved with no reintervention.

Hospital readmission occurred for 4 patients (all SG, overall incidence 8%). Of these, there was no relationship assigned to the study device; instead: one was unrelated to the procedure or device (communicable illness), two definitely related to the procedure (one for reaction to medication and the other occult nausea and vomiting that resolved overnight in hospital), and the final patient probably procedure-related (readmission nausea managed with enteral feeding during readmission).

3.4. Safety outcomes

In total, there were 15 and 8 adverse events recorded for RYGB and SG procedures respectively (Table 4). None of the AEs was classified as severe and most were mild (11/15, 73% RYGB, 5/8, 62% SG). One difference between the two groups was in the timing of events, where more of the RYGB events occurred during the index hospital visit (12/15, 80%) in contrast to the SG events which mostly occurred during the time post-discharge (6/8, 75%). No adverse events were related to leaks and there were no deaths.

4. Discussion

Complications related to the staple line in bariatric procedures remain a concern and have a negative impact on patient outcomes. Reinforcement of the staple line with buttressing material has been shown in studies to reduce varying complications to different degrees. The present study assessed the clinical use in bariatric procedures of a post-market stapler cartridge with pre-attached absorbable PGA buttressing material across multiple countries, institutions, and surgeons.

The results of this study support the continued use of the stapler cartridge with pre-loaded buttress in a broad range of settings and users. There were no leaks detected during or after the procedure and no relevant bleeding (≥50 mL) related to the staple line intraoperatively. The staple line and the buttress could be visually assessed, and any bleeding that was observed was minor and managed with either electrocautery or clips. When adverse events occurred, these were generally attributable to reasons other than the device, including complications away from the staple line or illness unrelated to the surgery.

The observed rates of bleeding and leak after common bariatric procedures compare favorably with literature reports, where rates of 1–3% have been reported for bleeding [1,8,9] and 1–4% have been reported for leaks [1,3,4,7]. Precise rates will depend on the surgery (RYGB versus SG) and clinical details such as whether staple line reinforcement was used. Due to the limited size of the present analysis, direct comparisons may not be reliable, but these results provide an indication of equivalent, to potentially improved outcomes.

There is not complete agreement in the literature about the efficacy of staple line reinforcement [11,21–23]. One potential contributor to the uncertainty may be the different effects reported on different outcomes. While one type of reinforcement may significantly reduce bleeding rates, the same may have a non-significant effect on leaks compared to other reinforcement methods [1]. An international consensus panel concluded that reinforcement is effective to reduce bleeding at the staple line, but no consensus was reached regarding buttressing and leak rates [23]. As noted earlier, analyses comprising many patients have demonstrated the benefits of reinforcement over non-reinforcement and among different methods of reinforcement [1,4]. One systematic review and meta-analysis comprising 148 studies and 40,653 patients found leak rates after sleeve gastrectomy with absorbable membrane buttressing, similar to that used in the present study, to be 0.7%, significantly lower than non-reinforced (1.9%), suture reinforcement (1.2%) and biological material reinforcement (bovine pericardial strips, 2.7%) [4].

4.1. Strengths

A strength of this study is how the tested device may impact the surgical practice of utilizing buttressing material: outside of the

Table 4
Safety data.

Parameter	RYGB	SG	Overall
Adverse events			
Events, N	15	8	23
Classification			
Mild	11/15 (73%)	5/8 (62%)	16/23 (70%)
Moderate	4/15 (27%)	3/8 (38%)	7/23 (30%)
Timing			
In-hospital (index)	12/15 (80%)	2/8 (25%)	14/23 (61%)
Post-discharge	3/15 (20%)	6/8 (75%)	9/23 (39%)
Relatedness of AE			
Procedure-related, n/N (%)	11/15 (73%)	7/8 (88%)	18/23 (78%)
Possible device involvement, n/N (%)	2/15 (13%)	0/8 (0%)	2/23 (9%)
Related to leaks, n/N (%)	0/15 (0%)	0/8 (0%)	0/23 (0%)
Related to bleeding, n/N (%)	2/15 (13%)	0/8 (0%)	2/23 (9%)
Adverse events by patient			
Any AE, n/N (%)	9/19 (18%)	6/32 (12%)	15/51 (29%)
More than 1 AE, n/N (%)	5/19 (26%)	1/32 (3%)	6/51 (12%)
Death, n/N (%)	0/19 (0%)	0/32 (0%)	0/51 (0%)

