World Journal of Surgery and Surgical Research

Research Article
Published: 11 Nov, 2022

Leaks after One Anastomosis Gastric Bypass at Hight Volume Bariatric Centers

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Abstract

Background: One Anastomosis Gastric Bypass (OAGB) is rapidly gaining popularity and is now the third most common bariatric procedure performed in the world. Leak remains one of the most dreaded complications after OAGB. Data regarding leaks after OAGB is scary.

This study aims to document the incidence, presentation, morbidity, mortality, and management of leaks after OAGB at high-volume bariatric centers.

Methods: We collected data from Electronic medical records of all patients who underwent OAGB performed between January 2017 and December 2021 at Assuta Bariatric Centers (ABCs).

Data included patients' characteristics, surgical procedure, early postoperative complications, and their classification according to Clavien-Dindo classification.

Multivariate logistic regression analysis was performed to identify significant factors contributing to the development of leaks after OAGB.

Results: We identified 6,722 patients who underwent a primary (75.9%) or revisional (24.1%) OAGB procedure at ABCs between January 2017 and December 2021. Their preoperative mean age and Body Mass Index (BMI) was 40.6 ± 11.3 years, and 41.2 ± 4.6 kg/m^2, respectively, and 75.1% were females. A total of 31 patients (0.46%) developed leaks after OAGB. The most common site was at gastro-jejunal anastomosis (71.0%). The median time for diagnosis was 2 (0 to 14) days. Most cases were treated surgically. Intensive care unit admission post-surgery {Adjusted OR=90.067 [(95% CI: 35.469-228.711), p<0.001]}, Year of operation (2017-2018 *vs.* 2019-2021) {Adjusted OR=2.965 [(95% CI: 1.399-6.286), p=0.005]} and smoking {Adjusted OR=3.619 [(95% CI: 1.295-10.11), p=0.014]} were found to be a significant factor for the development of leak post OAGB.

Conclusion: The overall rate of leaks after OAGB is very low. Although yet to be established, a learning curve for OAGB need to be established. Postoperative ICU admission and smoking were found to have significant risk factors for the development of leaks post OAGB. Early surgical treatment is the preferred treatment option.

Keywords: Leak; One anastomosis gastric bypass; Morbid obesity; Postoperative complication

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Received Date: *06 Oct 2022*
Accepted Date*: 04 Nov 2022*
Published Date*: 11 Nov 2022*

Citation:
Sakran N, Raziel A, Hod K, Azaria B, Goitein D, Kaplan U, et al. Leaks after One Anastomosis Gastric Bypass at Hight Volume Bariatric Centers. World J Surg Surgical Res. 2022; 5: 1419.

Introduction

One Anastomosis Gastric Bypass (OAGB), which Rutledge first reported in 1997 [1], has gradually gained wide acceptance in recent years. Nowadays, after two consensus statements, OAGB is considered a recognized bariatric procedure with an acceptable complication rate [2-4]. Reviews of the literature found OAGB to be not inferior in terms of weight loss and remission of obesity-related comorbidities than Roux-en-Y Gastric Bypass (RYGB) [5,6].

Recent bariatric surgery trends analysis in Israel found that OAGB is the most common procedure performed with equal distribution between private and public hospitals [7].

Leaks after OAGB is a dreadful complication. A systemic review of OAGB outcomes reported a mean leak rate is 0.96% (0% to 5%) [8]. It's comparable to other bariatric procedures such as RYGB and Sleeve Gastrectomy (SG) [9,10]. Most leaks arise from Gastrojejunal Anastomosis (GJA). However, leaks can occur in the gastric staple line and even due to iatrogenic causes such as the small bowel and colon [11,12]. Moreover, a series by Genser et al. reported that 57% of leaks were of undetermined origin even after surgical exploration [11].

This study aims to report a large volume ABCs leak rate and define contributing factors for leaks after OAGB.

Materials and Methods

Study design

Using MDClone software, the electronic medical records of all patients who underwent OAGB at the ABCs (4 centers of excellence).

