



Management of Staple Line Leaks Following Sleeve Gastrectomy—a Systematic Review

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Abstract

Background A staple line leak following a sleeve gastrectomy is associated with significant morbidity and mortality. No uniform guideline or consensus exists with regard to the optimal treatment approach to managing a staple line leak.

Objectives The objective of this systematic review is to assess the efficacy and success rates of the different treatment strategies for staple line leak following sleeve gastrectomy.

Methods A thorough search through four online electronic databases was conducted using predefined search criteria. Our primary outcome measure was to review the treatment options described in the management of the staple line leak following laparoscopic sleeve gastrectomy. Successful initial management was defined as the proportion of cases that were successfully treated using the first modality described, with no escalation to another treatment option.

Results A total of 26 articles were included in this systematic review. Successful initial management of 62% was achieved in patients who underwent endoscopic management, 76% in those who underwent surgery and 82% in patients treated conservatively. A total of 7 patient deaths were noted, all of which were patients who underwent surgery as the initial management of their staple line leak.

Conclusion Prompt identification and adequate source control are crucial to successfully manage a staple line leak following sleeve gastrectomy. Treatment options are influenced by the clinical status of the patient. A stepwise treatment escalation approach is required to improve outcomes.

Keywords Bariatric surgery · Sleeve gastrectomy · Staple line leak

Introduction

Sleeve gastrectomy is the most common procedure performed worldwide in the management of the obesity epidemic [1]. Of all postoperative complications, a staple line leak is most feared by bariatric surgeons. A staple line leak may present in a variety of ways, ranging from fulminant peritonitis and sepsis with multi-organ failure, to intra-abdominal collections and fistula formation [2]. A staple

line leak most often occurs from the proportion of the staple line closest to the gastro-oesophageal junction [3]. Within the literature, the causes of a staple line leak are broadly grouped into two separate domains: ischaemic and mechanical causes [4]. The incidence of a staple line leak following sleeve gastrectomy is low; different case series quote incidence rates between 1.1 and 5.3% [5]. Despite its low incidence rate, it is associated with significant morbidity and mortality. Several different treatment strategies have been described for the management of a staple line leaks following sleeve gastrectomy in the current literature. These include surgery, endoscopic intervention and conservative management. However, there is no uniform guideline or consensus with regard to the optimal treatment approach. The aim of this systematic review is to assess the efficacy and success rates of the different treatment strategies for staple line leak following sleeve gastrectomy.

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Methods

A thorough search of the pre-existing literature regarding the management of staple line leak following sleeve gastrectomy was performed. It was conducted with adherence to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidance [6]. Four online electronic databases were searched (PubMed, Web of Science, Medline and Embase) for published articles between 1946 and 2018. The search was performed utilising MeSH search terms and key words, these included “laparoscopic sleeve gastrectomy”, “sleeve gastrectomy”, “laparoscopic bariatric surgery”, “staple line leak”, “staple line leak management”, “treatment” and “management” (Appendix). Boolean operators (AND or OR) were integrated into the search in order to maximise article capture. The end search result was further supplemented by hand searching the reference lists from included and excluded articles.

A pre-defined specific inclusion criterion was created for this systematic review. This included full text, English language articles that reported leak rates and subsequent treatment strategies. It was mandatory that included articles contained a chronological description of all treatment options undertaken in the management of the gastric leak and whether the treatment was successful. Individual case reports and conference presentations were excluded. Articles where data extraction regarding previous treatment and outcomes that were unclear were excluded.

Following the final search, titles and abstracts for each manuscript were screened, assessed and compared to the inclusion criteria and included if appropriate. Figure 1 highlights the flow diagram of included articles. Two authors

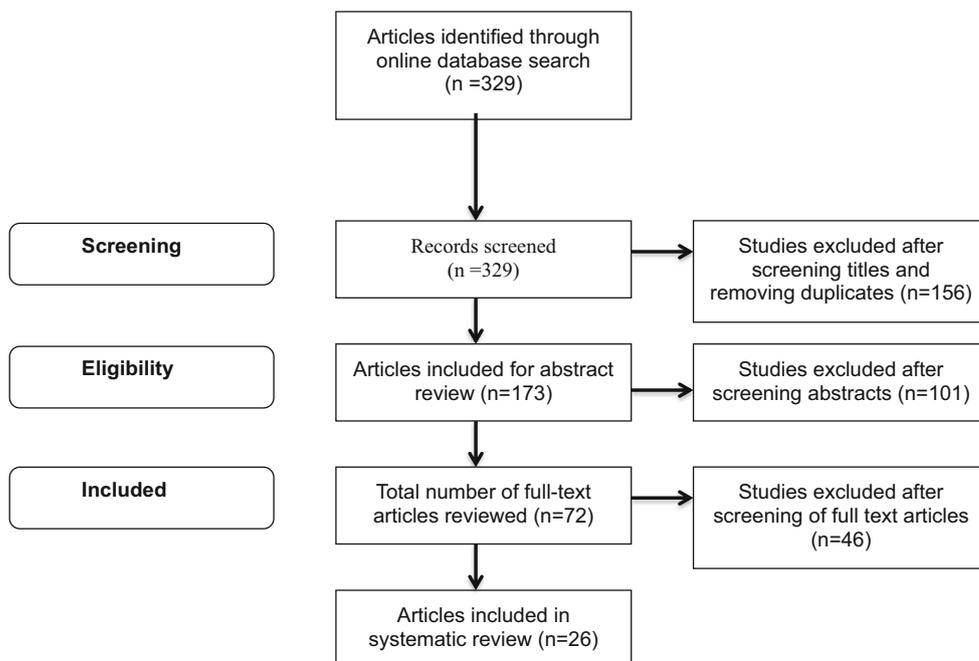
independently performed data extraction and quality assessment of included articles. Any disparities were solved with a consensus decision following a discussion. Data was collected including individual patient demographics for each sleeve gastrectomy leak patient, operative technique used for the laparoscopic sleeve gastrectomy and management strategies used in the management of the leak. Leaks were classified as per the International Sleeve Gastrectomy Expert Panel consensus statement [7], based on the timing of the presentation of the leak following the initial sleeve gastrectomy as follows: acute (1–6 days), early (1–6 weeks), late (6–12 weeks) and chronic (> 12 weeks). Our primary outcome measure was to review the treatment options described in the management of the staple line leak following laparoscopic sleeve gastrectomy. Successful initial management was defined as the proportion of cases that were successfully treated using the first modality described with no escalation to another treatment option. The secondary outcome measure was the overall success rates for these treatment options.

