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Sleeve gastrectomy and the risk of leak: a systematic analysis of 4,888 patients

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Abstract
Introduction Sleeve gastrectomy has become a popular stand-alone bariatric procedure with comparable weight loss and resolution of comorbidities to that of laparoscopic gastric bypass. The simplicity of the procedure and the decreased long-term risk profile make this surgery more appealing. Nonetheless, the ever present risk of a staple-line leak is still of great concern and needs further investigation.
Methods An electronic literature search of MEDLINE database plus manual reference checks of articles published on laparoscopic sleeve gastrectomy for morbid obesity and its complications was completed. Keywords used in the search were "sleeve gastrectomy" OR "gastric sleeve" AND "leak." We analyzed 29 publications, including 4,888 patients. We analyzed the frequency of leak after sleeve gastrectomy and its associated risks of causation.
Results The risk of leak after sleeve gastrectomy in all comers was 2.4%. This risk was 2.9% in the super-obese [body mass index (BMI) > 50 kg/m^2] and 2.2% for BMI < 50 kg/m^2. Staple height and use of buttressing material did not affect leak rate. The use of a size 40-Fr or greater bougie was associated with a leak rate of 0.6% compared with those who used smaller sizes whose leak rate was 2.8%. Leaks were found at the proximal third of the stomach in 89% of cases. Most leaks were diagnosed after discharge. Endoscopic management is a viable option for leaks and was documented in 11% of cases as successful.
Conclusions Sleeve gastrectomy has become an important surgical option for the treatment of the ever growing morbidly obese population. The risk of leak is low at 2.4%. Attention to detail specifically at the esophagogastric junction cannot be stressed enough. Careful patient selection (BMI < 50 kg/m^2) and adopting the use of a 40-Fr or larger bougie may decrease the risk of leak. Vigilant follow-up during the first 30 days is critical to avoid catastrophe, because most leaks will happen after patient discharge.

Keywords Sleeve gastrectomy · Gastric sleeve · Leak · Bleeding · Buttressing · Bougie size

Sleeve gastrectomy has become a common procedure in the field of bariatric surgery. It was initially used in the super-obese to get them to a safer weight to undergo a more complex procedure but many have found sufficient weight loss and resolution of comorbidities with the sleeve alone [1–3]. The simplicity of the procedure and the decreased risk profile make this surgery very appealing. However, the ever present risk of a staple-line leak is still of great concern and needs further investigation. This analysis documents the results of 4,888 sleeve gastrectomies performed by surgeons worldwide and presented in 29 publications from peer-reviewed journals. These data provide insight into avoiding the complication of leak and how they can best be managed if encountered.

Materials and methods

An electronic literature search of MEDLINE database plus manual reference checks of articles published on

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laparoscopic sleeve gastrectomy for morbid obesity and its complications was completed. Keywords used in the search were "sleeve gastrectomy" OR "gastric sleeve" AND "leak." This gave us 459 articles, which were then limited by the following conditions: human, English, adult, published during the past 10 years. This decreased the number of publications to 249. These 249 articles were manually screened to determine their value in answering our questions: "What is the risk of leak in sleeve gastrectomy? What are the associated complications, stricture or bleed? Can these be avoided?" Articles were excluded if their focus was not sleeve gastrectomy and its complications. We also excluded review articles, revisional surgery, single-incision, duplicates, and studies with less than 50 patients. This gave us a final pool of 29 publications that met our criteria and that demonstrate international experience with 4,888 sleeve gastrectomy patients and their outcomes (Fig. 1). Because our interest was in the complications of sleeve gastrectomy, the data that we collected reflected this interest and included: BMI, intraoperative leak test, type of staples used, staple-line buttressing, sizing device used, operative time, leak, stricture, bleeding, the location and time of diagnosis of the complication and its management, and % excess weight loss. These data are documented in Table 1. The great majority of these publications are retrospective chart review case series. By definition, this makes comparison of the data and its analysis difficult and the conclusions drawn significantly less strong than a blinded, randomized, control trial. However, we feel very strongly that the information, trends, and differences found from the analysis of these publications provide significant information to direct further study on the topic and perhaps safer surgery with fewer complications. The data were analyzed by Mann–Whitney nonparametric method with the assistance of the statistical services available at University Hospitals Case Medical Center. The difference was considered significant if $P < 0.05$.

