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# **Research Article**

# Early Safety Outcomes of Laparoscopic One Anastomosis Gastric Bypass in Patients with Class III, IV and V Obesity

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## ARTICLEINFO

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# ABSTRACT

Background: Recent studies have reported higher postoperative complication rates in patients with severe obesity who undergo bariatric surgery. The extremely obese patient deserves special consideration: significant comorbidities, technical difficulties, and increased postoperative morbidity and mortality are all expected in this patient population. Current data are limited and discrepant on the relationship between patients with class IV obesity (body mass index (BMI) ≥50-59.9 kg/m<sup>2</sup>), and class V obesity (BMI ≥60 kg/m<sup>2</sup>). This study compared early postoperative complications (≤30-day) following one-anastomosis gastric bypass (OAGB) morbidity in patients with class III, IV, and V obesity. Methods: Retrospective analysis of perioperative OAGB outcomes in three BMI groups at a high-volume hospital. Operative time, length of stay (LOS), and overall early postoperative complication rates were studied. Complications were ranked by Clavien-Dindo classification (CDC). Results: Between January 2017-December 2021, consecutive patients with obesity class III (n=2,950), IV (n=256), and V (n=23) underwent OAGB. BMI groups were comparable in gender, age, and associated comorbidities. Mean operative time was significantly longer in the higher BMI groups: class III (66.5±25.6 min), IV (70.5±28.7 min), and V  $(80.0\pm34.7 \text{ min})$ , respectively (p= 0.018); no difference in LOS. In respective BMI classes,  $\leq$ 30-day complication rates were 3.2%, 3.5%, and 4.3% (p=0.926). The respective number of patients with CDC grades of 1-2 were 45 (1.5%), 6 (2.3%), and 1 (4.3%), p=0.500; and in grade  $\geq 3a$ , 25 (0.8%), 1 (0.4%), 0 (0.0%), p= 0.669. No significant differences in rates of early complications, reoperations, and readmissions were found in revisional patients across BMI groups. There was 0.06% mortality (n= 2 in 3,229), both in BMI class III. Conclusion: OAGB is a safe metabolic bariatric surgery procedure in patients with class III, IV, and V obesity in the perioperative term with comparable  $\leq$ 30-day morbidity in the three BMI groups.

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# 1. Introduction

Class III obesity is defined as body mass index (BMI)  $\geq$ 40-49.9 kg/m<sup>2</sup>, Class IV obesity as BMI  $\geq$ 50-59.9 kg/m<sup>2</sup>, and Class V as BMI  $\geq$ 60 kg/m<sup>2</sup>. The prevalence of higher obesity classes is increasing [1, 2]. Patients with class IV and class V obesity suffer greatly from associated comorbidities (e.g., type 2 diabetes, hypertension, hyperlipidemia, obstructive sleep apnea). They may benefit from metabolic bariatric surgeries (MBS), yet their higher BMIs may also be associated with increased perioperative risks [3-7]. Significant comorbidities, technical difficulties, and increased postoperative morbidity and mortality are all expected in the extremely obese patient population.

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Performing any MBS procedure in patients with class IV and V obesity can be challenging, especially due to the thickening of the abdominal wall and abundant adipose tissue. The one-anastomosis gastric bypass (OAGB) procedure first reported by Rutledge *et al.* in 1997 [8, 9] has gradually gained wide acceptance and was recently endorsed by the American Society for Metabolic and Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) [10]. Several studies have reported OAGB outcomes in high-BMI cohorts and found comparable 30-day safety results relative to sleeve gastrectomy (SG) [11-14]. In addition, a systematic review comparing OAGB, Roux-en-Y gastric bypass (RYGB), and sleeve gastrectomy (SG) concluded that OAGB was an equally safe and effective operation for managing patients in high BMI groups [15].

The current study of early OAGB outcomes was conducted at a highvolume bariatric center in Israel [16]. A survey by the Israel Central Bureau of Statistics conducted in 2017 found that 48% of the Israeli population above the age of 20 were overweight or obese [17]. Analysis of trends in MBS in Israel found that over the last several years, the most commonly performed MBS procedure shifted from SG to OAGB [5]. The aim of this study was to evaluate the perioperative safety of OAGB in patients with class IV and V obesity in comparison with those with class III obesity.