Due to the heterogeneity of the data, no formal statistical analysis or comparison was performed. The Oxford Centre for Evidence-Based Medicine classification and the GRADE framework were used in order to assess and grade the levels of evidence for each included article [8, 9]. No ethical approval was required for this study.

Results

A total of 329 articles were identified, and after implementing the inclusion and exclusion criteria, 26 articles were included

Fig. 1 PRISMA flow diagram of literature search and article assessment



in the systematic review (Fig. 1). Included articles were classified as per the Oxford Centre for Evidence-Based Medicine classification.

Patient demographics were obtained and noted (Table 1) [10–35]. Data specifically related to patients who suffered from a staple line leak was extracted and recorded when possible. Staple line leak rates were calculated; the leak rate ranged from 0.20 to 55% in the included studies. Articles that only presented the management of leak patients as a total cohort sample were excluded from this calculation. Fifty percent of the included articles included a total cohort staple line leak rate of less than 2%. Articles published prior to 2010 had a median leak rate of 4%, whereas articles published between 2017 and present were noted to have a median leak rate of 1.35%.

Clinical data regarding intraoperative technique was recorded. The size of the bougie used varied across all studies. A 36-Fr bougie was commonly used (27%). Seven articles described the use of a bougie greater than 40 Fr in size. Of all of the included articles, 10 of which (38%) reported using a 60-mm-sized stapling cartridge to create the sleeve. The remaining articles did not specify the size of cartridge used. Surgical practice with regard to staple line reinforcement was recorded. Seventeen articles (65%) described the use of staple line reinforcement, and 3 articles stated that they did not routinely reinforce their staple lines of their sleeve gastrectomy patients. A variety of reinforcement techniques were described; suturing the staple line was the most utilised method. With regard to performing a leak test, 15 articles described the routine use of an intraoperative leak test. Methylene blue insertion was the most frequently used leak test (10 articles). Eight articles (31%) would routinely place a surgical drain at the end of the procedure.

Endoscopic management of a staple line leak was described by 15 articles (a total of 108 patients) (Table 2). The GOJ ($n = 57$) was the most common anatomical site of the staple line leak in patients who underwent endoscopic treatment and 52% of the patients presented with an early leak. Of the 15 articles describing endoscopic management, 73% utilised endoscopic treatment as a first-line treatment option for all of their patients within their study. Only 53% of the articles that described endoscopic management of a staple line leak used solely an endoscopic approach to treatment. The remaining 47% described endoscopic management in combination with another treatment modality (surgery or radiological drainage). The most common endoscopic intervention described was the placement of an endoscopic stent (81 cases), followed by the placement of an endoscopic clip (26 cases). One article described the use of fibrin glue placement as a management option for a sleeve leak. None of the articles included in this systematic review described the use of endoscopic double pigtail stent insertion. Of the articles that solely described endoscopic stent placement as a treatment strategy, a successful initial management rate of 62% was achieved.

Fifteen patients (14%) required further endoscopic treatment. The treatment escalation rate to another intervention (i.e. unsuccessful initial management rate) was noted. A total of 5 patients (4.6%) who were initially treated with an endoscopic treatment approach required salvage surgery.

A total of 20 articles described the initial management of a staple line leak with surgery in 74 patients (Table 3). The GOJ was the most common recorded anatomical site of a leak in patients who underwent initial surgical management. Twenty-four patients were diagnosed with an acute leak. Ten articles presented clearly an initial laparoscopic approach to leak management in 34 patients. Peritoneal washout, drain placement and staple line reinforcement were the most frequent surgical procedures described (11 articles, 37 patients), followed by washout and drainage (9 articles, 29 patients). Two articles described combined operative drainage and endoscopic stent placement (8 patients). The success rate of the surgical management of a staple line leak ranged from 0 to 100%. A successful initial management rate of 76% (56 patients) was reported. Sixteen patients (22%) required escalation to a second-line treatment approach. The most common second-line intervention was endoscopy and stent placement, performed in 11 patients. There were 7 reported deaths (mortality rate of 9.7%) in all articles that described the initial management of a sleeve gastrectomy staple line leak with surgery. The causes of death for these patients were sepsis (4 cases), acute liver failure (1 case), pneumonia (1 case) and cardiac arrest (1 case). Of all patients that suffered an acute staple line leak that was treated with surgery ($n = 21$), a primary successful management rate of 62% was noted. A subgroup analysis of patients with an acute leak noted a much higher successful initial management rates with laparoscopic surgery (83%, 10/12) when compared to open surgery (33%, 3/9).

