Robotic Roux-en-Y Gastric Bypass as a Revisional Bariatric Procedure: a Single-Center Prospective Cohort Study

Published version:

DOI:10.1007/s11695-019-04117-7

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Robotic Roux-en-Y Gastric Bypass as a revisional bariatric procedure: a single-center prospective cohort study

Short Title: Role of robot in revisional bariatric surgery

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Abstract

Background: Roux-en-Y Gastric Bypass (RYGB) is the procedure of choice to manage the failure of primary bariatric surgery. However, the current evidence on the role of the robotic technology in revisional bariatric surgery is very limited.

The aim of this study is to report safety and effectiveness of revisional RYGB performed with the DaVinci Robotic Surgical System (R-rRYGB) after failed primary bariatric surgery.

Methods: Clinical data of consecutive patients undergoing R-rRYGB were included in a prospectively collected database. Intraoperative findings, early postoperative outcomes and 1-year follow-up results were considered. Primary outcome was postoperative morbidity rate. Secondary outcomes were conversion to open surgery, length of stay, percentage of Excess Weight Loss (%EWL), resolution of complications, and costs.

Results: A total of 68 patients underwent R-rRYGB at our Department from 2011 to 2016. Primary procedures were laparoscopic adjustable gastric banding (n=10), vertical banded gastroplasty (n=43), and sleeve gastrectomy (n=15). Conversion rate to open surgery was 2.9%. Postoperative morbidity rate was 8.8%, with no anastomotic leaks reported. Total cost for surgical procedure was 14334.7 ± 2920.4 €.

Conclusions: Revisional RYGB is a complex procedure, but can be performed with the robotic approach with a low morbidity rate. Weight loss outcomes and resolution of complications of the index procedure are satisfactory.

Keywords: RYGB; Robot; Revisional bariatric surgery

INTRODUCTION

Bariatric surgery has been established as the most effective treatment modality for severe obesity, leading to sustainable weight loss and resolution of obesity-related comorbidities such as diabetes, hypertension, obstructive sleep apnea, and dyslipidemia in the long-term follow-up. [1] [2] [3]

Nevertheless, revisional surgery is required in 10-56% of patients, mainly due to inadequate weight loss, weight regain or complications related to the index procedure. [4] [5] Laparoscopic Roux-en-Y Gastric Bypass (RYGB) is the most commonly performed revisional bariatric procedure. [5] [6] [7] However it is a challenging operation, with higher rates of both intraoperative and postoperative complications than primary bariatric surgery. [8] [9] [10]

The use of the robotic technology might represent a valid alternative to the laparoscopic approach in performing such a complex surgical procedure, mainly due to the three dimensional magnified vision and the enhanced surgical dexterity. [11] Even though the robotic platform has been widely used in several bariatric procedures, there are limited data about robotic revisional bariatric surgery. [12] [13] [14] [15] [16] [17] [18]

The aim of this study is to investigate the outcomes in a consecutive series of patients undergoing Robotic revisional Roux-en-Y Gastric Bypass (R-rRYGB) after primary bariatric surgery.

MATERIALS AND METHODS

Patients undergoing R-rRYGB with the DaVinci Surgical System (Intuitive Surgical Inc, Sunnyvale, CA, USA) after failed previous restrictive bariatric surgery were included in a prospectively collected database.

This study has been approved by the local medical ethics committee. During the study period robotic revisional RYGB was the conventional approach performed in our Institution. All patients included in the study signed a detailed informed consent regarding the surgical procedure and the robotic approach. Revisional bariatric surgery with the laparoscopic approach was available upon patient's request.

Patient baseline characteristics, type of index procedure and indications for revision were recorded. Primary bariatric surgical procedures were laparoscopic Adjustable Gastric Banding (LAGB), Vertical Banded Gastroplasty (VBG) and Sleeve Gastrectomy (SG).

Indications for revision were weight loss failure, symptomatic gastro-esophageal reflux (GER) and persistent dysphagia. Weight loss failure was defined as insufficient weight loss after primary surgery or progressive weight regain according to the Reinhold criteria. [19] The definition of postoperative GER was based on the presence of symptoms and esophagitis at upper endoscopy despite proton pump inhibitor treatment.

Exclusion criteria were anesthesiologic contraindications to surgery, and complications requiring emergency surgery (i.e. band erosion, small bowel obstruction).

