OBES SURG (2017) 27:530–535
DOI 10.1007/s11695-016-2465-9

HOW I DO IT

Double Pigtail Stent Insertion for Healing of Leaks Following Roux-en-Y Gastric Bypass. Our Experience (with Videos)

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Published online: 23 November 2016

Abstract
Background Roux-en-Y gastric bypass (RYGB) is complicated by a leak in 0–4.3% of cases. Treatment by fully covered stents has been reported to be associated with some life-threatening complications. We report our experience of insertion of double pigtail stents.
Methods Thirty-three patients (20M, 43 years-20/65), presenting with a leak at an average of 10 days after RYGB (4–35), were treated by double pigtail stent insertion and a nasojejunal feeding tube. Sixty percent of these patients had undergone surgical drainage prior to stenting for control of sepsis. Thirty leaks were located at the top of staple line and three at the gastro-jejunal anastomosis. At a 4-weekly follow-up, ablation or re-stenting was performed depending on status of fistula closure and patients were placed on normal diet.
Results At the first follow-up, 10/33 fistulae healed, one patient presented with clinical failure (3%) and needed surgery, and 22/33were re-stented. Twenty-one out of these 22 developed a secondary sub-clinical gastro-gastric fistula and one, instead, developed complex (gastro-gastric, gastro-colic) fistula. All (22) primary fistulae healed following four more weeks of treatment. Average treatment duration was of 61 days (28–99). Thirty-two patients (97%) at a follow-up of 1–33 months are asymptomatic.
Conclusions Leaks following RYGB can be successfully and safely managed by double pigtail stents. Upper gastric staple line leaks are responsible for the formation of a secondary sub-clinic gastro-gastric fistula which needs no additional treatment.

Keywords Bariatric surgery · Roux-en-Y gastric bypass (RYGB) · Gastric leak · Pigtail stent · Endoscopic internal drainage · Surgical obesity complications

Introduction

Roux-en-Y gastric bypass (RYGB) is the most common surgical procedure performed for morbid obesity [1]. Staple lines

Electronic supplementary material The online version of this article (doi:10.1007/s11695-016-2465-9) contains supplementary material, which is available to authorized users.

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and double anastomosis are necessary to achieve restriction and malabsorption. Cases between 0 and 4.3% are complicated by leaks and are the second leading causes of death in patients undergoing RYGB [1]. They are localized mostly at the level of gastro-jejunal anastomosis. However, locations could be at the level of gastric pouch staple line, excluded stomach staple line or jejuno-jejunal anastomosis. Usually, they appear early, within 7 days of primary surgery, and clinically, they are responsible for systemic or localized sepsis. Fully covered self-expandable metal stent (FCSEMS) has been used, for treatment of proximal leaks since jejuno-jejunal site can be accessed with difficulty by a flexible scope. However, overall outcomes are conflicting and they are burdened by high level of migration rate (up to 66%) and 5% of mortality related to stent complications [2–4]. Alternatively, traditional care for anastomotic complications after gastrointestinal (GI) surgery has been obtaining source control surgically, combined with medical treatment of infection, thus allowing the leak to heal naturally [5] despite the fact that surgical management has been associated to high morbidity and mortality [6, 7]. We retrospectively reviewed our experience with a novel procedure of placement of double pigtail stent in the management of leaks following RYGB.

Patients and Methods

Since March 2013, 20 male and 13 women, with an average age of 43 years (20–65), were addressed to our referral endoscopic center, for leaks following RYGB between 4 and 35 days of primary surgery (average 10 days). Informed consent was obtained from all individual participants included in the study. Institutional Review Boards approved the study for human research.

A leak was defined as extravasation of contrast medium across the staple line defect or a gastro-jejunal disruption at the CT scan or an upper GI contrast swallow study coupled with sepsis. Upper endoscopy under radiologic control was used to confirm the defect and perform evaluation of the collection. Subsequently, endoscopic internal drainage (EID) was performed by means of a double pigtail stent (3 to 10 cm long, 7–8.5–10 Fr diameter) (Visio® Gflex Europe, Nivelles-Belgium or Advanix® Boston Scientific, Massachusetts-Boston-USA) chosen according to the size of the wall defect and the collection (video 1). In all patients, for the first 4 weeks, a feeding tube was left in place in an efferent loop. At first control (4 weeks), definitive stent removal or re-stenting was performed and patients were started on normal oral diet if the collection outside gastric lumen was well organized and fully drained by pigtail (Fig.1a, b). Definite withdrawal of the stent was achieved by 3 months of the second endoscopy.