Conservative management of a staple line leak was described in 12 articles (33 patients) (Table 4). The GOJ was reported as the most common site of staple line leak in this cohort. All 12 articles described conservative management (incorporating antimicrobial therapy and nutritional support) as the first-line treatment approach of managing the staple line leak. A total of 5 articles (13 patients, 29.3%) utilised a conservative management approach in combination with percutaneous drainage of intraabdominal collections. Of the remaining 7 articles, 3 of which the authors had described leaving a drain following the initial surgery. A successful initial management rate of 82% (27 patients) was achieved with a conservative management approach. The remaining 6 patients all underwent an endoscopic stent placement following a failed initial conservative management approach of their leak.

One article described a novel technique of managing a staple line leak—endoluminal vacuum therapy (E-Vac) (Table 5). Nine leaks were managed using E-Vac. The leaks were classified as follows: 3 acute, 3 early and 3 chronic. None of these patients received E-Vac as an initial treatment strategy for their

Table 1 Demographics of patients with a staple line leak and intraoperative technique

Reference	Number of leaks	Cohort size	Leak rate of cohort	Gender ratio (M:F)	Median age (range)	Median BMI (range)	Size of bougie	Staple size used	Staple line reinforcement	Intraoperative leak test	Placement of surgical drain
Moloney [10]	6	183	3.3%	*	*	*	40Fr	60 mm	No	No	No
Spicka [11]	3	223	1.30%	*	*	41 (39–42)	*	*	No	*	*
Rawlins [12]	1	55	1.90%	*	*	*	26.4F endoscope	60 mm	Yes—Vicryl suture and fibrin sealant	Air insufflation test	Yes
Albanopoulos [13]	12	353	3.40%	*	*	*	38 Fr	60 mm	Yes—continuous suture or clips or gore seamguard	No	Yes in 201 cases (57%) [§]
Keren [14]	26	26	100%	12:4	39 (21–60)	42 (35–51)	*	*	*	*	*
Casella [15]	6	200	3%	2:4	42 (28–50)	54 (41–60)	48 Fr	60 mm	Yes—oversewing (2 cases)	Methylene blue	No
El-Sayes [16]	27	49	55%	*	*	*	42 Fr	*	Yes—Peri-Strips Dry® with Veritas® Collagen Matrix	Methylene blue	No
Leeds [17]	9	35	26%	2:7	41 (27–73)	39 (33–62)	*	*	*	*	*
Abd Ellatif [18]	11	1395	0.79%	*	*	*	<= 36 Fr (60%) >= 44 Fr (40%)	*	Yes—447 cases (307 running suture 140 bovine pericardium) [§]	Methylene blue	Yes in 319 cases (23%) [§]
Gibson [19]	1	500	0.2%	*	*	*	32 Fr	60 mm	Yes	*	*
Hoogerboord [20]	1	166	0.6%	0:1	*	*	42 Fr	60 mm	No	No	No
Szewczyk [21]	8	565	1.42%	*	*	*	34 Fr	60 mm	Yes—continuous suture to staple line	Methylene blue	Yes
Currò [22]	1	200	0.50%	*	*	*	36Fr	*	Yes—clips	Methylene blue	Yes in 50% [§]
Wahby [23]	10	712	1.40%	*	*	*	32–36Fr (60%) > 38 Fr (40%)	*	Yes 220 cases (53 running suture, 67 bovine pericardium) [§]	Methylene blue	No
Rossetti [24]	1	145	0.70%	*	*	*	36 Fr	*	No	Air insufflation test	No
Sethi [25]	15	1550	1%	*	*	*	28–34 Fr (19%) 35–39 Fr (35%) 40+Fr (46%)	*	Yes	Yes 86%—Surgeon preference [§]	No
Montuori [26]	6	418	1.40%	4:2	*	*	36 Fr	60 mm	Selected cases only	Methylene blue	Yes
Klimczak [27]	13	13	100%	5:8	42 (31–55)	46 (40–51)	*	*	*	*	*
Southwell [28]	21	21	100%	7:14	44 (32–58)	41 (31–58)	*	*	*	*	*
Behrens [29]	1	34	3%	*	*	*	36 Fr	*	Yes—oversewn	No	No
Weiner [30]	12	686	1.70%	7:5	*	*	42 Fr	*	When needed	Methylene blue	Yes
Hany [31]	8	920	0.90%	*	*	*	36 Fr	60 mm	Invaginated with continuous suture in 50% of cases [§]	No	Not routinely
Nocca [32]	6	163	3.7%	*	*	*	36 Fr	*	*	Methylene blue	Yes
Skrekas [33]	4	93	4%	*	*	*	36 Fr	60 mm	Yes inverting stitch	Methylene blue	Yes
Csendes [34]	16	343	4.60%	*	*	*	38 Fr	*	85% of cases had staple line reinforcement [§]	Methylene blue	Yes in 98%
Dapri [35]	4	75	5%	*	*	*	34 Fr	*	50/75 reinforcement (25 seamguard, 25 suturing) [§]	Air insufflation test	Yes

