

One-Anastomosis Gastric Bypass Versus Sleeve Gastrectomy for Morbid Obesity: a Systematic Review and Meta-analysis

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Abstract We aim to review the available literature on obese patients treated with one-anastomosis gastric bypass (OAGB) or laparoscopic sleeve gastrectomy (LSG), in order to compare the clinical outcomes and intraoperative parameters of the two methods. A systematic literature search was performed in PubMed, Cochrane Library, and Scopus databases, in accordance with the PRISMA guidelines. Seventeen studies met the inclusion criteria incorporating 6761 patients. This study reveals increased weight loss, remission of comorbidities, shorter mean hospital stay, and lower mortality in the OAGB group. The incidence of leaks and intra-abdominal bleeding was similar between the two approaches. Well-designed, randomized controlled studies, comparing LSG to OAGB, are necessary to further assess their clinical outcomes.

Keywords One-anastomosis gastric bypass · Sleeve gastrectomy · Obesity · Bariatric surgery · OAGB

Introduction

Obesity is a rising epidemic, and bariatric surgery continues to be the main therapeutic modality for a high rate of sustainable weight loss [1] and enhanced metabolic profile [2]. A standalone bariatric procedure that currently has gained increased popularity is laparoscopic sleeve gastrectomy (LSG) [3, 4]. In fact, LSG was the most frequent bariatric procedure in the USA in 2013 [5]. LSG is a mainly restrictive procedure that preserves the normal gastrointestinal continuity without any anastomoses.

One-anastomosis gastric bypass (OAGB) is also an alternative safe, feasible, and effective bariatric procedure [6]. It employs a long gastric tube in conjunction with an antecolic loop gastrojejunal anastomosis [7]. Since the landmark study of Rutledge [7], additional reports [8, 9] have demonstrated excellent outcomes in obese patients treated with OAGB. As

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the number of studies assessing the feasibility of OAGB increases, it is necessary to examine whether the results between the two techniques are at least equivalent. The purpose of this study is to summarize the existing evidence comparing the surgical outcomes of OAGB and LSG in the treatment of morbid obesity.

Materials and Methods

Search Strategy and Article Selection

The present study was conducted in accordance with the protocol agreed by all authors and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses [10]. A thorough literature search was performed in PubMed (Medline), Cochrane Central Register of Controlled Trials (CENTRAL), and Scopus (Elsevier) databases (last search: June 3, 2017) using the following terms in every possible combination: “omega loop,” “one anastomosis,” “single-anastomosis,” “mini-gastric bypass,” and “sleeve gastrectomy.” Inclusion criteria were (1) original reports with >10 patients, (2) written in the English language, (3) published from 1980 to 2017, (4) conducted on human subjects, and (5) reporting outcomes of LSG or OAGB on obese patients. Two independent reviewers (DEM and VST) extracted the data from the included studies. Any discrepancies between the investigators about the inclusion or exclusion of studies were discussed with the guarantor author (DZ) in order to include articles that best matched the criteria, until consensus was reached. Moreover, the reference lists of all included articles were assessed for additional potentially eligible studies.

Data Extraction

For each eligible study, data were extracted relative to demographics (number of patients, mean age, sex, comorbidities, preoperative body mass index (BMI)) and to the intraoperative parameters and outcomes (mean operative time, mean hospital stay, bougie diameter, revisions, intraoperative and postoperative complications, remission of comorbidities, and percentage of excess weight loss (%EWL) after 12 and 24 months). Two authors (DEM and VST) performed the data extraction independently and compared the validity of the data. Any discrepancies were discussed with the guarantor author (DZ), until consensus was reached.

Statistical Analysis

Based on the extracted data, regarding the categorical outcomes, the odds ratios (ORs) and 95% confidence interval

(CI) were calculated, based on the extracted data, by means of random-effects model (the Mantel-Haenszel statistical method), where the number of studies providing data was sufficient. OR <1 denoted outcome was more frequent in the OAGB group. Continuous outcomes were evaluated by means of weighted mean difference (WMD) with its 95% CI, using random-effects (inverse variance statistical method) models, appropriately to calculate pooled effect estimates. In cases where WMD <0, values in the OAGB group were higher. We chose the random-effects model because we did not expect that all the included studies would share a common effect size. Between-study heterogeneity was assessed through Cochran’s Q statistic and by estimating I^2 [11].

