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REVIEW ARTICLE

Efficacy and Safety of Stents in the Treatment of Fistula After Bariatric Surgery: a Systematic Review and Meta-analysis

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Abstract
Fistula development is a serious complication after bariatric surgery. We performed a systematic review and meta-analysis to assess the efficacy of fistula closure and complications associated with endoscopic stent treatment of fistulas, developed after bariatric surgeries, particularly Roux-en-Y gastric bypass (RYGB) and gastric sleeve (GS). Studies involving patients with fistula after RYGB or GS and those who received stent treatment only were selected. The analyzed outcomes were overall success rate of fistula closure, mean number of stents per patient, mean stent dwelling time, and procedure-associated complications. Current evidence from identified studies demonstrates that, in selected patients, endoscopic stent treatment of fistulas after GS or RYGB can be safe and effective.

Keywords Sleeve · Bypass · Bariatric · Stent · Fistula

Introduction

According to the World Health Organization, the worldwide prevalence of obesity has more than doubled since 1980. In 2014, > 1.9 billion adults aged ≥ 18 years were overweight, of which > 600 million were obese [1]. Obesity is an important risk factor for some cancers and osteoarticular and cardiovascular diseases, particularly acute myocardial infarction and stroke, which were the main causes of death in 2012 [1]. Fortunately, controlling comorbidities such as hypertension and diabetes mellitus by treating obesity is possible, thereby reducing morbidity and mortality among patients [2–4].

Surgery is the most effective long-term treatment for patients with morbid obesity and thus has been increasingly performed in recent years [4]. According to the American Society for Metabolic and Bariatric Surgery [5], the

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approximate number of bariatric surgeries performed in the USA was 179,000 in 2013; 193,000 in 2014; and 196,000 in 2015. Gastric sleeve (GS) was the most frequent procedure (53.8%), followed by Roux-en-Y gastric bypass (RYGB) (23.1%), revision surgery (13.6%), gastric banding (5.7%), and duodenal switch (0.6%). Although these procedures are considered safe, the increasing number of procedures is associated with a significant number of related complications [6].

Fistula development is one of the most serious complications, with incidences ranging from 1 to 8.3% after laparoscopic RYGB and from 0 to 7% after GS [7–14]. Until recently, fistula was preferably treated with surgery; however, surgery is associated with higher morbidities than currently available, less invasive therapeutic options [15–18].

Some studies have reported the successful nonsurgical conservative treatment of fistulas after bariatric surgery [19–21]. These less invasive therapeutic options include several endoscopic techniques. The closure of fistulas, developed after bariatric surgery, using metal clips alone or combined with other endoscopic procedures has been described [22–26].

The use of fibrin glue and endoscopic drainage has also been reported for endoscopically treating fistulas [27–30]. Furthermore, the effective treatment of fistulas, developed after bariatric surgery, with stent placement has been described [31–38].

In 2016, the European Society of Gastrointestinal Endoscopy, in its guidelines, indicated that temporary stent placements can be considered for treating fistulas or benign esophageal perforations (strong recommendation; low quality of evidence) [39]. Furthermore, the American Society for Metabolic and Bariatric Surgery recommends stent placement, among other endoscopic techniques, for treating fistulas developing after bariatric surgery [40].

This study aimed to assess the efficacy of fistula closure and the complications associated with endoscopic stent treatment of fistulas, which developed after bariatric surgeries, particularly GS and RYGB.

Materials and Methods

Data Sources and Searchers

This systematic review and meta-analysis was conducted according to the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA), was approved by the Research Ethics Committee of the Clinics Hospital of the School of Medicine of the University of São Paulo, and was registered in the international database PROSPERO (www.crd.york.ac.uk/prospero; protocol no: CRD42016050143) [41]. For this type of study, formal consent is not required.

Studies were identified by searching electronic databases, namely MEDLINE, Embase, Cochrane, and LILACS, and reviewing the selected studies' bibliographic references. The last search was conducted in October 2016. The search strategy for MEDLINE was "(Bariatric * OR metabolic surgery OR stomach stapling OR gastroplasty OR sleeve OR bypass) AND (leak * or fistula *)."

