Metabolic surgery in South Africa: an initial academic hospital experience

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Background: In South Africa, 42.0% of adult females and 13.5% of adult males are classified as obese, the highest recorded numbers in Sub-Saharan Africa. Metabolic surgery has been proven to be a safe and effective treatment, yet due to demand on government resources has only been performed to a limited extent in public hospitals. The aim of this study was to describe the safety and efficacy of performing metabolic surgery at a single academic hospital in South Africa.
Methods: This was a single centre retrospective review of 57 metabolic surgery procedures performed from October 2011 to September 2017 at Tygerberg Hospital, Cape Town, South Africa. The primary outcome was safety including mortality and adverse events. Secondary outcomes included effect of surgery on weight and diabetes resolution.
Results: A total of 57 patients underwent laparoscopic metabolic surgery, of which 44 (83.0%) were female with a mean age (standard deviation) of 42.8 (8.0) years. Fifty-six patients (98%) underwent Roux-and-Y gastric bypass and one (2%) had a sleeve gastrectomy performed. There were no mortalities and overall morbidity was 14.0%, with 3 (5.3%) classified as major and 5 (8.8%) as minor. The follow-up rate at 1 year was 100%. Mean preoperative body mass index (BMI) was 58.8 kg/m2, and comorbidities included hypertension (59.6%), Type 2 Diabetes (42.1%), and dyslipidaemia (36.8%). There were no conversions to open surgery and at one year the mean (95% confidence interval) percentage excess body mass index loss was 50.4% (44.0–56.8%).
Conclusions: Metabolic surgery can be performed safely in the public sector in South Africa, with short-term safety and efficacy outcomes comparable to international reports. Larger scale studies are needed to determine long-term outcomes and cost-effectiveness.
Key words: Obesity, metabolic surgery, laparoscopic Roux-and-Y gastric bypass

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Introduction

At the start of the millennium the World Health Organization (WHO) declared obesity a worldwide epidemic.[1] From 1980 to 2015, the largest worldwide increase in obesity prevalence was seen in men aged 25–29 years living in countries with a low-middle socio-demographic index.[2] Lingering widespread poverty and progressive urbanization leads to low-cost, easily available foods, high in sugar and salt, and with little nutritional value. In South Africa, 42.0% of adult females, and 13.5% of adult males are classified as obese, the highest recorded numbers in Sub-Saharan Africa.[3]

Metabolic surgery (MS) has long been known to be effective in the management of weight, but has also emerged as effective treatment of obesity related co-morbid disease, decreasing mortality and the burden on Health Systems.[4] Sleeve gastrectomy (SG) and Roux-and-Y gastric bypass (RYGB) are emerging as the most commonly utilized procedures.[5,6] In a joint statement by the International Diabetes Organizations, MS is recommended as treatment for Type 2 Diabetes (T2D) in patients with a Body Mass Index (BMI) ≥ 40 kg/m^2 (class III obesity) regardless of the level of glucose control and patients with a BMI 35–40 kg/m^2 (class II obesity) with poorly controlled hyperglycaemia.[7] Surgery should also be considered in patients with poorly controlled hyperglycaemia, with a BMI of 30–34.9 kg/m^2 (class I obesity). The 2017 Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) guidelines for the management of T2D estimate the number of people living with diabetes in Africa to increase by 140% by the year 2040, and their recommendations are in accordance with international guidelines.[8]

MS has been performed in the private sector in South Africa with excellent outcomes, but there are limited reports representing public hospitals, none of which report on the performance of RYGB.[9-11] With an increasingly obese and undernourished public patient population, studies on outcomes after MS in government hospitals are lacking. Since

2011 Tygerberg Hospital has been performing RYGB in small volumes, but due to the alarming increase in referrals, mainly from endocrinologists (both public and private), a formal MS program has now been established. The program includes a dedicated multidisciplinary team (MDT), a weekly MS list, participation in an international database, and international accreditation. This is a retrospective observational report of our initial experience with the main aim to assess the short-term safety of performing MS in a tertiary academic hospital in South Africa.

Methods

Patient selection

This was a retrospective review of a prospectively maintained database of MS procedures performed at a single Tertiary Academic Centre, between 1 October 2011 to 31 September 2017. The regional Health Research Ethics Committee approved the protocol (S16/08/157).