Results

Twenty-three patients (60%) had already been subjected to surgical drainage of the collection arising out of gastric leaks in view of controlling ongoing sepsis. Forty percent instead (ten patients) were not re-operated, because they were relatively stable and presented with only localized peritonitis (reviewer 1, comment 2) and had not undergone any surgical or radiologic drainage prior to stenting. Thirty leaks (91%) were localized at the level of the cardia on the upper staple line, whereas only three leaks were at the gastro-jejunal anastomosis site. The defect was smaller than 1 cm. Technical success was defined as successful

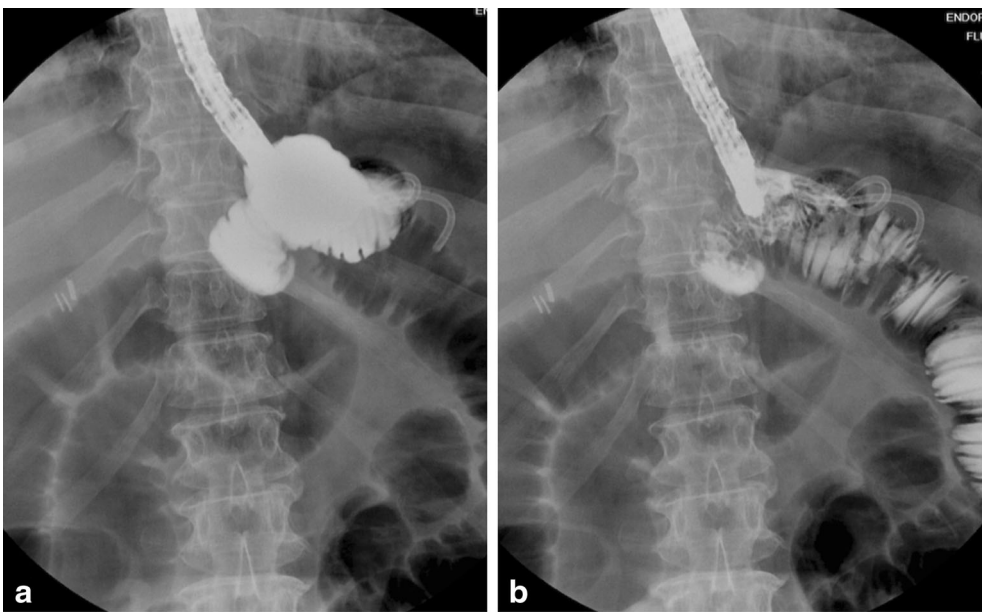

Fig. 1 **a**, **b** Control at 4 weeks by double pigtail drainage of leak following RYGB. Absence of contrast medium extravasation

drainage of intra-abdominal collection with resolution of the systemic inflammatory response syndrome (SIRS) and was achieved in 30 out of 33 pts (91%). Three out of ten patients with no drain pre-stenting had to undergo surgery with complementary drainage 1 day following endoscopic procedure because of persistent sepsis. All surgical drainages were removed by 15 days after primary endoscopy sessions. Clinical failure was reported in 1/33 (3%) who developed ischemia with consequent stenosis at the level of the cardia 25 days after primary surgery and 17 by pigtail delivery requiring emergency surgery with total gastrectomy. All the other 32 patients underwent endoscopy control at 28 days. The three fistula located at the level of the gastro-jejunal anastomosis were healed, pigtails were withdrawn, and patients left hospital the day after with normal oral diet. Between the 29 patients presenting a fistula of the upper part of the staple line, we found persistent extravasation of contrast medium in 22 patients (76%) with appearance of secondary sub-clinic gastro-gastric fistula (GGF) (orifice <5 mm) (video 2, video 3). One out of 22 patients presented with a complex fistula with necrosis in the perigastric cavity—gastro-colonic fistula in addition of the GGF (Fig.2a, b). All these 22 patients, with initial cardia fistula and still presenting with extravasation of contrast medium at first follow-up and with secondary GGF, were re-stented by pigtail and 21 out of 22 remained on normal diet. Only the patients with complex fistula underwent endoscopic necrosectomy, pigtail re-stenting, and nose-jejunal feeding tube for four more weeks before being put on normal diet and definitive removal of pigtail, at an overall of 99 days of treatment. Gastro-colic fistula healed but persisted a sub-clinic GGF.

Clinical success defined as absence of sepsis, normal alimentation, and excessive weight loss was achieved in 32 out 33 patients (97%). Pigtails were definitively removed with an average of 61 days (28–99), requiring a median of three endoscopy sessions (2–4).

After an average follow-up of 10 months (1–33), none of the patients needed revision surgery, and all 32 patients (97%) are doing well with good loss of excessive weight.

Overall results are listed in Table 1.