In cases where multiple studies analyzed the same population (i.e., series from the same hospital), only the larger study or the one with the longest follow-up (if the sample was similar) was included in the meta-analysis.

Quality and Publication Bias Assessment

The Newcastle-Ottawa Quality Assessment Scale (NOS) [12] was used as an assessment tool to evaluate non-RCTs. The scale’s range varies from zero to nine stars. Studies with a score equal to or higher than 5 were considered to have adequate methodological quality to be included. The RCTs were assessed for their methodological quality with the tools that are used to evaluate the risk of bias according to the Cochrane Handbook for Systematic Reviews of Interventions [13]. Two reviewers (DEM and VST) rated the studies independently, and the final decision was reached by consensus.

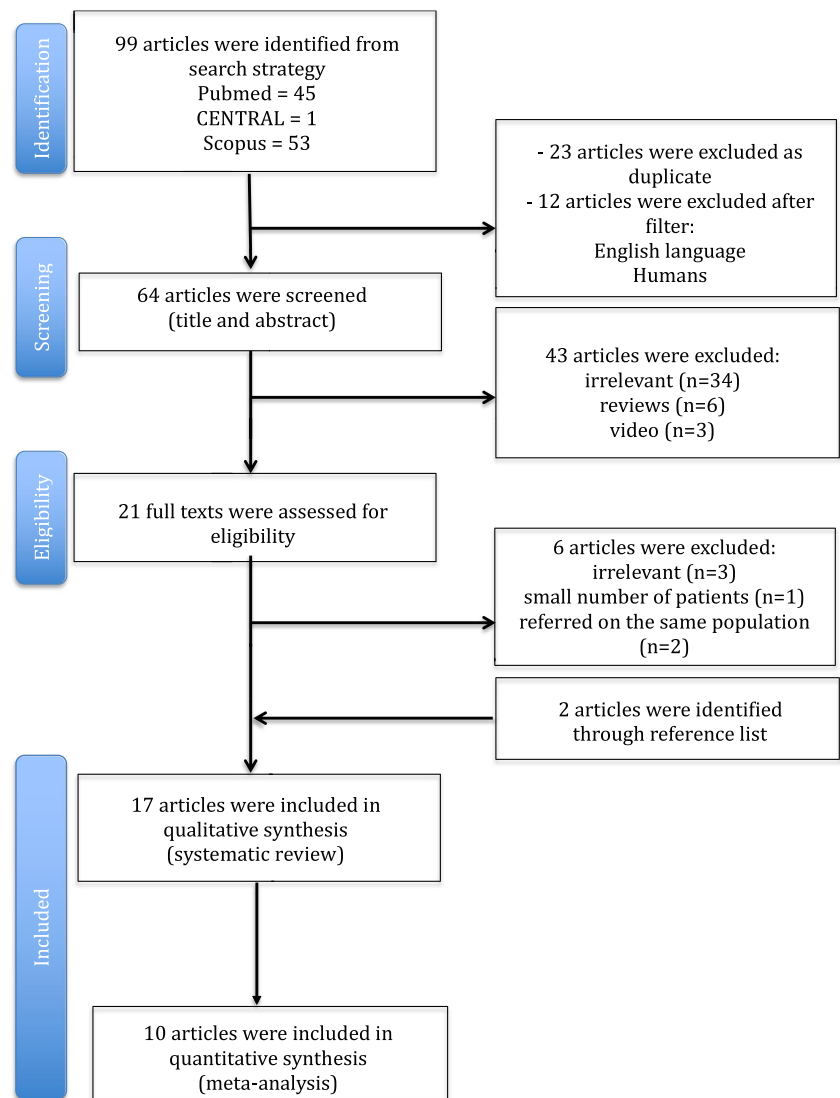
The existence of publication bias was assessed by the visual inspection of funnel plots. It could not be further evaluated using Egger’s formal statistical test [14] because the number of the studies included in the analysis was not adequate (less than 10), thus compromising substantially the power of the test.