Study Selection

Randomized clinical trials, observational cohort studies, and case series were considered eligible. Only full-text articles were selected. Inclusion and exclusion criteria are summarized below:

Inclusion criteria

- Studies that included patients with fistula after RYGB or GS
- Studies wherein stent placement was the only endoscopic method for treating fistula

Exclusion criteria

- Studies wherein patients underwent bariatric surgery using techniques other than GS or gastric bypass
- Studies without a clear description of the endoscopic treatment
- Studies that included patients who underwent a combined endoscopic treatment

The extracted data were associated with the (1) characteristics of the studies, namely inclusion and exclusion criteria; (2) characteristics of the population; (3) type of intervention, considering the technique and stent type used; and (4) different outcomes. The extracted data were divided into two groups: fistulas after RYGB and those after GS. Comprehensive Meta-Analysis software (Englewood, NJ) was used for meta-analysis of the data and the risk of bias was assessed using the Critical Appraisal Checklist for Case Series of the Joanna Briggs Institute [42].

Data Synthesis and Analysis

Patients' demographic data (e.g., age, BMI, fistula location, and time to diagnosis) were analyzed for studies with available data. Regarding time to diagnosis, fistulas were classified as acute (≤ 7 days), early (between 1 and 6 weeks), late (between 6 and 12 weeks), and chronic (> 12 weeks) [43].

Outcomes

The primary outcome was the success rate of fistula closure, defined as the percentage of patients with successful fistula closure, as confirmed by contrast X-ray and/or digestive endoscopy, after stent placement.

The secondary outcomes were rate of stent migration, mean stent dwelling time, mean number of stents per patient, and mean period to fistula diagnosis.

Results

Search Results

The literature search yielded 5706 studies in MEDLINE and 3768 studies in the remaining databases. After excluding duplicated studies, 8877 studies were preselected. Of 8877 studies, 28 fulfilled the inclusion criteria and the criteria for quantitative and qualitative analysis and thus were included in this review (Fig. 1). All selected studies were published between 2006 and 2016 (Table 1). No prospective, comparative, and randomized studies were found in the literature. Therefore, only case series studies were included.

The outcomes were assessed in two subgroups: fistulas after GS and those after RYGB. For the analysis of each outcome, only studies with sufficient data were included. Seven studies were included in both subgroups.

Twenty-four studies, having 187 patients, were included in the GS group. The mean age of the patients was 42.94 ± 0.46 years, mean BMI was 40.04 ± 0.38 kg/m^2, overall success rate was 72.8% (Fig. 2), mean number of stents per patient was 1.4 ± 0.03, mean period for fistula diagnosis was 3.35 ± 0.28 days after surgery, and mean stent dwelling time was 48.77 ± 0.58 days. The stent migration rate was 28.2% considering all studies (Fig. 3).

The selected studies were subsequently divided into those that only used stents for specifically treating post-bariatric surgery complications and those that used ordinary

