ORIGINAL CONTRIBUTIONS





Less Morbidity with Robot-Assisted Gastric Bypass Surgery than with Laparoscopic Surgery?

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Abstract

Introduction Although several studies have compared totally robot-assisted gastric bypass (RA-GB) to laparoscopic gastric bypass (L-GB), the clinical benefit of the robotic approach remains unclear.

Materials and Methods We compared perioperative outcomes of 82 consecutive patients undergoing RA-GB between 2013 and 2016 to 169 consecutive patients having undergone L-GB between 2009 and 2016. Secondary endpoints included duration of hospitalization, readmission rate, weight loss at 1 year, and the learning curve of RA-GB, assessed by operation times and complication rates.

Results There were no statistically significant differences between groups concerning age $(43.5 \pm 11.2 \text{ vs. } 42.2 \pm 12.4 \text{ years})$, body mass index $(42.4 \pm 5.0 \text{ vs. } 43.6 \pm 7.2 \text{ kg/m}^2)$, or comorbidities. The rate of revision surgery was higher in L-GB group without reaching statistical significance. No statistically significant difference was observed for duration of operation $(134 \pm 35 \text{ vs. } 135 \pm 37 \text{ min})$, readmission rate at 90 days (4.9% vs. 8.9%), or percentage of excess weight loss at 1 year (RA-GB vs. L-GB) (76.8% $\pm 20.5 \text{ vs. } 73.1\% \pm 23.5$). There were fewer statistically significant complications overall in RA-GB (9.8% vs. 21.9%, p = 0.019). Median duration of hospital stay was shorter for RA-GB (3 vs. 4 days, p < 0.0001). The mean duration of operation for RA-GB decreased from 153 min in 2014 to 122 min in 2016; p = 0.004.

Conclusion In our experience, the robotic approach for gastric bypass was associated with fewer postoperative complications compared to traditional laparoscopic gastric bypass. Cost increment associated with RA-GB remains an important drawback that hampers its widespread.

Keywords Gastric bypass · Robot-assisted surgery · Manual anastomosis · Minimal access surgery

Introduction

Morbid obesity is a major public health problem. According to the WHO, it affected 650 million people worldwide in 2016 [1]. Gastric bypass is the standard technique to obtain prolonged weight loss [2, 3]. First introduced by Masson in

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N. Goasguen NGoasguen@hopital-dcss.org 1969 [4], and modified by Griffen in 1977 (Roux-en-Y reconstruction) [5], it is a combined restrictive and malabsorption procedure.

Laparoscopy is presently the preferred surgical approach [6], as it allows for reduced postoperative pain and improves postoperative recovery [7]. Laparoscopic gastric bypass

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surgery remains a difficult procedure, with poor work ergonomics for the surgeon [8]. Robotic may overcome some limitations of laparoscopic methods and improve outcomes. Currently, several publications have compared laparoscopic to robotic bariatric surgery with inconclusive results [9–22].

As we believed that short- and medium-term surgical results of robot-assisted laparoscopic gastric bypass (RA-GB) would be comparable to laparoscopic gastric bypass, this cohort study aimed to compare the postoperative course of patients who underwent RA-GB to a historical cohort of patients having undergone laparoscopic gastric bypass (L-GB).The secondary goal was to evaluate the learning curve of the robotic approach based on duration of intervention and complication rate during the study period.

Materials and Methods

After having received approval from the ethics committee of the Diaconesses Croix Saint-Simon hospital group (Paris, France), we analyzed the outcomes of all adult patients who underwent a gastric bypass between 2009 and 2016 in our institution. The inclusion criteria complied with the guidelines of the French Health Authority regarding surgical treatment of obesity [23]. All patients had a Body Mass Index (BMI) \geq 40 kg/m² or a BMI \geq 35 kg/m² in association with at least one of the following comorbidities: hypertension, diabetes, sleep apnea, osteoarticular disorders, and nonalcoholic steatohepatitis. Patient consent was obtained prior to performing the surgical intervention.

A multidisciplinary team comprising nutritionist, endocrinologist, psychologist, and surgeon had monitored the patients for at least 6 months prior to surgical treatment.

Patient Data

Among the 251 patients who underwent bypass surgery between 2009 and 2016, 169 underwent L-GB and starting in 2013, 82 patients underwent RA-GB. Demographic characteristics, and perioperative and postoperative variables were collected retrospectively for L-GB, but prospectively for RA-GB. The percentage of excess weight loss was calculated based on the guidelines published by Deitel and Greenstein [24].

