Prospective Cohort Study

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Safety outcomes of bariatric surgery in patients with advanced organ disease: the ONWARD study: a prospective cohort study

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Introduction: Increasing numbers of patients with advanced organ disease are being considered for bariatric and metabolic surgery (BMS). There is no prospective study on the safety of BMS in these patients. This study aimed to capture outcomes for patients with advanced cardiac, renal, or liver disease undergoing BMS.

Materials and methods: This was a multinational, prospective cohort study on the safety of elective BMS in adults (≥ 18 years) with advanced disease of the heart, liver, or kidney.

Results: Data on 177 patients with advanced diseases of heart, liver, or kidney were submitted by 75 centres in 33 countries. Mean age and BMI was 48.56 ± 11.23 years and 45.55 ± 7.35 kg/m^2, respectively. Laparoscopic sleeve gastrectomy was performed in 124 patients (70%). The 30-day morbidity and mortality were 15.9% ($n = 28$) and 1.1% ($n = 2$), respectively. Thirty-day morbidity was 16.4%, 11.7%, 20.5%, and 50.0% in patients with advanced heart ($n = 11/61$), liver ($n = 8/68$), kidney ($n = 9/44$), and multi-organ disease ($n = 2/4$), respectively. Cardiac patients with left ventricular ejection fraction less than or equal to 35% and New York Heart Association classification 3 or 4, liver patients with model for end-stage liver disease score greater than or equal to 12, and patients with advanced renal disease not on dialysis were at increased risk of complications. Comparison with a propensity score-matched cohort found advanced disease of the heart, liver, or kidney to be significantly associated with higher 30-day morbidity.

Conclusion: Patients with advanced organ disease are at increased risk of 30-day morbidity following BMS. This prospective study quantifies that risk and identifies patients at the highest risk.

Keywords: bariatric surgery, heart failure, liver lailure, metabolic surgery, multi-organ failure, renal failure

Introduction

Bariatric and Metabolic Surgery (BMS) has achieved excellent safety in recent times with a 30-day mortality of around 0.08%[1]. These figures are similar, if not better, compared to the published outcomes for perceived low-risk procedures such as laparoscopic cholecystectomy[2]. This has led to an expansion of the criteria to include groups of patients hitherto considered too risky for BMS[3].

Patients with advanced diseases of organs such as the heart, liver, and kidney fall into this category. These patients can expect significant benefits from BMS that are not very dissimilar to patients without advanced organ disease. Many of them go on to achieve significant, durable weight loss[4,5] which in addition to other benefits, may also improve their prospects of undergoing an organ transplant[6].

There are now several studies demonstrating 'acceptable' risks of BMS in patients with advanced organ disease or 'failure'. However, these studies are retrospective[7] and typically have

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small numbers of patients[4,5] This has led to anxieties that the published literature on this topic may suffer from bias and may not represent the true picture[8].

The aim of the Safety Outcomes of Bariatric Surgery in Patients With Advanced Organ Disease (ONWARD) study was to capture safety outcomes of BMS in patients with advanced organ disease of the heart, liver, or kidney. The primary outcome measure was the 30-day morbidity and mortality following BMS in patients with advanced disease of the heart, liver, or kidneys. The secondary outcome measures were organ function at 30 days and 90 days and the identification of parameters that would help in further risk stratification of these patients.

HIGHLIGHTS

- This study shows the safety of bariatric and metabolic surgery in patients with advanced diseases of heart, liver, or kidneys.
- Overall, 30-day morbidity and mortality were 15.9% and 1.1%, respectively in these patients.
- Patients with multi-organ disease had the highest risk of morbidity or mortality.
- These data can help determine appropriate pathways for bariatric and metabolic surgery patients with advanced organ disease and help quantify risk assessment preoperatively to guide management.

Material and methods

Study design and population

We conducted a global, prospective, multicentre, observational cohort study of elective BMS in adults ($\geq$ 18 years) with advanced organ disease performed between 1/01/2021 and 30/09/2021. Inclusion criteria are described in Table 1. These cut-offs have been widely used in scientific literature to denote advanced diseases of these organs[9–11]. Subgroup analyses were performed using previously recognised cut-offs[12–14] to identify patients at higher risk.

Patients undergoing BMS but not meeting the criteria for an advanced disease of heart, liver, or kidney were excluded as were patients who had previously had an organ transplant or were having one concurrently with the BMS (or within 90 days of the BMS). All consecutive adult patients undergoing elective BMS at participating centres between these dates were included.

Registration and ethical approval

This project was approved as a multinational audit by the clinical governance team. All site project leads were asked to obtain local approvals including ethical approvals as necessary, following their local and national guidelines. Collaborators were also asked to obtain patient consent before submission of data and record that in patients' notes.

Protocol

The study protocol was circulated to all potential recruiting centres to outline the study processes prior to enrolment. This provided details of the inclusion/exclusion criteria, guidance on the need for local registration and study data requirements. A copy of the full study protocol is provided in the supplementary material, Supplemental Digital Content 1, http://links.lww.com/JS9/B165.

Data collection and handling

Data collection was performed prospectively and included patients' demographics, details of surgery performed, in-hospital and 30-day overall, and organ-specific morbidity and mortality. Follow-up protocols varied from unit to unit. Given this study was designed as an audit, we did not want to alter any existing practices in participating centres. This information was collected using 44 questions (Supplementary file, Supplemental Digital Content 1, http://links.lww.com/JS9/B165).

Morbidity was defined as any surgical or non-surgical complication which occurred in the postoperative period within 30 days of surgery. These were captured using the Clavien–Dindo (CD) Classification system for reporting surgical complications[15]. This allowed for easier comparison of data and captured all complications irrespective of their severity. If more than one complication occurred in the same patient, the highest CD score was reported.