Participants were considered for the MS program according to guideline recommendations, where MS is indicated in adult patients with a BMI ≥ 35 kg/m^2 and an associated obesity related comorbid disease, or patients with a BMI ≥ 40 kg/m^2, without any obesity related comorbid disease, and where lifestyle modification proved unsuccessful.[12] Participants were excluded from undergoing MS in the following instances; age < 20 years or > 60 years, current smoking or excessive previous or current alcohol or drug use/abuse, uncontrolled psychiatric illness, immobility or concurrent co-morbidity deemed too high anaesthetic risk (if evaluated as such by a specialist anaesthesiologist), contra-indication to laparoscopic surgery (inability to undergo general anaesthetic or multiple previous open abdominal surgeries), active underlying bowel disease (malignancy or inflammatory bowel disease), lack of commitment or resources with regards to the short, medium and long term adherence to follow-up and surveillance, and lastly, planned pregnancy in the two years following surgery.

Procedures

All patients underwent education regarding the MS program, were referred for psychiatric evaluation and attended two dietitian group sessions. If there was concern for the presence of an uncontrolled comorbid metabolic condition, evaluation by the endocrinologist was completed. Preoperative nutritional deficiencies were assessed and managed by the treating endocrinologist. Preoperative investigations included basic blood tests, a chest radiograph, abdominal sonography, and a gastroscopy, and all patients followed a 2-week preoperative low-calorie liquid diet.

RYGB was offered to all patients, with SG reserved for cases in which intraoperative assessment judged the performance of a RYGB as unsafe. All surgical procedures were performed according to a standardised technique, and in most cases in the presence of a South African Society for Obesity and Metabolism (SASOM) proctor. Postoperatively patients were accommodated in a ward (surgical, anaesthetic or medical) with at least high care monitoring capabilities for 24 hours, and discharge home was aimed for within 3 days. Plasma glucose was monitored intra- and postoperatively according to standard hospital protocol. Patients were discharged on a vitamin/mineral replacement regime available in the public sector and in accordance with post-metabolic surgery needs.[13] Lifelong daily proton pump inhibitor (PPI) therapy (lansoprazole 30 mg orally daily) was prescribed, and for the first two weeks after surgery patients were provided with low molecular weight heparin (enoxaparin 60 mg subcutaneously daily).

Patients were followed up at the endocrinologist run metabolic surgery clinic at 2 weeks, 3 months, 6 months, and thereafter annually. Postoperative endocrine surveillance included a proactive approach with regards to the expected micro and macronutrient deficiencies according to Endocrine Society Practice guidelines.[13] Postoperative endoscopy was performed on indication in symptomatic patients only.

Baseline data collected included demographics, weight, BMI, and the presence of comorbid disease. Secondary outcomes included procedural details (procedure performed, conversion to open surgery, operating time, intraoperative blood loss, postoperative ward, and length of postoperative hospital stay), and effect of surgery on weight and T2D status, as well as micronutrient status at follow-up. The primary outcome was safety, including mortality, and intraoperative events, and early and late postoperative adverse events.

Definitions

Follow-up, comorbid disease, weight loss, diabetes resolution, and adverse events were defined according to the American Society for Metabolic and Bariatric Surgery (ASMBS) outcome reporting standards.[14] Follow-up was defined as recent (< 6m), very short-term (6m–1yr), short-term (1yr–3yrs), medium term (3yrs–5yrs), and long-term (> 5yrs).

T2D was defined as a serum HbA1c > 6.5% or fasting glucose > 7 mmol/L at two occasions, or a known diagnosis of T2D on treatment. Stage 1 and 2 hypertension were defined as a blood pressure of 140-159/90-99 mmHg or >160/>100 mmHg respectively. Borderline dyslipidaemia was defined as LDL cholesterol 3.4–4.1 mmol/L, total cholesterol 5.2–6.2 mmol/L, and triglycerides 1.7–2.3 mmol/L. Confirmed dyslipidaemia was defined as LDL cholesterol > 4.1 mmol/L, total cholesterol > 6.2 mmol/L, and triglycerides > 2.3 mmol/L. Obstructive sleep apnoea (OSA) was confirmed in cases where an overnight sleep polysomnography test resulted in an Apnoea-Hypopnea Index (AHI) of > 5 events per hour, and it was suspected in patients with an Epworth Sleepiness Scale (ESS) score of more than 12.

