



Endoscopic closure techniques of bariatric surgery complications: a meta-analysis

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Abstract

Background Leaks following bariatric surgery, while rare, are potentially fatal due to risk of peritonitis and sepsis. Anastomotic leaks and gastro-gastric fistulae following Roux-En-Y gastric bypass (RYGB) as well as staple line leaks after sleeve gastrectomy have historically been treated multimodally with surgical drainage, aggressive antibiotic therapy, and more recently, endoscopically. Endoscopic clipping using over-the-scope clips and endoscopic suturing are two of the most common approaches used to achieve full thickness closure.

Methods A systematic literature search was performed in PubMed to identify articles on the use of endoscopic clipping or suturing for the treatment of leaks and fistulae following bariatric surgery. Studies focusing on stents, and those that incorporated multiple closure techniques simultaneously, were excluded. Literature review and meta-analysis were performed with the PRISMA guidelines.

Results Five studies with 61 patients that underwent over-the-scope clip (OTSC) closure were included. The pooled proportion of successful closure across the studies was 81.1% (95% CI 67.3 to 91.7). The successful closure rates were homogeneous ($I^2 = 39%$, $p = 0.15$). Three studies with 92 patients that underwent endoscopic suturing were included. The weighted pooled proportion of successful closure across the studies was shown to be 22.4% (95% CI 14.6 to 31.3). The successful closure rates were homogeneous ($I^2 = 0%$, $p = 0.44$). Three of the studies, totaling 34 patients, examining OTSC deployment reported data for reintervention rate. The weighted pooled proportion of reintervention across the studies was 35.0% (95% CI 11.7 to 64.7). We noticed statistically significant heterogeneity ($I^2 = 68%$, $p = 0.04$). One study, with 20 patients examining endoscopic suturing, reported rate of repeat intervention 60%.

Conclusion Observational reports show that patients managed with OTSC were more likely to experience healing of their defect than those managed with endoscopic suturing. Larger controlled studies comparing different closure devices for bariatric leaks should be carried out to better understand the ideal endoscopic approach to these complications.

Keywords Bariatric surgery · Endoscopic full thickness closure · Over-the-scope clips · Endoscopic suturing · Staple-line leaks

Bariatric surgery has proven to be the most effective method for providing long-term weight loss to patients with morbid obesity. The most popular bariatric interventions are sleeve gastrectomy and Roux-En-Y gastric bypass (RYGB). Both have been shown to be safe in adolescents and adults. The

leak rate ranges between 0.7 and 5.0% following sleeve gastrectomy and 1.7–2.5% following RYGB [1, 2]. While rare, these complications cause great morbidity and can be potentially fatal. Full-thickness gastrointestinal defects can lead to poor nutrition, skin breakdown, peritonitis, and sepsis [3]. With the growing popularity of bariatric surgery, it is of high priority to determine safe and effective ways to treat the complications that may ensue.

Treatment of choice for post-bariatric leaks and fistulae depends on the defect's character. The stability of the patient, age, size, and location of leak or fistula are important factors to consider when deciding on an optimal intervention

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[4]. Endoscopic techniques to manage these complications are seen as first-line therapy. Redo surgical intervention, including washout and drainage, may be required; however, these procedures are associated with substantial morbidity [3]. Surgical reintervention has also been found to delay the success of subsequent endoscopic treatment if redo surgery fails [5]. Due to this increased morbidity associated with surgical reoperation, there is growing interest in endoscopic closure techniques and identifying the optimal devices for treating these complications.

Two of the most popular endoscopic treatment modalities for defects following bariatric surgery are endoscopic suturing and over-the-scope clipping. Endoscopic over-the-scope clips (OTSC) are effective for rapid use for many indications, including gastrointestinal bleeding, fistulae, anastomotic leaks, and bariatric surgery anastomoses remodeling [6]. Endoscopic suturing devices have also been efficacious for various indications, including full thickness defect closure, leaks and fistula repair, stent fixation, and bariatric applications [7, 8]. Understanding which endoscopic treatments are the most effective can reduce morbidity from these rare but potentially fatal complications of bariatric surgery.

This study aimed to review the current literature surrounding endoscopic closure techniques and specifically compare the efficacy of over-the-scope clips versus endoscopic suturing for closure of bowel defects following bariatric surgery.

Objectives

Perform a meta-analysis to compare the efficacy of over-the-scope clips to endoscopic suturing specifically for closure of bowel defects post-bariatric surgery.

Materials and methods

A literature search in PubMed using keywords, “endoscopic closure device, fistula, and leaks,” “endoscopic closure techniques, fistula, and leaks,” “endoscopic full thickness closure,” “endoscopic management of fistulas and leaks,” and “endoscopic treatment of fistula and leaks,” was performed. Given the wealth of literature published on the topic, we excluded articles published before 2010, case reports, systematic reviews, and meta-analyses. Animal studies were also excluded. Only closures for post-bariatric leaks and fistulae were included.