Study data were collected and managed using REDCap electronic data capture tools. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies[16]. Data entered on REDCap were examined weekly for any missing or erroneous data throughout the study period, and site leads were contacted for clarification. Collaborators were routinely contacted at 32 days following surgery when the 30-day follow-up data had not been completed and at 92 days when the 90-day follow-up data had not been completed. The final dataset was downloaded on the 30 January 2022 once data queries had been resolved. Data were subsequently re-examined for omissions or abnormalities.

Role of the funding source

The sponsor had no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication

Table 1

Inclusion criteria for ONWARD study.

Organ	Inclusion Criteria
Heart	Left ventricular ejection fraction (LVEF) $\leq$ 40% AND New York Heart Association (NYHA) classification $\geq$ 2
Liver	Patients with chronic liver disease (such as cirrhosis, chronic viral hepatitis, chronic auto-immune hepatitis, alcoholic liver disease, non-alcoholic fatty liver disease (NAFLD) including non-alcoholic steatohepatitis (NASH), haemochromatosis, Wilson's disease, or any other cause of liver failure) with a model of end-stage liver disease (MELD) score of $\geq$ 8
Kidney	Patients on dialysis for end-stage renal disease (ESRD) OR estimated glomerular filtration rate (eGFR) <30 ml/min/1.73 m^2 [Stage 4 chronic kidney disease (CKD) (15–29 ml/min/1.73 m^2) or Stage 5 CKD (< 15 ml/min/1.73 m^2)]

ONWARD, Safety Outcomes of Bariatric Surgery in Patients With Advanced Organ Disease.

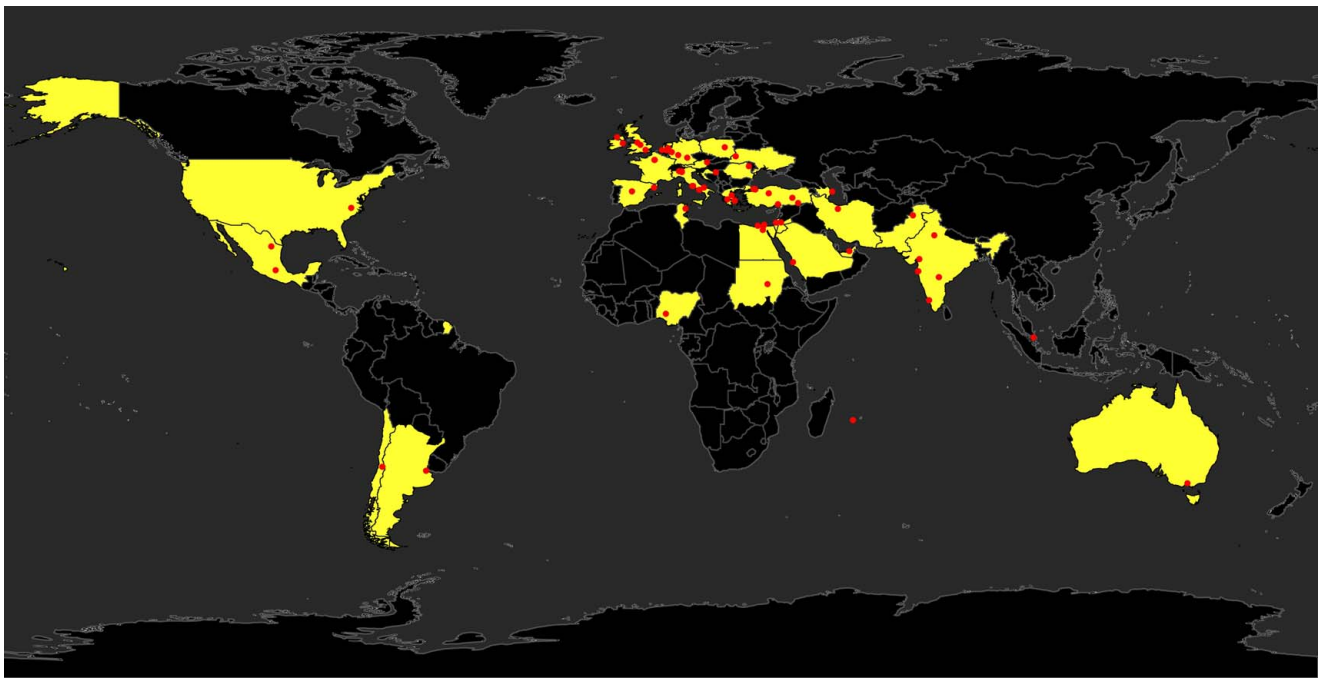

Figure 1. Distribution of centres and countries (participating centres are highlighted as red dots whilst countries are plotted in yellow).

Data reporting

The work has been reported in line with the STROCSS criteria[17]. Supplemental Digital Content 2, Supplemental Digital Content 2, http://links.lww.com/JS9/B166.

Theory

Propensity score matching was carried out to compare patients with organ failure in this study to the general population of BMS patients in the recently published GENEVA study[18,19]. Patients were matched for the following characteristics: sex, type 2 diabetes mellitus status (No diabetes; diet-controlled; oral hypoglycaemics; insulin therapy), hypertension, hypercholesterolaemia, obstructive sleep apnoea, smoking status, age, baseline BMI, and surgical procedure type.

The patients were matched using the nearest neighbour matching method which utilises a greedy search to match each sample with their nearest neighbour. Participants were matched in a 1:4 ratio, that is for each participant in the BMS cohort, four participants from the bigger GENEVA study were added. The distance was calculated using the Mahalanobis distance, which estimates the distribution closest to each point[20]. Standardised mean difference (SMD) was used to examine the balance of covariate distribution between treatment groups. This procedure was performed in R (R Core Team 2021) using the Matchlt package[21,22]. The outcome variable was the presence of a complication at 30-day follow-up.