We retrospectively reviewed all patients above 18 years old between January 1st, 2017, and December 31th, 2021, at ABCs. Patients were eligible for bariatric procedures according to the global clinical practice guideline for bariatric surgery [13]. The ABCs database maintains a prospective registry recording preoperative, peri- and post-operative safety and outcomes of all patients undergoing bariatric surgery. Postoperative data were collected *via* a frontal surgeon visit performed 14 days postsurgery and a telephone questionnaire filled by ABCs staff at 30 days postsurgery. Any adverse event was documented in the patient computerized medical records (MDClone).

Patients' baseline characteristics were documented, including demographic data, comorbidities, smoking, and preoperative BMI. Perioperative data included previous bariatric surgery, operative time, additional surgical procedure, length of hospital stay, surgery length, need for blood transfusion, and the need for Intensive Care Unit (ICU) admission post-surgery. Early postoperative adverse events (up to 30 days post-surgery) included readmissions, reoperation, readmission rate, and death were documented. We classified surgical adverse events according to the Clavien-Dindo Classification (CDC). CDC equal or below 2 were defined as minor adverse events, and CDC equal or above 3a were defined as a major adverse event [14].

Assuta Medical Center's ethics committee approved this study.

Definition of leak

The definition of leak itself and the time of onset vary in the literature. We decided to use the definition of leak as a confirmation of anastomosis dehiscence or gastrointestinal content leakage from either suture line or staple line. It can also include the presence of luminal content collection next to the anastomosis or staple line [15,16].

Patients were classified into two groups- a group of patients who had leaks and group who did not have leaks. The two groups were compared and analyzed in order to define prognostic factors for leaks after OAGB.

We categorized the leak site into three groups: GJA, gastric tube, and iatrogenic small bowel perforation. The time of diagnosis was also divided into three groups: Early - up to three days post-operatively, intermediate- 4 to 7 days postoperatively and late- any leak diagnosed on day 8 or later.

Statistical analysis

Analyses were performed using SPSS version 28.0. Continuous variables were reported as mean and Standard Deviation (SD), and qualitative variables were reported as frequencies and percentages.

Univariate analyses (i.e., independent t-test, Mann-Whitney U test, or chi-square test) were used to compare between patients who developed early postoperative leak and patients who did not and to identify potential risk factors related to early postoperative leak after OAGB.

Then, a multivariate logistic regression model using the backward stepwise selection method was applied in order to evaluate which of the predictors are independently associated with postoperative leak. The variables that were chosen to be inserted into the model are those with significant association with postoperative leak, and those with potential clinically significant. All statistical tests were two-tailed and statistical significance was set at $p<0.05$.

Results

General

We identified 6,722 patients who underwent OAGB between January 1st, 2017, and December 31th, 2021, and had completed their 30-day follow-up. The mean age was 40.6 ± 11.3 years, and 5,045 (75.1%) were women. The mean preoperative BMI was 41.2 ± 4.6 kg/m^2. The most common obesity-related co-morbidities were fatty liver (4646 (69.1%)), hyperlipidemia (2501 (37.2%)), type 2 diabetes mellitus (1847 (27.5%) and hypertension (1481 (22.0%)). OAGB was performed as revisional bariatric surgery in 1,617 (24.1%) of the patients, of which LAGB was the most common (1179 (17.5%)). Additional procedure was performed in 1,384 (20.7%) patients. The most common additional procedure was laparoscopic cholecystectomy, performed in 811 (12.1%) surgeries. The total early (<30 days) postoperative complication rate was 3.8%.

Patients' characteristics

Patients' characteristics are summarized in Table 1. Mean age was significantly higher in the leak group (47.2 ± 13.7 *vs.* 40.6 ± 11.5 in the leak and no-leak groups, respectively, p=0.004). Gender distribution, preoperative BMI, and obesity-related comorbidities were comparable between the two groups. The rate of smoker was significantly higher in the leak group (5 cases, 16.1%) and 424 (6.3%) patients in the leak and no leak groups, respectively, p=0.044).

Table 1: Patients' characteristics.