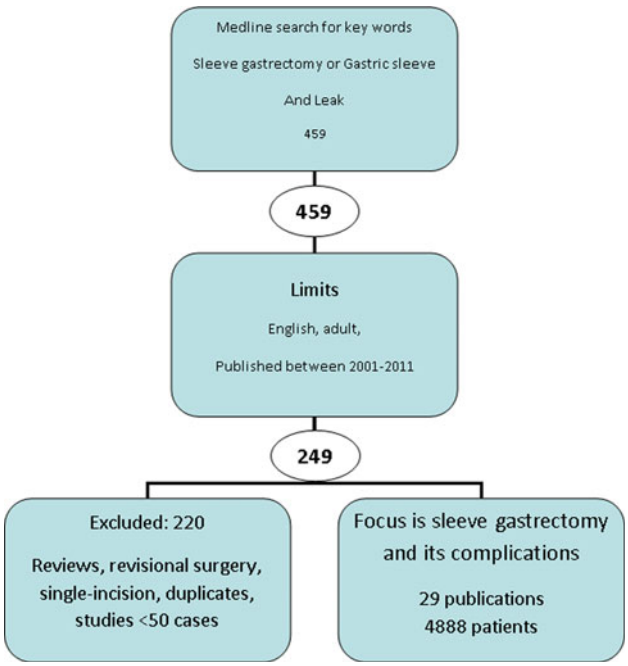

Fig. 1 Medline search was completed starting with the keywords "sleeve gastrectomy" or "gastric sleeve" and "leak"

Results

From the Medline search, 29 publications provided 4,888 patient records. The mean BMI ranged from 34 to 65.4 kg/m^2. All 29 studies documented a leak rate, which ranged from 0 to 7%. The mean leak rate for all 29 studies was 2.4%, which accounted for 115 leaks in 4,888 cases of sleeve gastrectomy. Six studies specifically addressed super-obese patients with a mean BMI $>$ 50 kg/m^2 [1, 4–6]. In the super-obese, the mean leak rate was 2.9% or 23 leaks of 771 patients compared with the leak rate of only 2.2% (92/4,117) for those with mean BMI $<$ 50 kg/m^2 (not significant $P > 0.05$).

Seven studies boasted no leak. These studies had a total of 1,151 patients. Their mean BMI range was 43–58 kg/m^2. They used different bougie sizes from 32- to 48-Fr to size their sleeves, and only one used staple-line buttressing material; however, two of the other six oversewed their staple lines. These leakless groups for the most part used two sizes of staples: 4.1–4.5 mm on the distal stomach (antrum) and 3.5 mm on the proximal body and fundus. Of these seven leakless publications covering 1,151 patients, there were only three bleeds and one stricture, which required reoperation. All seven publications demonstrated significant excess weight loss >50% at 12 months (only two reported as EWL the others as excess BMI loss).

Twenty-two studies documented a leak, and this ranged from 0.7 to 7% and represented 115 of 3,737 patients. The *n* ranged from 53 in a U.S. study to 540 patients in a Spanish study. Of those studies that documented a leak (76% or 22/29 studies), the location of the leak in the vast majority (92%, 58/63) was proximal, in the region of the esophagogastric junction. However, only 50% (11/22 studies) documented the location. Ten of 21 studies (48%) documented the time of diagnosis. The large majority of leaks occurred after discharge home. Fifty percent occurred more than 10 days postoperatively (11–31 days). Nineteen percent of those with leaks did not disclose the type of staple load used. For the most part, 71% (15/22) of surgeons in groups that had leaks used a greater staple height (4.1–4.5 mm) on the lower stomach and a shorter staple height 3.5 mm on the upper stomach as in the leakless groups. Five groups used staple-line reenforcement on all their patients. These five publications present 675 patients with a total of 20 leaks, a leak rate of 3%. On the contrary,