Data were visualised by mapping onto a cylindrical equidistant projection of the world map using in-house Python software (Python 3.7.7) based on Matplotlib (version 3.1.2) and Basemap (version 1.2.1). To locate each country on the map, the natural earth admin 0 countries file without boundary lakes was used, available at https://www.naturalearthdata.com/http//www.naturalearthdata.com/download/50m/cultural/ne_50m_admin_0_countries_lakes.zip). After rendering individual high-resolution maps within the Matplotlib/Python environment, graphs were finalised using EazyDraw, version 9. For clarity, participating centres have been highlighted as red dots whilst countries are plotted in yellow.

Results

A total of 97 surgeons from 75 centres in 33 countries (Fig. 1) submitted data on 177 patients who underwent BMS with advanced disease of heart ± liver ± kidney between 1 January 2021 and 30 September 2021 at the participating centres. Thirty-day morbidity and mortality data were available for 176 (99.4%) patients. Table 2 provides the basic demographics of these patients.

The mean age of the patients was 48.56 ± 11.23 years, and the mean BMI was 45.55 ± 7.35 kg/m^2. Just over half of the patients were male ($n=91$; 51.4%). A total of 79 (44.6%) patients were current or ex-smokers. Of the 177 patients, 61 had advanced cardiac disease (34.5%), 68 had advanced hepatic disease (38.4%), and 44 had advanced renal disease (24.9%). Four patients had advanced multi-organ disease. The majority of included patients also had other significant co-morbidities.

The most common surgical procedure performed was sleeve gastrectomy (SG) ($n=124$; 70%). This was followed by Roux-En-Y gastric bypass (RYGB) in 27 patients (15.3%) and one anastomosis gastric bypass in 21 (11.9%) of the patients. Only five patients (2.8%) underwent other procedures [two sleeve gastrectomy with bipartition, one single anastomosis

Table 2

Preoperative demographics of patients for each organ disease group.

	Cardiac dysfunction	Hepatic dysfunction	Renal dysfunction	Multiple organ dysfunction
N	61	68	44	4
Age [mean (SD)]	51.24 (8.97)	44.89 (12.85)	49.17 (9.59)	63.03 (7.46)
BMI [mean (SD)]	48.30 (7.72)	43.44 (7.08)	44.53 (5.89)	50.91 (7.46)
Sex (M), *N* (%)	24 (39.3)	42 (61.8)	23 (52.3)	2 (50.0)
Current/ex-smokers, *N* (%)	29 (47.5)	28 (41.2)	20 (45.5)	2 (50.0)
T2DM not on meds, *N* (%)	1 (1.6)	5 (7.4)	4 (9.1)	
T2DM on oral meds, *N* (%)	21 (34.4)	17 (25.0)	7 (15.9)	1 (25.0)
T2DM on insulin, *N* (%)	19 (31.1)	9 (13.2)	19 (43.2)	3 (75.0)
Hypertension, *N* (%)	56 (91.8)	36 (52.9)	32 (72.7)	4 (100.0)
OSA not on CPAP, *N* (%)	17 (27.9)	11 (16.2)	8 (18.2)	2 (50.0)
OSA on CPAP, *N* (%)	24 (39.3)	15 (22.1)	14 (31.8)	1 (25.0)
Hypercholesterolaemia, *N* (%)	39 (63.9)	47 (69.1)	23 (52.3)	3 (75.0)
Surgery type, *N* (%)				
SG	33 (54.1)	52 (76.5)	35 (79.5)	4 (100.0)
RYGB	16 (26.2)	8 (11.8)	3 (6.8)	
OAGB	11 (18.0)	5 (7.4)	5 (11.4)	
Other	1 (1.6)	3 (4.4)	1 (2.3)	
Organ-specific parameters				
Ejection fraction [mean (SD)]	35.49 (5.22)			38.67 (1.53)
NYHA Class, *N* (%)				
2	30 (49.2)			
3	30 (49.2)			2 (50.0)
4	1 (1.6)			1 (25)
MELD [mean (SD)]		9.92 (3.33)		14.25 (4.88)
BILIRUBIN [mean (SD)]		2.48 (5.82)		0.97 (0.52)
INR [mean (SD)]		1.22 (0.26)		1.17 (0.16)
CREATININE [mean (SD)]		8.38 (25.37)		1.84 (0.48)
eGFR [mean (SD)]			23.04 (6.86)	21.46 (5.00)
ON DIALYSIS (%)			25 (56.8)	1 (25)

Other procedures: Sleeve with transit bipartition, Laparoscopic Sleeve gastrectomy (previous gastric band), Laparoscopic Sleeve Gastrectomy with Loop Bipartition, SADI-S, and Conversion to Roux-en-Y Gastric Bypass.

CPAP, continuous positive airway pressure; eGFR, estimated glomerular filtration rate; INR, international normalised ratio; MELD, model for end-stage liver disease; NYHA, New York Heart Association; OAGB, one anastomosis gastric bypass; OSA, obstructive sleep apnoea; RYGB, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; T2DM, type 2 diabetes mellitus.

duodenal-ileal bypass with sleeve, and two revisional procedures (one previous gastric band converted to bypass and one previous gastric band converted to sleeve gastrectomy)] (Table 2).