	No Leak (n=6691)	Leak (n=31)	p-value
Age (years) mean±SD	40.6 ± 11.5	47.2 ± 13.7	0.004
Females (%)	5025 (75.1)	20 (64.5)	0.094
Preop. BMI (kg/m^2) mean ± SD	41.2 ± 4.5	41.9 ± 5.1	0.55
Diabetes Mellitus (%)	1836 (27.4)	11 (35.5)	0.317
Hypertension (%)	1474 (22.0)	7 (22.6)	>0.999
Hyperlipidemia (%)	2486 (37.2)	15 (48.4)	0.198
Fatty liver (NAFLD) (%)	4626 (69.1)	20 (64.5)	0.564
OSA(%)	530 (7.9)	2 (6.5)	>0.999
Smoker (%)	424 (6.3)	5 (16.1)	0.044

SD: Standard Deviation; Preop.: Pre-Operative; BMI: Body Mass Index; OSA: Obstructive Sleep Apnea

Table 2: Surgical characteristics.

	No Leak (n=6690)	Leak (n=31)	p-value
Operative time (minutes) mean ± SD (median)	67.2 ± 26.4 (61.0)	81.3 ± 56.8 (65.0)	0.246
Laparoscopic approach (%)	6688 (99.9)	31 (100)	0.999
Length of hospitalization (days) mean ± SD (median, range)	2.2 ± 1.1 (2.0, 1.0-38.9)	7.9 ± 11.3 (4.8, 1.3-55.9)	**<0.001**
Year of Operation - number of cases:			
2017 - 802 (n(%))	791 (98.6)	11 (1.4)	**<0.001**
2018 - 1158 (n(%))	1152 (99.5)	6 (0.5)	0.811
2019 - 1372 (n(%))	1367 (99.6)	5 (0.4)	0.66
2020 - 1567 (n(%))	1563 (99.7)	3 (0.2)	0.087
2021 - 1823 (n(%))	1817 (99.7)	6 (0.3)	0.42
Previous Bariatric surgery (%)	1605 (24.0)	12 (38.7)	0.089
LAGB	1169 (17.5)	10 (32.3)	**0.053**
SG	474 (7.1)	3 (9.7)	0.481
VBG	80 (1.2)	3 (9.7)	**0.006**
Additional Procedure (%)	1384 (20.7)	11 (34.4)	0.077
Post-operative ICU admission (%)	27 (0.4)	9 (29.0)	**<0.001**

MO: Morbid Obese; SO: Super Obese; SSO: Super-Super Obese; SD: Standard Deviation; ICU: Intensive Care Unit; LAGB: Laparoscopic Adjustable Gastric Banding; SG: Sleeve Gastrectomy; VBG: Vertical Banded Gastroplasty

Table 3: Leaks timing and treatment.

Source	Time of Diagnosis		Treatment		
	Type	Number of cases	Surgical	Endoscopic	Conservative
GJA (n=22)	Early (0 days to 3 days)	14	11 (78.6%)	0	3 (21.4)
	Intermediate (4 days to 7 days)	4	3 (75.0%)	0	1 (25.0%)
	Late (≥ 8 dyas)	4	1 (25%)	1 (25%)	2 (50%)
Gastric tube (n=5)	Early (0 days to 3 days)	4	3 (75%)	0	1 (25%)
	Intermediate (4 days to 7 days)	1	0	1 (100%)	0
	Late (≥ 8 dyas)	0	0	0	0
Small bowel (n=4)	Early (0 days to 3 days)	3	3 (100%)	0	0
	Intermediate (4 days to 7 days)	1	1 (100%	0	0
	Late (≥ 8 days)	0	0	0	0