Operative weight was defined as the patient's weight as measured closest to the time of surgery. Weight loss was measured in terms of percent total weight loss (%TWL) and percent excess BMI loss (%EBMIL). Percent TWL was calculated as %TWL = [(operative weight) – (follow-up weight)]/[(operative weight)] x 100, and %EBMIL was calculated as %EBMIL = [(operative BMI)-(follow-up BMI)]/[(operative BMI)-25] x 100. Complete remission of T2D was

defined as normal measures of glucose metabolism ($HbA1_c$ < 6% and fasting blood glucose < 5.6 mmol/L) in the absence of antidiabetic medications.

Adverse events were classified as intraoperative events, and early (< 30 days) and late (> 30 days) postoperative adverse events. Intraoperative events included any eventuality (surgical and non-surgical) that resulted in deviation from the standard theatre procedure. Postoperative adverse events were defined as major if they resulted in prolonged hospital stay (> 7 days), or if anticoagulant therapy, re-intervention or re-operation was needed.

Statistical analyses

Statistical analyses were performed with SPSS version 24 for Mac. Descriptive statistics were used and reported as number of patients and percentage of the cohort for discreet values, whereas continuous variables were expressed as mean (standard deviation), with ranges supplied when applicable. Changes in weight were analysed using a paired t-tests, and for comparisons of pre- and postoperative diabetes status, McNemar's was used, and a p-value < 0.05 considered as significant.

Results

Over a 6 year period, a total of 57 patients underwent MS at Tygerberg Hospital, with 28 (49.1%) of these performed in the most recent 12 months (Table 1). One patient was lost to follow-up 2 years after surgery, resulting in a 1-year postoperative follow-up rate of 100%.

The baseline characteristics and procedural details are presented in Table 2. Ninety seven percent of patients were diagnosed with class III obesity, and 84% of patients were classified as super obese (BMI ≥ 50 kg/m^2). For the initial 24 hours postoperatively, 49.1% of patients were treated in a high care unit (surgical or anaesthetic), and 50.9% of patients in the surgical intensive care unit (ICU). All patients were transferred to a general surgical ward after 24 hours. Discharge by postoperative day 3 was achieved in 21 (36.8%) of patients.

Table 3 and Figure 1 represent changes in weight 1 year postoperatively. A complete remission of T2D was observed in 15 patients (62.5%), with a statistically significant reduction from 24 patients (42.1%) with T2D at baseline, to 9 patients (17.3%) with T2D at 1 year follow-up (P = 0.0003). Thirteen patients with T2D (54.2%) could stop all of their antidiabetic medication, and a further 4 patients (16.7%) could decrease the number of medications needed for glucose control. Vitamin B12 deficiency was present in 3.5% (n=52) of patients at 1-year follow-up, with Vitamin D deficiency present in 52.6% (n= 41) of patients. Iron, folate, and calcium deficiencies were present in 21.1% (n=40), 12.3% (n=39), and 15.8% (n=54) of patients respectively.

There were no deaths recorded, and overall morbidity was 14.0% (Table 4). Surgical intraoperative events included bleeding (splenic ooze and port-site bleed), iatrogenic serosal bowel injury (stomach remnant and small bowel), solid organ injury (pancreas laceration and liver subcapsular hematoma), one stapler misfire, and blue dye leak during testing in 7 patients (12.3%). All of these events were noticed immediately and could be dealt with during the same anaesthesia. In one patient postoperative apnoea occurred minutes after extubation, necessitating re-intubation and overnight ventilation. Three major adverse events (5.3%) were recorded, accounting for all the readmissions in this series, with no patients requiring reoperation. Two patients developed deep vein thrombosis (DVT), 2 months and 2 years after surgery respectively, both treated with anticoagulation. A further patient was re-admitted 2 weeks postoperatively with sepsis, dehydration and renal failure, and a diagnosis of emphysematous pyelonephritis (secondary to a stag-horn