Results

Article Selection and Patient Demographics

The flow diagram of the literature search is shown in Fig. 1. Among the 97 articles in PubMed, CENTRAL, and Scopus databases that were retrieved, ten comparative studies [15–24] were included in the qualitative and quantitative synthesis and seven non-comparative studies [7, 25–30] were included in the qualitative synthesis. The study design was retrospective in nine [16, 17, 19, 21, 22, 25, 28–30], prospective in six [7, 15, 20, 24, 26, 27], and randomized controlled in two [18, 23] studies. The studies included were conducted in India [15, 17, 23], France [16, 27], Taiwan [18], UK [19], Italy [20, 21, 24], Germany [22], Greece [25], Spain [26], Austria [28], Israel

Fig. 1 One-anastomosis gastric bypass vs. sleeve gastrectomy flow diagram



[29], USA [7], and Egypt [30] and were published between 2001 and 2017. The OAGB sample size ranged from 15 to 1520 patients. The total sample size was 6761 patients; 1225 patients were treated with LSG and 5536 patients were treated with OAGB. Preoperative mean BMI was ≥ 30 kg/m² in all included patients. Characteristics of studies comparing the outcomes between patients treated with LSG and patients treated with OAGB are provided in Table 1. Baseline characteristics of the patients included in non-comparative studies are demonstrated in Table S1. The Newcastle-Ottawa rating scale assessment for all studies is shown in Table 1, and the quality assessment of RCTs is shown in Table S2. Perioperative and postoperative outcomes regarding comparative and non-comparative studies are presented in Table 2 and Table S3, respectively. Pooled ORs and I^2 and p values of heterogeneity for all outcomes are summarized in Table 3.

Mean Operative Time and Length of Hospital Stay

Mean operative time ranged from 44.8 to 112.1 min for the LSG group and from 52 to 92 min for the OAGB group (Table 2). Mean operative time was similar in both groups (WMD 4.80 [−10.71, 20.31]; $p = 0.54$) as shown in Table 3. The length of hospital stay ranged from 2 to 7.2 days for the LSG group, while it ranged from 2 to 4.5 days for the OAGB group (Table 3). According to our analysis, the length of hospital stay was greater in the LSG group (WMD 1.29 [0.45, 2.12]; $p = 0.002$).

Complications

According to our six-arm analysis, the incidence of leaks was similar between patients with either LSG or OAGB (OR 2.95 [95% CI 0.81, 10.81]; $p = 0.10$). Moreover, the incidence of intra-abdominal bleeding (OR 0.95 [95% CI 0.43, 2.11]; $p = 0.90$) and anemia (OR 0.65 [95% CI 0.34, 1.24];

Table 1 Characteristics of the comparative studies that were finally included in the meta-analysis. The first author of every study along with the year of publication, the journal, the country of origin, the time period of the study, the study design, the number of participants, and the number of female patients, along with the mean age, the mean preoperative body mass index (BMI), and the number of stars according to the Newcastle-Ottawa Quality Assessment Scale

Authors, year	Journal	Country	Time period	Type of study	Patients, <i>n</i>		Female, <i>n</i> (%)		Mean age (range)		Mean preoperative BMI (kg/m ²)		NOS ^a
					SG	OAGB	SG	OAGB	SG	OAGB	SG	OAGB	
Jammu and Sharma., 2015 [15]	<i>Obes Surg</i>	India	January 2007–March 2014	P	339	473	154 (45.4)	210 (71.2)	23	38	35	42.5	8
Kansou et al., 2016 [16]	<i>Int J Surg</i>	France	January 2010–July 2014	R	136	136	125 (91.9)	127 (93.4)	41.2 ± 12.3	41.2 ± 11.3	43.4 ± 6.5	42.8 ± 5.0	7
Kular et al., 2014 [17]	<i>Obes Surg</i>	India	February 2007–August 2013	R	76	72	N/A	N/A	N/A	N/A	N/A	N/A	7
Lee et al., 2014 [18]	<i>Obes Surg</i>	Taiwan	September 2007–June 2008	RCT	30	30	22 (68.8)	22 (73.3)	46.4 (8.1)	44.6 (8.6)	31 (2.8)	30.2 (2.2)	–
Madhok et al., 2016 [19]	<i>Obes Surg</i>	UK	N/A	R	56	19	31	9	51 (30–72)	45 (25–64)	65 (60–96)	67 (60–84)	7
Milone et al., 2015 [20]	<i>Int J Surg</i>	Italy	January 2009–January 2012	P	86	74	46 (53.5)	46 (62.2)	33.7 ± 5.61	34.9 ± 6.01	46.0 ± 4.77	47.3 ± 3.88	7
Musella et al., 2015 [21]	<i>Obes Surg</i>	Italy	January 2006–December 2014	R	110	96	30 (27.3)	38 (39.6)	49.2 ± 9.1	48.5 ± 8.7	48.1 ± 7.8	48.3 ± 9.2	7
Plamper et al., 2016 [22]	<i>Surg Endosc</i>	Germany	Since 2006	R	118	169	72 (61.0)	121 (71.6)	43.4 (±11.2)	43.2 (±11.1)	54.6 (±10.3)	54.1 (±6.6)	7
Seetharamaiah et al., 2016 [23]	<i>Obes Surg</i>	India	2012–2015	RCT	100	101	65	62	39.89 ± 11.75	42.89 ± 14.02	44.57 ± 7.16	44.32 ± 7.88	–
Tolone et al., 2015 [24]	<i>Surg Obes Relat Dis</i>	Italy	N/A	P	25	15	N/A	10 (66.6)	N/A	38 ± 8.2	46.1 (38–58)	46.4 (38–60)	6

