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Effect of BMI on safety of bariatric surgery during the COVID-19 pandemic, procedure choice, and safety protocols – An analysis from the GENEVA Study

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ABSTRACT

Background: It has been suggested that patients with a Body Mass Index (BMI) of $> 60 \text{ kg/m}^2$ should be offered expedited Bariatric Surgery (BS) during the Coronavirus Disease-2019 (COVID-19) pandemic. The main objective of this study was to assess the safety of this approach.

Methods: We conducted a global study of patients who underwent BS between 1/05/2020 and 31/10/2020. Patients were divided into three groups according to their preoperative BMI - Group I (BMI $< 50 \text{ kg/m}^2$), Group II (BMI $50\text{--}60 \text{ kg/m}^2$), and Group III (BMI $> 60 \text{ kg/m}^2$). The effect of preoperative BMI on 30-day morbidity and mortality, procedure choice, COVID-19 specific safety protocols, and comorbidities was assessed.

Results: This study included 7084 patients (5197;73.4 % females). The mean preoperative weight and BMI were $119.49 \pm 24.4 \text{ Kgs}$ and $43.03 \pm 6.9 \text{ Kg/m}^2$, respectively. Group I included 6024 (85 %) patients, whereas Groups II and III included 905 (13 %) and 155 (2 %) patients, respectively.

The 30-day mortality rate was higher in Group III ($p = 0.001$). The complication rate and COVID-19 infection were not different. Comorbidities were significantly more likely in Group III ($p < 0.001$). A significantly higher proportion of patients in group III received Sleeve Gastrectomy or One Anastomosis Gastric Bypass compared to other groups. Patients with a BMI of $> 70 \text{ kg/m}^2$ had a 30-day mortality of 7.7 % (2/26). None of these patients underwent a Roux-en-Y Gastric Bypass.

Conclusion: The 30-day mortality rate was significantly higher in patients with BMI $> 60 \text{ kg/m}^2$. There was, however, no significant difference in complications rates in different BMI groups, probably due to differences in procedure selection.

1. Introduction

Obesity is independently associated with higher morbidity and mortality from Coronavirus Disease-2019 (COVID-19) [1,2]. The obesity-related comorbidities [3], in addition to the imbalance between the pro-and anti-inflammatory mechanisms and dysregulated metabolic and inflammatory pathways [4–7], may contribute to the poorer outcomes seen in patients with obesity who develop COVID-19 infection. It

is speculated that the pandemic will worsen global obesity due to factors such as a more sedentary lifestyle, higher consumption of energy-dense food, reduced opportunities to undertake physical exercise, and reduced availability/ cessation of weight management services, including Bariatric Surgery (BS) [8].

Global surveys of bariatric surgeons were conducted in order to further understand the impact of the pandemic on BS globally [9]. Criteria were developed recommending prioritisation of BS for certain

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groups of patients [10]. Amongst other things, the authors of this landmark paper recommended expedited access for those with a Body Mass Index (BMI) of $> 60 \text{ kg/m}^2$. However, the risks and benefits of this recommendation have not been fully examined. In particular, all-cause and COVID-19 specific morbidity and mortality of BS in this group of patients compared to patients with lower BMI are not known. There is further scarce data in the scientific literature on the effect of BMI on procedure choice, COVID-19 specific protocol, and overall comorbidity burden.

The Global (GENEVA) study [11] examined outcomes of BMS performed globally during the COVID-19 pandemic. This study showed that 30-day mortality at 0.05 % and morbidity at 6.8 % with BS performed during the COVID-19 pandemic was similar to pre-pandemic figures. In this paper, we examine the effect of preoperative BMI on all-cause and COVID-19 related 30-day morbidity and mortality, procedure choice, COVID-19 safety protocols, and comorbidity burden in different BMI groups amongst GENEVA participants.

2. Subjects, materials and methods

2.1. Study design, setting, and population

The present study was a BMI-based analysis of the GENEVA study dataset. The GENEVA study was a global, multicentre, observational cohort study of BMS (elective primary, elective revisional, and emergency) in adults (≥ 18 years) performed between 1/05/2020 and 31/10/2020. The study start date was May 01, 2020, to exclude patients who underwent BMS before the pandemic's full scale, and its effect on surgical patients became widely known. The detailed methods of the GENEVA study have been previously described [11,12]. Appendix 1 includes the full Data Collection Questionnaires and GENEVA collaborators.