Thirty-day Morbidity and mortality

Overall, 28 patients (15.9%) experienced at least one 30-day morbidity. Of these, 14 patients (7.9%) had a minor complication (CD grade 1–2) and 14 patients (7.9%) had a major complication (CD grade 3–5) (Table 3). There were two 30-day mortalities (1.1%). One of these patients (Mortality No. 1) had advanced cardiac disease (baseline left ventricular ejection fraction (LVEF) = 34%; New York Heart Association Functional Classification (NYHA) = 3). The other patient (Mortality No. 2) had advanced renal and hepatic disease with cardiac impairment (estimated glomerular filtration rate (eGFR) = 17.93 ml/min/1.73 m^2; model for end-stage liver disease (MELD) score = 17.7; Mild mitral regurgitation and severe tricuspid regurgitation with Severe Pulmonary Hypertension; LVEF = 60%; NYHA = 4). Both of these patients died of an acute coronary event. Rates of complications by surgical procedure type are provided with supplementary file 1, Supplemental Digital Content 1, http://links.lww.com/JS9/B165.

Thirty-day Morbidity and mortality in different subgroups

Cardiac disease group ($n = 61$)

The majority of the patients with cardiac disease underwent SG (33 patients; 54.1%). The mean preoperative LVEF for these patients was 35.49% ± 5.22. There were 30 (49.2%) patients in NYHA categories 2 and 3 each, with only one (1.6%) patient in NYHA category 4 (Table 2). Overall 30-day morbidity and mortality in this group of patients were 16.4% ($n = 10/61$) and 1.6% ($n = 1/61$), respectively. Minor and major complications were seen in five (8.2%) patients each (Table 3). Three of these patients required re-laparoscopy (CD 3.2) for postoperative bleeding (4.92%) (one of these patients was on warfarin for anticoagulation preoperatively). One patient had a negative re-laparoscopy. One patient (CD 4) had Acute Coronary Syndrome with ST elevation and another patient (CD 5) died as mentioned earlier (Mortality No. 1).

These patients were further subdivided into two groups based on their LVEF (LVEF 36–40% $n = 31$; LVEF ≤ 35% $n = 30$) and NYHA categories. Only two patients (6.4%) had a complication when LVEF was between 36 and 40% as compared to eight patients (26.6%) when LVEF was less than or equal to 35%. When data were analysed by NYHA category (NYHA 2 = 30; NYHA 3 and 4 = 31), 3 patients categorised as NYHA 2 (10%) had a postoperative complication as compared to 7 (22.6%)

Table 3

Details of complications in each organ disease group.

	Cardiac	Hepatic	Renal	Multiple
No. Patients	61	68	44	4
Complication (CD), *N* (%)				
0	51 (83.6)	60 (89.6)	35 (79.5)	2 (50.0)
1	2 (3.3)	2 (3.0)	1 (2.3)	
2	3 (4.9)	3 (4.5)	2 (4.5)	1 (25.0)
3.1			1 (2.3)	
3.2	3 (4.9)	2 (3.0)	2 (4.5)	
4.1	1 (1.6)		2 (4.5)	
4.2			1 (2.3)	
5	1 (1.6)			1 (25.0)
Minor complications (CD 1–2)	5 (8.2)	5 (7.4)	3 (6.8)	1 (25.0)
Major complications (CD 3–5)	5 (8.2)	2 (2.9)	6 (13.6)	1 (25.0)
Specific complications				
Acute coronary syndrome	1			
Atrial fibrillation	1			
Bleeding	3	1		
Bowel obstruction		1		
Cardiac failure			2	
Decline in renal function	2	1	2	
Deep vein Thrombosis	1			
Gastric fistula with intra-abdominal collection			1	
Hypertensive crisis		1		
Pneumonia (COVID)		1		
Stricture		1		1
Vomiting			1	
Wound infection			1	

CD, Clavien–Dindo.

NYHA 3 and 4 patients. The majority of the complications in NYHA 3 and 4 category patients were major (Table 4).

Hepatic disease group ($n = 68$)

The majority of the patients with advanced hepatic disease also underwent SG (52; 76.5%). The mean preoperative MELD score for these patients was 9.92 ± 3.33 (Table 2). Overall, 30-day morbidity and mortality in this group of patients were 11.7% ($n = 8/68$) and 0% ($n = 0/68$), respectively. Minor complications were seen in five patients (7.4%) and major complications in two (2.9%) patients (Table 3). One patient required a re-laparoscopy for bowel obstruction post-SG and required an adhesiolysis. Another patient required a re-laparoscopy for vomiting due to post-SG stenosis.

These patients were further subdivided into two groups based on their MELD score (MELD <12 $n = 56$; MELD ≥ 12 $n = 12$). Four (4/56; 7.1%) patients had a complication when the MELD score was less than 12 as opposed to 3/12 (25%) when the MELD score was greater than or equal to 12 (Table 4).

Renal disease group ($n = 44$)

The majority of the patients with advanced renal disease also underwent SG ($n = 35$; 79.5%). More than half of the patients were on dialysis ($n = 25$; 56.8%). The mean preoperative eGFR for patients who were not on dialysis was 23.04 ± 6.86 ml/min/1.73 m^2 (Table 2). Overall, 30-day morbidity and mortality in this group of patients were 20.5% ($n = 9/44$) and 0% ($n = 0/44$), respectively. Minor and major complications were seen in three (6.8%) and six (13.6%) patients, respectively (Table 3). Of patients requiring complication management in intensive care, two patients (CD 4.1 and CD 4.2) developed cardiac failure post-operatively and one patient (CD 4.1) developed a gastric fistula with an intra-abdominal collection. This was treated with radiological drainage and antibiotics. One patient (CD 3.1) required dilatation of SG for stenosis and two more patients (CD 3.2) required a re-laparoscopy for bleeding.

Four (16%) patients who were on dialysis preoperatively developed a complication. Three of these patients required management in intensive care. Five patients (26.3%) who were not on dialysis preoperatively developed a postoperative complication; none required management in intensive care (Table 4).