^a The Newcastle-Ottawa Scale (NOS) was used for assessing the quality of non-randomized studies. Every study is judged on three perspectives: the selection, the comparability, and the ascertainment of the exposure of the study groups. The highest quality studies are awarded up to nine stars

R retrospective, P prospective, RCT randomized controlled trial, SG sleeve gastrectomy, OAGB one-anastomosis gastric bypass

Table 2 Summary of the assessment of the intraoperative parameters and outcomes of every comparative study that was included in the meta-analysis. The mean hospital stay, the mean operative time, the bougie diameter, the mortality rate, the remission of type 2 diabetes (T2D), hypertension (HTN), dyslipidemia, and gastroesophageal reflux disease (GERD), along with the percentage excess weight loss (%EWL) in 1 and 2 years, are demonstrated where available

Authors, year	LOS, days		MOT, min		Bougie diameter		Mortality, n (%)		T2D remission		HTN remission	
	SG	OAGB	SG	OAGB	SG	OAGB	SG	OAGB	SG	OAGB	SG	OAGB
Jammu and Sharma, 2015 [15]	–	–	60.0 (45–75)	57.5 (42–75)	OAGB = 38 F SG = 36–48 F	0 (0)	0 (0)	13	59	14	–	–
Kansou et al., 2016 [16]	–	–	–	–	36 F	0 (0)	0 (0)	19 (90.5%)	25 (92.6%)	30 (76.9%)	–	–
Kular et al., 2014 [17]	3.4 ± 2.4	2.5 ± 1.3	76.6 ± 28.3	52 ± 20.2	37 F	0 (0)	0 (0)	81%	92%	74%	–	–
Lee et al., 2014 [18]	–	–	–	–	28 F	0 (0)	0 (0)	–	–	–	–	–
Madhok et al., 2016 [19]	2	2	75 (50–252)	92 (63–189)	36 F	0 (0)	0 (0)	9	4	4	–	–
Milone et al., 2015 [20]	–	–	–	–	38 F	–	–	16	21	3	–	–
Musella et al., 2015 [21]	–	–	–	–	36–40 F	0 (0)	0 (0)	67	82	–	–	–
Plamper et al., 2016 [22]	7.2 (± 5.5)	4.5 (± 2.6)	112.1 (± 33.5)	81.7 (± 25.3)	30 F	1 (0.8)	0 (0)	–	–	–	–	–
Seetharamaiah et al., 2016 [23]	3.95 ± 0.73	3.2 ± 0.64	44.81 ± 10.62	64.81 ± 10.62	36 F	0 (0)	0 (0)	76.58%	83.63%	25%	–	–
Tolone et al., 2015 [24]	–	–	–	–	42 F	–	–	–	–	–	–	–