Surgical characteristics

Mean operative time and percentage of laparoscopic cases were comparable between the two groups (Table 2). We identified only 2 cases of open OAGB. Both cases were conversion of Vertical Banded Gastroplasty (VBG) to OAGB. The length of hospitalization was significantly longer in the leak group (7.9 ± 11.3 days *vs.* 2.2 ± 1.1 days, p<0.001). We found a decreasing leak rate along the years of our study, with a significantly higher leak rate in 2017, the first year of our study (11 patients, 1.4%) leaks, p<0.001). The percentage of previous bariatric surgery was higher in the leak group (12 patients, 38.7%) in the leak group *vs.* 1,605 patients (24.0%) in the no-leak group, p=0.089). When we evaluated the different revisional bariatric procedures, we found that these findings were significant in the patients who underwent Vertical Banded Gastroplasty (VBG) and higher in the LAGB but not in the patients who underwent LSG (3 patients, 9.4%), p=0.007, ten patients, 32.3%), p=0.053, and 3 patients (9.4), p=0.481, respectively). The additional procedure was not found to be a significant factor for leaks after OAGB. The postoperative Intensive Care Unit (ICU) admissions were significantly higher in the leak group (27 (0.4%) *vs.* 9 (29.0%) in the leak and no-leak groups, respectively, p<0.001).

Leaks description and treatment

A total of 31 patients (0.46%) developed leaks after OAGB (Table 3). The median time for the diagnosis was 2 (0 to 14) days. GJA was the most common site (22 patients, 71.0%), followed by gastric pouch (5 cases, 16.1%) and iatrogenic small bowel injury (4 patients, 12.9%). In the early leaks (0 to 2) days, most of the cases were treated operatively (78.6%, 75%, and 100% in the GJA, gastric tube, and small bowel, respectively). Conservative treatment was performed in 7 cases, most of whom were GJA leaks. The treatment included NPO, total parenteral nutrition, and broad-spectrum antibiotics. Two cases necessitate drainage of intra-abdominal collection by interventional radiology. Most of the gastric tube leaks were early leaks and were treated surgically (75%). The treatment for leaks from iatrogenic small bowel injury was surgically in 100% of cases. Surgical treatment was successful in all patients except for one in which the small bowel enterotomy was not diagnosed in the first operation and was successfully sutured in the second surgery. We identified four cases that necessitate explorative laparotomy. The first case involved a small bowel injury. Although it was an early leak the patient was presented with severe sepsis, and the surgeon chose to perform an explorative laparotomy. The second case was

Table 4: Surgical adverse events.

	No Leak (n=6690)	Leak (n=31)	p-value
Total early complication (%)	226 (3.4)	9(29.0)	**<0.001**
Bleeding (%)	131 (2.0)	2 (6.5)	0.125
Obstruction (%)	17 (0.3)	2 (6.5)	**0.003**
Infections* (%)	11 (0.2)	3 (9.7)	**<0.001**
CDC ≤ 2(%)	101 (1.5)	4 (12.9)	**0.001**
CDC ≥ 3a (%)	67 (1.0)	7 (22.6)	**<0.001**
Readmission (%)	113 (1.7)	17 (54.8)	**<0.001**
Reoperations (%)	40 (0.6)	21 (67.7)	**<0.001**
Death	0 (0.0)	2 (6.5)	**<0.001**

*Infections include superficial, deep and urinary tract infection
SD: Standard Deviation; CDC: Clavien-Dindo Classification; NA: Not Applicavle

Table 5: Multivariate logistic regression analysis for potential risk factors.

	Adj. OR	95% CI	p-value
Age	1.03	0.997-1.065	0.072
Smoking	3.619	1.295-10.11	**0.014**
Year of Operation (2017-2018 *vs.* 2019-2021)	2.965	1.399-6.286	**0.005**
ICU Admission	90.067	35.469-228.711	**<0.001**
Gender, Women	0.661	0.306-1.426	0.291
Previous Bariatric Surgery	1.541	0.710-3.344	0.274

The model was calculated using stepwise method
Adj. OR: Adjucent Odds Ratio; CI: Confidence Interval; ICU: Intensive Care Unit

an intermediate leak from small bowel that was treated with suture and prolonged parenteral nutrition afterward. The third case was an intermediate leak from small GJA that was treated first by suture, and after failure, RYGB reconstruction was performed. The last case was a late GJA leak. The patient presented with severe sepsis and underwent emergent laparotomy with suture of the leak.