## 2. Methods

# 2.1. Study Design

Retrospective cohort study utilizing data that was retrieved from electronic medical records. Data collected included pre-, peri-, and 30-day postoperative outcomes of 3299 primary and revisional OAGB procedures that were conducted at the Assuta Bariatric Centers (ABCs). Patients with class IV or V obesity were compared to those with class III looking at baseline characteristics, operative factors, and  $\leq$ 30-day postoperative complications. The study protocol was approved by the institutional review board (43-20-ASMC 13/9/2020). Informed consent was waived due to the retrospective and anonymous nature of data collected. All patients above the age of 18 years who underwent OAGB between January 1, 2017 and December 31, 2021 and had class III, IV, or V obesity were included.

#### 2.2. Study Procedure and Outcomes

All operative data (operative time, laparoscopic or other approaches, length of stay in hospital [LOS], prior MBS procedures, additional procedures) and operative follow-up were recorded by the multidisciplinary surgical team into patients' electronic medical records as were complications during the first 30 postoperative days. Complications were categorized according to the Clavien-Dindo classification (CDC) [18]. Complications ranked as a CDC grade 1-2 was regarded as minor, while a CDC grade  $\geq$ 3a-5 were termed as major

TABLE 1: Patient characteristics.

events. The standardized surgical technique and postoperative care regimen for OAGB used in our center have been detailed previously [19].

#### 2.3. Statistical Analysis

Analyses were performed using the IBM SPSS statistical package (version 28.0, SPSS Inc, IBM Corp., Armonk, NY). Continuous variables were presented as means and standard deviations (SD), while categorical variables were presented as frequencies and percentages. Data normality was assessed using the Kolmogorov-Smirnov test. Between group differences were analyzed using the Kruskal-Wallis test, Chi-square test, or Fisher's exact test, as appropriate. All statistical tests were two-tailed, and statistical significance was set at p<0.05. For multiple comparisons, a false detection rate (FDR) <0.1 was considered significant.

#### 3. Results

# **3.1.** Patient Characteristics

Between January 1, 2017, and December 31, 2021, eligible 3,229 patients underwent OAGB, and completed their 30-day follow-up. Mean age was  $39.0\pm11.8$  years, and 2,361(73.1%) were women. Mean preoperative BMI was  $44.2\pm4.0$  kg/m<sup>2</sup>. The most common obesity-related comorbidity was hyperlipidemia (1,137; 35.2%), followed by type2 diabetes mellitus (T2DM) (824; 25.5%). OAGB was performed as revisional MBS in 687 (21.3%) patients, and an additional procedure was performed in 623 (19.3%) patients. The total early (<30 days) postoperative complication rate was 3.2%. Most of the patients were classified as class III obesity (2,950; 91.4%), followed by IV (256; 7.9%) and V (23; 0.7%) obesity. There were no differences between these three groups with regard to baseline patients' characteristics, except BMI (43.3±2.6, 53.3±2.5, and 62.23±1.9 kg/m<sup>2</sup> in patients with class III, IV, and V obesity, respectively; p<0.001) (Table 1).

#### **3.2. Surgical Characteristics**

The mean operative time was significantly longer as BMI increased. Respective mean operative time in class III, IV, and V was  $66.5\pm25.6$ ,  $70.5\pm28.7$ , and  $80.0\pm34.7$  minutes; p=0.018. Length of hospitalization was similar across groups with no statistically significant difference. The most common previous MBS procedure was laparoscopic adjustable gastric banding (LAGB), followed by SG. In respective class III, IV, and V groups, 465 (15.8%), 37 (14.5%), and 5 (2.7%) patients had a history of previous LAGB (p=0.624). Laparoscopic cholecystectomy, performed in 392 (12.1%) patients, was the most common additional procedure, followed by repair of diaphragmatic (hiatal) hernia in 196 (6.0%) patients. There was no statistical difference between the three study groups in terms of previous MBS type or additional procedures (Table 2).