Authors, year	HTN remission		Dyslipidemia remission		OSAS remission		GERD remission		%EWL after 1 year		%EWL after 2 years	
	OAGB	SG	OAGB	SG	OAGB	SG	OAGB	SG	OAGB	SG	OAGB	SG
Jammu and Sharma, 2015 [15]	41	11	42	–	–	–	–	–	–	–	–	–
Kansou et al., 2016 [16]	34 (81.0%)	–	–	22 (75.9%)	37 (92.5%)	–	–	34.3	38.2	–	–	–
Kular et al., 2014 [17]	76%	72%	90%	86%	97%	33%	72%	69	63	66.2	71.6	–
Lee et al., 2014 [18]	–	–	–	–	–	–	–	–	–	–	–	–
Madhok et al., 2016 [19]	1	–	–	7	2	–	–	45	58	38	66	–
Milone et al., 2015 [20]	5	–	–	–	–	–	–	–	–	–	–	–
Musella et al., 2015 [21]	–	–	–	–	–	–	–	52.4	64.7	–	–	–
Plamper et al., 2016 [22]	–	–	–	–	–	–	–	57.3	66.2	–	–	–
Seetharamaiah et al., 2016 [23]	35.84%	–	–	–	–	–	–	–	–	–	–	–
Tolone et al., 2015 [24]	–	–	–	–	–	–	–	56	63 (56–69)	–	–	–

%EWL percentage of excess weight loss, SG sleeve gastrectomy, OAGB one-anastomosis gastric bypass, T2D type 2 diabetes, HTN hypertension, OSAS obstructive sleep apnea syndrome, GERD gastroesophageal reflux disease

Table 3 Summary of the analysis of the categorical and continuous outcomes

	Number	OR (95% CI)*	Heterogeneity	
			I^2 (%)	p
Categorical outcomes				
T2D remission	7	0.46 [0.32, 0.64]	29	0.21
HTN remission	6	0.67 [0.49, 0.90]	0	0.65
Dyslipidemia remission	2	0.32 [0.19, 0.56]	0	0.73
OSAS remission	3	0.48 [0.21, 1.09]	34	0.22
Leaks	6	2.95 [0.81, 10.81]	38	0.17
Malnutrition	2	0.09 [0.01, 0.88]	11	0.29
Anemia	2	0.65 [0.34, 1.24]	0	0.46
Bile reflux	7	4.55 [1.87, 11.05]	31	0.19
Marginal ulcer	3	0.13 [0.02, 0.74]	0	0.61
Intra-abdominal bleed	5	0.95 [0.43, 2.11]	0	0.59
Revisions	4	6.18 [2.09, 18.26]	0	0.74
Mortality	8	10.52 [1.24, 89.20]	0	0.45
Continuous outcomes				
MOT	5	4.80 [-10.71, 20.31]	99	<0.00001
MHS	3	1.29 [0.45, 2.12]	84	0.002
%EWL after 1 year	5	-6.52 [-11.65, -1.40]	85	<0.0001
%EWL after 2 years	2	-16.78 [-38.92, 5.37]	95	<0.0001

T2D type 2 diabetes, HTN hypertension, OSAS obstructive sleep apnea syndrome, MOT mean operative time, MHS mean hospital stay, OR odds ratio, WMD weighted mean difference, CI confidence interval

$p = 0.19$) was comparable between the two groups. The incidence of malnutrition (OR 0.09 [95% CI 0.01, 0.88]; $p = 0.04$) and marginal ulcer (OR 0.13 [95% CI 0.02, 0.74]; $p = 0.02$) was greater in the OAGB group. The incidence of bile reflux disease was greater in patients that underwent LSG (OR 4.55 [95% CI 1.87, 11.05]; $p = 0.0008$). Forest plots regarding complications are demonstrated in Figure S1.

Revisions and Mortality

The incidence of revisions was significantly increased in the LSG group (OR 6.18 [95% CI 2.09, 18.26]; $p = 0.001$). Mortality was significantly increased in the LSG group (OR 10.52 [95% CI 1.24, 89.20]; $p = 0.03$).

Resolution of Comorbidities

Seven studies [15–17, 19–21, 23] assessed the postoperative type 2 diabetes (T2D) remission which was greater in the

OAGB group (OR 0.46 [95% CI 0.32, 0.64]; $p < 0.00001$) (Fig. 2). According to our six-arm analysis, hypertension (HTN) remission was increased in patients treated with OAGB (OR 0.67 [95% CI 0.49, 0.90]; $p = 0.008$) (Fig. 2). Resolution of dyslipidemia was also increased in the OAGB group (OR 0.32 [95% CI 0.19, 0.56]; $p < 0.0001$) (Fig. 2). The postoperative obstructive sleep apnea syndrome (OSAS) remission was similar between the two modalities (OR 0.48 [95% CI 0.21, 1.09]; $p = 0.08$).