Table 1 Complications after sleeve gastrectomy

Study	Year	*n*	BMI	IOLT	Leak	%	Location	POD	MGT
Johnston [12]	2003	100	46.3	ND	1	1	Prox	ND	OR
Han [17]	2005	130	37.2	MB	1	1	ND	ND	ND
Cottam [1]	2006	126	65.4	ND	2	2	NA	ND	ND
Roa [18]	2006	62	41.4	ND	1	2	ND	1	OR
Lalor [19]	2007	148	44	ND	1	1	Prox	1	OR
Lee [10]	2007	216	49	MB	3	1	ND	ND	OR
Nocca [20]	2007	163	45.9	MB	9	6	ND	ND	OR
Weiner [11]	2007	120	60.7	MB	3	3	ND	2 early/l	OR
Felberbauer [3]	2008	126	48.1	ND	0	0	NA	NA	NA
Frezza [5]	2008	53	53.5	ND	2	4	ND	ND	OR
Kasalicky [21]	2008	61	42	MB	0	0	NA	NA	NA
Mui [22]	2008	70	40.8	MB	1	1	Prox	28 d	Stent
Rubin [23]	2008	120	43	ND	0	0	NA	NA	NA
Skrekas [24]	2008	93	46.9	MB	4	4	ND	ND	OR
Burgos [25]	2009	214	37.8	MB	7	3	6 prox/1 dist	4 early/3	OR/tpn
Chowbey [9]	2009	75	58	MB	0	0	NA	NA	NA
Fuks [16]	2009	135	49	MB	7	5	Prox	4	OR
Goitein [26]	2009	55	45	ND	0	0	NA	NA	NA
Kakoulidis [27]	2009	79	34	ND	1	1	Prox	late	Stent
Menenakos [28]	2009	261	45.2	ND	10	4	Prox	ND	OR/stent
Sanchez [7]	2009	540	43.1	ND	11	2	ND	ND	tpn/OR
Stroh [6]	2009	144	54.5	ND	10	7	ND	ND	OR
Armstrong [29]	2010	185	44	None	0	0	NA	NA	NA
Csendes [30]	2010	343	37.5	MB	16	5	14 prox/2 dist	11 early/5	OR/tpn
Dapri [13]	2010	75	47	Air	4	5	2 prox/2 dist	>10 days	stent
Lacy [31]	2010	294	49.9	ND	11	4	11 prox	>11 days	OR
Ser [32]	2010	118	38	Air	4	3	Prox	ND	OR
Srinivasa [4]	2010	253	50	Air	6	2	ND	ND	OR
Bellanger [8]	2011	529	44	ND	0	0	NA	NA	NA

Study	Year	Stapler	Buttress	Bougie	OR	Bleed	Stricture	Location	POD	%EWL
Johnston [12]	2003	ND	No	30–36-Fr	ND	0	0	NA	NA	58
Han [17]	2005	ND	No	48–Fr	ND	1	0	ND	ND	83
Cottam [1]	2006	3.5	Tisseel	46–50-Fr	143	0	5	ND	ND	45
Roa [18]	2006	4.1/3.5	Suture	52–Fr	80	0	0	NA	NA	53
Lalor [19]	2007	4.5/3.5	Suture	44–52-Fr	ND	1	1	Iincisura	3 w	ND
Lee [10]	2007	4.8/3.5	Yes	32-Fr	66	0	0	NA	NA	59
Nocca [20]	2007	4.1/3.1	ND	ND	ND	1	2	ND	ND	59
Weiner [11]	2007	4.1/3.5	SG/PS/vic	32–44-Fr	75	1	0	NA	NA	ND
Felberbauer [3]	2008	4.5/3.5	PDS	48-Fr	ND	0	1	ND	10 m	>50
Frezza [5]	2008	4.1/3.5	PS/SG	29–34-Fr	70	1	0	NA	NA	52
Kasalicky [21]	2008	3.5	No	38-Fr	105	1	0	NA	NA	ND
Mui [22]	2008	4.8	No	32-Fr	NA	0	1	Incisura	lm	63
Rubin [23]	2008	4.1/3.5	Suture	48-Fr	100	0	0	NA	NA	ND
Skrekas [24]	2008	3.5	Suture	36-Fr	121	0	0	NA	NA	67
Burgos [25]	2009	4.1/3.5	Maxon	32–38-Fr	ND	0	0	NA	NA	ND
Chowbey [9]	2009	4.1/3.5	SG	36-Fr	60	0	0	NA	NA	59
Fuks [16]	2009	4.8/3.5	No	34-Fr	103	0	0	ND	ND	59