	Obesity Class III	Obesity Class IV	Obesity Class V	P-value	
	(n=2,950)	(n=256)	(n=23)		
Age (years) mean $\pm$ SD	39.0±11.7	38.5±12.5	42.5±13.9	0.329	
Females, n (%)	2,173 (73.7)	171 (66.9)	17 (73.9)	0.059	

Preop. Bl	MI (kg/m <sup>2</sup> ) mean $\pm$ SD	43.3±2.6	53.3±2.5	62.23±1.9	< 0.001
Smoker, i	n (%)	181 (6.1)	20 (7.8)	2 (8.7)	0.509
Comorbio	lities				
•	Type 2 diabetes mellitus, n (%)	766 (26.0)	51 (19.9)	7 (30.4)	0.090
•	Hypertension, n (%)	555 (18.8)	47 (18.4)	8 (34.8)	0.146
•	Dyslipidemia, n (%)	1046 (35.5)	83 (32.4)	8 (34.8)	0.621
•	Fatty liver (NAFLD), n (%)	2,024 (68.6)	173 (67.6)	18 (78.3)	0.571
•	OSA, n (%)	210 (7.1)	25 (9.8)	3 (13)	0.119

Obesity Class III, body mass index [BMI] ≥40-49.9 kg/m<sup>2</sup>; Obesity Class IV, BMI ≥50-59.9 kg/m<sup>2</sup>; Obesity Class V, BMI ≥60 kg/m<sup>2</sup>. Preop: Preoperative: BMI: Body Mass Index; NAFLD: Non-alcoholic Fatty Liver Disease; OSA: Obstructive Sleep Apnea; SD: Standard Deviation.

#### TABLE 2: Surgical Characteristics.

	Obesity Class III	Obesity Class IV	Obesity Class V	D b	
	(n=2,950)	(n=256)	(n=23)	P-value	
Operative length (minutes)	66.5±25.6	70.5±28.7	80.0.247.((2.0)	0.010	
mean±SD (median)	(61.0) (64.0)		80.0±34.7 (62.0)	0.018	
Laparoscopic approach, n (%)	2,948 (99.9)	254 (99.6)	23 (100.0)	>0.999	
	2.2±1.1	2.4±1.9	2.3±0.4	0.121	
Length of hospitalization (days) mean±SD (median, range)	(2.0, 1.9-2.2)	(2.0, 1.9-2.2)	(2.1, 1.9-2.6)	0.131	
Previous Bariatric surgery, n (%)	638 (21.6)	44 (17.2)	5 (21.7)	0.250	
• LAGB, n (%)	465 (15.8)	37 (14.5)	5 (2.7)	0.624	
• LSG, n (%)	185 (6.3)	11 (4.3)	0 (0.0)	0.211	
• VBG, n (%)	37 (1.3)	5 (2.0)	0 (0.0)	0.548	
Additional Procedure, n (%)	573 (19.4)	48 (18.8)	2 (8.7)	0.419	
• Diaphragmatic hernia repair <sup>1</sup> , n (%)	176 (6.0)	19 (7.4)	1 (4.3)	0.608	
• Cholecystectomy <sup>1</sup> , n (%)	364 (12.3)	27 (10.5)	1 (4.3)	0.363	
• Partial gastrectomy <sup>1</sup> , n (%)	45 (1.5)	5 (2.0)	0 (0.0)	0.724	
• Ventral hernia repair <sup>1</sup> , n (%)	30 (1.0)	3 (1.2)	0 (0.0)	0.863	

Obesity Class III, body mass index [BMI]  $\geq$ 40-49.9 kg/m<sup>2</sup>; Obesity Class IV obesity, BMI  $\geq$ 50-59.9 kg/m<sup>2</sup>; Obesity Class V obesity, BMI  $\geq$ 60 kg/m<sup>2</sup>. SD: Standard Deviation; LAGB: Laparoscopic Adjustable Gastric Banding; LSG: Laparoscopic Sleeve Gastrectomy; VGB: Vertical Banded Gastroplasty. <sup>1</sup>Additional procedures during the surgery - could be more than one additional procedure in one surgery.

