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Article in *Obesity Research & Clinical Practice* · July 2024

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30-day morbidity and mortality of revisional bariatric surgery – An international multi-centre collaborative (BROAD) study[☆]

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Abbreviations: RBS, Revisional Bariatric Surgery; SG, Sleeve gastrectomy; RYGB, Roux-en-Y gastric bypass; OAGB, One anastomosis gastric bypass; GERD, Gastroesophageal reflux disease; IWR, Inadequate weight loss; WR, Weight regain; BMI, Body Mass Index; CD, Clavien Dindo; S.D., Standard deviation of mean; OR, Odds ratio; A1C, Glycated hemoglobin; T2DM, type 2 Diabetes Mellitus.

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<https://doi.org/10.1016/j.orcp.2024.06.001>

Received 12 November 2023; Received in revised form 12 May 2024; Accepted 3 June 2024

Available online 1 July 2024

1871-403X/© 2024 Published by Elsevier Ltd on behalf of Asia Oceania Association for the Study of Obesity.

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ARTICLE INFO

Keywords:

Revisional bariatric surgery

Morbidity

Mortality

Multi-centric

International

RYGB

OAGB

Sleeve gastrectomy

ABSTRACT

Introduction: Revisional bariatric surgery (RBS) for insufficient weight loss/weight regain or metabolic relapse is increasing worldwide. There is currently no large multinational, prospective data on 30-day morbidity and mortality of RBS. In this study, we aimed to evaluate the 30-day morbidity and mortality of RBS at participating centres.

Methods: An international steering group was formed to oversee the study. The steering group members invited bariatric surgeons worldwide to participate in this study. Ethical approval was obtained at the lead centre. Data were collected prospectively on all consecutive RBS patients operated between 15th May 2021 to 31st December 2021. Revisions for complications were excluded.

Results: A total of 65 global centres submitted data on 750 patients. Sleeve gastrectomy (n = 369, 49.2 %) was the most common primary surgery for which revision was performed. Revisional procedures performed included Roux-en-Y gastric bypass (RYGB) in 41.1 % (n = 308) patients, One anastomosis gastric bypass (OAGB) in 19.3 % (n = 145), Sleeve Gastrectomy (SG) in 16.7 % (n = 125) and other procedures in 22.9 % (n = 172) patients. Indications for revision included weight regain in 615(81.8 %) patients, inadequate weight loss in 127(16.9 %), inadequate diabetes control in 47(6.3 %) and diabetes relapse in 27(3.6 %). 30-day complications were seen in 80(10.7 %) patients. Forty-nine (6.5 %) complications were Clavien Dindo grade 3 or higher. Two patients (0.3 %) died within 30 days of RBS.

Conclusion: RBS for insufficient weight loss/weight regain or metabolic relapse is associated with 10.7 % morbidity and 0.3 % mortality. Sleeve gastrectomy is the most common primary procedure to undergo revisional bariatric surgery, while Roux-en-Y gastric bypass is the most commonly performed revision.

Key points:

- Revision bariatric surgery for additional weight loss or metabolic relapse is increasing worldwide
- Sleeve gastrectomy is the most common primary procedure to undergo revisional bariatric surgery.
- Roux-en-Y gastric bypass is the most frequently performed revisional bariatric surgery.
- The 30-day morbidity in the current study was 10.7% and mortality was 0.3%

Introduction

Revisional Bariatric Surgery (RBS) for Inadequate Weight Loss (IWL) or Weight Regain (WR) following initial significant weight loss or relapse of metabolic co-morbidities is widely accepted in the management algorithms for Bariatric Surgery patients [1,2]. In the last published survey by the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO), approximately 9.0 % (n = 62,801) of all bariatric procedures performed worldwide in 2018 were revisional [3]. Despite this, there is a paucity of data on the safety of RBS. Most studies evaluating morbidity and mortality after RBS tend to be either single centre [4], registry data [5], or retrospective studies [6,7] which have their obvious limitations. To the best of our knowledge, there is no multinational, prospective data on this topic.