Table 1 continued

Study	Year	Stapler	Buttress	Bougie	OR	Bleed	Stricture	Location	POD	%EWL
Goitein [26]	2009	ND	No	32–46-Fr	120	0	0	NA	NA	ND
Kakoulidis [27]	2009	4.1/3.5	Suture	32-Fr	75	2	0	NA	NA	100
Menenakos [28]	2009	4.1/3.5	PS	38-Fr	58	0	0	NA	NA	65.7
Sanchez [7]	2009	4.1/3.5	Suture	32–38-Fr	ND	ND	1	ND	ND	63
Stroh [6]	2009	ND	0.5	32-Fr	93	2	1	ND	ND	ND
Armstrong [29]	2010	4.1/3.5	No	40-Fr	111	2	0	NA	NA	47
Csendes [30]	2010	4.8/3.5	Maxon	38-Fr	ND	8	3	Incisura	ND	ND
Dapri [13]	2010	4.8/3.5	PDS	34-Fr	ND	0	ND	ND	ND	ND
Lacy [31]	2010	4.1/3.5	Suture	32-Fr	ND	3	3	2 inc/1 eg	Late	ND
Ser [32]	2010	4.8/3.5	Suture	Endo	118.5	0	1	ND	ND	81.5
Srinivasa [4]	2010	ND	No	36-Fr	106	5	3	ND	ND	ND
Bellanger [8]	2011	4.1/3.5	No	34-Fr	ND	ND	ND	ND	ND	68

BMI body mass index, *MGT* management, *Stapler* stapler leg length, *Bougie* Bougie size, *OR* operative time, *POD* postoperative day, *%EWL* % excess weight loss, *ND* not disclosed, *NA* not applicable, *PS* Peri-Strips, *SG* Seamguard, *IOLT* intraoperative leak test

five groups document that they did not reenforce the staple-line by any means. These represent 16 leaks out of 688 patients, or 2.3%. Nine groups oversewed their staple-line every time. The oversewed groups had 1,891 patients with 56 leaks, a 3% leak rate. All patients had significant excess weight loss ranging from 50 to 100% among the group of studies that documented leaks.

Fourteen of the 29 studies did not document their intraoperative leak test. Of those studies that did document a leak test, 62% used methylene blue.

Seventeen of 22 groups that described leaks took the patients back to the operating room (OR) for management often in combination with stent and drain placement. Eighteen of the publications document OR time, which ranged from 58 to 143 min.

Discussion

The seduction of surgeons by sleeve gastrectomy is due to its multiple advantages: less complex laparoscopic procedure, no enteric anastomosis and no risk of internal hernia, dumping syndrome, or marginal ulcer. In addition, sleeve gastrectomy decreases the level of ghrelin hormone, has a less malnutritive effect, allows continued endoscopic access to the pancreaticobiliary system, and provides comparative weight loss and subsequent resolution of comorbidities that parallels gastric bypass surgery. Several studies now have demonstrated that the laparoscopic sleeve gastrectomy is safe and provides similar weight loss and resolution of comorbidities to that of duodenal switch or Roux-en-Y gastric bypass [2, 7]. Bellanger et al. recently published their results of 529 patients without leaks and %EWL of 68% at 1 year [8]. Chowbey et al. also had no leaks in their 75 patients with a mean %EWL of 59% at 1 year postoperatively [9]. Their mean OR time was 60 min. Similarly, Lee et al. demonstrated %EWL of 59% after 1 year follow-up of 216 patients with a mean BMI of 49 kg/m^2 and had a leak rate of only 1.4% [10].