Surgical adverse events

As seen in Table 4, the total early postoperative complication rate was significantly higher in the leak group (9 patients (29.0%) *vs.* 226 patients (3.4%), p<0.001). The most common adverse event was bleeding, which was comparable between the two study groups. The rate of obstruction and infections was significantly higher in the leak group compared to the no-leak group (2 patients (6.5%) and 3 (9.7%) *vs.* 17 patients (0.3%) and 11 (0.2%), p=0.003 and p<0.001, respectively). The rate of minor and major postoperative complications, according to the CDC, the rate of readmission and reoperation were significantly higher in the leak group (Table 4).

We identified 2 cases of mortality within 30 days postsurgery. Both cases were in the leak group. One patient developed septic shock due to leak at the GJA, and the second event occurred post a leak at the GJA, which developed after successful endoscopic treatment for intraluminal bleeding.

Multivariate analysis

We performed a multivariable logistic regression analysis to assess potential risk factors for postoperative leak after OAGB. Intensive care unit admission post-surgery {Adjusted OR=90.06 [(95% CI: 35.46-228.71), p<0.001]}, year of operation (2017-2018 *vs.* 2019-2021) {Adjusted OR=2.965 [(95% CI: 1.399-6.286), p=0.005]} and smoking {Adjusted OR=3.619 [(95% CI: 1.295-10.11), p=0.014]} were found to be a significant factor for the development of leaks after OAGB (Table 5).

Table 6: Studies of leaks post OAGB.

Authur	No. of patients	Leak s n (%)	Year
Noun et al. [26]	1000	7 (0.7)	2012
Musella [12]	2678	5 (0.18)	2017
Parmar et al. [8]	12807	0.96%	2018
YOMEGA study [5]	117	1 (0.85)	2019
Liagre et al. [29]	2670	46 (1.7)	2019
Current study	6722	31 (0.46)	

Discussion

The purpose of this study was to review and analyze our leaks after OAGB leak cases in order to define prognostic factors. Overall, our leak rate was 0.46% which is comparable to the current literature [8]. We found that OAGB has a significant learning curve which should be further defined. Age, smoking, year of operation, ICU admission, and previous bariatric surgery influence the incidence of leaks. However, multivariate Analysis found only smoking, ICU admission, and year of surgery as significant factors for leak occurrence after OAGB.

Age is not considered a risk factor for the development of complications after bariatric surgery. A systemic review found equal outcomes and complication rates in elderly patients compared to younger populations [17]. We found that patients who had leaks after OAGB were significantly older (47.2 ± 13.7 *vs.* 40.6 ± 11.5, p=0.004). The multivariate analysis found a trend toward age as a factor that could influence the rate after OAGB leak. However, Their findings were not statistically significant. A multivariate analysis on the MBSAQIP data registry found age as a statistically significant independent prognostic factor for leaks after RYGB [18]. Further research is needed to evaluate the influence of age on complications post OAGB.

Smoking is considered a risk factor for post-bariatric surgery complications [19]. A study evaluating 30 days outcome of bariatric surgery based on MBSAQIP found that smoking was a significant risk factor for leaks after RYGB {RR=1.78 [(95% CI 1.33-2.39), p<0.001]} [20]. We found that smokers had significantly higher risk of developing leaks after OAGB {Adjusted OR=3.619 [(95% CI: 1.295-10.11), p=0.014]}. Kermansaravi et al. recommend stopping smoking 6 weeks before OAGB and never restarting smoking again [21]. In Israel, smoking is not considered a contraindication for OAGB. Based on our results, new Israeli preoperative guidelines should address this subject and consider smoking a contraindication for OAGB.