[§] Data not specifically available for patients with sleeve gastrectomy leaks

Table 2 Outcomes following endoscopic management of staple line leaks

Reference	Number of leaks	Number of leaks treated endoscopically	Location of leak ^s	Classification of leak ^s	First treatment approach of managing the leak	Intervention	Success rate	Escalation to second-line treatment approach	Complications
Moloney [10]	6	6	*	*	Yes	Stent (IR drain for subdiaphragmatic abscess if present) Over the scope clip	6/6 (100%)	N/A	*
Keren [14]	26	26	GOJ 22 Antral 4	Acute 12 Early 16 Chronic 1	No (intra-abdominal collections initially drained)	Fibrin glue Stent	21/28 (81%)	7 patients needed additional endoscopic treatment	*
Casella [15]	6	1	GOJ 1	Early 1	Yes		1/1 (100%)	N/A	*
El-Sayes [16]	27	8	*	Acute 3 Early 4 Chronic 1	Yes (1/8)		8/8 (100%)	N/A	*
El-Sayes [16]	27	5	*	Acute 2 Early 2 Chronic 1	Yes (4/5)	LAP repair and Stent	5/5 (100%)	N/A	*
El-Sayes [16]	27	1	*	Chronic 1	No	Open drainage and stent	1/1 (100%)	N/A	*
Abd Ellatif [18]	11	5	GOJ 5	Early 4 Late 1	Yes	Stent (and percutaneous drainage)	4/5 (80%)	1 case required another stent followed by salvage surgery	*
Szewczyk [21]	8	4	*	Acute 4	Yes	Stent ± complementary therapy	Unclear	*	*
Curro [22]	1	1	*	Early 1	Yes	Stent (and percutaneous drainage)	1/1 (100%)	N/A	*
Wahby [23]	10	5	GOJ 5	Early 4 Late 1	Yes	Stent (and percutaneous drainage)	4/5 (80%)	1 case required another stent followed by salvage surgery	*
Sethi [25]	15	5	*	*	Yes	Stent	4/6 (67%)	2 cases required salvage surgery	*
Montuori [26]	6	2	*	*	Yes	Stent (and percutaneous drainage)	2/2 (100%)	N/A	*
Klimczak [27]	13	13	GOJ 13	Early 12 Chronic 1	Yes (10/13)	Stent	13/13 (100%)	N/A	*
Southwell [28]	21	21	GOJ 14 Mid 3 Distal 1 Multiple 3	Early 12 Acute 6 Late 1 Chronic 2	Yes (5/21)	Stent ± complementary therapy	15/21 (71%)	5 cases required further stent 1 case required salvage surgery	15% needed stent removal due to symptoms
Weiner [30]	12	1	*	*	Yes	Stent	1/1 (100%)	*	*
Hany [31]	8	2	Prox 2	Early 2	Yes	Stent (and percutaneous drainage)	1/2 (50%)	1 case required stent repositioning	*
Dapri [35]	4	2	GOJ 2	Early 2	Yes	Stent	2/2 (100%)	*	*

N/A not applicable, GOJ gastro-oesophageal junction, Unk unknown, Mid middle, LAP laparoscopic, Prox proximal
^s Data regarding the location and classification of the leak was extracted when possible only for patients who underwent endoscopic management

Table 3 Outcomes following surgical management of staple line leaks

Reference	Number of leaks	Number of leaks treated with Surgery	Location of leak [§]	Classification of leak [§]	First treatment approach of managing the leak	Intervention	Success rate	Escalation to second line treatment approach	Complications
Spicka [11]	3	3	*	*	Yes	LAP peritoneal washout and drain	2/3 (67%)	1 case (clips, washout, excision of fistula, stent)	*
Albanopoulos [13]	12	9	*	*	Yes	Peritoneal washout and drain	5/9 (56%)	4 case required OGD + stent	3 deaths (Acute Liver failure, CA, Pneumonia)
El-Sayes [16]	27	7	*	Early 5 Late 1 Chronic 1	Yes	LAP peritoneal washout and drain	7/7 (100%)	N/A	*
El-Sayes [16]	27	1	*	Early 1	Yes	OP peritoneal wash and drain	1/1 (100%)	N/A	*
Abd Ellatif [18]	11	6	GOJ 6	Acute 6	Yes	LAP peritoneal washout, drain and re-suture of staple line	5/6 (83%)	1 case required endoscopic stent	*
Gibson [19]	1	1	Prox 1	*	Yes	LAP peritoneal washout and drain	1/1 (100%)	N/A	*
Hoogerboord [20]	1	1	*	Acute 1	Yes	LAP peritoneal washout and drain	1/1 (100%)	N/A	*
Szewczyk [21]	8	3	HIS 3	Acute 3	Yes	OP, suture closure of opening, washout, drain	0%	3 cases required further laparotomy	3 deaths (Sepsis)
Wahby [23]	10	5	GOJ 5	Acute 5	Yes	LAP peritoneal washout, re-suture and drain	4/5 (80%)	1 case required endoscopic stent	*
Sethi [25]	15	6	*	*	Yes	Operative drainage and stenting	6/6 (100%)	N/A	*
Montuori [26]	6	4	GOJ 6	Acute 1	Yes	OP washout, oversewn of defect—1 case	0%	*	1 death (sepsis)
Behrens [29]	1	1	Prox 1	Acute 1	Yes	LAP washout—3 cases Washout and oversewn of leak	0%	3 cases required endoscopic stent Re-leak on day 8 post op commenced on conservative management with TPN and abx	*
Weiner [30]	12	3	*	*	Yes	LAP lavage, oversewing and suction drainage	3/3 (100%)	*	*
Weiner [30]	12	6	*	*	Yes	LAP lavage, oversewing, suction drainage and stenting	6/6 (100%)	*	*
Weiner [30]	12	2	*	*	Yes	OP lavage, oversewing, suction drainage and stenting	2/2 (100%)	*	*
Nocca [32]	6	6	*	*	Yes	Peritoneal toilet with reinforcement of staple line and drainage	6/6 (100%)	*	*
Skrckas [33]	4	1	*	*	Yes	Plication with omentum and drainage	1/1 (100%)	*	*
Csendes [34]	16	3	*	Acute 2 Early 1	Yes	Exploration, cleaning, drains	3/3 (100%)	N/A	*
Csendes [34]	16	5	*	Acute 5	Yes	Exploration, cleaning, re-suture, drains	3/5 (60%)	Additional percutaneous drain required	*
Dapri [35]	4	1	Antum 1	Early 1	Yes	LAP lavage and drainage	0/0 (0%)	1 case required OGD and stenting	*