Multiple organ disease group ($n = 4$)

Four patients had multiple organ advanced diseases—one patient with advanced cardiac and hepatic disease, two patients with advanced cardiac and renal disease, and one patient with advanced renal and hepatic disease with some cardiac impairment. All patients underwent SG in this group. Two patients developed 30-day morbidity ($n = 2/4$; 50%). One patient required total parenteral nutrition for a gastric stricture (CD 2). One patient died ($n = 1/4$; 25%)) as described earlier (Mortality No. 2) (Table 4).

Changes in organ function at 30/ 90 days

A mean improvement in LVEF of 3.42% ± 5.6 was seen for 45 patients at 30 days (Supplementary Table 1, Supplemental Digital Content 1, http://links.lww.com/JS9/B165). No change in NYHA was noticed for 27 patients (56.2%), with improvement by one point for 20 (41.7%) patients and by two points for one patient (2.1%). The mean MELD score improved by 1.72 ± 2.03 for 50 patients. Mean eGFR improved by 2.92 ± 6.19 for 16 patients.

At 90 days, a mean improvement in LVEF of 7.82% ± 6.64 was seen for 49 patients. No change in NYHA was noticed for 9 patients (17.6%), with improvement by one point for 35 (68.6%) patients, by 2 points for 6 (11.8%), and by 3 points for one patient (2%). The mean MELD score improved by 2.07 ± 3.33 for 49 patients. Mean eGFR improved by 5.85 ml/min/1.73 m^2 ± 5.3 for 15 patients.

Concerning dialysis, 25 patients with advanced renal disease (eGFR <30 ml/min/1.73 m^2) were on dialysis preoperatively. Two of these patients were able to come off dialysis at 30-day and 90-day follow-ups. However, of the 16 patients not on dialysis preoperatively, two were requiring dialysis at the 30-day and 90-day follow-up (preoperative eGFR 25 and 30 ml/min/1.73 m^2, respectively).

Propensity score matching

For propensity score matching, each of the 171 patients in the ONWARD database (six patients were excluded due to missing data) was matched with four patients in our previously published large global collaborative study (GENEVA) database (Supplementary file, Supplemental Digital Content 1, http://links.lww.com/JS9/B165). Pre-matching, only one SMD was less than 0.2. Post-matching, all SMDs were less than 0.2. Pre-matching, there was a statistically significant difference in the complications between the two databases (GENEVA 4.2% vs. ONWARD 16.4%; $P < 0.001$). This difference persisted post-matching (GENEVA 6.6% vs. ONWARD 16.4%; $P < 0.001$) (Tables 5, 6).

Table 4

Patient demographics and complications divided by subgroups in each organ disease group.

	Cardiac				Hepatic		Renal		
	EF 36–40	EF ≤ 35	NYHA 2	NYHA 3&4	MELD <12	MELD ≥ 12	No preop dialysis	On preop dialysis	Multi-organ disease
N	31	30	30	31	56	12	19	25	4
Age (mean (SD))	52.84 (7.91)	49.65 (9.79)	52.10 (8.86)	50.39 (9.14)	44.17 (13.11)	48.17 (11.47)	49.96 (9.54)	48.57 (9.77)	63.2 (7.5)
BMI (mean (SD))	48.49 (7.50)	48.09 (8.06)	47.23 (6.89)	49.33 (8.42)	42.45 (6.35)	48.07 (8.68)	44.33 (5.86)	44.68 (6.04)	50.9 (7.5)
Sex (M), *N* (%)	12 (38.7)	12 (40.0)	9 (30.0)	15 (48.4)	36 (64.3)	6 (50.0)	10 (52.6)	13 (52.0)	2 (50.0)
Current/ ex-smoker, *N* (%)	15 (48.4)	14 (46.7)	11 (36.7)	18 (58.1)	25 (44.6)	3 (25.0)	11 (57.9)	9 (36.0)	2 (50.0)
Surgery type, *N* (%)									
LSG	19 (61.3)	14 (46.7)	17 (56.7)	16 (51.6)	43 (76.8)	9 (75.0)	13 (68.4)	22 (88.0)	4 (100.0)
RYGB	5 (16.1)	11 (36.7)	9 (30.0)	7 (22.6)	7 (12.5)	1 (8.3)	2 (10.5)	1 (4.0)	
OAGB	7 (22.6)	4 (13.3)	3 (10.0)	8 (25.8)	4 (7.1)	1 (8.3)	4 (21.1)	1 (4.0)	
Other		1 (3.3)	1 (3.3)		2 (3.6)	1 (8.3)		1 (4.0)	
T2DM not on meds, *N* (%)		1 (3.3)	1 (3.3)		5 (8.9)		3 (15.8)	1 (4.0)	
T2DM on oral meds, *N* (%)	13 (41.9)	8 (26.7)	9 (30.0)	12 (38.7)	13 (23.2)	4 (33.3)	4 (21.1)	3 (12.0)	1 (25.0)
T2DM on insulin, *N* (%)	9 (29.0)	10 (33.3)	12 (40.0)	7 (22.6)	6 (10.7)	3 (25.0)	6 (31.6)	13 (52.0)	3 (75.0)
Hypertension, *N* (%)	31 (100.0)	25 (83.3)	28 (93.3)	28 (90.3)	29 (51.8)	7 (58.3)	13 (68.4)	19 (76.0)	4 (100.0)
OSA not on CPAP, *N* (%)	8 (25.8)	9 (30.0)	8 (26.7)	9 (29.0)	11 (19.6)		3 (15.8)	5 (20.0)	2 (50.0)
OSA on CPAP, *N* (%)	15 (48.4)	9 (30.0)	12 (40.0)	12 (38.7)	11 (19.6)	4 (33.3)	4 (21.1)	10 (40.0)	1 (25.0)
Hypercholesterolaemia, *N* (%)	18 (58.1)	21 (70.0)	14 (46.7)	25 (80.6)	40 (71.4)	7 (58.3)	10 (52.6)	13 (52.0)	3 (75.0)
Complication (CD), *N* (%)									
0	29 (93.5)	22 (73.3)	27 (90.0)	24 (77.4)	51 (92.7)	9 (75.0)	14 (73.7)	21 (84.0)	2 (50.0)
1		2 (6.7)	1 (3.3)	1 (3.2)	1 (1.8)	1 (8.3)	1 (5.3)		
2	1 (3.2)	2 (6.7)	1 (3.3)	2 (6.5)	3 (5.5)		1 (5.3)	1 (4.0)	1 (25.0)
3.1							1 (5.3)		
3.2	1 (3.2)	2 (6.7)	1 (3.3)	2 (6.5)		2 (16.7)	2 (10.5)		
4.1		1 (3.3)		1 (3.2)				2 (8.0)	
4.2								1 (4.0)	
5		1 (3.3)		1 (3.2)					1 (25.0)
CD (1–2)	1 (3.2)	4 (13.3)	2 (6.7)	3 (9.7)	4 (7.1)	1 (8.3)	2 (10.5)	1 (4.0)	1 (25.0)
CD (3–5)	1 (3.2)	4 (13.3)	1 (3.3)	4 (12.9)		2 (16.7)	3 (15.8)	3 (12.0)	1 (25.0)