Bariatric procedures have a learning curve, and OAGB is no exception. The impact of learning curve on surgical outcomes and adverse events is well known. However, it was never clearly defined. According to a recent systemic review, the learning curve in SG varies between 30 to 200 cases, and in RYGB varies between 30 to 500 patients [22]. One of the main reasons for leak after bariatric surgery is technical error of the surgeon. We defined that the leak rate is correlated to the surgeon's learning curve. Our study found significant higher risk for leak after OAGB in the first two years of our study (2017-2018) compared to the last three years (2019-2021) {Adjusted OR=2.965 [(95% CI: 1.399-6.286), p=0.005]} (Table 5). The first OAGB surgery in Israel was performed in 2015, and since then, the rate of the procedure has gradually increased. The number of surgeons in our study was high. Hence it would be difficult to deduce the number of cases for the learning curve of OAGB. Furthermore, most surgeons are experienced bariatric surgeons who perform OAGB in the public system. It seems that the learning curve of OAGB is less steep than RYGB, as was found in another study that evaluates the learning curve of OAGB [23]. Further research regarding the number of surgeries needed in order to master the procedure with an acceptable adverse events rate is needed.

The outcome and adverse events of revisional bariatric surgery are worse than primary procedure [24]. Our study confirms these findings in cases of previous VBG and trend higher leak rate after LAGB. The rate of leak was not significantly higher after SG. Further research is needed to address this subject.

We found that leaks were associated with significantly higher rate of other adverse events. There were higher rate of obstruction, infection, readmissions, reoperation, and deaths in the leak group compared to the no-leak group. Similar findings were found in another study that compared outcomes of leaks after RYGB [18]. Leaks after bariatric surgery are considered a dreadful complication, and these results highlight the importance of early detection and prompt treatment for this complication.

Postoperative ICU admission was a significant factor in the development of leaks. Masoomi et al. identified multiple factors associated with higher risk for leak after RYGB [25]. They include open surgery, congestive heart failure, chronic renal failure, age above 50 years, male sex, and chronic lung disease. Genser et al. found that hypertension and heavy smoking were predicting factors for leaks after OAGB [11]. Our multivariate analysis found smoking as a significant factor as well. However, in terms of obesity-related comorbidities, only postoperative ICU admission, usually reserved for patients with severe lung or cardiac disease, was found to be a significant risk factor after OAGB leak. Further research is needed to define predisposing factors for leak development after OAGB.

As seen in Table 6, different studies report an overall leakage rate ranging from 0.1% to 1.7%, which is comparable to our study (0.46%). The median time for diagnosis in our study was 2 (0 to 14) days, as compared to another study [26,27], and shorter than other publications (up to 10 days) [11,28]. This could be attributed to thorough patient education and short follow-up post-surgery interval that ABCs staff perform. As in other publications, the most common leak site was at the GJA [11,28]. The most common leak site was at the GJA (71.0%). Most publications reported the same [21,28], while in others, the gastric tube was the most common site [25,29]. Patients with GJA leak has more severe initial presentation than other location. They are usually transferred to the OR for further treatment. In our study group, 68.2% of patients with GJA leak were treated surgically compared to lower-rated surgical treatment (60%) in gastric tube leak. Aggressive treatment, including early laparoscopy with re-exploration of the anastomosis and gastric pouch, reduce morbidity and mortality [11,25,27]. In our study, the majority of treatments involved surgery which is a common practice and could be due to the fact ABCs is a private hospital that prefers a fast solution with shorter length of hospitalization. With that being said, Liagre et al. [29] which practice in private hospitals, published a paper showing higher rate of conservative treatment (72%). They concluded that the management of leak after OAGB should be guided by the clinical presentation and the presence, location, and size of the abscess and/or leak.

Our study is not without limitations. First, this is a retrospective study. Second, the study is based on surgeries performed in a private hospital. In Israel, most surgeons perform difficult cases in the public hospital, leading to selection bias. With that being said, the large population study strengthens this study significantly.

Conclusion

OAGB is a safe bariatric procedure with low leak rate. It has a learning curve that needs to be defined. The most common site of leak is the GJA, and surgical treatment is the most common treatment option with excellent results. Smoking and postoperative ICU admission was found to be significant risk factors for the development of leaks after OAGB.

Ethical Standards/Human and Animal Rights

The study was approved by the Assuta Medical Centers' ethics committee (approval number 43-20-ASMC).

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