Weight Loss Outcome

In our study, we examined the postoperative %EWL after 12 and 24 months. It ranged between 34.3 and 69 after 12 months and between 38 and 66.2 after 12 months for the LSG group. In addition, the %EWL for the OAGB group ranged between 38.2 and 66.2 after 12 months and between 66 and 71.6 after 24 months. According to our analysis (Fig. 3), the %EWL after 1 year was increased in the OAGB group (WMD -6.52 [95% CI -11.65, -1.40]; $p = 0.01$). However, the %EWL after 2 years was similar between the two groups (WMD -16.78 [95% CI -38.92, 5.37]; $p = 0.14$) (Fig. 3). Only one study [28] assessed the %EWL at 10 years postoperatively regarding LSG (%EWL 54.0 ± 26.7).

Publication Bias

Heterogeneity was low regarding the categorical outcomes. In contrast, heterogeneity was high regarding the continuous outcomes. The funnel plots that were produced in order to assess publication bias are shown in Figures S2–S4. The asymmetries that were found are mainly attributed to the small number of the included studies, thus proposing that more are necessary in order to eliminate publication bias. Egger's test was not performed due to the small number of the studies that were included.

Discussion

The LSG has gained increased popularity as a standalone procedure for morbid obesity [3]. However, another bariatric procedure that has attracted the interest of a significant number of bariatric surgeons is OAGB [6]. This systematic review and meta-analysis identified 17 articles comparing LSG and OAGB as two alternative bariatric procedures, measuring patients' outcomes published between 2001 and 2017. No similar meta-analysis was identified through literature search. The articles included in this study bring us closer to linking the implementation of either method with improved standards of safety and efficiency.

The present study demonstrates that both LSG and OAGB are well-tolerated, feasible, and effective surgical approaches.

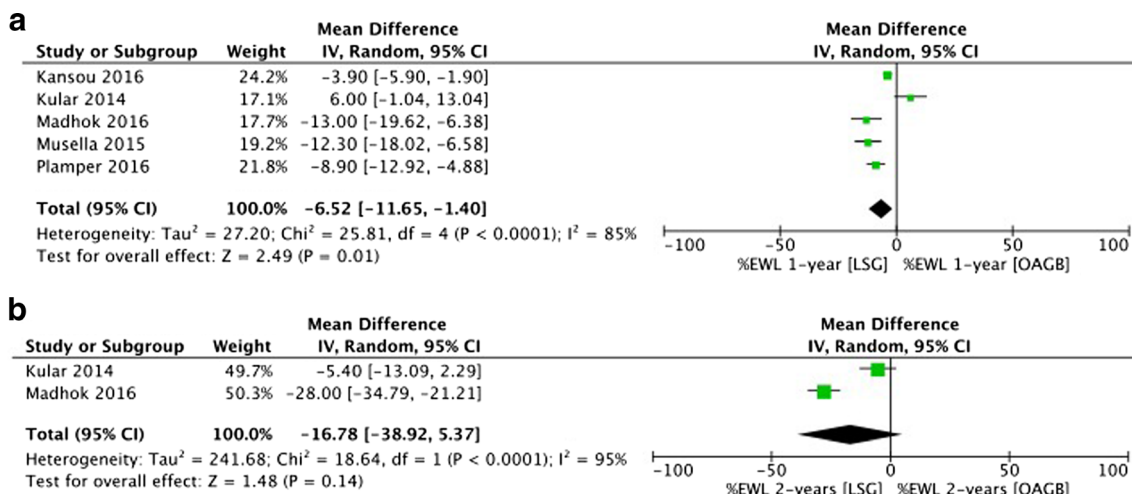


Fig. 2 Forest plot describing the differences in **a** percentage of excess weight loss (%EWL) after 1 year and **b** %EWL after 2 years. **a** %EWL after 1 year was significantly greater in one-anastomosis gastric bypass. **b** %EWL after 2 years was similar between the two groups