All patients underwent a comprehensive routine preoperative workup. Preoperative upper endoscopy was obtained in all patients to rule out the presence of esophagitis, described according to the Los Angeles classification. [20] In case of Helicobacter Pylori infection, amoxicillin-clarithromycin containing triple therapy was administered and the urea breath test was performed to confirm the eradication.

The radiological study of the upper gastrointestinal tract was performed in all patients using a low-density barium sulfate suspension to evaluate the presence and location of the gastric banding and the shape and size of the gastric pouch in VBG patients and of the gastric sleeve in SG patients.

Surgical technique

All procedures were performed by two surgeons (MM, FR) with more than 20 years of experience in laparoscopic surgery and more than 100 procedures each in robotic surgery. Robotic surgeries were performed with a da Vinci Si robotic platform until June 2015, then with a da Vinci Xi robotic platform. The technique is described in details elsewhere. [21] Briefly, a small gastric pouch (around 20-30 cm^3) was created using a laparoscopic linear stapler.

In LAGB patients the silicon gastric banding was dissected and removed together with the fibrous capsule that surrounded it. Gastric transection was performed with a laparoscopic linear stapler starting on the lesser curve approximately 6cm from the gastric cardia, using a 12-mm calibration bougie.

In VBG patients, the first step of the procedure was the identification and dissection of the pseudo-pylorus, that is generally covered by dense adhesions. The gastric pouch was created with a horizontal transection above and beyond the portion of stomach including the pseudo-pylorus, leaving the previous vertical staple line intact, in the absence of pouch dilatation. In case of pouch dilatation, we performed a vertical transection of the gastric pouch in order to reduce its volume.

In SG patients, we performed a horizontal gastric transection with a linear stapler approximately 6 cm distally from the gastric cardia along the lesser curve to create the gastric pouch. In case of gastric sleeve dilatation or residual gastric fundus, the stomach was resected longitudinally using a 12mm calibration bougie before the horizontal transection.

In case of hiatal hernia larger than 3 cm, a posterior hiatoplasty with 2-3 non – absorbable stitches was performed.

The proximal jejunum was transected at 70 cm from the ligament of Treitz with a linear stapler, and used to perform an antecolic end-to-side running two-layer hand-sewn gastro-jejunal (GJ) anastomosis with absorbable sutures. The 150-cm alimentary limb was completed with a side-to-side jejuno-jejunal (JJ) hand-sewn anastomosis. We routinely performed a 150 cm limb gastric bypass regardless of preoperative BMI in revisional bariatric surgeries. [22] We performed a "double loop" gastric bypass technique with no mesenteric opening, therefore there was no need of mesenteric closure. The GJ anastomosis was tested with a methylene blue test, and a peri-anastomotic drain was placed.

Follow-up assessment

During the study period, patients underwent a radiological study of the upper gastrointestinal tract with water-soluble contrast medium at postoperative day 2. Oral intake was then started in the absence of anastomotic leak or strictures. Based on the available evidence we changed our practice, and nowadays we perform postoperative radiological examination only in case of clinical warning sign.

Cost analysis included: costs associated with surgical tools (semi-disposable robotic, laparoscopic, and DaVinci Surgical System maintenance), operative room time, length of postoperative hospital stay (including Intensive Care Unit - ICU), routine postoperative surgical care, diagnosis and treatment of postoperative complications. Operative room costs included healthcare personnel, medications, and structure costs. To calculate the cost of each postoperative complication, the following items were assessed: laboratory and microbiology analysis, medical therapy, radiology, surgical and therapeutical interventions. The initial cost of purchase of the robotic system was not taken into consideration.

The follow-up protocol included clinical evaluation at 1, 3, 6, 12 month and annually thereafter to assess weight, Body Mass Index (BMI), percentage of Excess Weight Loss (%EWL) and resolution of complications associated with the index bariatric procedure that led to R-rRYGB.

Statistical analysis

All data have been prospectively collected in a dedicated database. Primary outcome was postoperative morbidity rate according to the Clavien-Dindo classification. [23] Secondary outcomes were conversion to open surgery, length of stay, %EWL, resolution of complications, and costs.

Quantitative data are given as mean and standard deviation, and categorical data are expressed as percentage. The χ^2 test was used to compare proportions. The Student t test was used to compare normally distributed variables. All P values were 2-sided. A level of 5% was set as the criterion for statistical significance. The data were collected on an Excel spreadsheet. The statistical analysis was performed using SPSS (IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY:IBM Corp).