Major complications were significantly less for sleeve gastrectomy patients (4.6%) compared with patients who had laparoscopic gastric bypass (10.6%) or duodenal switch (39.3%) by the same surgeons [10]. Preoperative weight and BMI were greater in the sleeve patients in this study. The sleeve patients had a greater overall weight loss than patients who had laparoscopic gastric bypass or duodenal switch, but %EWL was greater in the gastric bypass and duodenal switch patients. %EWL may be deceivingly lower in the sleeve group. This can be explained because patients with more excess weight preoperatively will have a lower %EWL even though they may have lost more actual weight than a patient with less excess weight preoperatively. Finally, a smaller study of 26 patients has published data with stable excess weight loss of 55% as well as significant decrease in ghrelin activity from 593 to 257 pg/ml at 5 year follow-up [2]. These results are mirrored by our analysis of 4,888 patients, demonstrating an overall leak rate of 2.4% and consistent excess weight loss of greater than 50%.

From our analysis of the literature, leak occurs from 0–7% of sleeve gastrectomy cases. There does appear to be a significantly higher leak rate in patients with a BMI $>$ 50 kg/m^2. From the 29 publications analyzed, we see a leak rate of 3% in the super-obese patient population [1, 4–6, 9, 11]. This is similar to the increased risk of leak in super-obese patients after gastric bypass. However, Cottam et al. performed 126 sleeve gastrectomies on patients with a mean BMI 65.3 kg/m^2 with only two leaks

(1.6%) [1]. They only used blue load staples (3.5 mm) compared with most other groups who use 4.1–4.8 mm staples on the antrum.

Two other factors that may have influenced their favorably low leak results are that they used Tisseel on all their staple-lines and they used a larger bougie size (46–50-Fr) in general compared with most groups. Fibrin glue also was used to cover the staple-line by Bellanger et al. [8] who recently published their study of 529 cases without a leak. Fibrin glue has been used for endoscopic therapy of postoperative leaks after sleeve gastrectomy but has not been documented as a regularly used product to prevent leak in sleeve gastrectomy. The evidence for the use of fibrin glue is currently limited and will require larger studies before a fair judgment of its utility in preventing leak in sleeve gastrectomy can be determined. Alternatively, using a larger bougie size may give greater clearance at the dreaded esophagogastric junction thereby reducing the risk of leak. This may be supported by the fact that surgeons who used a bougie size of 40-Fr or greater had a 0.6% leak rate (5/897 cases). The leak rate was 2.8% (110/3,991) in groups who used a bougie size $<$ 40-Fr ($P < 0.05$). This difference was statistically significant, thus favoring the use of a bougie of 40-Fr to avoid leak. This difference was independent of BMI. Weiner et al. have demonstrated that bougie size, 32-Fr vs. 44-Fr, does not have a significant influence on weight loss after sleeve gastrectomy [12]. Interestingly, even though Cottam et al. used one of the larger bougie sizes, 46–50-Fr, this group presented with the most strictures 5/126 (4%). This is counterintuitive, because larger bougie size is usually employed to avoid stricture formation. The authors explain that oversewing the staple-line in their initial sleeve experience was the likely culprit. Once they switched to using fibrin glue, they no longer experienced stricture.