The main assessment criterion for our study was the rate of postoperative complications at 30 days, as evaluated by the Dindo-Clavien classification [25]. All patients who had a complication grade 1 or higher were included in the complication rate. Complications were deemed severe when the grade was 3 or greater.

The secondary criteria were the duration of the hospitalization, the rate of readmission, the weight loss at 1 year, and the learning curve based on duration of operation and complication rates. The complication rate was calculated using the overall number of complications divided by the number of procedures for each year under scrutiny. We compared the duration of interventions in the first year to the last year of the RA-GB cohort at different steps of the operation (total duration, docking duration, duration of gastrojejunal anastomosis, jejunojejunal anastomosis). A non-exhaustive medical economic analysis was made to compare the two approaches.

Surgical Technique

The type of procedure (robotic or laparoscopic) depended on surgeon's discretion. Briefly, after the acquisition of the robot by our institution, three surgeons (AV, NG, OO) started to perform all gastric bypass using the robotic platform, whereas two surgeons (see acknowledgment) did not take part in any robotic surgery. Robotic procedures were always performed by two senior surgeons, and a single surgeon (AV) was present in all robotic procedures. Supplementary file 1 shows the number of each procedure by year.

Laparoscopy gastric bypass was performed according to a standard technique [26] (Antecolic and antegastric Roux-en-Y limb of 150 cm). We performed the gastrojejunal and jejunojejunal anastomoses with an endo-GIATM 60-mm stapler; the entry holes for the stapler were closed with a continuous suture of Vicryl® 2-0. All interventions were performed by experienced surgeons in laparoscopic and bariatric surgery.

The robot-assisted gastric bypass was performed according to the technique described by Germain [27]. We used the da Vinci® system from Intuitive Surgical Inc. (Sunnyvale, USA) with four robotic arms. The gastric pouch was created by the assistant surgeon with an endo-GIATM 60-mm stapler. An antecolic and antegastric Roux-en-Y limb of 150 cm was positioned in a counterclockwise set-up. The gastrojejunal and the jejunojejunal anastomoses were made with full-thickness Velock® 3-0 running sutures.

Anastomotic integrity was systematically tested with intraluminal injection of methylene blue in both approaches.

The Postoperative Protocol

The postoperative protocol was the same for both cohorts. Patients were allowed to drink water in the evening of the intervention; pureed food was started on postoperative day 2.

Based on the clinical and biological criteria, the patients could generally be discharged on postoperative day 3. Upon discharge, a single daily dose of omeprazole, Tinzaparin sodium injection 4500 IU per day, compression stockings for 28 days, as well as vitamin supplementation were prescribed.

Statistical Analyses

Continuous variables were expressed as means with their standard deviation (SD) or medians with Interquartile Range (IQR), as appropriate. Normally distributed variables were analyzed using the Student *t* test while non-parametric variables were analyzed using the Wilcoxon test. Categorical variables were expressed as percentages. The association between categorical variables was analyzed using Pearson's Chi-square test or Fisher's exact test as appropriate. All variables with probability values < 0.05 were considered to be statistically significant. A logistic regression model was used to control for possible confounding factors. All statistical analyses were performed using R software (Free Software Foundation, University of Paris–Jussieu) by a medical biostatistician (KZ).

Results

Between 2009 and 2016, a total of 251 patients underwent a gastric bypass surgery. One hundred sixty-nine patients underwent L-GB and starting in 2013; the RA-GB cohort included 20 patients the first year (2013), 27 patients in the

second year (2014), 15 in the third (2015), and 20 in the fourth (2016) (supplementary file 1).

Table 1 presents the comparison of demographic data. There were no significant differences between the two groups with regard to age, gender, initial weight, BMI, comorbidities (e.g., arterial hypertension (AHT), prior abdominal surgery, diabetes, cardiovascular disease, or rheumatologic complications), and the American Society of Anesthesiologists (ASA) score. There was a significant difference between the two groups in terms of the rate of sleep apnea (41.4% vs. 24.9%, p = 0.012) and the rate of smoking (7.3% vs. 19.5%, p = 0.007) favoring RA-GB versus L-GB.