## 3.3. Surgical Adverse Events

The respective early postoperative complication rate ( $\leq 30$  days) was comparable between study groups (95 [3.2%], 9 [3.5%], 1 [4.3%]; p=0.926) (Table 3). The percentages of total complications by CDC grade, class III, IV, and V groups, and primary and revisional OAGB are presented in (Figure 1). CDC 2 is the most frequent grade, with higher

presentation among class IV obese patients (2.3%) compared to class III (1.6%), and among revisional OAGB (1.4%) compared to primary OAGB (1.3%) as well. The distribution of minor complications (CDC grade  $\leq 2$ ) and major complications (CDC grade  $\geq 3a-5$ ) over the study period is presented in (Figure 2) by primary and revisional OAGB. There is a decreasing trend in minor and major complications over the study period.

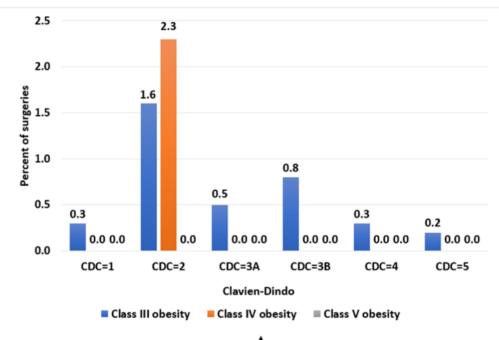
#### **TABLE 3:** 30-Days postoperative adverse events.

	Class III obesity		Class IV obesity		Class V obesity		P-value	
	Total	Revisional	Total	Revisional	Total	Revisiona	Total/	
	(n=2950)	(n=638)	(n=256)	(n=44)	(n=23)	l (n=5)	Revisional	
Total Early Complication (<30 Day), n (%)	95 (3.2)	29 (4.5)	9 (3.5)	2(4.5)	1(4.3)	0 (0.0)	0.926/0.888	
• Bleeding, n (%)	51 (1.7)	14 (2.2)	5 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.787/0.578	
• Leak, n (%)	10 (0.3)	5 (0.8)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0.952/0.824	
• Obstruction, n (%)	2 (0.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.910/NA	
• Small bowel injury, n (%)	1 (0.03)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.954/0.962	
<ul> <li>Respiratory complications, n (%)</li> </ul>	6 (0.2)	3 (0.5)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.753/0.891	
• Infection, n (%)	4 (0.1)	1 (0.2)	1 (0.4)	1 (2.3)	0 (0.0)	0 (0.0)	0.598/0.042	
• Acute renal failure, n (%)	3 (0.1)	2 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.868/0.926	
CDC≤2, n (%)	45 (1.5)	12 (1.9)	6 (2.3)	1 (2.3)	1(4.3)	0 (0.0)	0.500/0.937	
DC≥3A, n (%)	25 (0.8)	11 (1.7)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0.669/0.651	
Carly readmission (<30 days), n (%)	47 (1.6)	15 (2.4)	4 (1.6)	2 (4.5)	1 (4.3)	0 (0.0)	0.568/0.622	

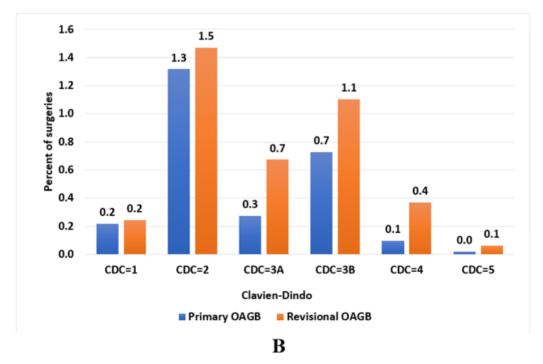
Early reoperations (<30 days), n (%)	17 (0.6)	5 (0.8)	1 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)	0.871/0.824
30-day mortality rate, n (%)	2 (0.06)	1 (0.16)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.910/0.962

FDR (false discovery rate) > 0.950 for all of the above comparisons.