In this study, we divided patients undergoing primary BMS into three groups – BMI $< 50 \text{ kg/m}^2$ (Group I), BMI $50\text{--}60 \text{ kg/m}^2$ (Group II), and BMI $> 60 \text{ kg/m}^2$ (Group III). Three groups were compared with each other for 30-day all-cause and COVID-19 specific morbidity and mortality, procedure choice, COVID-19 safety protocols, as well as comorbidity burden.

2.2. Data collected and handling

2.2.1. Variables examined

In this study, we included patients' demographics, preoperative comorbidities, preoperative BMI, details of surgery performed, preoperative COVID-testing protocols and outcomes, in-hospital and 30-day COVID-19, and surgery-specific morbidity and mortality.

2.2.2. The primary outcomes

30-day all-cause and COVID-19 specific morbidity and mortality in different groups.

2.2.3. The secondary outcomes

Procedure choice, COVID-19 safety protocols, and preoperative comorbidities in different groups.

2.2.4. Bias

This is an observational study; hence prone to selection bias. Data were, however, collected anonymously to reduce reporting bias. Collaborators were further repeatedly reminded of the importance of submitting data for all consecutive patients during the study period.

2.2.5. Statistical methods

Continuous data were presented as mean \pm standard deviation (SD) or median (IQR) depending on data distribution. Frequencies were used to summarise categorical variables. Independent t-test or Mann Whitney U test was used to examine differences between continuous variables

depending on data distribution. A Chi-Square test was used to compare categorical variables. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) statistical software, version 27.0 (SPSS Inc).

3. Results

A total of 470 surgeons from 179 centers in 42 countries submitted data on 7092 adult patients who underwent primary BMS between 01/05/2020 and 31/10/2020 at the participating centers. Of these, complete 30-day morbidity and mortality data were available for 7084 (99.88 %) patients by Dec 10, 2020.

The mean age was 40.35 ± 11.9 years, and 5197 (73.4 %) were females. The mean preoperative weight and BMI were $119.49 \pm 24.4 \text{ Kg}$ and $43.03 \pm 6.9 \text{ kg/m}^2$, respectively. The majority of the patients had a BMI $< 50 \text{ kg/m}^2$ (Group I – $N = 6024$ (85 %)), whereas Group II (BMI $50\text{--}60 \text{ kg/m}^2$) and Group III (BMI $> 60 \text{ kg/m}^2$) included 905 (13 %) and 155 (2 %) patients respectively. Table 1 compares the basic demographic data of three groups.

The prevalence of comorbidities within the whole cohort was 68.9 % (4879 patients). 1534 (21.65 %) patients had diabetes; 421 (5.9 %), 860 (12.1 %), and 253 (3.6 %) had diet Controlled diabetes, diabetes on oral medication, and insulin-dependent diabetes, respectively. A total of 2189 (30.9 %) patients suffered from hypertension, 1523 (21.5 %) had hypercholesterolaemia, and 1806 (25.5 %) had obstructive sleep apnoea; 949 (13.4 %) on CPAP and 857 (12.1 %) not on CPAP.

Table 2 compares comorbidities amongst the three study groups. Patients in group III were significantly more likely to suffer from obesity-related comorbidities ($p < 0.001$). Further analysis of individual comorbidities showed that 31 % of patients in group III suffered from type 2 diabetes mellitus (T2DM) compared to 26.3 % and 19.7 % in Group II and Group I, respectively ($p < 0.001$). Similarly, group III patients were significantly more likely to be suffering from hypertension (HTN) or obstructive sleep apnoea (OSA) ($p < 0.001$).

Table 3 shows the preoperative workup specific to COVID-19. A significantly higher percentage of patients in group I was advised self-isolation preoperatively – 44.8 % compared to 39.6 % and 36.8 % in groups II and III, respectively ($p = 0.002$). Most patients in each group underwent some preoperative test to rule out active COVID-19 infection or to confirm immunity. However, group III patients (89 %) were significantly more likely to have undergone preoperative testing compared to groups II and I (82.7 % and 80.5 % respectively, $p = 0.01$).

The surgical procedure varied significantly depending on the patients' BMI (Table 4). Although SG was the commonest procedure in each group, a significantly higher proportion of patients (71.6 %) in group III received SG compared to group II (58.5 %) and group I (55.6 %) ($p < 0.001$). OAGB was also more frequently performed for patients in group III (14.8 %) compared to group II (14 %) and group I (9.2 %) ($p < 0.001$). The proportion of patients who received RYGB was significantly higher in group I (30.9 %) compared to 23.9 % and 7.7 % in Group II and Group III, respectively ($p < 0.001$). Table 5.