All patients were assessed at 30 days. At 1 year, 88 patients were lost to follow-up (35%), 34 in the RA-GB group, and 54 in the L-GB group (41.5% vs. 32.0%, p = 0.177). Table 2 summarizes the postoperative course for the two groups. Postoperative complications were more frequently observed in the L-GB group (21.9% vs. 9.8%, p = 0.019). However, no significant difference was found between the groups regarding the rate of severe complications (6.1% vs. 13.0% for RA-GB and L-GB respectively; p = 0.149). It is worth noticing that the readmission rate at 90 days is almost double in the L-GB (RA-GB 4.9% vs. L-GB 8.9%; p = 0.385) even if it did not reach statistical significance.

| | RA-GB $(n = 82)$ | | L-GB $(n = 189)$ | | р |
|---------------------------|------------------|---------------|------------------|--------------|---------------------|
| | % | n | % | п | |
| Female | 87.8 | 72 | 84.6 | 143 | 0.499 [†] |
| Age* | 43.5 | [32.3–54.7] | 42.2 | [29.8–54.6] | 0.418^{\parallel} |
| ASA score [‡] | 2.5 | [2.0-3.0] | 3.0 | [2.0-3.0] | 0.33 [¶] |
| Height* (m) | 1.7 | [1.6–1.8] | 1.65 | [1.5–1.7] | 0.513 [∥] |
| Weight* (kg) | 116.3 | [100.2–132.4] | 119 | [95.5–142.5] | 0.34^{\parallel} |
| BMI* (kg/m ²) | 42.4 | [37.4–47.4] | 43.6 | [36.4–50.8] | 0.10^{\parallel} |
| Comorbidities | | | | | |
| AHT | 32.9 | 27 | 33.1 | 56 | 0.974^{\dagger} |
| Diabetes | 14.7 | 16 | 30.3 | 29 | 0.649^{\dagger} |
| Smoker | 7.3 | 6 | 19.5 | 33 | 0.02^{\dagger} |
| GERD | 23.2 | 19 | 9.5 | 16 | 0.003^{\dagger} |
| Coronary artery disease | 2.4 | 2 | 3.5 | 6 | $1^{\$}$ |
| SAS | 41.4 | 34 | 24.9 | 42 | 0.007^{\dagger} |
| Hiatal hernia | 15.8 | 13 | 14.8 | 25 | 0.826^{+} |
| Previous surgery | | | | | |
| Gastric band | 11.0 | 9 | 18.9 | 32 | 0.11^{\dagger} |
| Sleeve gastrectomy | 4.9 | 4 | 7.7 | 13 | 0.572# |
| Abdominal surgery | 43.9 | 36 | 47.9 | 81 | 0.549^{\dagger} |

RA-GB robot-assisted gastric bypass, *L-GB* laparoscopic gastric bypass, *ASA* American Society of Anesthesiologists, *BMI* body mass index, *AHT* arterial hypertension, *GERD* gastroesophageal reflux disease, *SAS* sleep apnea syndrome

* Mean [standard deviation], [‡] median [interquartile range], [†] Chi-squared test, [§] Fisher's exact test, ^{\parallel} bilateral Student's *t* test, [¶] bilateral Wilcoxon test, # Correction Yates

 Table 1
 Patient demographics

 and history
 Image: Comparison of the second seco

Table 2 Postoperative course

| | RA-GB $(n = 82)$ | | L-GB $(n = 169)$ | | р |
|----------------------------------|------------------|-----------|------------------|-----------|-----------------------|
| | % | n | % | n | |
| DOS†, (days) | 3.0 | [3.0-4.0] | 4.0 | [3.0–5.0] | < 0.0001 [¶] |
| Dindo-Clavien grade $[28] \ge 1$ | 9.8 | 8 | 21.9 | 36 | 0.019 ^{§,} |
| Dindo-Clavien grade $[28] \ge 3$ | 6.1 | 5 | 13.0 | 22 | 0.149^{\parallel} |
| D30 Readmission rate | 3.7 | 3 | 8.3 | 14 | 0.271 |
| D90 Readmission rate | 4.9 | 4 | 8.9 | 15 | 0.385∥ |

RA-GB robot-assisted gastric bypass, L-GB laparoscopic gastric bypass

[†] DOS duration of stay (median and interquartile range), ^{§,} Chi-squared, $^{\parallel}$ correction Yates, ¶ bilateral Wilcoxon test

Table 3 summarizes the postoperative complications. No differences were observed in the rate of anastomotic fistula (RA-GB 2.4% vs. L-GB 3.0%, p = 0.815), duration of operation, $(134 \pm 35 \text{ vs. } 135 \pm 37 \text{ min}, p = 0.925)$, or blood loss (26 ml vs. 36 ml, p = 0.054). The rate of revision surgery was higher in L-GB group (26.6% vs. 15.9%) but it was not statistically significant. Moreover, revision surgery was not associated with a higher complication rate in this series (Supplementary file 2).