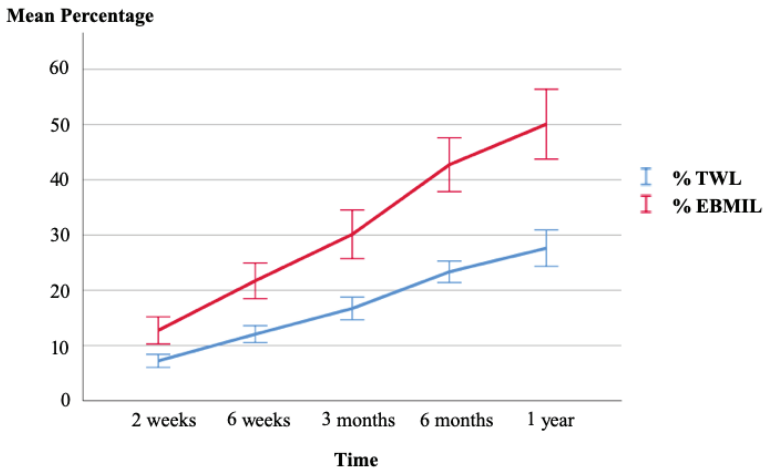

Figure 1. Change in weight 1 year post-operatively. Error bars represent 95% Confidence Intervals. %TWL = Percentage Total Weight Loss, %EBMIL = Percentage Excess Body Mass Index Loss.

Table 1. Follow-up rate during the study period

Follow-up rate (N=57)				
Time after surgery	**Patients operated n (%)**	**Eligible patients**	**Patients who presented**	**Follow-up rate (%)**
< 6 months	21 (36.8%)	57	57	100%
6 months – 1 year	7 (12.3%)	36	36	100%
1 year – 3 years	17 (29.8%)	29	28	96.6%
3 years – 5 years	9 (16.1%)	12	11	91.7%
> 5 years	3 (5.4%)	3	2	66.7%

Table 2. Baseline characteristics and procedural details

Patient characteristic (N=57)	n (%) or mean (SD) [range]
Age (years)	42.8 (8.0) [23-58]
Female sex	44 (83.0)
Weight (kg)	156.3 (32.7) [91-242]
BMI (kg/m2)	58.8 (10.7) [37-83]
< 35	0
35-39.9	2 (3.5)
40-49.9	7 (12.3)
50-59.9	21 (36.9)
60-69.9	17 (29.8)
70-79.9	7 (12.3)
≥ 80	3 (5.3)
Diabetes	
No diabetes	33 (57.9)
Diabetes	24 (42.1)
Hypertension	
No hypertension	23 (40.4)
Stage 1 hypertension	19 (33.3)
Stage 2 hypertension	15 (26.3)
Dyslipidaemia	
No dyslipidaemia	34 (59.7)
Borderline dyslipidaemia	2 (3.5)
Confirmed dyslipidaemia	21 (36.8)
OSA	
No OSA	28 (49.1)
Confirmed testing – no treatment	3 (5.3)
Confirmed testing – home CPAP	8 (14.0)
Suspected symptoms – no treatment	18 (31.6)
GERD	
No GERD symptoms and normal gastroscopy	23 (40.4)
GERD confirmed on gastroscopy	34 (59.6)
Procedural details	
Procedure	
SG without cholecystectomy	1 (1.8)
RYGB with cholecystectomy	11 (19.3)
RYGB without cholecystectomy	45 (78.9)
Operating time (min)	185.0 (48.5) [95-330]
Blood loss (ml)	66.1 (65.4) [10-250]
Conversions to open	0 (0)
Postoperative ward	
High care ward	28 (49.1)
Intensive care unit	29 (50.9)
Postoperative hospital stay (days)	3.9 (1.1) [3-7]

SD = Standard Deviation, BMI = Body mass Index, OSA = Obstructive Sleep Apnoea, CPAP = Continuous Positive Airway Pressure, GERD = Gastro Esophageal Reflux Disease, SG = Sleeve Gastrectomy, RYGB = Roux and Y

Table 3. Change in weight at 1 year (N=39)

	Mean (SD, 95%CI)
Δ Weight (kg)	44.4 (18.1, 37.4–51.3)
Δ BMI (kg/m2)	16.4 (6.2, 13.9–18.9)
%TWL	27.6 (8.1, 24.3–30.9)
%EBMIL	50.4 (15.8, 44.0–56.8)