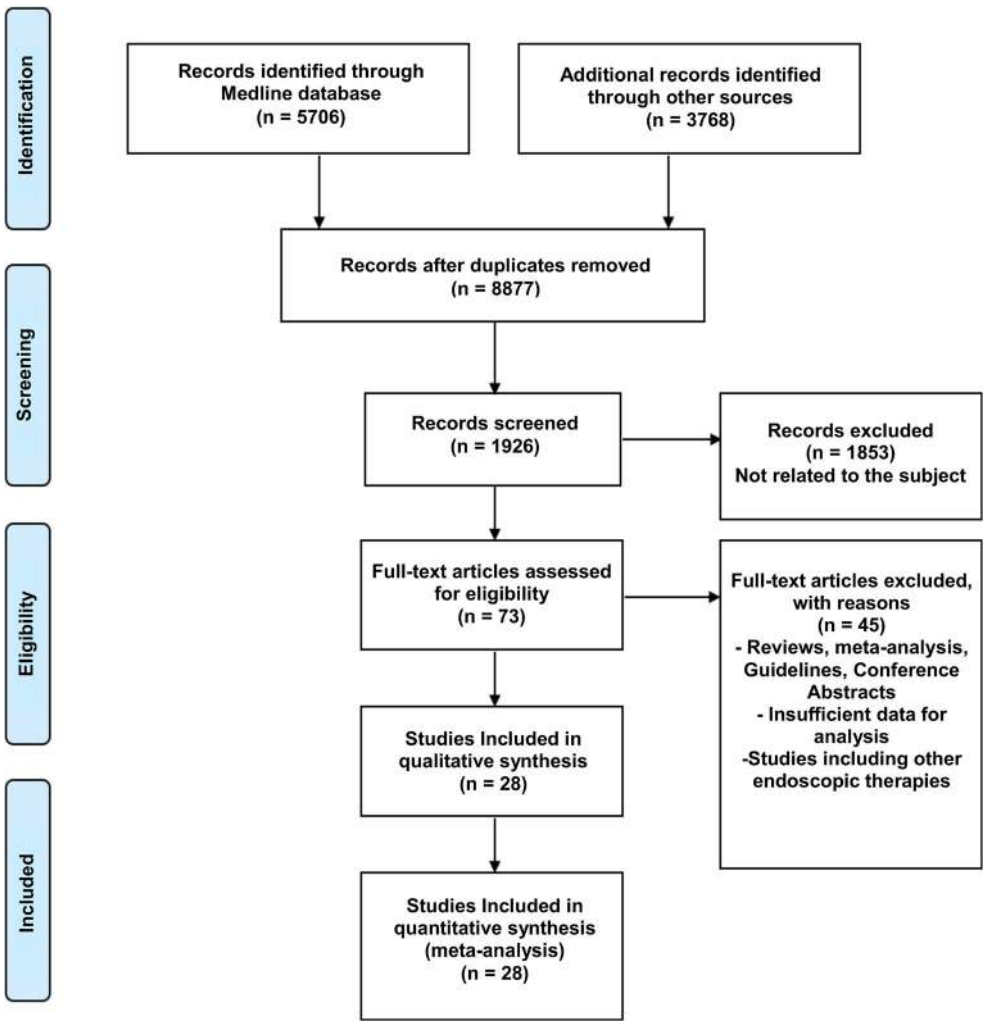

Fig. 1 Flow diagram

Table 1 Search results. *FCSEMS* fully covered self-expandable stent, *PCSEMS* partially covered self-expandable stent

Studies			
Study	Population	Surgery	Stent
Rebibo L, 2016	9	Sleeve	Hanarostent
van Wezenbeek MR, 2016	12	Sleeve/bypass	Hanarostent
Quezada N, 2015	29	Sleeve/bypass	FCSEMS
Périssé LG, 2015	29	Sleeve/bypass	FCSEMS
Fishman S, 2015	26	Sleeve	Hanarostent ou Megastent
Matlok M, 2015	3	Sleeve	Wallflex
Moon RC, 2015	6	Sleeve	–
Juza RM, 2015	5	Sleeve	Wallflex or Alimax-E
Liu S.Y.-W. 2015	2	Sleeve	Megastent
Alazmi W, 2014	17	Sleeve	Ultraflex + Polyflex
Galloro G, 2014	4	Sleeve	Megastent
Aras A, 2014	3	Sleeve	Uncovered biodegradable stent
Leenders BJ, 2013	9	Sleeve/bypass	Hanarostent or Endoflex
Freedman J, 2013	35	Bypass	Danis Stent
Simon F, 2013	9	Sleeve	Hanarostent
El Mourad H, 2013	28	Sleeve/bypass	Ultraflex + Polyflex
Fischer A, 2013	2	Sleeve	PCSEMS
Marr B, 2012	4	Sleeve	Wallflex
Yimcharoen P, 2011	8	Sleeve/bypass	Alimax-E or Evolution or Ultraflex or Polyflex
de Aretxabala X, 2011	4	Sleeve	FCSEMS
Inbar R, 2011	3	Sleeve	SX-ELLA
Tan JT, 2010	8	Sleeve	FCSEMS
Blackmon SH, 2010	10	Sleeve/bypass	Alimax-E stent
Nguyen NT, 2010	3	Sleeve	Allimax-E or Wallflex
Casella G, 2009	3	Sleeve	Ultraflex
Edwards CA, 2008	6	Bypass	Polyflex
Fukumoto R, 2007	3	Sleeve/bypass	Polyflex
Salinas A, 2006	17	Bypass	Ultraflex

esophageal stents. The migration rates in the former and latter subgroups were 31.5 and 27.1%, respectively.