Studies on RBS [8] do not always clearly differentiate between RBS

for IWL/WR or metabolic benefits and RBS for complications. These are two entirely different cohorts of patients with differing safety profiles and needs. RBS for complications is often inevitable whereas RBS for IWL/WR or metabolic relapse needs to be justified based on its risk versus benefit profile.

The BROAD study is a prospective, global, multicentre study evaluating the 30-day morbidity and mortality of RBS for IWR/WL and metabolic relapse.

Methods

The study consisted of an international steering group of bariatric surgeons (Appendix 1). The steering group invited bariatric surgeons globally to participate in this study through their networks, social media, and mailing lists of surgeons and bariatric societies. Ethical approval was obtained from the ethics committee at the lead study centre (ECR/624/Inst/MH/2014/RR-20). Collaborators were instructed to follow local regulatory requirements for participation in the study. Co-morbidities like Diabetes, hypertension, etc. were identified and treated by respective specialists according to hospital and national guidelines and protocols.

The primary endpoint was 30-day morbidity and mortality following revisional bariatric surgery. Data were collected on all consecutive patients undergoing revisional bariatric surgery who met the inclusion/exclusion criteria at the respective participating centres.

Inclusion criteria:

1. Revisional bariatric/metabolic procedures for
 - i. Inadequate weight loss (IWL) or weight regain (WR)
 - ii. Inadequate diabetes remission or diabetes relapse
1. Revision surgery performed between 15th May 2021 and 31st December 2021 (inclusive)
2. Patients aged ≥ 18 years

Exclusion criteria:

1. Primary bariatric surgeries
2. Revision done for complications/emergency conditions such as post-operative bleeding, leak, internal hernia, Gastro-esophageal reflux disease (GERD), bile reflux, malnutrition, etc.
3. Patients below 18 years of age

Data collection

Collaborators were asked to submit data on a password-protected database. This data was screened by the principal investigator, and patients not fitting the inclusion criteria were excluded.

Statistical Analysis

Categorical variables were expressed as frequency (percentage) and continuous variables as (Mean $\pm$ Standard deviation) with ranges.

Results

A total of 65 centres (Europe=39, Asia=19, South America=3, North America=2, Africa=2) submitted data on 750 RBS patients. 30-day safety data were available for all the patients. The mean age of patients was 44.2 ± 11 years and 586 (78.1 %) of patients were females. Mean pre-operative weight and body mass index (BMI) at the time of revisional surgery were 111.1 ± 23.6 kg and 40.5 ± 7 kg/m² respectively. Type 2 Diabetes was present in 16.5 % (n = 124) patients. Sleeve gastrectomy (n = 369, 49.2 %) was the most common primary bariatric procedure undergoing revision. The demographic profile of patients as per the primary procedures is given in Table 1.

Indications for revision included WR in 81.7 % (n = 613) patients, IWL in 16.9 % (n = 127), inadequate diabetes control in 6.3 % (n = 47), and diabetes relapse in 3.6 % (n = 27) patients. In patients with WR, the mean regain was 26.3 ± 14.8 kg.

RYGB (n = 308, 41.1 %) was the most frequently performed revision procedure. Gastro-esophageal reflux disease (GERD) was reported in 56.8 % of patients undergoing revision RYGB. A larger proportion of patients who underwent revision to OAGB had diabetes (28.3 %) as compared to revision SG (21.6 %) or RYGB (11 %). The demographic profile of patients according to the revisional procedure performed is

shown in Table 2. SG (n = 369) was most revised to RYGB (n = 187, 50.7 %) followed by OAGB (n = 122, 33 %), while the adjustable band (n = 207) was most revised to RYGB (n = 87, 42 %) and SG (n = 77, 37.2 %). The mean duration between primary and revisional surgery was 8.3 ± 5.5 years (range 1–36). The choice of revisional procedure as per the primary procedure is shown in Table 3.