RESULTS

A total of 117 revisional RYGB were performed in our Institution between January 2011 and December 2016. Of these, 2 were performed with open approach, 47 with laparoscopic approach and 68 (58.1%) with the robotic system, and were therefore included in the study. Table 1 shows the baseline characteristics of the patients included in the study. Mean preoperative weight and BMI were respectively 94.7 ± 20.1 kg and 35.8 ± 7.1 kg/m^2. Patients underwent R-rRYGB after LAGB (n=10, 14.7%), VBG (n=43, 63.2%) or SG (n=15, 22.1%). In 4 LAGB patients (5.9%) the reoperation was conducted as a two-stage procedure and R-rRYGB was performed 6.7 ± 1.3 months after LAGB removal.

The most common indications for revisional surgery were persistent dysphagia (n=23, 33.8%) and GER (n=22, 32.4%), followed by weight regain (n=14, 20.6%) and insufficient weight loss (n=9, 13.2%).

Perioperative outcomes

Mean operative time was 265.6 ± 54.1 minutes: it significantly decreased over time (from 286.3 ± 38.0 min of the first 30 cases to 224.1 ± 48.4 of the last 10 cases, p<0.001). Conversion to open surgery was necessary in 2 (2.9%) patients for severe intra-abdominal adhesions. The intra-operative methylene-blue test was negative for anastomotic leak in all cases. Postoperative morbidity rate was 8.8%. Overall, there were 4 grade I-II (1 pulmonary embolism, 2 pneumonias and 1 bleeding treated conservatively without need of blood transfusions), 1 grade IIIb (small bowel perforation requiring reoperation at postoperative day 3) and 1 grade IVa (severe pneumonia requiring 4 days of ICU stay) Clavien-Dindo complications. There were no postoperative GJ leaks. There were no deaths. Mean length of postoperative hospital stay was 5.5 ± 3.9 days.

Follow-up results

A total of 59 (86.7%) patients were available for clinical evaluation at 1-year after surgery: 5 (7.3%) patients were lost to follow-up, 4 (5.8%) patients decided to continue follow-up at the center where they underwent primary bariatric operation.

Overall, mean weight and BMI decreased significantly, to 79.5 ± 16.0 kg (P<0.001) and 30.3 ± 5.5 kg/m^2 (P<0.001), respectively.

Of the 23 patients undergoing R-rRYGB for weight loss failure, 20 (86.9%) completed the 1-year follow-up protocol, weight and BMI decrease**d** from 109.8 ±18.8 kg to

93.8 ± 18.2 kg (p=0.006) and from 41.0 ± 6.7 kg/m^2 to 32.7 ± 6.3 kg/m^2 (p<0.0001) respectively, with a mean %EWL of 55.4 ± 34.7%.

Among the 16 of the 22 patients (72.7%) who underwent R-rRYGB for GER and were available for 1-year evaluation, 14 (87.5%) reported complete symptom remission off proton pump inhibitors, while 2 (12.5%) required acid-reducing medications.

All 23 patients who underwent revisional surgery for dysphagia had resolution of their symptoms postoperatively.

New-onset dysphagia developed in 2 (2.9%) patients at 2 months after surgery. Both patients underwent upper endoscopy showing a GJ anastomotic stricture successfully treated with one session of endoscopic balloon dilatation.

Overall cost per procedure was 14334.7 ± 2920.4 €. Table 2 summarizes costs. The intraoperative costs significantly decreased over time, from 12168.7 ± 1438.4 € in the first 30 cases to 9708.5 ± 515.7 in the last 10 cases (p<0.001), due to the reduction in operative time, the decreased use of laparoscopic linear staplers, and the reduction in maintenance costs with the multi-disciplinary use of the system. (Figure 1)

DISCUSSION

Revisional surgery is accounting for up to 10% of all bariatric procedures performed worldwide. [24] The optimal reoperative procedure is still under debate, since only a few heterogeneous studies without long-term results have been published. [6] A recent survey including 460 bariatric surgeons from 62 Countries showed that almost 75% of bariatric surgeons consider RYGB as the most common procedure performed after restrictive primary bariatric surgery. [7]

However, laparoscopic conversion of primary restrictive procedure to RYGB is technically challenging and is associated with a higher rate of complications than primary RYGB. [8] [9]