None of the included studies provided data regarding the fistula size. Thirteen studies provided data regarding the fistula location; of 90 patients, 94.4% had fistula in the proximal third of the residual stomach, 4.4% in the middle third, and 1.1% in the distal third.

Fifteen studies provided data regarding the time to fistula diagnosis; of 92 patients, 48.91% had acute fistula (1–7 days after surgery), 34.78% had early fistula (1–6 weeks after surgery), 6.52% had late fistula (6–12 weeks after surgery), and 8.7% had chronic fistula [43]. None of the evaluated studies reported perforation cases. Bleeding requiring additional endoscopic treatments was reported for two patients (1.06%).

Eleven studies, having 108 patients, were included in the RYGB group. The mean age was 42.96 ± 0.65 years, and the mean BMI was 43.48 ± 0.68 kg/m^2. The overall success rate was 76.1% (Fig. 4), stent migration rate was 30.5% (Fig. 5), mean number of stents per patient was 1.28 ± 0.092, and mean stent dwelling time was 42.83 ± 1.91 days. No study provided data regarding the fistula size; therefore, calculating the mean time to fistula diagnosis was not possible.

Only three studies provided data on the time to fistula diagnosis; of 17 patients, 52.82% had acute fistula (1–7 days after surgery), 35.29% had early fistula (1–6 weeks after surgery), no patient had late fistula (6–12 weeks after surgery), and 5.88% had chronic fistula [43]. Two cases (1.85%) of perforation were reported among the included studies, and there were no reported cases of significant bleeding caused by the procedure.

Discussion

Although fistula development after bariatric surgery is rare, it can significantly increase patient morbidity and mortality [44,

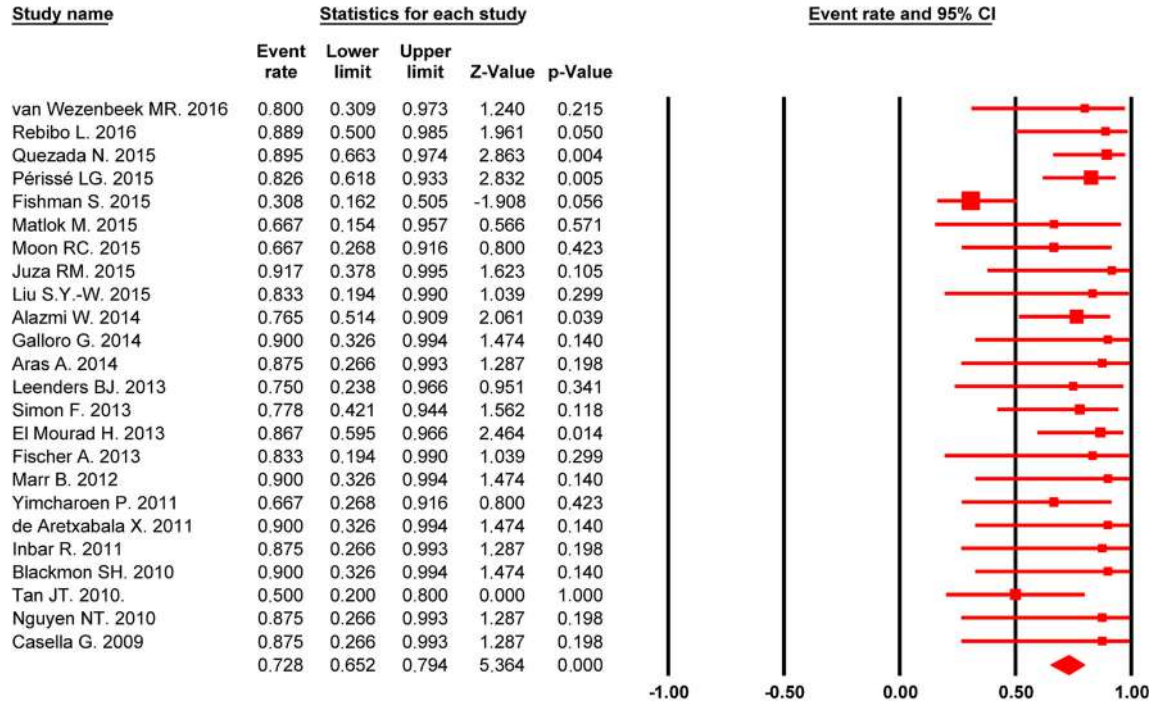

Fig. 2 Gastric sleeve: Forrest plot showing the overall success rate of fistula closure

45]. The obesity epidemic and elevated number of bariatric procedures have increased the number of cases of fistulas developing after GS and RYGB [1, 5].