GOJ gastro-oesophageal junction *Unk* unknown, *HIS* angle of His, *Prox* proximal, *LAP* laparoscopic, *OP* laparotomy, *CA* cardiac arrest

[§] Data regarding the location and classification of the leak was extracted when possible only for patients who underwent Surgical management

Table 4 Outcomes following conservative management of staple line leaks

Reference	Number of leaks	Number of leaks treated conservatively	Location of leak [§]	Classification of leak [§]	First treatment approach of managing the leak	Intervention	Additional therapies	Drain placed during initial surgery	Success rate	Escalation to second line treatment approach
Rawlins [12]	1	1	HIS	Acute 1	Yes	Conservative	Abx, PN	Yes	1/1 (100%)	No
Albanopoulos [13]	12	3	*	*	Yes	Conservative	*	Yes	0% (0/3)	3 case required OGD + stent
Casella [15]	6	5	GOJ 4 Midgastric 1	Acute 3 Early 2	Yes	Conservative with CT-guided drainage	Abx, PPI, TPN/EN	No	2/5 (40%)	3 case required OGD + stent
El-Sayes [16]	27	1	*	Early 1	Yes	Conservative with CT-guided drainage	Abx, PN	Yes	1/1 (100%)	N/A
Rossetti [24]	1	1	GOJ 1	Acute 1	Yes	Conservative	Abx, TPN	*	1/1 (100%)	N/A
Sethi [25]	15	4	GOJ 13 Distal 1 Unk 1	Acute 2 Early 13	Yes	Conservative	NBM, Abx	*	4/4 (100%)	N/A
Hany [31]	8	5	Prox 4 Distal 1	Early 5	Yes	Conservative	Abx, continuing oral intake	*	5/5 (100%)	N/A
Hany [31]	8	1	*	*	Yes	Conservative with CT-guided drainage	Abx	*	1/1 (100%)	N/A
Skrekas [33]	4	3	*	*	Yes	Conservative	Abx, TPN, NBM	Yes	3/3 (100%)	N/A
Csendes [34]	16	3	*	Acute 1 Early 2	Yes	Conservative	Abx, TPN	*	3/3 (100%)	3/3 100%
Csendes [34]	16	5	*	Acute 3 Early 2	Yes	Conservative with percutaneous drain	EN	*	5/5 (100%)	5/5 100%
Dapri [35]	4	1	Antrum 1	Early 1	Yes	Percutaneous drain	*	*	1/1 (100%)	*

N/A not applicable, GOJ gastro-oesophageal junction, HIS angle of His, Unk unknown, LAP laparoscopic, Prox proximal, Abx antibiotics, PPI proton pump inhibitors, NBM nil by mouth, PN parenteral nutrition, EN enteral nutrition

[§] Data regarding the location and classification of the leak was extracted when possible only for patients who underwent Surgical management

Table 5 Novel treatment strategies for staple line leaks

Reference	Number of leaks	Number of leaks treated with novel approach	Location of leak	Classification of leak	First treatment approach of managing the leak	Intervention	Success rate	Escalation to second line treatment approach	Complications
Leeds [17]	9	9	*	Acute 3 Early 3 Chronic 3	No	E-Vac therapy	8/9 (89%)	1 case surgery	1 case pancreatitis 1 failed source control

staple line leak. A successful initial management rate of 88% (8 patients) was achieved; the remaining 1 patient required salvage surgery. Complications related to E-Vac were noted; 1 patient developed pancreatitis presumed secondary to E-Vac whilst another patient had failed source control.

The overall quality of the evidence noted in this systematic review was poor (Table 6). Published data regarding staple line leak management following sleeve gastrectomy was predominantly obtained from retrospective case series and was anecdotal in nature. The GRADE framework was utilised in order to evaluate the quality of the articles included in addition to proposing a management strategy for staple line leak management (Table 6). None of the studies included directly compared the effectiveness of different management strategies that can be utilised for the management of a staple line leak following sleeve gastrectomy. We pooled all relevant and available data in order to establish separate cohorts of patients with a staple line leak as per their initial intervention that they received. Calculation of primary intervention success rates for each modality facilitated a descriptive comparison of outcomes.