Pedziwiatr et al performed a systematic review and metanalysis including 21 studies for a total of 14763 patients and found a statistically significant increased rate of overall morbidity (18.6% vs. 8.6%, RR 1.54 p=0.003) and mortality (0.62% vs. 0.21%, RR=3.03 p=0.02) in patients undergoing revisional RYGB compared to patients undergoing primary RYGB. [10]

The robotic technology, allowing a three dimensional magnified vision and an increased surgical dexterity, including the possibility to perform hand-sewn intracorporeal gastrointestinal anastomoses, could offer some advantages in complex procedures requiring anastomotic suturing over the standard laparoscopic approach. [11] [25] [26]

While there are several studies assessing specifically the results of robot-assisted bariatric surgery, the evidence regarding robot-assisted revisional bariatric surgery is limited. [14] [15] [16] [17] [27] [28] [29] Specific data regarding the outcomes after robot-assisted revisional RYGB are even more scarce. [18] In addition, a comprehensive cost-analysis of patients undergoing R-rRYGB has never been performed.

The only study published in literature that specifically assessed the outcomes of R-rRYGB is that by Bindal et al. They retrospectively reviewed 32 patients undergoing R-rRYGB after LAGB (16 patients), SG (11 patients) or RYGB (5 patients). No R-rRYGB was converted to open surgery and mean operative time was 226 minutes. No patients experienced postoperative anastomotic leak, hemorrhage, GJ stricture; there was no mortality. [18]

The current study represents the largest series specifically assessing the outcomes of R-rRYGB after primary restrictive bariatric surgery, aiming at shed more light on the possible benefits of the robotic technology in this field. We have shown that this complex procedure is safe and feasible: we reported a conversion rate to open surgery of 2.9% and a postoperative morbidity rate of 8.8% that compare favorably to the data of laparoscopic revisional RYGB published in literature. [8] [9] [10] We have also found that R-rRYGB is effective in resolving complications secondary to the index bariatric procedure, and leads to significant weight loss in those patients who experienced weight loss failure after primary restrictive procedure.

One of the most critical steps in revisional RYGB is the construction of the GJ anastomosis, due to the presence of scarring, adhesions and the limited gastric remnant after previous VBG and SG. A recent meta-analysis of 14 studies by Mahawar et al. has shown that the anastomotic leak rate is higher after revisional laparoscopic RYGB than primary RYGB (5.8% vs. 1.0%). [9] In literature there are no specific data of the possible role of the robotic technology in reducing the risk of anastomotic leak in patients undergoing revisional RYGB. The most significant advantage we experienced by using the DaVinci robot is the increased surgical dexterity in performing the hand-sutured GJ anastomosis. This was true especially for VBG patients, in which the gastric tissue available to perform the GJ anastomosis was very limited due to the need to transect the gastric pouch above the pseudo-pylorus. In contrast the creation of the gastric pouch either mechanically or hand-sewn was challenging in our experience with laparoscopic revisional RYGB. Technical difficulties in performing the GJ anastomosis with a mechanical circular stapler required conversion to open surgery in 18.2% of cases. Moreover, in our laparoscopic revisional series, we had a 6.3% postoperative leak rate despite of the anastomotic technique used (mechanical circular or linear or hand-sewn). In the present series we have reported no intraoperative or postoperative anastomotic leaks. Furthermore, only 2 (2.9%) patients had a GJ anastomotic stricture, successfully treated with endoscopic balloon dilatation. Our findings seem to confirm the potential benefit of the robotic platform in reducing the anastomotic stricture rate, as already demonstrated in primary RYGB (1.3 vs. 3.9%), in the absence of data concerning revisional RYGB. [27] [29]

Robotic procedures are traditionally associated with high costs related to prolonged operative time and semi-disposable robotic tools.

Primary robotic RYGB is reported to be more expensive than laparoscopic RYGB. Bailey et al considered 4 studies comparing the costs of laparoscopic and robotic primary RYGB. [28] They found that the expected costs of robotic RYGB was higher than laparoscopic RYGB. However, these studies were heterogeneous in the design and in the analyzed costs, and were conducted in different countries with different health care systems.

To the best of our knowledge, a detailed analysis of costs related to R-rRYGB has never been performed. This is the first study to report a comprehensive economic evaluation of costs related to R-rRYGB, including costs associated with surgical tools (semi-disposable robotic, laparoscopic and the DaVinci Surgical System maintenance), operative room time, length of postoperative hospital stay, routine postoperative surgical care, diagnosis and treatment of postoperative complications. We found a mean cost of 14334.7 ± 2920.4 € per procedure.