Studies that included other endoscopic closure techniques, including stents, were excluded. Studies that incorporated multiple concomitant closure approaches (such as clipping in addition to a stent) in their data were also excluded. This allowed us to compare patients who

underwent only over-the-scope clipping versus endoscopic suturing. Some studies included many patients, but a smaller number that underwent only OTSC or suturing. In these instances, the data for the smaller group of patients were included in our analysis. If the study did not report data specific to this smaller group, it was excluded. Randomized controlled trials, observational cohort studies, and case series were considered eligible. Any study with ≤ 5 patients that met inclusion was excluded. The PRISMA diagram is pictured in Fig. 1.

Statistical analysis

We conducted the meta-analysis using the MedCalc software [9]. For meta-analysis, MedCalc first transforms proportions into a quantity (the Freeman–Tukey variant of the arcsine square root-transformed proportion) suitable for the usual random-effects summaries [10]. The pooled proportion is calculated as the back transform of the weighted mean of the transformed proportions, using DerSimonian–Laird weights for the random-effects model [11]. We have reported the pooled proportions with 95% confidence intervals (95%CI). The heterogeneity was assessed by I^2 , and P values for the test of heterogeneity were also reported.

Results

Eight studies were included in the systematic review. Five studies with 61 patients that underwent OTSC closure reported clinically successful closure rates (Table 1). The weighted pooled proportion of successful closure across the studies was 81.1% (95% CI 67.3 to 91.7) (50/61) (Fig. 2). The successful closure rates between studies were homogeneous and relatively similar ($I^2 = 39\%$, $p = 0.15$). Three studies with 92 patients that underwent endoscopic suturing reported the clinically successful closure rates (Table 2). The weighted pooled proportion of successful closure across the studies was 22.4% (95% CI 14.6 to 31.3) (20/92) (Fig. 3). The successful closure rates between studies were homogeneous ($I^2 = 0\%$, $p = 0.44$) and relatively similar. Only three of the studies, totaling 34 patients, examining OTSC deployment reported data for reintervention rate. The weighted pooled proportion of reintervention across the studies was 35.0% (95% CI 11.7 to 64.7) (12/34) (Fig. 4). We noticed statistically significant heterogeneity between studies, with reintervention rates ranging between 9.1% (1/11) and 62.5% (5/8) ($I^2 = 68\%$, $p = 0.04$). Only one study examining endoscopic suturing reported their rate of repeat intervention. Reintervention was required in 60% of their patients (12/20).

Of the 61 included patients that underwent clip closure for their bariatric defect, 41 were closures of fistulae.