The median duration of hospital stay was 3 [3–4] days for the RA-GB group vs. 4 [3–5] days for the L-GB group, (p = 0.038).

Bariatric Results

The average percentage of excess weight loss at 1 year in the RA-GB group was $71.3\% \pm 20.5$ vs. $73.7\% \pm 23.5$, in the L-GB group (p = 0.360).

| Table 3 | Posto | perative | comp | olications |
|---------|-------|----------|------|------------|
|---------|-------|----------|------|------------|

| | RA-GB (<i>N</i> =82) | | L-GB (N=169) | | |
|---------------------------------|-----------------------|-----|--------------|-----|----|
| | n | % | n | % | |
| Anastomotic leak | 2 | 2.4 | 5 | 3.0 | ns |
| Anastomotic stenosis | 0 | 0.0 | 5 | 3.0 | ns |
| Bleeding* | 2 | 2.4 | 7 | 4.1 | ns |
| Ulcer | 1 | 1.2 | 0 | 0.0 | ns |
| Deep surgical site abscess | 2 | 2.4 | 2 | 1.2 | ns |
| Postoperative pulmonary disease | 0 | 0.0 | 5 | 3.0 | ns |
| Nausea and vomiting | 3 | 3.7 | 10 | 5.9 | ns |
| Rhabdomyolysis | 0 | 0.0 | 1 | 0.6 | ns |
| Abdominal pain | 1 | 1.2 | 4 | 2.4 | ns |
| Idiopathic fever | 2 | 2.4 | 3 | 1.8 | ns |

Logistic regression model was perform prior to this analysis to confirm that no cofounders factors could interfere with the comparison between robotic and laparoscopic approach

RA-GB robot-assisted gastric bypass, L-GB laparoscopic gastric bypass

* Intra-abdominal or intra-lumenal

Learning Curve Analysis for the RA-GB Group

Table 4 presents the comparison of durations for the overall procedure and the main intraoperative steps for the first and the last year of the study. A significant decrease was seen for all of the surgical steps, except for the docking time. Operative duration decreased until the 22nd operation, showed a slightly increase between the 23rd and the 41st (from 133 to 141 min) to finally drop again after the 42nd (Fig. 1).

The first complication occurred in the 15th patient. The complication rate dropped after the52nd intervention (Fig. 2).

Discussion

Outcome comparison between RA-GB (from the first patient) and the historical L-GB cohort showed RA-GB to be associated with lower overall complication rate. Of notice, this difference was no longer observed for severe complication rate. Also RA-GB was associated with a shorter hospital stay, without increasing the operative time. Our results support the notion that RA-GB is at least as effective as L-GB. In spite of the fact that the rate of revision surgery was higher in L-GB

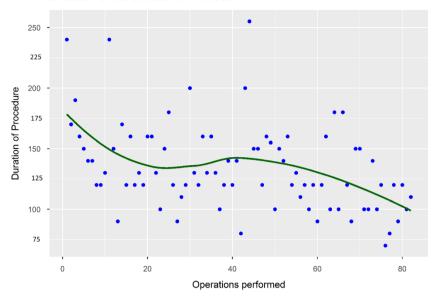
Table 4Comparison of durations for the overall procedure and themain intraoperative steps between patients undergoing RA-GB in 2013and in 2016

| | 2013 Mean | n = 21 [Min– max] | 2016 Mean | n = 20 [Min– max] | р |
|-----------------|--------------|-------------------------|--------------|-------------------------|----------|
| Total duration | 153.3 | [95–195] | 122.3 | [75–215] | 0.004 |
| Docking | 22.9 | [10-45] | 19.3 | [10-50] | 0.206 |
| Console time | 126.0 | [65–175] | 96.0 | [60–180] | 0.002 |
| G-J anastomosis | 21.0 | [13-30] | 14.7 | [8-35] | 0.003 |
| J-J anastomosis | 23.3 | [15-40] | 14.1 | [10-25] | < 0.0001 |

Comparison of the mean with the bilateral Student's t test

G-J gastrojejunal, J-J jejunojejunal

Fig. 1 Operative times (cumulative average duration (in minutes)) for RA-GB (from the first patient). RA-GB: robotic-assisted gastric bypass



Evolution of the Duration of Procedure

group, it was not associated with a higher complication rate. These results are in accordance with the literature that showed all adverse events rate similar to or slightly higher than primary gastric bypass [28]. In the long term, there was no significant difference in the percentage of excess weight loss between the two groups, but the important loss of follow-up rate (35%) observed after 1 year forbids any definitive conclusion.