Discussion

Leak and fistula following bariatric surgery can be life threatening in the same circumstances [8]. Surgical treatment by primary closure of defect usually fails because of associated inflammation and tissue edema. Wise drainage is the best option in the case that requires exploratory surgery [9, 10]. Drainage coupled with broad-spectrum antibiotics and adequate nutritional supports is literally the *primus movens* for non-surgical treatment of the healing process in case of well-controlled leaks without hemodynamics instability, since it can achieve control of local sepsis [9, 10]. FCSEMS diverts enteric contents away from the leak allowing oral intake and can help fistula closure by secondary intention, but there is no evidence to suggest faster or more efficient healing [5]. Furthermore, FCSEMS are complicated by distal migration, secondary stenosis, and even fatal adverse events in a serious number of patients and especially following RYGB due to the diversion of pylorus that normally prevent distal stent migration. An Ovesco® clip and Overstitch™ endoscoping suture system have been used to anchor stent [11], with increase in costs without significant success. The development of new designed SEMS is manly aimed to reduce the risk of migration and the risk of granulation tissue formation at the edges of the stent. However, our personal experience with anti-migration stents suggests that, being larger and longer, they result in increased risk of inducing ischemia of the GI tube, thus enlarging the dehiscence of staple line or anastomosis defect.

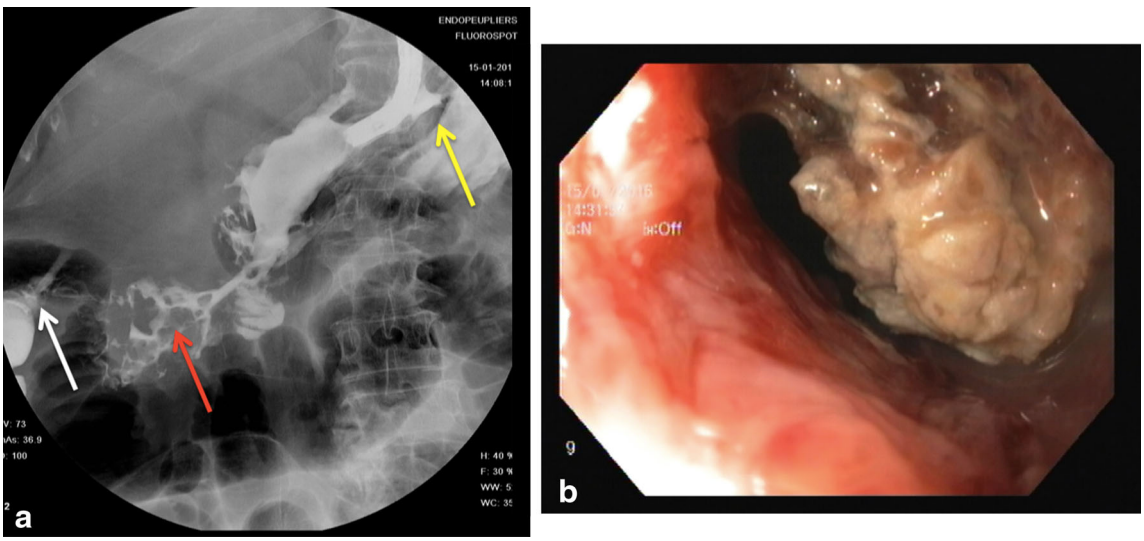

Fig. 2 **a**, **b** Necrosis (*red arrow*) in the perigastric pseudo cavity, with secondary opacification of the stomach (*yellow arrow*) and colon (*white arrow*) due to secondary gastro-gastric and gastro-colic fistula formation

Table 1 Overall results

Patient no.	Leak localization	Surgical drainage	Technical outcome of EID	First control	Second control	Third control
1	Cardia	N	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
2	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
3	G-J anastomosis	Y	Positive	Positive	–	–
4	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
5	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
6	G-J anastomosis	Y	Positive	Positive	–	–
7	Cardia	Y	Positive	Positive	–	–
8	Cardia	Y	Positive	Positive	–	–
9	Cardia	N	*Negative—surgical complementary drainage*	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
10	Cardia	N	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
11	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
12	Cardia	Y	Positive	Positive	–	–
13	Cardia	Y	Positive	*Clinical failure—emergency surgery*	–	–
14	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
15	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
16	Cardia	N	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
17	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
18	Cardia	N	*Negative— surgical complementary drainage*	Positive	–	–
19	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
20	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
21	Cardia	Y	Positive	GGF + GCF (re-stenting, feeding tube)	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF
22	G-J anastomosis	Y	Positive	Positive	–	–
23	Cardia	N	Positive	Positive	–	–
24	Cardia	N	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
25	Cardia	N	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
26	Cardia	N	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
27	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
28	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
29	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
30	Cardia	Y	Positive	Positive	–	–
31	Cardia	N	*Negative—surgical complementary drainage*	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
32	Cardia	Y	Positive	Sub-clinical GGF (re-stenting, normal diet)	Sub-clinical GGF	–
33	Cardia	Y	Positive	Positive	–	–