Morbidity/Mortality outcomes: 30-day morbidity was reported in 10.7 % (n = 80) patients. Of these, forty-nine (6.5 %) complications were Clavien Dindo (CD) grade 3 or higher, recognized as major complications. Revision to RYGB (13.6 %) was associated with the highest incidence of complications, followed by SG (7.2 %). A detailed breakdown of complications as per CD grade is given in Table 4. The mean duration of hospital stay was 3.3 ± 4.5 days (range 1 to 35). Re-admission within 30 days was reported in 4.8 % (n = 28) of patients. Two patients (0.3 %) died within 30 days of surgery. One patient died following revision of OAGB with ring implantation due to gastric perforation and peritonitis, requiring re-exploration. Another patient died due to portal vein thrombosis and fulminant hepatic failure after revision RYGB.

Conservative management was successful in 48.7 % (n = 40) patients, without any need for further interventions. Further surgical, endoscopic, and radiological interventions were needed in 35.3 % (n = 29), 12.2 % (n = 10), and 3.7 % (n = 3) patients respectively.

Discussion

The current study is the largest multinational study that has evaluated outcomes following revisional bariatric surgery. The study showed that 30-day morbidity and mortality following revisional bariatric surgery performed for weight loss or metabolic benefit were 10.7 % and 0.3 % respectively. The incidence of serious complications was low. Two patients died in the current cohort.

As the acceptance of bariatric surgery is increasing, number of patients who require revision surgery due to weight regain or long-term complications is also rising [9]. From 2011 to 2015, the number of revisional bariatric procedures performed in the USA doubled from 6 to 13.6 % [10]. In the registry study by El Chaar [11], 6 % of total sleeve gastrectomies were revisions, while 9 % of total RYGB were revisions. According to the Metabolic and Bariatric Surgery Accreditation Quality Initiative Program (MBSAQIP) database study [12] by Clapp et al., revision bariatric surgery is the third most common bariatric surgery performed. A recent retrospective study by McLennan et al. [13] on 158, 424 patients reported revisions in 10,589 (6.7 %) patients.

American Society for Metabolic and Bariatric Surgery (ASMBS) categorizes revision surgery as conversion, corrective, or reversal [14]. The current study included revisions only for weight regain/inadequate weight loss or for inadequate metabolic benefit. Revisions for post-bariatric complications like a leak, GERD, internal hernia, malnutrition, etc. are unavoidable and are likely to be associated with higher

Table 1
Pre-operative demographics of primary bariatric surgery patients.

Patient characteristics	Sleeve Gastrectomy (n = 369)	Adjustable gastric band (n = 207)	RYGB (n = 110)	OAGB (n = 17)	Others (n = 47)	Total Primary procedures (n = 750)
Age (years)	42.64 $\pm$ 10.44	47.4 $\pm$ 11	45.26 $\pm$ 11.2	42.48 $\pm$ 10.1	47.7 $\pm$ 11.3	44.2 $\pm$ 11
Females (n)	285 (77.2 %)	165 (79.7 %)	82 (74.5 %)	16 (94.1 %)	38 (80.9 %)	586 (78.1 %)
Males (n)	84 (22.8 %)	42 (20.3 %)	28 (25.5 %)	1 (5.9 %)	9 (19.1 %)	164 (21.9 %)
Weight (kg)	129.32 $\pm$ 28.75	121.5 $\pm$ 23.73	128.72 $\pm$ 26.8	129.7 $\pm$ 18.54	105.1 $\pm$ 20.5	111.1 $\pm$ 23.6
Body Mass Index (kg/m ²)	40.43 $\pm$ 7.27	41.57 $\pm$ 6.82	39.44 $\pm$ 6.9	40.64 $\pm$ 7.28	38.4 $\pm$ 6.3	40.5 $\pm$ 7
Type 2 Diabetes (n)	58 (15.7 %)	35 (16.9 %)	16 (14.5 %)	6 (35.3 %)	9 (19.1 %)	124 (16.5 %)
Hypertension (n)	113 (30.6 %)	60 (29 %)	35 (31.8 %)	7 (41.2 %)	12 (25.5 %)	227 (30.2 %)
Sleep apnea (n)	76 (20.6 %)	49 (23.7 %)	15 (13.6 %)	1 (5.9 %)	14 (29.8 %)	155 (20.7 %)
Dyslipidemia (n)	118 (32 %)	52 (25.1 %)	27 (24.5 %)	4 (23.5 %)	20 (42.5 %)	221 (29.5 %)
GERD (n)	171 (46.3 %)	68 (32.9 %)	28 (25.5 %)	5 (29.4 %)	16 (34 %)	288 (38.4 %)

*Continuous variables are expressed as Mean $\pm$ Standard deviation (S.D.)
Abbreviations: RYGB= Roux-en-Y Gastric Bypass, OAGB= One anastomosis Gastric bypass, GERD= Gastro-esophageal reflux disease

Table 2
Pre-operative demographics of revisional bariatric surgery patients.