device in this analysis, buttressing material must be exogenously applied to the stapler cartridge. The application must also be repeated for each stapler cartridge, which will add operative time for procedures such as SG where multiple firings are required to create the sleeve. A French study of sleeve gastrectomy in patients at high risk of leak or bleeding complications (possessing risk factors such as hypertension, anti-coagulation therapy, and high BMI) examined the impact of an absorbable membrane buttress material versus no buttressing and found that, on average, use of the buttress added 12 min to the operating time [18]. In the context of the present study, such manipulation would add 25% to the median operating time of 48 min across the SG operations performed here. Such a considerable increase would potentially increase the resource burden of care, as well as increasing patient risks due to longer anesthesia time.

4.2. Limitations

This study is limited in that it does not provide a direct comparison to non-reinforced staple reloads. Concurrent data on complications and adverse event rates for the participating surgeons would provide additional context for the rates reported in the present study. Use of reinforcement is at the discretion of the surgeon based on the procedure and the circumstances at hand, which may have contributed to limited patient numbers for analysis. Establishment of a larger, randomized controlled study would more clearly inform whether differences occur in using the stapler cartridges with pre-attached reinforcement versus other methods of reinforcement or non-reinforcement of the staple line. Despite these limitations, the current study presents a snapshot of application of the cartridge with attached reinforcement in a variety of settings, used by a variety of surgeons, illustrating its usability and the demonstration of low rates of leakage, bleeding and other adverse events associated with the device.

5. Conclusion

Overall, these results support that the use of pre-loaded reinforced reloads had minimal safety concerns by observing adverse events in 51 RYGB or SG surgeries for up to 30-days post procedure and across multiple institutions with different local practices. This study adds to existing literature supporting the safety of utilizing buttressing material in conjunction with bariatric procedures, and particularly using this pre-loaded stapler reload that may simplify the application for surgeons who normally place buttressing material manually. Additional studies with larger cohorts will be needed to validate these results and to optimize techniques that minimize staple line complications, including rates of bleeding and leakage.

Ethical approval

Written informed consent for participation and publication was obtained from all study patients, and the study was approved by the Institutional Review Boards of each of the participating institutions (see Supplemental Table 1). The study was registered with clinicaltrials.gov (NCT02500537).

Funding

The study is sponsored and funded by Covidien (now owned by Medtronic PLC; Mansfield, MA), which contributed to the study design, data collection and analysis, and manuscript writing. The lead author (AA) had full access to all study data and final responsibility for the decision to submit for publication. The authors were not paid to write this article by the sponsor or any other agency. The data interpretation presented in this manuscript was performed solely by the authors herein with medical writing support provided by Medtronic being performed in accordance with Good Publication Practice (GPP3) guidelines (http://www.ismpp.org/gpp3).

Author contributions

AA, SM, ML, SN, JH, LJ, OF enrolled patients and collected data. AA interpreted the patient data and drafted the manuscript. SM, ML, SN, JH, LJ, OF critically reviewed the manuscript and provided editorial comments. All authors have read and approved of the final manuscript and agree to be accountable for the work.

Conflicts of interest statement

Study sponsorship and support for data analysis and medical writing was provided by Covidien (now owned by Medtronic PLC; Mansfield, MA). All authors (or their institutions) received research support from Covidien to conduct this study.

Dr. Ahmed reports research and non-financial support from Medtronic during the conduct of the study; along with grants from MSD and WL GORE that are outside the submitted work.

Dr. Morales-Conde reports research and non-financial support from Medtronic during the conduct of the study; as well as other support from Bard Davol, Stryker, Mönlycke, Ethicon, and Medtronic outside the submitted work.