Stricture is an uncommon but well-recognized risk after sleeve gastrectomy. The mean stricture rate for the collection of publications analyzed was 0.5% (22/4,284). Stricture rate was not significantly different between groups who oversewed the staple-line: 0.5% (10/2,137) compared with 0.4% (4/989) for those who did not oversew the staple-line. Admittedly the rate of stricture is so low that it is difficult to see any difference between treatments. Similarly, the use of reenforcement strips and oversewing does not seem to decrease the already low incidence of clinically significant bleeds. The overall bleed rate that required surgical intervention was 0.7% (38/3,819). When exclusively comparing groups that oversewed the staple-line or used reenforcement strips the bleed rate was 0.9% (15/1,672). This was the same for groups that did not use any type of staple-line protection: stitch or strip (9/989).

Dapri et al. reiterated our findings in their prospective, randomized trial that compared staple-line buttressing, oversewing with unprotected staple-line [13]. This was a small study of 25 patients per group that demonstrated no difference in leak. The authors suggest that staple-line buttressing decreases bleeding; however, the decrease was from 60 to 30 ml on average per case. The clinical significance of this is questionable. Due to the overall low incidence of bleeding and stricture after sleeve gastrectomy, it was not possible to discern a type of association with leak from the data available.

The analysis of the data clearly suggests that leak primarily occurs at the proximal portion of the staple-line. Only 52% of studies documented the location of the leak and 89% of these were at the esophagogastric junction. This danger zone may be thinner than the rest of the stomach. Elariny et al. demonstrated that the stomach has different thickness throughout with the fundus being the thinnest at approximately 1.7 mm [14]. This begs the question of whether a white load (2.5 mm staple height) should be used for the upper most staples as green loads are used for the antrum because of its thickness.

Certain groups advocate measures to avoid stapling too close to the esophagogastric junction and have had success in eliminating leaks [8]. Many factors may contribute to the success of Bellanger et al. [8], but it is difficult to tease out one that is most responsible for their success. They discuss the principles for reducing risk of leak, which are reiterated throughout much of the literature on sleeve gastrectomy and are as follows: assure good staple formation by allowing time for tissue compression, avoid creating a stricture by not stapling too close to the incisura, and avoid stapling too close to the GE junction. There is no evidence available that directly addresses any of these items specifically but rather observations and comments found throughout the sleeve literature.

Timing of leak is very important. Of the 52 leaks that had a documented time of diagnosis, 40 were more than 10 days postoperatively and thus required rehospitalization. This suggests that approximately 79% of leaks will occur as a late event, and the majority will be managed by minimally invasive means, including endoscopic stenting. Oshiro et al. published that operative management often fails to resolve the leak due to poor tissues and inflammation [15]. Operative management is useful for debridement and drainage, but closure of the defect usually fails due to the poor tissues. Fuks et al. found that regardless of their experience, leak was a significant risk in the super-obese [16]. They had seven leaks of 135 cases, six of which went back to the OR and all required reintervention and endoscopic stenting. Endoscopically placed stents combined with percutaneous drainage and a short duration of parenteral nutrition usually provide a good result. Some have used endoscopically placed fibrin glue with variable success [33].

Conclusions

Our analysis has demonstrated that laparoscopic sleeve gastrectomy provides comparative weight loss to gastric bypass with minimal risk. Sleeve gastrectomy can be performed successfully with a leak rate of approximately 2.4% and clinically significant bleeding and stricture rate of less than 1%. Leak occurs at the esophagogastric junction in 89% of the time, and very often the diagnosis occurs after the patient has already been discharged.

The risk of leak is greater in patients with BMI > 50 kg/m^2. Bougie size of <40-Fr also is associated with increased risk of leak. Oversewing or buttressing of the staple-line does not have a clinically significant effect on leak. Management of early leak should not be delayed and is most effectively treated by operative or percutaneous drainage and endoscopic stenting. Late leak often can be managed by percutaneous drainage and endoscopic stenting. Sufficiently powered, prospective, randomized studies are needed to evaluate the role of fibrin glue, staple height, and distance between the GE junction and the staple-line independently and in combination on leak and complication after laparoscopic sleeve gastrectomy. The present systematic analysis has provided a starting point for designing studies that address points of interest to bariatric surgeons.

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