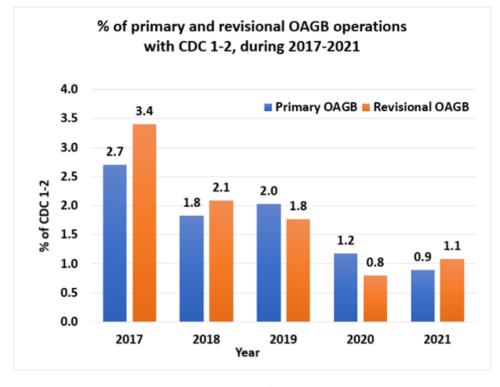
Obesity Class III, body mass index [BMI]  $\geq$ 40-49.9 kg/m<sup>2</sup>; Obesity Class IV, BMI  $\geq$ 50-59.9 kg/m<sup>2</sup>; Obesity Class V, BMI  $\geq$ 60 kg/m<sup>2</sup>. SD: Standard Deviation; CDC: Clavien-Dindo Classification; NA: Not applicable.



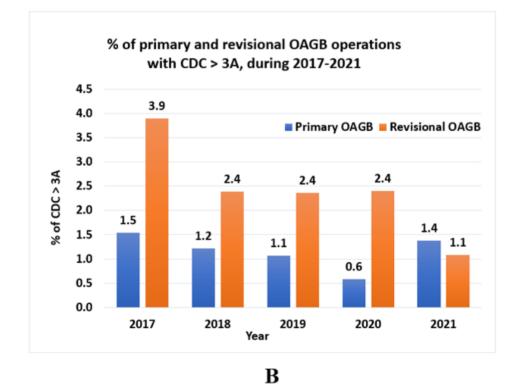




**FIGURE 1:** Percent of total OAGB procedures with complications within Clavien-Dindo Classification (CDC) categories (n=3,229) in patients with **A**) class III (BMI $\geq$ 40.0 kg/m<sup>2</sup>), class IV (BMI $\geq$ 50.0 kg/m<sup>2</sup>) or class V (BMI $\geq$ 60.0 kg/m<sup>2</sup>) obssity; and **B**) primary and revisional patients.



Α



**FIGURE 2:** Percent of primary and revisional OAGB procedures by year (2017-2021) with complications within Clavien-Dindo Classification [CDC]: **A**) grade 1-2, and **B**) grade 3a-5.

The most common adverse event was bleeding (56; 1.7%). In class III and IV, respectively, 28 and 4 cases of extra-luminal bleeding and 23 and 1 cases of intra-luminal bleeding were identified. There were no cases of bleeding in the class V group. There was no statistical difference between the three obesity groups in term of early postoperative complications, including early readmission and reoperation, as well as the postoperative intensive care unit admissions (Table 3). The most common reason for reoperation due to bleeding and 7 cases due to leak in the class III group. There was only one case of reoperation in the class IV group due to bleeding from the staple line. There were no reoperations in the class V group.

Similarly, the rate of early complications, reoperations, and readmissions post revisional OAGB surgeries were similar in all three BMI groups (Table 3). Only two revisional cases have developed infection 30 days post-operation, one case relates to class III and the other to class IV. In class V there was no infection event; after adjusting to multiple comparisons, infection rate was not different between the BMI groups (p=0.042, FDR>0.999). We identified only 1 adverse event in the class V group, a 43-year-old male patient with a BMI of 63.0 kg/m<sup>2</sup> who underwent an uneventful OAGB surgery. He was readmitted one week later due to abdominal pain. Computed tomography of the chest and abdomen was normal, and he was discharged home the following day.

There were 2 deaths within 30 days of surgery (mortality rate: 0.06%). Both cases were in the class III group. One patient developed septic shock due to leak at the gastroenteroanastomosis (GEA). The second event occurred following a leak at the GEA, which developed after successful endoscopic treatment for intra-luminal bleeding.

# 4. Discussion

In the last several years, the most frequently performed MBS procedure in Israel is OAGB. We aimed to evaluate the perioperative outcomes of primary and revisional OAGB patients with class IV and V obesity relative to class III obesity in a sample of 3,229 consecutive patients. Postoperative patient-reported complications did not differ in level of CDC severity across BMI groups or in the primary vs. revisional cohorts. Mortality was low (n=2; 0.06%) and was limited to patients with class III obesity. Although the class III group was markedly larger, no statistically significant difference in the proportion or severity of overall  $\leq$ 30-day complications was observed except for the length of operative time, which increased as the BMI class increased.