Discussion

Globally, laparoscopic sleeve gastrectomy is becoming the most common bariatric procedure performed for obesity management [36, 37]. Published outcomes reveal a comparable mid-term weight loss rates when compared with Roux-en-Y gastric bypass [38]. This systematic review highlights a significant variation in clinical practice with regard to intraoperative surgical technique and the management of a staple line leak following a sleeve gastrectomy.

The incidence of staple line leak following sleeve gastrectomy varied in this systematic review. One article reported a 55% leak rate [16]. It is worth highlighting that 51% of their patients underwent their sleeve gastrectomy in a local hospital and were subsequently referred to the bariatric unit for management of their staple line leak. One may hypothesise that the hospitals where the sleeve gastrectomy was performed were not large volume centres. Therefore, the 55% leak rate is not a true representation of a single unit's leak rate, rather an accumulation of patients who suffered from a staple line leak both

from within the bariatric centre and adjacent hospitals. Only 2 articles in this review documented the cause for the staple line leak in 24 patients. This included a stenosis at the incisura ($n = 18$), stenosis within the mid-sleeve ($n = 5$) and a proximal stenosis ($n = 1$). This information was absent from the vast majority of the articles included in this systematic review. One article reported 4 antral leaks; however, they did not identify a cause or specify whether this was secondary to technical failure.

With regard to endoscopic stent placement, the included literature was very vague describing the rationale behind stent placement (i.e. bridging the perforation or stenting the stricture). Only 5 articles specifically discussed the reasoning for stent placement. Of which, 2 articles stated that the stent was used to occlude the site of the perforation. The remaining 3 articles described that the stent spanned the gastro-oesophageal junction. This information regarding the rationale for and the location of stent placement was underreported in the literature. This serves as an important data point for future studies to include.

An important preoperative surgical decision is selecting the correct sized bougie to use. Within this systematic review, a 36-Fr bougie size was most frequently used (27%). This finding is consistent with the recommendations from the International Sleeve Gastrectomy Expert Panel Consensus Statement, who advocated utilising a bougie size between 32 and 36 Fr as the use of a smaller bougie (< 32 Fr) is associated with higher complication rates [7]. Published systematic reviews have subsequently demonstrated that a lower staple line leak rate has been noted when a bougie > 40 Fr has been utilised [39, 40]. In this systematic review, only 7 articles utilised a bougie greater than 40 Fr in size.

Staple line reinforcement has been a controversial topic that has been frequently debated. Previously published literature has revealed conflicting evidence regarding long-term morbidity and leak rates between cohorts of patients who underwent staple line reinforcement and those who did not [41, 42]. A meta-analysis published in 2017, that assessed 7 randomised controlled trials (patient cohort size of 845 patients) that reviewed oversewing staple line, concluded that oversewing the staple line did not reduce the risk of staple line leak or decrease the overall complication rates [43]. However, they did demonstrate that oversewing the staple line did prolong the operative time

Table 6 GRADE review of evidence quality

Management of a staple line leak following sleeve gastrectomy		Quality assessment							
Summary of findings		Quality assessment							
Intervention	No. of studies	Data analysis	Consensus	Risk of bias	Inconsistency	Indirectness	Imprecision	Grade of recommendation	Quality of Evidence
								1—strong 2—weak	A—high B—moderate C—low D—very low
Conservative management	12	33 patients, 82% successful initial management rate. 5 articles (13 patients) utilised concurrent percutaneous drain placement. 6 patients required escalation to a second line intervention	A conservative management approach to a staple line leak can be implemented when there is no systemic compromise. The presence of intra-abdominal collections will require concomitant drainage. Appropriate antimicrobial cover and nutritional support should be implemented.	Serious ^a	Not serious	Serious ^b	Serious ^c	2	C
Surgical management	20	74 patients, 76 % successful initial management rate. Laparoscopic approach—36 patients managed laparoscopically. 0 deaths in this cohort. Escalation to second line intervention in 19% Open approach—38 patients managed. 7 deaths in this cohort. Escalation to second line intervention in 26%	Surgical management of a staple line leak should be considered in the setting of an acute postoperative leak with the presence of sepsis. Thorough washout and drain placement is advocated. When possible, a laparoscopic approach should be undertaken. This will facilitate a reduction in the systemic impact of open surgery in the context of a patient with preexisting physiological compromise. The only mortalities recorded in this review were in the sub-cohort of patients who underwent open surgery	Serious ^a	Not serious	Serious ^b	Serious ^c	2	C
Endoscopic management	15	108 patients. A successful initial management rate of 62% was achieved. 81 patients underwent stent placement. 15 patients required further endoscopic treatment. 5 patients required salvage surgery following failed endoscopic management	Endoscopic management should include stent placement. This will facilitate occlusion and diversion of gastric content from the origin of the leak. Chronic leaks may be an appropriate target for endoscopic intervention. Intra-abdominal collections will require additional drainage for sepsis source control.	Serious ^a	Not serious	Serious ^b	Serious ^c	2	C

^a Included articles varied in study design and quality. Sources of bias included selection bias and institutional bias

^b Indirect data acquisition from published case series. Additional sources of indirectness include difference in the interventions described and dissimilarities between reported outcome measures. Indirect comparison of leak management strategies

^c No direct comparison of interventions or subsequent outcomes. No formal reporting of confidence intervals and marked heterogeneity of data. Low total number of events within each domain

[43]. Sixty-five percent of the articles in this systematic review described routine use of staple line reinforcement.