CD, Clavien–Dindo; CPAP, continuous positive airway pressure; EF, ejection fraction; LSG, laparoscopic sleeve gastrectomy; MELD, model for end-stage liver disease; NYHA, New York Heart Association; OAGB, one anastomosis gastric bypass; OSA, obstructive sleep apnoea; Postop, postoperative; Preop, preoperative; RYGB, Roux-en-Y gastric bypass; T2DM, type 2 diabetes mellitus.

Discussion

This global prospective study of the safety of BMS in patients with advanced diseases of the liver, heart, or kidney found an overall 30-day morbidity and mortality rate of 15.9% and 1.1%, respectively. 30-day morbidity was 16.4%, 11.7%, 20.5%, and 50.0% in patients with advanced heart ($n = 11/61$), liver ($n = 8/68$), kidney ($n = 9/44$), and multi-organ disease ($n = 2/4$), respectively. Corresponding figures for 30-day mortality were 1.6% ($n = 1/61$), 0% (0/68), 0% (0/44), and 25.0% ($n = 1/4$). A comparison of these results with a propensity score-matched cohort of general BMS patients from the GENEVA study demonstrated that advanced disease of the heart, liver, and kidney was associated with higher 30-day morbidity following BMS.

The overall 30-day morbidity and mortality of 16.4% and 1.1% appear to be higher than 4.2% and 0.04%, respectively, that we found in a recent large global study of an unselected cohort of patients undergoing primary BMS[19]. The difference in 30-day morbidity narrowed somewhat on matching but was still highly significant. To the best of our knowledge, there is no other study comparing 30-day morbidity in patients with advanced organ disease undergoing BMS with that in an unselected cohort.

Our data also show that patients with end-organ disease preoperatively are likely to experience significant benefits from BMS. At 90 days of follow-up, there was an improvement in cardiac, hepatic, and renal function in this cohort of patients.

BMS has previously been demonstrated to improve systolic function for patients with established left ventricular dysfunction[23,24]. This was also demonstrated in our study with an improvement in both LVEF and NYHA classification. The mechanisms behind this improvement are not fully understood but are likely multifactorial including reduced left ventricular hypertrophy, and resolution of metabolic dysfunction to improve cardiac muscle function and relaxation[23]. When it comes to the liver, although patients with potentially reversible stages of liver disease are known to derive benefits from BMS[25], the picture for patients with more severe forms of hepatic dysfunction is less clear. Remarkably, patients with advanced hepatic disease in the current study noticed an improvement in MELD scores at 30-day and 90-day follow-ups. A recent randomised controlled trial has demonstrated that patients with non-alcoholic steatohepatosis have significant histological improvement following MBS which is more effective than lifestyle intervention or optimised medical therapy[26]. Other studies have demonstrated that this effect can also be seen in advanced liver fibrosis patients[27]. Bariatric-metabolic surgery is also known to significantly improve renal function through reduced nephron damage and decreased inflammation alongside other factors such as improvements in

Table 5

A comparison of GENEVA and ONWARD data before and after propensity score matching (4:1).