The pathophysiology of fistulas developing after bariatric surgery is multifactorial and can be divided into ischemic and/or mechanical (staple failure, tension in the anastomosis or along the staple line, hematoma, and distal stenosis). In both situations, intraluminal pressure appears to exceed tissue resistance along the staple line or anastomosis, leading to fistula formation [46–49].

Treatment of fistulas developing after bariatric surgery is challenging and complex. The use of broad-spectrum antibiotics, proton pump inhibitors, fluid collection drainage (via surgery, guided by X-ray or endoscopy), and nutritional support are essential for initially stabilizing these patients. Different definitive treatments, including surgical and/or

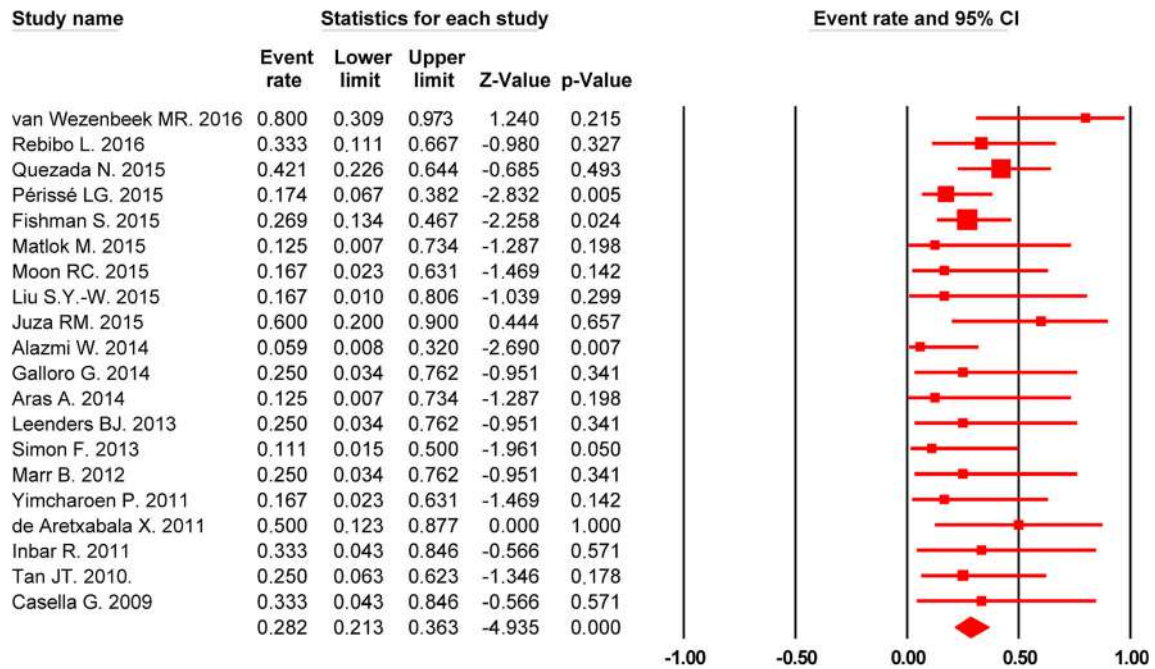

Fig. 3 Gastric sleeve: Forrest plot showing the mean stent migration rate

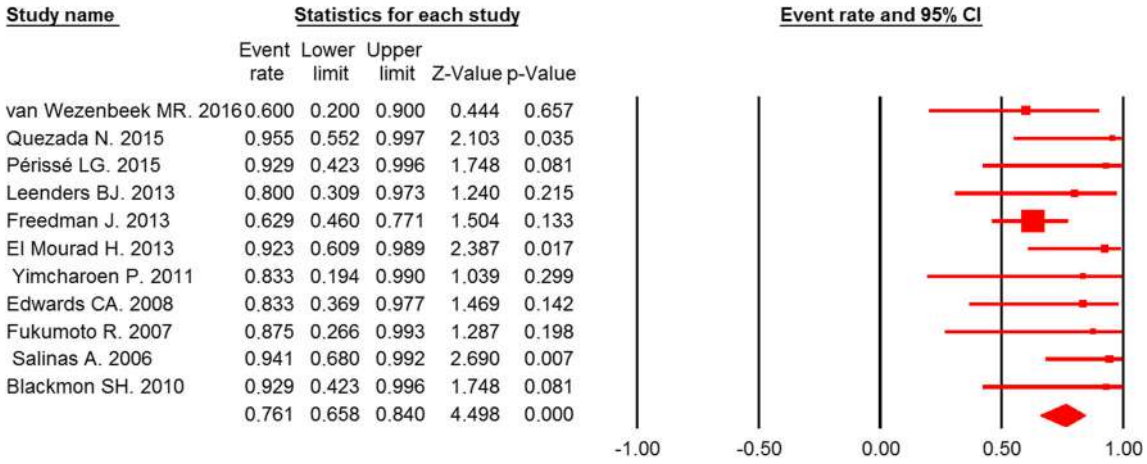

Fig. 4 Roux-en-Y gastric bypass: Forrest plot showing the overall success rate of fistula closure

endoscopic treatment, can be performed in acute and chronic fistula cases [50–52].

In acute and early fistula cases, surgical intervention with cavity drainage and an attempt of primary fistula repair with suture or materials such as biological glue can be performed in clinically unstable patients, but the recurrence rates are high. Moreover, in clinically stable patients with acute and early fistulas, nonsurgical, less invasive strategies may be used. After adequately draining the collected fluid via endoscopy or guided X-ray, different endoscopic treatments such as endoscopic suture, placement of metal clips, fibrin glue, or stents may be used. Among the endoscopic treatments, stent placement has been gaining importance, and several studies [31–38] have reported high success rates.