Fig. 1 PRISMA diagram

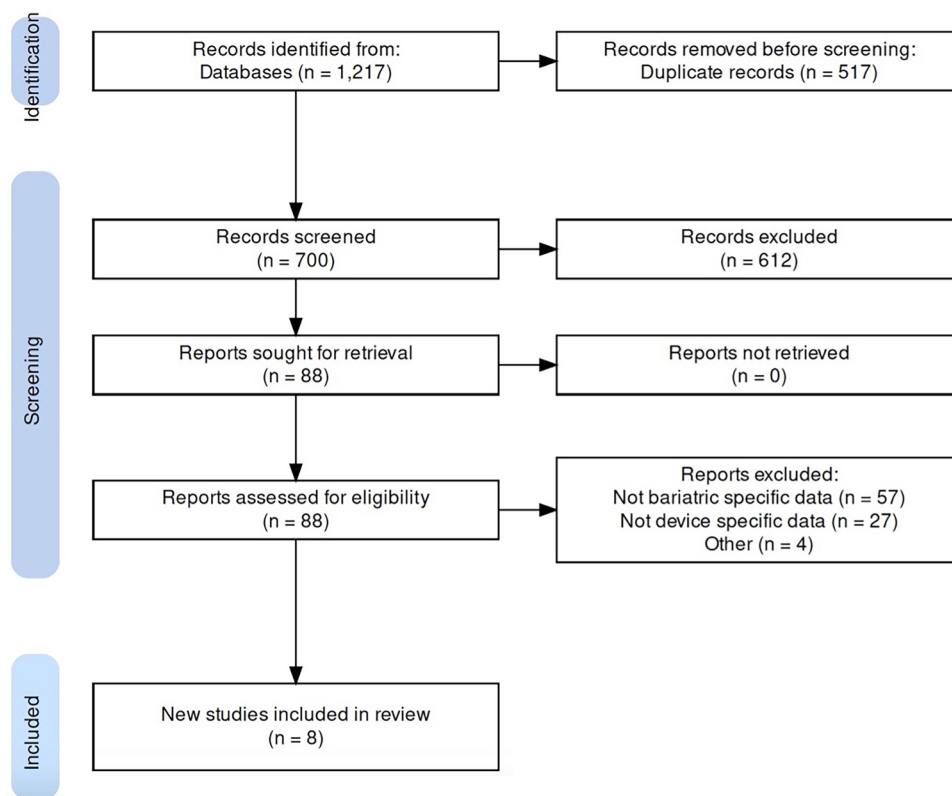


Table 1 OTSC-included articles

Study	Year	<i>n</i>	Defect type	Successful closure (<i>n</i>)	Definition of success	Repeat intervention (<i>n</i>)
Benosman et al. [12]	2018	7	Fistulae	7	Clinical	Not reported
Keren et al. [13]	2015	20	18 upper staple line and 2 antral leaks post-sleeve gastrectomy	17	Clinical	Not reported
Law et al. [14]	2015	8	Gastro-gastric fistulae post-RYGB	4	Clinical	5
Mercky et al. [15]	2014	15	14 fistulae post-sleeve gastrectomy, 1 fistula post-RYGB	13	Clinical and radiological	6
Baron et al. [16]	2012	11	Chronic fistulae	9	Clinical	1

Eighteen patients underwent clipping of upper staple line leaks following sleeve gastrectomy and 2 had antral staple line leaks. Of the 92 patients evaluated that underwent endoscopic suturing, 72 were closures of fistulae. The other twenty patients underwent closure of an anastomotic leak, 18 of which received sleeve gastrectomy and the other two RYGB.

Discussion

Our meta-analysis compares the efficacy of OTSC versus endoscopic suturing when repairing leaks and fistulae following bariatric surgery. Pooled data showed that over-the-scope clips were much more likely to close bariatric defects

when compared to endoscopic suturing successfully. Our data also showed that over-the-scope clips were less likely to require repeat intervention than endoscopic suturing.

With respect to OTSC, previous systematic reviews and meta-analyses determined success rates of 67 and 85% for closure of complications post-bariatric surgery [20, 21]. However, these reviews included articles that included patients treated with OTSC and other modalities, including stents. Our literature review did not find any previous systematic reviews or meta-analysis that pooled data to determine the success of endoscopic suturing for closing bariatric leaks or fistulae.

It is important to recognize that using OTSC may favor the closure of some defects while suturing may favor others. Endoscopic suturing has been shown to be successful