Prior MBS studies have found that BMI is an independent predictor of operative time [20, 21], and that prolonged operative time is directly correlated with increased MBS complications [22, 23]. Yet, in the current OAGB-specific study, although operative time was higher in each respective BMI class (III, IV, V:  $66.5\pm25.6$ ,  $70.5\pm28.7$ , and  $80.0\pm34.7$  minutes; p= 0.018), this difference did not increase the rates of  $\leq$ 30-day complications, reoperations, or readmissions.

A survey of 789 MBS surgeons worldwide regarding selection of surgery and management of patients with class IV obesity found that identifying the safest effective procedure for high-BMI patients was a primary challenge [24]. With respect to OAGB, a recent systematic review by Parmar et al. that directly compared OAGB to SG and RYGB in class IV and V obesity concluded that the safety of OAGB was equivalent to that of the other two procedures [15]. Still, the existing evidence conflicts on the topic of perioperative complications in higher-BMI patients after OAGB, SG, and RYGB. Nasser et al. national database analysis comparing perioperative outcomes of high-BMI classes after SG and RYGB found statistically significant differences between groups in complications, readmissions, and mortality but not in terms of reoperations [25]. Gray et al., in a study of perioperative outcomes after robotic SG and RYGB in BMI class III, IV, and V patients, matched in baseline characteristics, and Singhal et al., in a propensity score-matched analysis of high-BMI OAGB, SG, and RYGB patients found no significant differences in intraoperative complications, operative time, postoperative complications, or readmissions between groups [26, 27]. Studies specific to OAGB in comparison to SG in high-BMI patients found comparable rates of early complications [11, 12, 14, 281.

Evidence also varies in reports of non-OAGB MBS procedures that focus on elevated comorbidities in patients with class IV and V obesity. Some studies show a direct correlation between the disease burden and incidence of  $\leq$ 30-day morbidity and mortality compared to those with class III obesity [28-30]. In the current study, the higher rate of comorbidities in the class V group was not significantly different from that of the class III and IV groups and thus could not be directly compared to other studies.

In the current study, the early OAGB postoperative complication rate inclusive of all BMI categories and both primary and revisional procedures was 3.2-4.3%, with no mortality in the two highest BMI classes. We found a trend toward a higher rate of total early adverse events in the two highest BMI groups, but this did not reach statistical significance (p=0.926). Moreover, this difference was not found in revisional surgery. Long-term, rigorous study designs, with higher representation of class V obesity, are needed to facilitate more precise comparisons of perioperative complications between high-BMI groups.

# 5. Conclusion

OAGB was a safe MBS procedure in patients with BMI class IV and V without a significantly increased risk of complications compared to patients with class III obesity. These findings were consistent across primary and revisional surgeries. Further investigation of both perioperative and long-term complications is needed in patients with class IV and V obesity undergoing OAGB.

#### Limitations and Strengths

The main strength of this study is the large sample size. There are several limitations of the study. First, the main outcome of this study, early postoperative complications, were monitored by telephone calls performed 30 days post-surgery. This may result in missing data lack of compliance. However, patients are also instructed to attend the center where the operation was performed in case of any complication during the first 30-day post-surgery. This procedure ensures that there are no complications that could have been missed, even among patients that refused to complete the telephone survey. Next, although the general

study sample size is notably large, the BMI groups were unbalanced, and class V group had insufficient power due to its extreme condition. Further, we investigated only early postoperative complications, and long-term adverse were not evaluated. However, outcomes of several large mid- and longer-term OAGB patient series have been published [31-35], but very short-term safety studies are less common. Last but yet important, as surgeons preferred to perform the more difficult cases in public rather than private hospitals, the potential for selection bias may exist. Moreover, all OAGB surgeries that were included in this study were performed by highly experienced bariatric surgeons. Therefore, our results may not be generalizable to OAGB procedures carried out at public hospitals or by less experienced surgeons.

#### **Conflicts of Interest**

None.

#### Acknowledgments

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# Statement of Ethics

The study protocol, and all procedures of the study were approved as compliant with the medical center's ethical standards.

# **Informed Consent**

Informed consent was waived due to the retrospective and anonymous nature of data collected.

#### Ethical Standards / Human and Animal Rights

The study was approved by the Assuta Medical Centers' ethics committee (43-20-ASMC 13/9/2020).

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