Stent placement reduces intraluminal pressure, considered to be the major cause of fistula occurrence and development. The exclusion of the fistula site reduces peritoneal contamination by esophagogastric and enteric secretions and accelerates the healing process. Moreover, the exclusion of the fistula site allows the early return to oral or enteral feeding, thereby avoiding prolonged periods of parenteral nutrition [53].

In this meta-analysis, stent placement was effective for treating fistulas in both the GS and RYGB groups, with success rates of 73 and 76.1%, respectively, and a low number of stents per patient.

Partially or fully covered metal stents and self-expandable plastic stents are most frequently used for treating complications developing after bariatric surgery. In theory, partially covered metal stents should minimize the risk for migration. Partially covered metal stents reportedly have a lower rate of migration than fully covered metal stents and plastic stents when used for treating esophageal perforations [54]. However, to our knowledge, to date, no studies have demonstrated the superiority of a specific type of benign stent for treating fistulas after bariatric surgery. Although these stent types were used in the studies included in the current review, performing a subgroup analysis to evaluate outcomes of each stent type was not possible because of insufficient data provided in the studies.

Despite potential benefits of stent placement in managing fistulas, several complications associated with the procedure have been reported; bleeding and perforation are the most severe. However, this meta-analysis revealed that stents were well tolerated and resulted in a low rate of severe complications in the RYGB and GS groups. There were no reported perforation cases in the GS group and only 1% of patients had