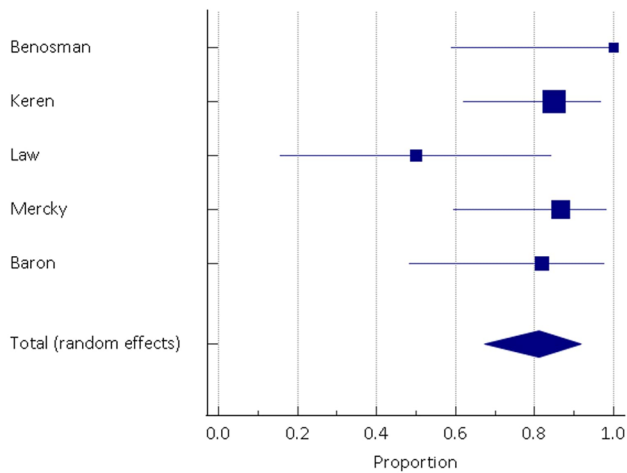


Fig. 2 OTSC success rate forest plot

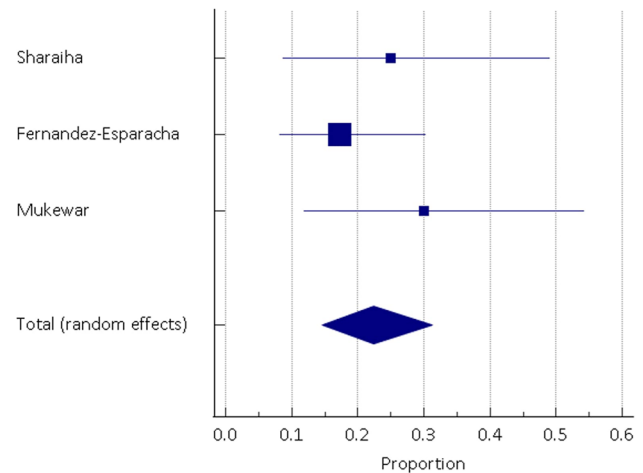


Fig. 3 Endoscopic suturing success rate forest plot

at closing various chronic enteric fistulae and is best studied for gastro-gastric fistulae following RYGB. Thus, endoscopic suturing should be considered one of the initial treatment options for the closure of large defects [22]. Generally, OTSC is more effective for acute rather than chronic leaks due to difficulty closing fibrotic tissue [23, 24]. The size and chronicity of the defect undoubtedly dictates the management approach and device indicated. These clinical features of the defect impact patient outcomes following endoscopy as well. Due to the lack of controlled studies that managed homogeneous defects, superiority between OTSC and endoscopic suturing cannot be determined. Controlled studies that focus on solely OTSC and endoscopic suturing for the management of defects of similar size and age are required to draw these conclusions. While our study examined the sole use of one endoscopic device versus another, many researchers and clinicians have found increased success when using a combination of endoscopic closure modalities. Specifically, the usage of OTSC to anchor stents or to close smaller leaks that remain after stent removal has shown promise. The dual therapy of OTSC in combination with stents yielded a successful closure rate of 82% and a migration rate of 18% [25]. Other endoscopic closure modalities, including

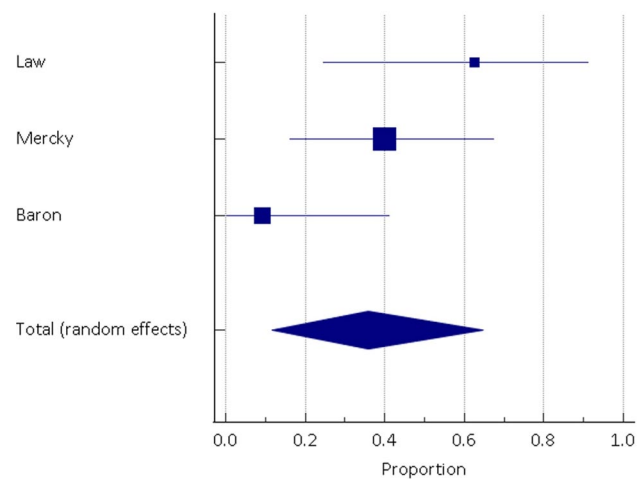


Fig. 4 OTSC repeat intervention rate forest plot

cyanoacrylate, balloon dilation, and various clip types have also succeeded in closing post-bariatric leaks when used with stents [26].

Handling these rare complications should also be multidisciplinary in approach. Because of these defects' complicated nature and the many treatment options available,

Table 2 Endoscopic suturing-included articles

Study	Year	n	Defect type	Successful closure (n)	Definition of success	Repeat intervention (n)
Sharaiha et al. [17]	2016	20	18 leaks post-sleeve gastrectomy, 2 leaks post-RYGB	5	Clinical or endoscopic or radiological	Not reported
Fernandez-Esparrach et al. [18]	2010	52	Gastro-gastric fistulae	9	Endoscopic or radiological	Not reported
Mukewar et al. [19]	2016	20	Gastro-gastric fistulae post-RYGB	6	Clinical or endoscopic or radiological	12

collaboration between experienced endoscopists and bariatric surgeons may lead to better results [27].

Limitations

Our study has several limitations. First, due to missing data, several studies had to be excluded from quantitative analysis. Many studies reported data from cohorts that utilized clips or suturing along with other endoscopic treatment modalities. To control for this and compare the efficacy of only OTSC versus only suturing, these studies had to be excluded. Also due to missing data, we were unable to compare leak size, leak age, and mean number of endoscopic interventions for each cohort due to a lack of data of these variables.

Our analysis was also limited by only including only retrospective studies. These studies often used different definitions of therapy success. To partly control for this, we were not interested in immediate technical success, only clinical success. These studies still had different definitions of clinical success, and whether endoscopic or radiological confirmation was required to deem intervention successful or not was inconsistent across included articles. Sample sizes in each individual study were also rather small. Lastly, due to the limited number of studies, subgroup analyses comparing defects following gastric sleeve versus RYGB were not possible.

Conclusion

In summary, observational reports show that patients managed with OTSC were more likely to experience healing of their defect than those managed with endoscopic suturing. Both techniques have been found to be successful at managing bariatric complications in existing literature for different types of leaks. Larger controlled studies comparing different endoscopic closure devices should be carried out to better understand the ideal endoscopic approach to manage these rare complications of bariatric surgery.

Declarations

Disclosures Dr. Christopher DuCoin has received consulting fees from Intuitive, Medtronic, and Johnson & Johnson. Dr. Salvatore Docimo has received speaker payments from BD, Medtronic, and Boston Scientific. Mr. William Doyle, Mr. Alexander Netzley, Dr. Rahul Mhaskar, Dr. Abdul Diab, Dr. Samer Ganam, and Dr. Joseph Sujka have no conflicts of interest to disclose.

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