Specific robotic expenses due to semi-disposable robotic instruments are fixed and consist in approximately one third of the total costs (5959.6 €/procedure). We have observed a significant reduction in operative time (from 286.3 ± 38.0 min of the first 30 cases to 224.1 ± 48.4 of the last 10 cases ($p=0.001$) and related cost (from 2911.1 ± 386.6 € to 2278.3 ± 492.7€ respectively, $p<0.001$) during the study period (Figure 1). This, along with the decreased use of laparoscopic linear staplers, and the reduction in maintenance costs with the multi-disciplinary use of the system, led to a significant reduction of overall intraoperative costs per surgical procedure (from 12168.7 ± 1438.4 € of the first 30 cases to 9708.5 ± 515.7 € of the last 10 cases, $p<0.001$). A detailed comparison of cost- analysis of the laparoscopic series was beyond the scope of the study. In our laparoscopic series, the total cost per procedure was 3176.5 ± 850.5 €. Laparoscopic procedures are less expensive due to the absence of specific semi-disposable instruments and of the robotic system maintenance fee. However, the clinical benefits that we found have prompted us to consider the robotic approach as the standard approach to revisional RYGB in our Institution.

A limitation of the study is represented by the short-term analysis. Nevertheless, the aim of the study was to show the feasibility and safety of the robotic approach in revisional surgery, and we considered the 12 months follow-up appropriate.

CONCLUSIONS

This is the first study assessing specifically the outcomes of robotic revisional RYGB after primary restrictive bariatric surgery in a large number of patients, suggesting that the robotic technology can be considered a valid alternative to the laparoscopic approach in such complex procedure requiring intracorporeal anastomosis. Based on the results of this study, further comparative and possibly randomized controlled trials are needed to confirm the benefits of the robotic approach to the patients undergoing revisional bariatric surgery.

DISCLOSURE STATEMENT

Conflict of Interest: none of the authors have conflict of interest to declare

Funding: no funding has occurred in the preparation and conduct of the study

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

Informed consent: For this type of study, formal consent is not required.

Table 1 - Baseline characteristics of the study patients

	R-rRYGB (n=68)
Mean age (years)	48.7 ± 9.2
Mean BMI (kg/m²)	35.8 ± 7.1
Mean weight (kg)	94.7 ± 20.1
Sex:	
Male (%)	2 (2.9%)
Female (%)	66 (97.1%)
Comorbidities:	
Hypertension (%)	24 (35.3%)
Diabetes (%)	2 (2.9%)
OSAS (%)	6 (8.8%)
Dyslipidemia (%)	2 (2.9%)
Hypotyroidism (%)	10 (14.7%)
Time from index procedure (months)	96.9 ± 60.9
Upper endoscopy	
HP infection (%)	7 (10.3%)
Esophagitis (%)	38 (55.9%)
Metaplasia (%)	2 (2.9%)

R-rRYGB = Robotic revisional Roux-en-Y Gastric Bypass; BMI = Body Mass Index; OSAS = Obstructive Sleep Apnea Syndrome; HP = Helicobacter Pylori

Table 2 – Detailed costs per patient

	Unit cost	Total cost in €	Total cost in USD
Length of stay	560 €/day 2000€/day ICU (Intensive Care Unit) stay	3164.7 ± 2363.3 €	3607.7 ± 2694.1 USD
Postoperative costs	78.3 ± 11.4 € /uncomplicated case	125. 3 ± 238.4 €	142.9 ± 271.8 USD
Operating room time	610 €/hour	2700.9 ± 550.8 €	3079.0 ± 627.9 USD
Surgical tools	5659,6 €/robotic tools 384.3€/laparoscopic stapler 164.7€/laparoscopic cartridge	6596.1 ± 229.0 €	7519.6 ± 261.0 USD
Robotic maintenance	18807.52 €/month	1747.6 ± 1064.5 €	1992.3 ± 1213.6 USD
Total		14334.7 ± 2920.4 €	16341.6 ± 3329.3 USD

All costs were collected in Euros (€). Currency conversions from Euros to United States Dollars (1 Euro = 1.14 USD) were calculated as of 26th February 2019.

Figure 1 – Cost of the procedure

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