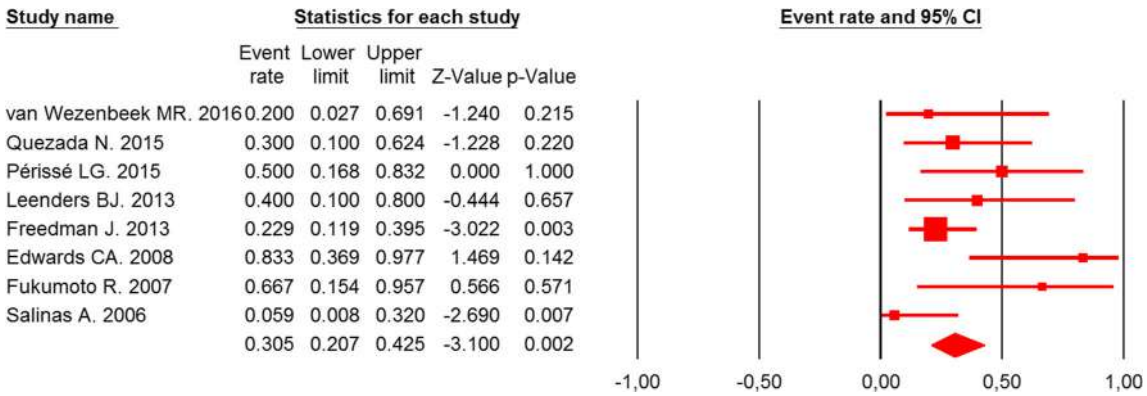

Fig. 5 Roux-en-Y gastric bypass: Forrest plot showing the mean stent migration rate

significant bleeding. In the RYGB group, the rate of perforation was only 1.85%, and there were no reported cases of significant bleeding.

However, stent migration remains a challenge. The rate of stent migration was high in both the groups (GS group, 28%; RYGB group, 30.6%). The occurrence of migration delays fistula closure, increases the number of endoscopic procedures, and, consequently, increases the likelihood of severe adverse events.

Several alternatives, including stent fixation with placement of metal clips or endoscopic suture, have been reported for preventing migration [55–58]. However, additional studies are warranted to recommend the routine use of these procedures.

In this context, novel stent types, including extra-long fully covered self-expandable metal stents (length, 18–24 cm), have been developed for treating complications developing after GS; these stents should minimize the risk for migration. The proximal stent portion is placed in the mid-esophagus, and the distal portion is placed in the distal segment or first duodenal portion, thus promoting total gastric exclusion. Furthermore, a bigger diameter (22–28 mm) combined with a softer and more malleable material allows a more precise adaptation to the post-GS anatomy [59].

This meta-analysis demonstrated that the migration rate was higher in the subgroup of stents that were specifically designed for complications developing after bariatric surgery than in the subgroup of esophageal stents. This may be explained by the small number of studies included in the former subgroup (four studies) and by the fact that one of the studies reported a migration rate different from the other three studies (80%), significantly increasing the migration rate in this subgroup. Moreover, the absence of comparative studies prevented inferring the superiority of one stent over the other.

Studies [43, 60] have reported a low success rate of therapies wherein stents were used for treating chronic fistulas. Assessing the efficacy of stenting in each subgroup according to the time of fistula presentation is necessary. Results generally would indicate the use of this method more precisely; however, unavailability of data prevented this analysis.

The greatest challenge of the current review was data extraction because of the high heterogeneity among the studies and the lack of sufficient data. Moreover, there was high heterogeneity among patients, fistula characteristics, and types of stents used among the selected studies.

Most studies did not provide data regarding the fistula location, size, and time to diagnosis. Furthermore, the use of endoscopic techniques combined with stent placement without a detailed description of the procedures was commonly observed among the selected studies. These factors prevented a more detailed evaluation of the subgroups and hindered the collection of valuable data regarding important parameters such as the best type of stent to be used or whether stent placement was beneficial for treating chronic fistulas.

Therefore, further studies are needed to confirm the findings of the current review and to clarify important characteristics of fistulas and stents that result in the best response to endoscopic stent treatment. This would allow a more precise indication of the type of therapy for treating fistulas after bariatric surgery.

In summary, the main limitations of the current review were the lack of randomized clinical trials in the literature. Other limiting factors were the high heterogeneity of the population under study, the lack of sufficient data in the selected studies, and, as a result, the impossibility to perform an individualized analysis of the outcomes according to fistula size, location, time to diagnosis, and type of stents used.

Conclusion

The results of this systematic review and meta-analysis indicate that, in appropriately selected patients, endoscopic treatment of fistulas after GS or RYGB via stent placement can be safe, with a low rate of severe adverse complications, and effective, with a high success rate of fistula closure.

Compliance with Ethical Standards

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

Ethical Approval Statement All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Statement Informed consent does not apply for this study.

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