SD = Standard Deviation, CI = Confidence Interval, BMI = Body Mass Index, %TWL = Percentage Total Weight Loss, %EBMIL = Percentage Excess Body Mass Index Loss

Table 4. Adverese events

Event (N=57)	n (%)
Intra-operative events	15 (26.3)
Surgical	14 (24.6)
Bleeding	2 (3.5)
Bowel injury	2 (3.5)
Solid organ injury	2 (3.5)
Stapler misfire	1(1.8)
Blue dye leak	7 (12.3)
Non-surgical	1 (1.8)
Postoperative apnoea	1 (1.8)
Adverse events	8 (14.0)
Major	3 (5.3)
Early (< 30 days) major A/E	1 (1.8)
Late (> 30 days) major A/E	2 (3.5)
Minor	5 (8.8)
Early (< 30 days) minor A/E	3 (5.3)
Late (> 30 days) minor A/E	2 (3.5)
Mortality	0 (0)
Others	
Postoperative dysphagia	1 (1.8)
Postoperative regurgitation	1 (1.8)
GERD symptoms present	6 (10.5)
GERD confirmed on gastroscopy	1 (1.8)

A/E = Adverse event, GERD = Gastro-Esophageal Reflux Disease

kidney stone) was made, and treated successfully with JJ-stent placement and intravenous antibiotics. Minor adverse events (8.8%) included lignocaine infusion toxicity (n=1), gastroparesis (n=1), wound sepsis (n=1), and dumping syndrome (n=2). One patient developed postoperative dysphagia, and one complained of regurgitation, but in both cases endoscopy and contrast swallows were normal. A further six patients underwent postoperative gastroscopy for heartburn. There was no evidence of esophagitis, marginal ulceration or anastomotic strictures reported, but in one patient Barret's oesophagus changes were confirmed.

Discussion

This report, with short-term follow-up (79% < 3 years), confirms that RYGB can be performed safely in a government hospital setting in South Africa, with mortality (0%) and morbidity (14%) rates comparable to international outcomes. The predominantly middle aged female patient cohort, with a mean BMI of 59 kg/m^2 and 42.1% of patients known with T2D, is comparable to both national and international patient populations undergoing MS.[9-11] The mean BMI of our initial experience leans towards the higher end of the scale when compared to most series, and this is likely reflected in the reported operating time of 185 minutes. When at the beginning of the learning curve, it is prudent to select patients with a lower BMI in order to minimise perioperative risk.

The current study is the only report on RYGB performed in a government setting in South Africa, and provides a detailed description of intraoperative events that might be expected when performing MS. There were no conversions to open surgery, and all events were immediately recognised, with no need for reoperation or known long-term consequences for the patient. Major morbidity after MS has fallen from 5% in older large database reports, to 3% more recently.[15,16] In our series we had no anastomotic leaks, but worldwide the risk remains at 0.09% in randomised controlled trials, and 1.14% in observational studies.[17] Our major and minor morbidity rate of 5.3% and 8.8% respectively also compares well to the limited national numbers available.[9-11] In the current series, where postoperative endoscopy is performed on indication in symptomatic patients only, no marginal ulceration was noted at follow-up. Due to initial reports of marginal ulceration in up to 16% of patients undergoing RYGB, and due to a paucity in studies regarding ideal duration of treatment at the time, we placed all patients on lifelong PPI therapy.[18] There is ongoing debate surrounding the optimal duration of treatment, but recent evidence suggests that a 90-day regimen is superior to a 30-day regimen, and we have adjusted our practice accordingly.[19]

OSA was present in 50.9% of patients, mostly diagnosed based on symptomatology scoring, and most patients did not have preoperative home treatment. One patient required overnight ventilation due to postoperative apnoea. Recent recommendations include the use of the STOP-Bang score in conjunction with saturation monitoring as screening tool for OSA, and we are adjusting accordingly.[20] Due to the low volume of metabolic procedures at our centre, and the often overloaded and understaffed surgical wards, patients were treated in a high-care or ICU for the first 24 hours postoperatively. The demand for high care beds in an academic centre, coupled with the fact that apnoea monitoring and early mobilization form the cornerstone of immediate postoperative care in patients undergoing MS, will lead to innovative postoperative care strategies over time, helping to formulate future guidelines.