A total of 479 (6.8 %) patients developed a complication with 30 days of surgery. There was no statistical difference in the incidence of complications between the three groups ($p = 0.688$). The rates of COVID-19 infection were not different between the groups: 1.3 % of patients in group III contracted COVID-19 within 30 days of surgery compared to 0.6 % and 0.5 % of groups II and I, respectively ($p = 0.286$). Ten patients died within 30 days of surgery. Group III patients were significantly more likely to experience a 30-day mortality ($n = 3$; 1.9 %) compared to Group I ($n = 6$; 0.1 %) and Group II ($n = 1$; 0.1 %).

Overall, 26 patients with a BMI of $> 70 \text{ kg/m}^2$ underwent primary bariatric surgery in this cohort. The mean BMI for this cohort was $74.88 \pm 6.3 \text{ kg/m}^2$. There was an equal proportion of males and females in this group (14 females; 53.8 %). With regards to comorbidities, 24 patients (92.3 %) had at least one comorbidity. This included diabetes (9 patients; 34.6 %), hypertension (16 patients; 61.5 %), Sleep Apnoea not on

Table 1
Comparison between the three groups according to the demographic data and smoking.

	Group I BMI < 50	Group II BMI 50–60	Group III BMI > 60	p
Age (years)	(n = 6016)	(n = 903)	(n = 153)	
Min. – Max.	18 – 76	18 – 74	18 – 71	0.103
Mean ± SD.	40.3 ± 11.8	41.2 ± 12.5	39.3 ± 11.7	
Sex	(n = 6023)	(n = 905)	(n = 155)	
Female	4516 (74.9 %)	587 (64.9 %)	94 (60.6 %)	# < 0.001 *
Male	1507 (25 %)	318 (35.1 %)	61 (39.4 %)	
Missing data	1 (0.1 %)	0 (0 %)	0 (0 %)	
Ethnicity of patient	(n = 6024)	(n = 905)	(n = 155)	
I	9 (0.1 %)	1 (0.1 %)	0 (0 %)	MC p < 0.001
II	349 (5.8 %)	42 (4.6 %)	7 (4.5 %)	*
III	73 (1.2 %)	12 (1.3 %)	2 (1.3 %)	
IV	1198 (19.9 %)	93 (10.3 %)	13 (8.4 %)	
V	10 (0.2 %)	4 (0.4 %)	0 (0 %)	
VI	4385 (72.8 %)	753 (83.2 %)	133 (85.8 %)	
White vs non	(n = 6024)	(n = 905)	(n = 155)	
No	1639 (27.2 %)	152 (16.8 %)	22 (14.2 %)	< 0.001 *
Yes	4385 (72.8 %)	753 (83.2 %)	133 (85.8 %)	
Smoking status	(n = 6023)	(n = 905)	(n = 155)	
Current smoker	885 (14.7 %)	143 (15.8 %)	11 (7.1 %)	# 0.008 *
Ex-smoker	766 (12.7 %)	134 (14.8 %)	28 (18.1 %)	
Non-smoker	4372 (72.6 %)	628 (69.4 %)	116 (74.8 %)	
Missing data	1 (0.01 %)	0 (0 %)	0 (0 %)	

p: p-value for comparing between the studied categories

* : Statistically significant at p ≤ 0.05

I: American Indian or Alaska Native. A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment.

II: Asian. A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

III: Black or African American. A person having origins in any of the black racial groups of Africa. Terms such as 'Haitian' or 'Negro' can be used in addition to 'Black or African American.'

IV: Hispanic or Latino. A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term 'Spanish origin' can be used in addition to 'Hispanic or Latino.'

V: Native Hawaiian or Other Pacific Islander. A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

VI: White. A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

CPAP (6 patients; 23.1 %), Sleep Apnoea on CPAP (11 patients; 42.3 %) and Hypercholesterolaemia (7 patients; 26.9 %). The majority of the patients in this group underwent LSG (21 patients; 80.8 %), followed by OAGB (4 patients; 15.4 %). One patient underwent the Single Anastomosis Duodenal Ileal Bypass. Six patients (23.1 %) had at least one complication, and two patients (7.7 %) died (1 * pulmonary embolism, 1 * pulmonary embolism, and COVID pneumonia).

4. Discussion

4.1. Discussion of the Results

This study showed that the mortality rate was significantly higher in patients with BMI > 60 kg/m² in comparison with those with lower BMI. At the same time, complication rates were not significantly different

Table 2
Comparison between the three groups according to Comorbidities.