When managing a staple line leak, there are two important factors that should be considered—the acuteness of the presentation of the leak following the sleeve gastrectomy and the presence of fulminant sepsis. These two variables are likely to influence initial management. The endoscopic management approach permits direct visualisation of the site of leak, and an assessment of the size of the leak and integrity of the gastric mucosa. It also carries less of a physiological burden for the patient when compared to surgery. Advances in technology and techniques now permit combining endoscopy and additional endoscopic therapies in the management of a leak (clip placement, fibrin glue, etc.). Endoscopic placement of a stent enables exclusion of site of the perforation from the direction of GI tract transit; they reduce intraluminal pressure in addition to allowing the patient to continue to take per oral feeding, thus maintaining nutritional intake [44]. Endoscopic stent placement was the most common endoscopic intervention described in this systematic review. However, it is important to establish that stent placement would not sufficiently manage any concurrent of pre-existing intra-abdominal collections. In this systematic review, a total of 21 patients underwent percutaneous drainage of intra-abdominal collections and placement of endoscopic stent, resulting in an 86% successful treatment rate. Previously published studies advocated the use of stent placement in patients who presented with chronic leaks; we noted in this systematic review patients undergoing stent placement for acute leaks. None of the articles that described endoscopic management of the leak utilised endoscopic double pigtail stent insertion. This newly described intervention is gaining popularity as a treatment strategy for staple line leak following sleeve gastrectomy and is likely to serve as one of the main interventions for staple line leak management in the future. Endoscopic drainage via pigtail drain placement as a treatment modality possesses several theoretical advantages as a management strategy for staple line leak following bariatric surgery when compared to percutaneous drainage. Whilst percutaneous drainage of an intra-abdominal collection would facilitate sepsis control, it unfortunately dictates that the patient must have external drainage. The presence of an external drain is not without its associated complications; high drain output may lead to fluid losses, and subsequent electrolyte imbalances, corrosive drain content and frequent contact with skin may result in recurrent skin infection and the patient is of risk of developing an external fistula [45, 46]. The presence of an external drain may adversely impact on the patients' quality of life [47], whereas endoscopic drainage would overcome these limitations via establishing internal drainage [48]. In addition, it takes advantage of normal gastrointestinal tract physiology (peristaltic wave-induced pressure gradient) to promote fluid drainage into the gastrointestinal tract lumen [48]. From the patients' perspective, it is reported as being

better tolerated when in comparison to conventional self-expanding metal stents [49]. A cost-effective analysis of stent usage in the management of sleeve gastrectomy leaks published in 2018 concluded that double pigtail stent was more cost effective than a covered stent; this will clearly have significant financial implications in the context of a symptomatic sleeve gastrectomy leak which is normally associated with a prolonged hospital stay [50]. Published case series have highlighted the high successful treatment rates associated with endoscopic internal drainage via pigtail stent drainage of intra-abdominal collections following a sleeve gastrectomy staple line leak [51–53]. Donatelli et al. published their experience (the largest series to date) of managing 67 patients with a staple line leak with endoscopic internal drainage [51]. They reported a 78.2% clinical success rate following treatment. After a mean follow-up of 316 days, a good clinical outcome was noted [51]. This minimally invasive approach to collection drainage is both safe and clinically effective [52]. Further evidence has emerged from the literature that endoscopic internal drainage serves as an effective treatment strategy for intra-abdominal collection drainage not only following bariatric surgery, but also for a range of other gastrointestinal tract procedures [48]. As the published literature on endoscopic internal drainage expands, in time, it is likely that this intervention will serve as one of the principle management strategies for a staple line leak following a sleeve gastrectomy.

The presence of sepsis and haemodynamic instability mandates urgent treatment. The priority is obtaining adequate source control through washout and drainage. Fistula excision in the acute setting is ill-advised in light of inflamed and friable tissue [54]. Definitive management of the fistula can be undertaken at a later time once sepsis control has been achieved. In this systematic review, surgical management of a staple line leak had the second highest successful initial management rate (76%–56 patients). When the included articles described clearly the nature of the surgical intervention (a laparoscopic or open approach), a comparison of success rates was undertaken. Of the 36 patients who underwent a laparoscopic washout, an 81% success treatment rate was achieved when compared to 43% successful rate in the open surgery cohort. A total of 7 patient deaths were noted in all of the studies that described surgical management of a staple line leak. There were no reported deaths in the studies that utilised a conservative or endoscopic management approach. Open surgery is likely to carry a significant stress burden for the patient who is already physiologically compromised due to sepsis. The death rates in the patients who underwent surgery may serve as a proxy measure; these were the sickest patients requiring emergency surgical intervention. What is lacking in these studies is quantifiable clinical parameter to inform the reader of the true extent and severity of their leak. Inclusion of core vital signs, haematological and biochemical derangement and the presence of organ failure would allow an appreciation

of the extent of their physiological instability. Without this information, it is difficult to discriminate between if the deaths were contributable to the sickest patients undergoing surgery or whether an accumulative effect of another physiological hit (in the context of another surgical procedure) contributed to the mortality rates.

Another important aspect to highlight is the variability in practice amongst institutions with regard to their management approach to sleeve gastrectomy leak. It is possible that some institutes adopt a lower threshold for surgical re-intervention than others; this may artificially skew the perception of the severity of the leak. In addition, local resources may influence management, notably the availability of interventional radiology for percutaneous drain placement.