Y Yes, *N* No, *GGF* gastro gastric fistula, *GCF* gastro colic fistula, *G-J* gastro jejunal anastomosis

Furthermore, they are not well tolerated by the patients, who commonly complain of pain, vomiting, and discomfort. Insertion of double pigtail stent to manage the leak and fistula has been adopted with a high successful rate by our team for defects following sleeve gastrectomy, as well as oncology and benign GI surgery. It facilitates by achieving EID, promotion of granulation tissue, and treatment of local sepsis, allows early removal of surgical drain, thus hastens fistula healing, and permits patients to even have normal diet with double pigtail in place [12, 13]. In this series, 1/3 of patients did not need, at all, any form of drainage, because they were stable with localized sepsis and EID was enough to solve infection. The other 2/3 of patients, instead, needed drainage of abdominal collection, because they had generalized peritonitis with multi-organ failure on presentation or because EID was not enough to solve sepsis (technical failure in three patients). So, trans-abdominal drainage is primarily done to control sepsis and resuscitate the patients but not aimed at defect closure. EID by double pigtail stents facilitates inside drainage and thus allows to remove external drainage early, avoiding chronic fistula due to the re-hepitelization of the tract of external drainage. Furthermore, double pigtail stent works like a foreign body and stimulates granulation tissue growth. This "neo tissue" tends to push the stent associated with consequent watertight occlusion of the defect. They are well tolerated by patients even when left in place with patients on normal diet, with no mortality and very few morbidity such as migration or bleeding Bouchard et al. recently reported a series of 33 patients with the leak following bariatric surgery, and on the ground of their results and our experience, they consider that EID with double pigtail stents offers an attractive alternative to SEMS-based treatment with a similar rate of success [14]. In our specific series of leak following RYGB, we confirm a very high rate (97%) of clinical success even if the peculiar thing in this series was the percentage of the location of primary leaks, i.e., at the level of cardia—maybe because of erroneous extension of staple line on the GE junction. Additionally, we demonstrate development of a secondary gastro-gastric fistula following EID of upper gastric staple line leaks. The size of GGF was very small in all the cases, and opacification of excluded stomach happened only if contrast injection is performed in the direction of fistula. If the opacification was done at the level of cardia, preferential passage of medium contrast was through the gastro-jejunal anastomosis with normal empting of gastric pouch, and this may explain the success in terms of weight loss in our patients. Furthermore, we report of a complex fistula (gastro-gastric, gastro-colic) with necrosis that we successfully treated like a wall-off pancreatic necrosis with drainage and endoscopic necrosectomy. This particular approach confirms and supports our claim that management of leaks following GI surgery should be performed directly by endoscopic internal drainage because this option is more physiologic even without routinely placed external drainage, thus avoiding secondary complications due to the implanted endoscopic material (migration, perforation, etc.). We believe that for treatment of leaks following GI surgery, mere occlusion of defect may not be sufficient but effective drainage is the most important factor for fistula healing. However, multicentric comparative studies are needed for establishing this treatment modality as the first line of therapy.

Corredeguas et al. already reported the secondary GGF following the gastro-jejunal leak [1]. Incidence of secondary GGF in our series appears higher than reported, but often, there are unknown because of disparity in follow-up schemes implemented by different surgeons and institutions [1]. This complication is due to a failed staple line [15] with leaking and is well documented that a leak is the important predisposing factor for the developments of viscera-visceral fistulas in the GI tract. Although GGF is not considered a life-threatening complication and its management begins with medical approach and careful patient observation, surgical revision is indicated in case of inadequate weight loss or weight regain [1].

Conclusion

Management of leaks following RYGB by placement of double pigtail stents is safe and useful even as the first line approach in patients with local sepsis. EID of a leak localized at the level of the upper gastric staple line results in the majority of patients in a secondary gastro-gastric fistula that do not require additional treatment as long as it has small caliber and weight loss is achieved. However, surgical intervention is needed in case of persistently septic patients and in cases of non-optimal weight loss.

Compliance with Ethical Standards

Funding The authors have no financial arrangements or commercial associations that might be a conflict of interest in relation to this manuscript.

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

Statement of Informed Consent Informed consent was obtained from all individual participants included in the study.

Statement of Human and Animal Rights The study has been approved by the appropriate institutional ethics committee and has been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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