Comorbidity data	Group I BMI < 50	Group II BMI 50–60	Group III BMI > 60	p
Any co-morbidity	(n = 6024)	(n = 905)	(n = 155)	
No	1965 (32.6 %)	220 (24.3 %)	19 (12.3 %)	< 0.001 *
Yes	4059 (67.4 %)	685 (75.7 %)	136 (87.7 %)	
Diabetes				
No	4835 (80.3 %)	667 (73.7 %)	107 (69 %)	< 0.001 *
Yes	1189 (19.7 %)	238 (26.3 %)	48 (31 %)	
Hypertension				
No	4322 (71.7 %)	494 (54.6 %)	78 (50.3 %)	< 0.001 *
Yes	1702 (28.3 %)	411 (45.4 %)	77 (49.7 %)	
Sleep apnea not on CPAP				
No	5361 (89 %)	746 (82.4 %)	120 (77.4 %)	< 0.001 *
Yes	663 (11 %)	159 (17.6 %)	35 (22.6 %)	
Sleep apnoea on CPAP				
No	5328 (88.4 %)	703 (77.7 %)	104 (67.1 %)	< 0.001 *
Yes	696 (11.6 %)	202 (22.3 %)	51 (32.9 %)	
Hypercholesterolaemia				
No	4749 (78.8 %)	698 (77.1 %)	113 (72.9 %)	0.117
Yes	1275 (21.2 %)	207 (22.9 %)	42 (27.1 %)	
Other				
No	4274 (70.9 %)	650 (71.8 %)	99 (63.9 %)	0.129
Yes	1750 (29.1 %)	255 (28.2 %)	56 (36.1 %)	

p: p-value for comparing between the studied categories

* : Statistically significant at p ≤ 0.05

Table 3
Comparison between the three groups according to the preoperative COVID-specific protocol and workup.

	Group I BMI < 50	Group II BMI 50 – 60	Group III BMI > 60	p
Self-isolation	(n = 5882)	(n = 883)	(n = 152)	
No	3183 (52.8 %)	525 (58 %)	95 (61.3 %)	# 0.002 *
Yes	2699 (44.8 %)	358 (39.6 %)	57 (36.8 %)	
Preoperative COVID-19 test to rule out active infection or confirm immunity?	(n = 6024)	(n = 905)	(n = 155)	
No	1176 (19.5 %)	157 (17.3 %)	17 (11 %)	0.010 *
Yes	4848 (80.5 %)	748 (82.7 %)	138 (89 %)	

MC: Monte Carlo. p: p-value for comparing between the studied categories

* : Statistically significant at p ≤ 0.05

#: p-value excluded missing data from comparing between the studied categories

amongst the three BMI groups. Preoperative BMI influenced procedure choice as well as COVID-19 safety protocols, and those with higher BMI were more likely to be suffering from obesity-associated comorbidities.

Many guidelines recommend surgery as the first line of management

Table 4
Comparison between the three studied groups according to surgical procedures.

Procedure	Group I	Group II	Group III	P
	BMI < 50 (n = 6024)	BMI 50 – 60 2 (n = 905)	BMI > 60 3 (n = 155)	
LSG	3348 (55.6 %)	529 (58.5 %)	111 (71.6 %)	< 0.001*
LOAGB	555 (9.2 %)	127 (14 %)	23 (14.8 %)	< 0.001*
Others	258 (4.3 %)	33 (3.6 %)	9 (5.8 %)	0.417
LRYGB	1863 (30.9 %)	216 (23.9 %)	12 (7.7 %)	< 0.001*

* Statistically significant at $p \leq 0.05$

Table 5
Comparison between the three studied groups according to the outcome; complications, COVID infection, and death rate.

	Group I	Group II	Group III	p
	BMI < 50 (n = 6024)	BMI 50–60 (n = 905)	BMI > 60 (n = 155)	
Complications				
No	5623 (93.3 %)	839 (92.7 %)	143 (92.3 %)	0.688
Yes	401 (6.7 %)	66 (7.3 %)	12 (7.7 %)	
CD Complications				
No	5623 (93.3 %)	839 (92.7 %)	143 (92.3 %)	0.688
1	144 (2.4 %)	20 (2.2 %)	2 (1.3 %)	0.644
2	109 (1.8 %)	24 (2.7 %)	3 (1.9 %)	0.227
3.1	28 (0.5 %)	4 (0.4 %)	1 (0.6 %)	$MC_p = 0.727$
3.2	81 (1.3 %)	12 (1.3 %)	2 (1.3 %)	0.997
4.1	27 (0.4 %)	4 (0.4 %)	1 (0.6 %)	$MC_p = 0.726$
4.2	6 (0.1 %)	1 (0.1 %)	0 (0 %)	$MC_p = 1.000$
5	6 (0.1 %)	1 (0.1 %)	3 (1.9 %)	$MC_p = 0.001^*$
COVID within 30 days				
No	5993 (99.5 %)	900 (99.4 %)	153 (98.7 %)	$MC_p = 0.286$
Yes	31 (0.5 %)	5 (0.6 %)	2 (1.3 %)	