Documented deaths only occurred in the cohort of patients who underwent open surgery for the management of their leak. Of the 36 patients who underwent laparoscopic surgical management of their staple line leak, only 7 required an escalation to a second-line treatment (19%), whereas of the 38 patients who underwent open surgery, 10 patients (26%) needed second-line treatment. It is clear that surgical management has a role as a step up, escalation therapy in patients who have failed to heal with conservative measures. Surgical excision of the fistula tract, conversion to gastric bypass and jejunal patch were some of the techniques described in this systematic review.

For those patients who are haemodynamically stable with no systemic compromise, a conservative management approach can be adopted. Within this systematic review, a conservative management approach had the highest successful initial management rate of 82%. The presence of intra-abdominal collections will influence the need for drainage. Three included articles had placed a drain following their surgery, thus facilitating the creation of a controlled fistula. Whereas 5 articles (13 patients, 29.3%) described a conservative management approach in combination with percutaneous drainage of intra-abdominal collections, those patients who are commenced on conservative management imply a degree of stability. A total of 8 articles described the routine use of postoperative drain placement following laparoscopic sleeve gastrectomy [34, 35, 26, 32, 12, 33, 21, 30]. Of these articles, the duration of keeping the drain in situ also varied (3–7 days). Globally, this may not be a standard practice for bariatric surgeons. These articles were reviewed and no clear reason for this practice was recorded; rather, it appeared that this was the institution's standard approach with laparoscopic sleeve gastrectomy. A possible explanation for this is that drain placement is considered a mitigation strategy for a staple line leak and its routine use was being implemented during the early phases of the learning curve for surgeons performing laparoscopic sleeve gastrectomy. However, of the 8 articles, 4 of which have been published after 2013. A more likely explanation is that this is a representation of variability in surgical practice. One article described the novel use of endoluminal vacuum therapy; however, none of these patients

received this therapy as a first-line treatment option. This highlights the ongoing interest in the management of staple line leaks with additional therapeutic interventions being described and trialled.

There are limitations to this systematic review. In light of the heterogeneity of the studies, no formal statistical analysis of the reported outcomes was conducted. The nature of the articles included serve as weak levels of evidence (case series and small cohort studies). There were no randomised control trials directly comparing treatment options. There were limited articles that presented solely on the management of a staple line leak; the emphasis was predominantly on large case series of successful sleeve gastrectomy, with only a small focus on the technical management of a staple line leak. Determining the exact sequence of treatment escalation was difficult and serves as a potential source of bias. Another limitation of this study is the potential source of selection bias of the articles included. Whether articles had initially intended on undertaking one intervention but subsequently elected to perform another intervention in light of the clinical situation and apparent risk to patient. Each included manuscript was specifically reviewed for the chronological sequence of the management performed. Articles presented their management strategy performed with no reference to whether they had initially considered another intervention but changed their strategy in light of the clinical risk. The main weakness within the current literature regarding staple line leak management is that there is significant heterogeneity in the terminology used to describe a staple line leak in the surgical literature. In light of the heterogeneity, it makes it very difficult to directly compare patient outcomes when treated with different interventions. Establishing a standardised definition for a staple line leak would enable grouping of similar patients and subsequent analysis of reported global patient outcomes. A classification system of such would need to include both the timing of the leak and the presence of organ failure. As highlighted in this systematic review, clinical data regarding the severity of the leak is often missing. This information is essential in order to compare outcomes and to determine best standard of practice. Another area that requires addressing in the literature is the management of an acute leak resulting in an intra-abdominal collection. We noted in this systematic review that both percutaneous drainage and surgical intervention were used. Of those patients undergoing surgery, washout and drain placement were most frequently performed. This potentially serves as an idea for a prospective, comparative trial (percutaneous vs laparoscopic drainage of early staple line leaks). However, in light of the incidence of staple line leak, the creation and recruitment to such a trial would be difficult. A potential method of overcoming this difficulty is promoting global data collection on complications following bariatric surgery on a bariatric surgery-specific database. This would accrue adequate numbers of patients with this complication. However, it would be essential that a standardised classification system be

implemented to record the severity of leaks. This would allow homogeneity of the data, risk stratification into subcohorts and prospective outcome evaluation.

Conclusion

A staple line leak following a sleeve gastrectomy still remains the principle cause of postoperative morbidity and mortality. Prompt identification and correct treatment of the leak are required in order to improve patient outcomes. No uniform approach to managing a leak has been approved by consensus. What is clear is that early sepsis management is crucial. Treatment options for definitive source control are influenced by the clinical status of the patient, local resources and expertise. For patients with no instability, a conservative approach to management can be adopted. Early source control through a

laparoscopic approach is likely to be superior to open surgery as the physiological stress impact of the surgery is reduced for the patient. What is clear is the need for a stepwise treatment escalation approach from minimally invasive to invasive surgery. Further research is required to identify the optimal treatment algorithm (both timing and intervention) for patients who suffer a staple line leak following sleeve gastrectomy.

Compliance with Ethical Standards

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

Informed Consent No informed patient consent was required for this systematic review.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

Appendix

Search algorithm example

Database: Pubmed

Syntax: “laparoscopic sleeve gastrectomy”
 “sleeve gastrectomy”,
 “laparoscopic bariatric surgery”,
 “staple line leak”,
 “staple line leak management” ,
 “treatment”
 “management”

Boolean operators (AND or OR) used to combining search algorithm. For example
 “treatment” OR “management”

Results: 258 hits

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