Dr. Legrand reports non-financial support from Medtronic, other from Medtronic during the conduct of the study.

Dr. Nienhuijs reports research and non-financial support from Medtronic during the conduct of the study; as well as grants from Educational grant to obesity center by Medtronic outside the submitted work.

Dr. Himpens reports non-financial support from Medtronic, and personal fees from Ethicon during the conduct of the study.

Dr. Jiao reports non-financial support from Medtronic, other from Medtronic during the conduct of the study.

Dr. Facy reports research and non-financial support from Medtronic during the conduct of the study.

Guarantor

Ahmed Ahmed.

Research registration number

Name of the registry: Clinicaltrials.gov.

Unique Identifying number or registration ID: NCT02500537.

Hyperlink to your specific registration (must be publicly accessible and will be checked): https://clinicaltrials.gov/ct2/show/NCT02500537?term = reinforced + reload&draw= 2&rank= 1.

Availability of data and material

The data and support documents (i.e. study protocol) that support the findings of this study are available from Medtronic, but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Medtronic.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Acknowledgements

Study sponsorship and funding was provided by Covidien (now owned by Medtronic PLC; Mansfield, MA). Data analyses were performed by Medtronic in partnership with the academic authors. The authors had unrestricted access to the data. The authors would like to thank the following contributors, employees of Medtronic, who provided: statistical support (Sylvain Anselme), administrative support (Stephanie Herrmann-Stevenson), and medical writing and editorial support (Gregory M Sindberg, PhD) which was completed in accordance with Good Publication Practices (GPP3).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijso.2021.100337.