	Pre-matching				Post-matching			
	GENEVA	ONWARD	*P*	Standardised difference pre-matching (95% CI)	GENEVA	ONWARD	*P*	Standardised difference post-matching (95% CI)
Number	6770	171			684	171		
Mean age (year)[a]	40.32 (11.85)	48.68 (11.21)	< 0.001	0.725 (0.573–0.877)	46.99 (11.38)	48.68 (11.21)	0.081	0.15 (– 0.018 to 0.318)
Mean BMI (kg/m^2)[a]	41.86 (9.99)	45.63 (7.29)	< 0.001	0.43 (0.278–0.582)	44.61 (7.47)	45.63 (7.29)	0.111	0.137 (– 0.03 to 0.305)
Sex (male)[b]	1802 (26.6)	84 (49.1)	< 0.001	0.477 (0.325–0.629)	297 (43.4)	84 (49.1)	0.209	0.115 (– 0.053 to 0.282)
Current/ ex-smoker[b]	1834 (27.1)	77 (45.0)	< 0.001	0.38 (0.228–0.532)	250 (36.5)	77 (45.0)	0.051	0.173 (0.005–0.341)
T2DM[b]	390 (5.8)	10 (5.8)			40 (5.8)	10 (5.8)		
Diet-controlled	798 (11.8)	44 (25.7)	1	0.004 (– 0.148 to 0.155)	182 (26.6)	44 (25.7)	1	0 (– 0.168 to 0.168)
Oral hypoglycaemics	224 (3.3)	47 (27.5)	< 0.001	0.363 (0.211–0.515)	188 (27.5)	47 (27.5)	0.892	0.02 (– 0.148 to 0.188)
Insulin therapy			< 0.001	0.711 (0.559–0.863)			1	0 (– 0.168 to 0.168)
Hypercholesterolaemia[b]	1463 (21.6)	108 (63.2)	< 0.001	0.927 (0.774–1.079)	411 (60.1)	108 (63.2)	0.517	0.063 (– 0.104 to 0.231)
Hypertension[b]	2093 (30.9)	123 (71.9)	< 0.001	0.9 (0.747–1.052)	461 (67.4)	123 (71.9)	0.295	0.099 (– 0.069 to 0.266)
Obstructive sleep apnoea on CPAP[b]	900 (13.3)	51 (29.8)	< 0.001	0.41 (0.258–0.562)	175 (25.6)	51 (29.8)	0.304	0.095 (– 0.073 to 0.262)
Obstructive sleep apnoea not on CPAP[b]	821 (12.1)	37 (21.6)	< 0.001	0.256 (0.104–0.408)	147 (21.5)	37 (21.6)	1	0.004 (– 0.164 to 0.171)
Surgery type			< 0.001	0.362 (0.21–0.514)			0.155	0.171 (0.003–0.339)
LSG	3983 (58.8)	124 (72.5)			447 (65.4)	124 (72.5)		
RYGB	2085 (30.8)	27 (15.8)			151 (22.1)	27 (15.8)		
OAGB	702 (10.4)	20 (11.7)			86 (12.6)	20 (11.7)		

[a]Numerical variables reported as mean (SD), statistical test performed is *t*-test.

[b]Categorical variables reported as number of participants (%), statistical test performed is $\chi 2$ test.

CPAP, continuous positive airway pressure; GENEVA, Global 30-day outcomes after bariatric surgery during the COVID-19 pandemic; LSG, laparoscopic sleeve gastrectomy; OABG, one anastomosis gastric bypass; ONWARD, outcomes of bariatric surgery in patients with advanced organ disease; RYBG, Roux-en-Y gastric bypass; T2DM, type 2 diabetes mellitus.

hypertension[28]. Two patients in the current cohort who were on dialysis preoperatively were no longer needing dialysis on follow-up At the same time, surgery was not able to prevent two other patients from progressing to dialysis. Interestingly; however, the current study shows that patients on dialysis had lower morbidity as opposed to those with advanced renal disease but were not on dialysis. Future studies will need to examine if being on dialysis preoperatively allows for a more stable homoeostatic environment in the perioperative period.

Patients with obesity and end-stage organ disease face significant barriers to organ transplantation due to their increased weight[6]. Many transplant centres enforce BMI cut-offs for determining patients' eligibility for transplant waiting lists. In patients with severe obesity, BMS can offer a viable 'bridge' to transplant and in some cases, organ function improves to such an extent that a transplant is no longer needed[6]. Furthermore, patients who underwent a BMS before a kidney transplant do not appear to be at an increased risk of graft failure or death following the transplant[29]. Our prospective data could prove useful in developing clinical pathways for these patients as organ transplant teams and patients could use it to understand if the additional risks of BMS outweigh the risks of transplantation at the patient's usual weight. At the same time, one also has to consider additional benefits of BMS in terms of weight loss and amelioration of obesity-associated co-morbidities.

In the general population receiving BMS, SG appears to be associated with a reduced risk of morbidity and mortality in comparison with RYGB[30]. This probably explains why the

Table 6

Complications in propensity score-matched populations.

	Pre-matching				Post-matching			
	GENEVA (6770)	ONWARD (171)	*P*[a]	SMD	GENEVA (684)	ONWARD (171)	*P*[a]	SMD
30-day complication			< 0.001	0.423 (0.271–0.574)			< 0.001	0.358 (0.19–0.527)
CD 0	6485 (95.8)	143 (83.6)			639 (93.4)	143 (83.6)		
CD 1	96 (1.4)	5 (2.9)			14 (2.0)	5 (2.9)		
CD 2	78 (1.2)	9 (5.3)			9 (1.3)	9 (5.3)		
CD 3.1	18 (0.3)	1 (0.6)			5 (0.7)	1 (0.6)		
CD 3.2	65 (1.0)	7 (4.1)			12 (1.8)	7 (4.1)		
CD 4.1	23 (0.3)	3 (1.8)			4 (0.5)	3 (1.8)		
CD 4.2	2 (0.0)	1 (0.6)			1 (0.1)	1 (0.6)		
CD 5	3 (0.0)	2 (1.2)			0 (0.0)	2 (1.2)		

CD, Clavien–Dindo; ONWARD, outcomes of bariatric surgery in patients with advanced organ disease; SMD, standardised mean difference.

[a]Fisher's exact test.