With the exception of a single patient undergoing SG, all patients had a RYGB performed, and 19.3% of these were accompanied by a cholecystectomy. The SG was decided on in a patient with a BMI of 83 kg/m^2, where after port placement and liver retraction, limited space and concern for Roux limb reach, suggested a SG to be a safer procedure. At the start of our program, all patients underwent preoperative abdominal ultrasonography, and cholecystectomy was performed for the presence of gallstones.[21] Although controversial due to a reported incidence of postoperative cholelithiasis in up to 38% of patients, we currently follow a conservative approach to asymptomatic gallstone disease.[22-24] In patients with symptomatic gallstones a staged approach is followed due to the increased risk of perioperative complications associated with concomitant cholecystectomy.[25] Should patients develop postoperative choledocholithiasis, laparoscopic assisted endoscopic retrograde cholangiography (ERCP) is considered.[26]

Total weight loss 2–3 years after RYGB ranges between 25.5% and 33.3% in randomised controlled trials (RCT), and our number of 27.6% also compares well to local reports of 29.1%.[9,27,28] Complete remission of T2D can be expected in 78% of diabetics after MS, and 62.5% of diabetics in the current report attained this goal.[29] Reports on T2D remission rates 10 years after MS indicate a fall from 70% to 40%, especially in patients with diabetes duration of longer than 4 years at the time of operation.[30] Pre-existing malnutrition in obese individuals can be exacerbated after MS. The number of patients with postoperative micronutrient deficiencies in our cohort is well below the prevalence of pre-existing (preoperative) micronutrient deficiencies reported in the literature, but it remains a concern in patients with perceived limited resources.[31] Preoperative patient screening is a major contributor to acceptable longer-term outcomes, and large-scale prospective studies are needed to answer questions regarding eligibility criteria for the South African public patient population.

Limitations of the current study include the low volume of patients reported on, as well as the retrospective nature, relying on accurate database entry. Longer-term adverse events such as internal herniation, stomal ulceration and stenosis, and micronutrient deficiencies, especially of concern after RYGB, remain potential risks in a patient population where both immediate and long-term access to health care might be challenging.[32,33] With reference to the Core Outcome Set for the Benefits and Adverse Events of Bariatric and Metabolic Surgery (The BARIACT Project), a further limitation of this study is the absence of data on overall quality of life and cardiovascular risk.[34]

The mortality after MS has in recent years fallen from 2% to 0.3%, and our results prove that it can be performed safely in a government hospital in South Africa.[35] High volume accredited centres and national registries do provide better outcomes, underlining the need for metabolic centres in South African academic hospitals.[36-38] The unique financial, patient volume, and resource restrictions of public health care in South Africa means that we will have to define the future role of MS in the public sector, while ensuring that this treatment option remains available to all patients.

Conclusion

This report is the first to confirm that Roux-and-Y gastric bypass can be performed safely in an academic hospital in South Africa. As outcomes are closely related to both surgeon and centre volume, larger scale studies are needed to answer questions regarding long-term safety and cost-effectiveness.

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Conflict of Interest

None

Author Contributions

All authors contributed to conceptualization, design, analysis and interpretation of data. All authors had a part in the drafting and critical revision of the content, as well as final approval of the version to be published.

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None

Abbreviations

WHO	World Health Organization
MS	Metabolic surgery
SG	Sleeve gastrectomy
RYGB	Roux-and-Y gastric bypass
T2D	Type 2 Diabetes Mellitus
BMI	Body Mass Index
SEMDSA	Society for Endocrinology, Metabolism and Diabetes of South Africa
MDT	Multi-disciplinary team
SASOM	South African Society for Obesity and Metabolism
PPI	Proton pump inhibitor
ASMBS	American Society for Metabolic and Bariatric Surgery
OSA	Obstructive sleep apnea
AHI	Apnea-Hypopnea Index
ESS	Epworth Sleepiness Scale
%TWL	Percent total weight loss
%EBMIL	Percentage excess body mass index loss
ICU	Intensive care unit
SD	Standard Deviation
CPAP	Continuous Positive Airway Pressure
CI	Confidence Interval
DVT	Deep vein thrombosis
ERCP	Endoscopic retrograde cholangiography
RCT	Randomised controlled trial
BARIACT	Benefits and Adverse Events of Bariatric and Metabolic Surgery

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