Patient characteristics	RYGB (n = 308)		OAGB (n = 145)		Sleeve Gastrectomy (n = 125)		Others (n = 172)	
Age (years)	45	± 11.1	41.4	± 9.5	45.24	± 12.19	44.4	± 10.7
Females (n)	260	(84.4 %)	100	(69 %)	94	(75.2 %)	132	(76.7 %)
Males (n)	48	(15.6 %)	45	(31 %)	31	(24.8 %)	40	(23.3 %)
Weight (kg)	106.2	± 22	117.7	± 24	122.12	± 23.99	112.3	± 23.1
Body Mass Index (kg/m ²)	39.1	± 6.4	42.9	± 7.5	41.39	± 7.72	40.3	± 6.7
Type 2 Diabetes (n)	34	(11 %)	41	(28.3 %)	27	(21.6 %)	22	(12.8 %)
Hypertension (n)	82	(26.6 %)	57	(39.3 %)	34	(27.2 %)	54	(31.4 %)
Sleep apnea (n)	51	(16.6 %)	43	(29.7 %)	35	(28 %)	26	(15.1 %)
Dyslipidemia (n)	78	(25.3 %)	66	(45.5 %)	29	(23.2 %)	48	(27.9 %)
GERD (n)	175	(56.8 %)	50	(34.5 %)	17	(13.6 %)	46	(26.8 %)

*Continuous variables are expressed as Mean ± Standard deviation (S.D.)
Abbreviations: RYGB= Roux-en-Y Gastric Bypass, OAGB= One anastomosis Gastric bypass, GERD= Gastro-esophageal reflux disease

Table 3
Revisional surgery types for various primary bariatric procedures.

Procedures	Revision	RYGB	OAGB	Sleeve Gastrectomy	Others	Total (Including others)
Primary	Adjustable gastric band	87 (11.6 %)	19 (2.53 %)	77 (10.27 %)	24 (3.2 %)	207 (27.6 %)
	OAGB	7 (0.9 %)	0	2 (0.27 %)	8 (1.1 %)	17 (2.27 %)
	RYGB	0	1 (0.13 %)	0	109 (14.5 %)	110 (14.67 %)
	Sleeve Gastrectomy	187 (24.9 %)	122 (16.3 %)	35 (4.7 %)	25 (3.33 %)	369 (49.2 %)
	Others	28 (3.7 %)	3 (0.4 %)	11 (1.5 %)	5 (0.7 %)	47 (6.3 %)
	Total	308 (41.1 %)	145 (19.3 %)	125 (16.7 %)	172 (22.9 %)	750 (100 %)

Abbreviations: RYGB= Roux-en-Y Gastric Bypass, OAGB= One anastomosis Gastric bypass.

Table 4
Distribution of complications in revision procedures as per Clavien Dindo Grade.

Clavien Dindo Grade	RYGB (n = 308)	OAGB (n = 145)	Sleeve Gastrectomy (n = 125)	Others (n = 172)	Total (n = 750)
1	9 (2.9 %)	1 (0.7 %)	2 (1.6 %)	4 (2.3 %)	16 (2.1 %)
2	7 (2.3 %)	2 (1.4 %)	2 (1.6 %)	4 (2.3 %)	15 (2 %)
3	24 (7.8 %)	4 (2.8 %)	4 (3.2 %)	11 (6.4 %)	43 (5.7 %)
4	1 (0.3 %)	2 (1.4 %)	1 (0.8 %)	0	4 (0.5 %)
5	1 (0.3 %)	0	0	1 (0.6 %)	2 (0.3 %)
Total	42 (13.6 %)	9 (6.2 %)	9 (7.2 %)	20 (11.6 %)	80 (10.7 %)
Bleed	9 (2.9 %)	3 (2.1 %)	3 (2.4 %)	3 (1.7 %)	18 (2.4 %)
Leak	3 (1 %)	2 (1.4 %)	3 (2.4 %)	5 (2.9 %)	13 (1.7 %)
Intestinal obstruction	6 (1.9 %)	0	0	5 (2.9 %)	11 (1.5 %)
Others	24 (7.8 %)	4 (2.8 %)	3 (2.4 %)	7 (4.1 %)	38 (5.1 %)
Total	42 (13.6 %)	9 (6.2 %)	9 (7.2 %)	20 (11.6 %)	80 (10.7 %)