majority (70% of included cases) of the patients in this study underwent an SG. Shorter operating times with SG compared to a bypass may offer further benefits in such high-risk cases. There may be additional potential benefits of SG in this group of patients. For renal transplant patients, previous SG has been demonstrated to be associated with a reduced risk of graft failure compared to those having received RYGB[29], and SG patients are at a reduced risk of renal stone development[31]. Following liver transplantation, SG has the additional benefit of more straightforward access to the ampullary region for endoscopic retrograde cholangiopancreatography should it be necessary for the management of biliary leak or stricture following transplantation. Finally, the pharmacokinetics and absorption of immunosuppressive agents may be more predictable following SG relative to gastric bypass procedures. Despite these potential benefits it was not possible to draw firm conclusions from the current study regarding the relative safety of SG in patients with end-stage organ disease compared to other BMS procedures due to the vast majority of patients in this series receiving SG. Although the majority of patients received SG, 30% of patients still had other procedures (mostly RYGB or one anastomosis gastric bypass). Procedure choice was not influenced in this study and was left to our collaborators to determine in consultation with their patients. Although it is generally considered that SG has a lower perioperative risk profile than bypass-type procedures, there is limited data on safety and efficacy of different BMS procedures for this cohort of patients. Furthermore, in patients with advanced liver disease it is important to consider the potential effect of bypass on liver function as there are reports of liver decompensation in patients with no pre-existing diagnosis of cirrhosis following a gastric bypass[32]. However, in the current study, this effect was not noted during the 30-day follow-up. Of the 68 patients with advanced liver disease in this study, 53 underwent LSG, and the remaining underwent some sort of bypass procedure. In the patients who underwent LSG, the mean improvement in MELD score at 30 days was 1.55 (only three patients had minimal deterioration). On the other hand, for the remaining patients, the mean improvement in MELD at 30 days was 2.2 (minimal deterioration in one patient). Though beyond the scope of this study, longer term data regarding impact on liver functions for different procedures would be interesting.

Data regarding the specific indication for BMS was not collected as part of the current study. It is well reported that BMS has a multi-modality effect contributing to weight loss and resolution of co-morbidities to improve functional health status[33]. In this population of end-stage organ disease patients, BMS is often being considered as a bridge to facilitate later solid organ transplantation. However, in some instances health status can improve sufficiently to the point where organ transplantation is no longer necessary. A previous meta-analysis has identified that 29.5% of renal failure patients who underwent BMS subsequently received a kidney transplant[6]. Of cardiac failure patients 29.3% received heart transplant whilst 8.5% had sufficient improvement in health status following BMS such that consideration of transplantation was no longer necessary. For hepatic failure patients results were even more favourable with 41.5% achieving transplant and 21.9% no longer requiring transplantation due to clinical improvement[6].

Significant strengths of the present study include its prospective nature, multicentre global participation, good sample size, and high (99.4%) rate of 30-day follow-up data completion. At the same time, several potential weaknesses must be considered when interpreting the data from this study. Due to a paucity of robust, prospective, data on this subject prior to this investigation, it was not feasible to perform a power calculation to define recruitment targets prior to commencing the study. However, the present data should be able to inform power calculations for future studies in this field. All data from participating centres were self-reported and we cannot independently confirm their authenticity. In particular, we cannot be sure that all morbidity/ mortality were reported. At the same time, given that data were analysed and reported anonymously, there was no incentive for inaccurate reporting. Similarly, though collaborators were repeatedly reminded to submit all consecutive patients meeting inclusive criteria during the study period, we cannot be sure if this was adhered to. The lack of robust historic data on this topic prevented a formal power calculation thus introducing further bias into our analysis. Also, because our primary endpoint was 30-day morbidity and mortality, our analysis cannot comment on weight loss or co-morbidity resolution outcomes. Indeed, there is published data confirming the efficacy of BMS in this group of patients. It was also not possible to assess how many patients may have gone on to receive organ transplantation. Due to the relatively low event rates of perioperative complications in each patient group it was not possible to draw specific conclusions regarding differences in complication types in the various forms of end-stage organ disease. It appeared there was an increased incidence of bleeding related complications in the cardiac disease group which was hypothesised to be secondary to increased use of anticoagulants or antiplatelet medication. However, it was not possible to identify any other potential patterns of complication types. Finally, though this is a multicentre study involving 75 centres in 33 countries, our findings may not apply to all populations and need further confirmation. Particularly as an international study there may be differences in operation choice between countries which could not be accounted for here. It is also important to note that number of centres in Europe that submitted data were proportionally larger than those from Oceania and the Americas. This may have implications for generalisability of this data.

Conclusion

The present study has demonstrated that patients with advanced disease of the liver and/or heart and/or kidney experience higher 30-day morbidity with BMS in comparison with a propensity-matched unselected cohort of general BMS patients. On subgroup analysis, patients with an LVEF less than or equal to 35%, NYHA class 3 and 4, MELD score of greater than or equal to 12, or advanced renal disease patients not on preoperative dialysis had even higher 30-day morbidity. These data can potentially help clinicians develop optimum care pathways for these patients.

Ethical approval

This project was approved as a multinational audit by the clinical governance team at University Hospitals Birmingham, NHS Foundation Trust, United Kingdom (UK) (Registration number 5459). All site project leads were asked to obtain local approvals

including ethical approvals as necessary, in accordance with their local and national guidelines.

Consent

All site project leads were asked to obtain local approvals including ethical approvals as necessary, following their local and national guidelines. Collaborators were also asked to obtain patient consent before submission of data and record that in patients' notes. Written informed consent was obtained from the patient for publication and any accompanying images and documented in the notes. A copy of the written consent will be made available for review by the Editor-in-Chief of this journal on request.

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Author contribution

ONWARD conceived by R.S. and K.M. Manuscript writing: K.M., W.H., T.W. and R.S. All authors have reviewed the manuscript and seen the final draft. Tables: Y.R., T.W. and V.R.C. Analysis: R.S., V.R.C., C.L. and G.G. Data collection and conduct: R.S. and K.M.

Conflict of interest disclosure

K.M. has been paid honoraria by various NHS trusts and Ethicon, Medtronic, Gore Inc, and Olympus for educational activities related to bariatric surgery. Other Authors have no conflicts of interest.

Research registration unique identifying number (UIN)

The Research Registry https://www.researchregistry.com/browse-the-registry#home/researchregistry9262.

Guarantor

I, Rishi Singhal, am the guarantor and accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Data availability statement

Anonymised Data for ONWARD and GENEVA study can be made available at request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Study protocol

A brief study protocol attached as an appendix. Supplemental Digital Content 1, http://links.lww.com/JS9/B165.

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