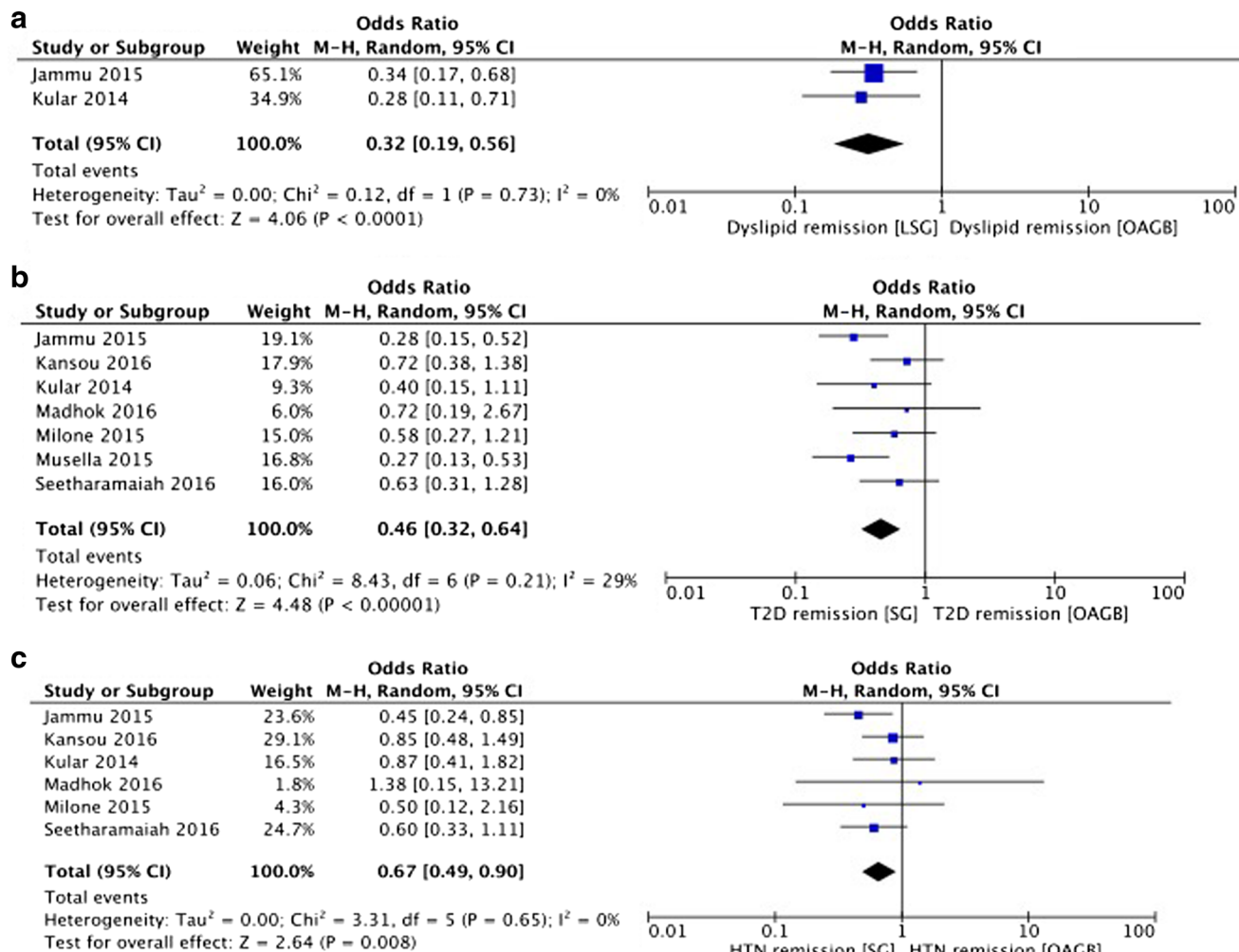


Fig. 3 Forest plot describing the differences in **a** dyslipidemia remission, **b** type 2 diabetes remission, and **c** hypertension remission. **a** Resolution of dyslipidemia was increased in the OAGB group. **b** Resolution of type 2

diabetes was increased in the OAGB group. **c** Resolution of hypertension was increased in the OAGB group

Mean operative time was similar between the two approaches. However, mean hospital stay was increased in patients treated with LSG.