Abbreviations: RYGB= Roux-en-Y Gastric Bypass, OAGB= One anastomosis Gastric bypass.

morbidity. However, revisions for weight loss or metabolic benefit are elective procedures and their morbidity should be considered at par with primary bariatric surgery.

In the current study, SG was the most common primary procedure requiring revision, while RYGB was the most performed revision. A meta-analysis by Guan et al. [15] reported a revision rate after SG of 10.4 %, but for patients with ≥ 10-year follow-up, the rate was 22.6 %. The most common reason for revision was insufficient weight loss or weight regain. In a study by Nasser et al. [16] on 29,454 revisional cases, 17,012 (57.8 %) underwent SG and 12,442 (42.2 %) underwent RYGB. In another study by Lazzati et al. [17], the rate of revision surgery after sleeve gastrectomy was 4.7 %, 7.5 %, and 12.2 %, at 5-, 7-, and 10 years post-primary procedure, respectively. The most common revisional procedure was gastric bypass (75.2 %), followed by re-sleeve (18.7 %). The main reasons for revisional surgery were the persistence of obesity (87.0 %) and gastroesophageal reflux disease (5.2 %). A study by McLennan et al. [13] reported Roux-en-Y gastric bypass (48.4 %) and sleeve gastrectomy (32.5 %) as the most common revisional procedures.

Revisional bariatric procedures are associated with a higher rate of perioperative complications and longer operative duration compared to primary procedures. [11,13]. This may be attributed to the technical difficulties associated with revision procedure and increased operative

time. In the current study, 30-day complications were seen in 80 (10.7 %) patients, of which 49(6.5 %) were Clavien Dindo grade 3 or higher and the mortality rate was 0.3 %. In comparison, the 30-day morbidity and mortality following elective primary bariatric surgery (n = 7084) was 6.76 % (n = 479) and 0.14 % (n = 10) in the multinational GENEVA audit [18]. In the Longitudinal Assessment of Bariatric Surgery (LABS) database study by Inabnet et al. [19], the rate of complications 30 days following revisional surgery was 15.1 % while the mortality rate was 0.4 %.

Though the current study focuses on the early morbidity of revisional bariatric procedures, the protocol specifies a further 3-year follow-up of all patients by study collaborators, which should reflect the long-term effectiveness and safety of these surgeries.

This is the first multinational study to examine complications of RBS. The strengths of our study include the global reach and prospective data collection with a large sample size. This study has several limitations. It only includes data from participating centres and may therefore not represent the real global picture. Also, though all reasonable care has been undertaken to ensure our collaborators knew the importance of submitting all consecutive patients during the study period, we cannot be certain of that. At the same time, repeated reminders should have encouraged it. Finally, data on complications were self-reported by

surgical teams and may therefore not represent an accurate picture. Authors though hope that anonymous data collection would have reduced any underreporting of complications.

Conclusion

Revisional Bariatric Surgery for insufficient weight loss/ weight regain or metabolic relapse is associated with 10.7 % morbidity and 0.3 % mortality. Sleeve gastrectomy is the most common primary procedure to undergo RBS, while RYGB is the most commonly performed revision.

Ethical agreement

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

Author agreement

The manuscript has been read and approved by all authors. All authors have signed the author consent form.

CRediT authorship contribution statement

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Declaration of Competing Interest

All authors declare that they have no conflict of interest related to the study.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.orcp.2024.06.001](https://doi.org/10.1016/j.orcp.2024.06.001).

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