References

[1] Shikora SA, Mahoney CB. Clinical benefit of gastric staple line reinforcement (SLR) in gastrointestinal surgery: a meta-analysis. Obes Surg 2015;25:1133–41. https://doi.org/10.1007/s11695-015-1703-x.
[2] Nedelcu M, Manos T, Gagner M, Eddbali I, Ahmed A, Noel P. Cost analysis of leak after sleeve gastrectomy. Surg Endosc 2017;31:4446–50. https://doi.org/10.1007/s00464-017-5495-z.
[3] Silecchia G, Iossa A. Complications of staple line and anastomoses following laparoscopic bariatric surgery. Ann Gastroenterol 2018;31:56–64. https://doi.org/10.20524/aog.2017.0201.
[4] Gagner M, Kemmeter P. Comparison of laparoscopic sleeve gastrectomy leak rates in five staple-line reinforcement options: a systematic review. Surg Endosc 2020;34:396–407. https://doi.org/10.1007/s00464-019-06782-2.
[5] Shikora SA. The use of staple-line reinforcement during laparoscopic gastric bypass. Obes Surg 2004;14:1313–20. https://doi.org/10.1381/0960892042583770.
[6] Cunningham-Hill M, Mazzei M, Zhao H, Lu X, Edwards MA. The impact of staple line reinforcement utilization on bleeding and leak rates following sleeve gastrectomy for severe obesity: a propensity and case-control matched analysis. Obes Surg 2019;29:2449–63. https://doi.org/10.1007/s11695-019-03883-8.
[7] Acquafresca PA, Palermo M, Rogula T, Duza GE, Serra E. Early surgical complications after gastric by-pass: a literature review. Arq Bras Cir Dig 2015;28:74–80. https://doi.org/10.1590/S0102-67202015000100019.
[8] Bransen J, Gilissen LP, van Rutte PW, Nienhuijs SW. Costs of leaks and bleeding after sleeve gastrectomies. Obes Surg 2015;25:1767–71. https://doi.org/10.1007/s11695-015-1584-z.
[9] Zafar SN, Felton J, Miller K, Wise ES, Kligman M. Staple line treatment and bleeding after laparoscopic sleeve gastrectomy. J Soc Laparoendosc Surg 2018;22(e2018):56. https://doi.org/10.4293/JSLS.2018.00056.
[10] Daskalakis M, Berdan Y, Theodoridou S, Weigand G, Weiner RA. Impact of surgeon experience and buttress material on postoperative complications after laparoscopic sleeve gastrectomy. Surg Endosc 2011;25:88–97. https://doi.org/10.1007/s00464-010-1136-5.
[11] Nguyen NT, Longoria M, Welbourne S, Sabio A, Wilson SE. Glycolide copolymer staple-line reinforcement reduces staple site bleeding during laparoscopic gastric bypass: a prospective randomized trial. Arch Surg 2005;140:773–8. https://doi.org/10.1001/archsurg.140.8.773.
[12] Cooper JD. Technique to reduce air leaks after resection of emphysematous lung. Ann Thorac Surg 1994;57:1038–9.
[13] Fischel RJ, McKenna Jr RJ. Bovine pericardium versus bovine collagen to buttress staples for lung reduction operations. Ann Thorac Surg 1998;65:217–9.
[14] Malapert G, Hanna HA, Pages PB, Bernard A. Surgical sealant for the prevention of prolonged air leak after lung resection: meta-analysis. Ann Thorac Surg 2010;90:1779–85. https://doi.org/10.1016/j.athoracsur.2010.07.033.
[15] Muramatsu T, Ohmori K, Shimamura M, Furuichi M, Takeshita S, Negishi N. Staple line reinforcement with fleece-coated fibrin glue (TachoComb) after thoracoscopic bullectomy for the treatment of spontaneous pneumothorax. Surg Today 2007;37:745–9. https://doi.org/10.1007/s00595-007-3512-x.
[16] Vaughn CC, Wolner E, Dahan M, Grunenwald D, Vaughn 3rd CC, Klepetko W, et al. Prevention of air leaks after pulmonary wedge resection. Ann Thorac Surg 1997;63:864–6.
[17] Fort JM, Gonzalez O, Caubet E, Balibrea JM, Petrola C, Garcia Ruiz de Gordejuela A, et al. Management of the staple line in laparoscopic sleeve gastrectomy: comparison of three different reinforcement techniques. Surg Endosc 2020. https://doi.org/10.1007/s00464-020-07773-4.
[18] Gayrel X, Loureiro M, Skalli EM, Dutot C, Mercier G, Nocca D. Clinical and economic evaluation of absorbable staple line buttressing in sleeve gastrectomy in high-risk patients. Obes Surg 2016;26:1710–6. https://doi.org/10.1007/s11695-015-1991-1.
[19] Parikh M, Issa R, McCrillis A, Saunders JK, Ude-Welcome A, Gagner M. Surgical strategies that may decrease leak after laparoscopic sleeve gastrectomy: a systematic review and meta-analysis of 9991 cases. Ann Surg 2013;257:231–7. https://doi.org/10.1097/SLA.0b013e31826cc714.
[20] Agha RA, Sohrabi C, Mathew G, Franchi T, Kerwan A, O'Neill N, et al. The PROCESS 2020 guideline: updating consensus preferred reporting of CasESeries in surgery (PROCESS) guidelines. Int J Surg 2020;84:231–5. https://doi.org/10.1016/j.ijsu.2020.11.005.
[21] Chen B, Kiriakopoulos A, Tsakayannis D, Wachtel MS, Linos D, Frezza EE. Reinforcement does not necessarily reduce the rate of staple line leaks after sleeve gastrectomy. A review of the literature and clinical experiences. Obes Surg 2009;19:166–72. https://doi.org/10.1007/s11695-008-9668-7.
[22] Miller KA, Pump A. Use of bioabsorbable staple reinforcement material in gastric bypass: a prospective randomized clinical trial. Surg Obes Relat Dis 2007;3:417–21. https://doi.org/10.1016/j.soard.2007.03.244. discussion 22.
[23] Rosenthal RJ, International Sleeve Gastrectomy Expert P, Diaz AA, Arvidsson D, Baker RS, Basso N, et al. International sleeve gastrectomy expert panel consensus statement: best practice guidelines based on experience of >12,000 cases. Surg Obes Relat Dis 2012;8:8–19. https://doi.org/10.1016/j.soard.2011.10.019.