Both techniques are associated with small rates of complications and revisions, being significantly safe. Leaks and hemorrhage are the main risks of bariatric procedures, due to the long stapled lines and gastrointestinal anastomosis. According to our findings, the incidence of leaks and hemorrhage was comparable between the two groups. Despite the bypassed duodenum in OAGB, the incidence of anemia was comparable between the two groups. In contrast, the incidence of malnutrition and marginal ulcer was increased in the OAGB group.

The risk of postoperative bile reflux, along with gastritis and/or esophagitis, remains one of the main criticisms regarding OAGB and originates from the first omega procedures performed by Mason and Ito in the 1960s [31]. According to a recent study in animal models [32], although the mean bile acid concentration was higher in rats that underwent OAGB compared to sham rats, the OAGB procedure was not related to an increased risk of precancerous or cancerous conditions of the esophagus. However, the results of the included studies demonstrate that the bile reflux is not a common problem, because the anastomosis is located low in the stomach. In fact, according to our analysis, the incidence of bile reflux disease was increased in the LSG group. These findings are also in accordance with the primarily restrictive characteristics of LSG. In the same context, Tolone et al. [24] have demonstrated that the SG approach contributes to increased esophageal reflux exposure and greater number of reflux episodes, while it has also been associated with augmented rate (14%) of Barrett's metaplasia at 10 years postoperatively [28].

Reoperation rate is always a concern when a novel technique is examined. In our study, the need for revisional operation was increased in the LSG group. This finding may be attributed to the fact that LSG is performed as a first operation in a two-stage approach, especially in super-obese patients. In the same context, mortality was increased in the LSG group, probably due to the increased preoperative BMI and/or comorbidities.

From the 17 studies included, 5 studies [16, 17, 19, 21, 22, 24, 25, 27–30] assessed %EWL after 1 year and 2 studies [7, 17, 19, 25–27] after 2 years. Only one study [28] assessed %EWL at 10 years postoperatively regarding LSG. According to our analysis, OAGB was associated with increased %EWL in 1 year. However, %EWL was similar between the two groups after 2 years. There was no available long-term data from comparative studies regarding %EWL. Nevertheless, Felsenreich et al. [28] have demonstrated that LSG is associated with increased weight regain at 10 years postoperatively.

Weight loss is directly associated with remission of T2D and dyslipidemia. In fact, OAGB resulted to greater T2D and

dyslipidemia remission compared to LSG, that is in accordance with its effect on %EWL. A possible explanation is that OAGB combines the effects of some restriction with fat malabsorption [33]. Moreover, OAGB resulted to increased HTN remission compared to LSG, possibly due to weight loss and the consequent control of obesity-related HTN.

This meta-analysis demonstrates the superiority of OAGB compared to LSG as a standalone procedure. Nonetheless, it also demonstrates the need for additional studies comparing LSG with the OAGB. Ideally, these would be randomized controlled studies, with prospective design and longer follow-up. For rare events, such as complications and mortality, a large sample is needed. The studies included offer a specific linkage to patient outcomes, complications, and weight loss.

The limitations of this meta-analysis reflect the limitations of the studies included. Nine studies [16, 17, 19, 21, 22, 25, 28–30] (53%) were retrospective, thus posing a certain limitation in this study. Six studies [7, 15, 20, 24, 26, 27] were prospective, and two studies [18, 23] were randomized controlled studies. Moreover, the small number of the studies included in the quantitative synthesis poses a certain publication bias.

On the other hand, the strengths of this study are (1) the clear data extraction protocol, (2) the well-specified inclusion-exclusion criteria, (3) the search in three different databases, (4) the quality assessment of the included studies, and (5) the detailed presentation of the results of data extraction and analysis.

Conclusion

This systematic review and meta-analysis identified 17 unique peer-reviewed studies of LSG and OAGB procedures with patient outcome data. These studies suggest that OAGB is associated with shorter mean hospital stay, increased %EWL in 1 year, greater remission of T2D, dyslipidemia, HTN, and OSAS, along with fewer cases of bile reflux disease, revisions, and lower mortality. On the other hand, LSG resulted to fewer cases of malnutrition and marginal ulcer. These results should be interpreted with caution due to the small number of randomized controlled studies. Future studies with greater clarity in significant outcomes, as in complications and %EWL, are necessary to demonstrate the differences in efficacy between LSG and OAGB.

Compliance with Ethical Standards

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

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent Does not apply.

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