We were unable to find any randomized trials comparing RA-GB to L-GB. There are, however, numerous monocenter cohorts, a few meta-analyses, and a national cohort study from the USA. The rates of complications for these various studies varied from 11 to 26.2% for L-GB vs. 2.2 to 29% for RA-GB [10–13], which matches the complication rates found in our study.

The rate of anastomotic leak in our study was 3% which compares favorably to the 1%-5% rate usually found in the

literature [29-31] Of notice, the technique used for anastomosis was not the same in the two groups, since we performed manual anastomoses for patients in RA-GB and mechanical anastomoses for patients in L-GB. Concerning this particular subject, the literature provides contradictive results with some reports showing fewer anastomotic leak with robotic approach [9, 12], while others reported the opposite [10, 13, 14]. The meta-analysis by Economopoulos et al., comparing laparoscopic to RA-GB, did not reveal any statistically significant difference in the rate of postoperative leaks (OR = 0.68 [0.32–1.45]), but found fewer anastomotic strictures after RA-GB [16].

Celio et al. [17] compared 2415 RA-GB with 135,040 L-GB over a 7-year period in the American BOLD (bariatric outcome longitudinal database) cohort. They observed a higher rate of complications and leaks and a longer operative

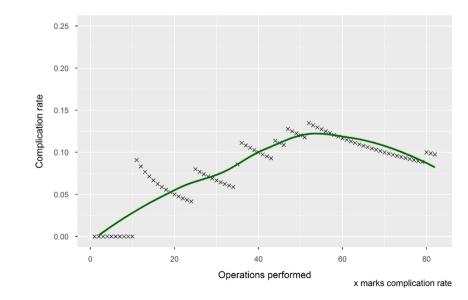


Fig. 2 Evolution of the cumulative complication rate from the first patient in robotic group

time in the RA-GB group. However, because of the poor quality of data (administrative data base) and the fact that the period of analysis (2007 to 2012) corresponds with the beginning of the uptake of the robotic technique in bariatric surgery, its results do not rule off this question. Indeed, due to the lack of tactile feedback, special caution is warranted when handling the small intestines with the robot, and it is probably that a certain number of complications observed at the beginning of the robotic may be overcome later on the learning curve.

We did not find any difference in operative time between the two groups what is in opposition with most comparative studies and meta-analyses that have shown RA-GB to be longer than standard laparoscopic surgery [11, 12, 18, 21, 32–34]. We, as others, found an improvement in operative time [20, 21] along the learning curve.

Our analysis of the learning curve based on the duration of the procedure and the complication rate places the turning point for better results in RA-GB between 40 and 50 procedures, whereas 50–100 procedures have been reported to be necessary for L-GB [35].

We found that the percentage of excess weight loss at 1 year did not differ statistically between patients undergoing RA-GB or L-GB which is in accordance with the literature [12, 18, 19, 36, 37]. We observed a high percentage of loss to followup at 1 year, but this is similar to other studies [15].

We found fewer complications in the RA-GB group. However, our study has the classical drawbacks of nonrandomized comparisons. Also, the single-center nature of this analysis and the low volume potentially limit its generalizability, but at opposite, this allow to avoid surgical variation and for that reason to evaluate only the surgical technique link to the device. Herein, postoperative care may have evolved and data in the L-GB group, which were retrospectively collected, may under-report complications and comorbidities. If, however, the lower rate of complications observed in RA-GB can be confirmed by other studies, this might be an advantage that should be taken into consideration when the two procedures are compared in the future.

Lastly, cost performance is an important issue regarding robotic surgery. In our institution, each robotic procedure has an additional cost of \notin 3500. Theoretically, as with many other technologies, the price of robotic machines is bound to come down. Furthermore, although this remains to be proven, the additional expenses may someday be offset by the advantages of robot-assisted surgery (e.g., easier dissection of the gastric pouch and faster manual anastomoses).

Conclusion

Notwithstanding the lack of formal proof and the fact that surgeons are naturally enthusiastic persons, we do believe that the use of robots is a significant step forward for surgeons. Although clinical advantage of RA-GB over L-GB may not be unanimous, we can actually estate that RA-GB is a safe and effective procedure in experienced hands.

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Compliance with Ethical Standards

Ethical Approval Statement For this type of study, formal consent is not required.

Informed Consent Statement Does not apply.

Conflict of Interest Disclosure Author 6, Author 3, and Author 4 are proctors for Intuitive Surgical and Covidien. Author 1 and Author 2 have no conflicts of interest or financial ties to disclose.

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