MC: Monte Carlo test

p: p-value for comparing between the studied categories

*Statistically significant at $p \leq 0.05$

for patients with BMI > 50 kg/m². [13,14], but there is little robust data in scientific literature examining outcomes in different BMI groups and none during the COVID-9 pandemic. Not only that, though A BMI cut-off of 50 kg/m² has been studied in the past [15,16], there is little data specifically focussing on higher BMI cut-offs of 60 and 70 kg/m².

The overall mortality rate in our study was 0.1 % which is comparable to the pre-pandemic rates.[17] However, the mortality rate was significantly higher in group III (1.9 %) in comparison with the other two groups (0.1 % each). Recently, Sun Y et al. [17] also reported that greater preoperative BMI was associated with a higher risk of 30-day mortality after adjusting for age, sex, and ethnicity. Although the widely used Obesity Surgery Mortality Risk Score (OS-MRS) [18] sets the cut-off point of BMI at ≥ 50 kg/m², in our study, the mortality rates in groups I and II were no different at 0.1 %. This probably highlights that in the era of laparoscopic BS, the cut-off of 50 kg/m² is no longer clinically relevant. Unsurprisingly, a recent metanalysis [19] showed that the OS-MRS score does not correlate with the early complications or mortality after bariatric surgery.

This was the reason we also examined higher cut-offs of 60 kg/m² and 70 kg/m² in this study. The study findings of 30-day mortality of 1.9 % in Group III and 7.7 % in those with BMI > 70 kg/m² are particularly interesting and need further confirmation. If confirmed, this data might suggest a need for further focussed measures at these high-risk groups of patients. Interestingly, both the deaths in BMI > 70 kg/m² were at least partly due to pulmonary embolism. This might suggest the need for studies specifically examining protocols for prophylaxis of venous thromboembolism in this high-risk cohort.

In this study, the complication rates were similar between the three groups despite the patients in group III having more medical comorbidities. The overall complication rate was 6.76 % (479 patients) in the whole cohort, with no significant difference noted due to the preoperative BMI. This may be because a higher proportion of patients in Group

III underwent an LSG or LOAGB, procedures known to be associated with lower 30-day complication rates in comparison with LRYGB [20, 21], which was more commonly performed in Group 1 and Group II.

Wilkinson et al. [22] found that patients with BMI > 60 kg/m² and BMI > 50 kg/m² who underwent SG had a significantly reduced relative risk of complications compared to those who underwent RYGB. They also concluded that SG might be the procedure of choice for patients with BMI > 60 kg/m² because of the decreased perioperative risk associated with multiple comorbidities, in addition to the lower 30-day postoperative complications compared to RYGB.

Patients with BMI > 70 kg/m² represent a particularly interesting group. It was noticed that trends with regards to the presence of comorbidities continued in this group with a higher prevalence in almost all comorbidities compared to the cohorts with lower BMI. It is interesting to note that no RYGB procedures were performed in this group, with the majority of patients undergoing the LSG. However, the most important finding within this group was the higher incidence of post-operative complications (23.1 %) and mortality (7.7 %).

A total of 38 (0.54 %) patients were diagnosed with SARS-CoV-2 infection within 30 days of surgery in this study. The incidence of COVID-19 infection was not different in different BMI groups. 31(0.5 %) of Group I, 5(0.6 %) of Group II, and 2(1.3 %) patients of III developed symptoms of COVID-19 within 30 days of surgery $p = (0.286)$.

Our database showed that 45 % of the patients had preoperative self-isolation, and 81 % had preoperative COVID-19 tests to rule out active infections or confirm immunity. Comparison of the safety measure among the different groups showed that 89 % of Group III had COVID-19 tests to rule out active infections or confirm immunity compared to 82.7 % and 80.5 % of Groups II and I, respectively; ($p = 0.010$). However, there was reduced advice for self-isolation in Group III compared to the other groups. This might be offset by higher testing in this group.

There was a higher prevalence of obesity-related comorbidities amongst the patients in group III than group II in our study. There is very little data in scientific literature exploring comorbidity burden with BMI cut-offs of 50, 60, and 70 kg/m² in patients undergoing BS.

4.2. Generalisability

This is the first large-scale international study assessing the effect of BMI on the outcomes of bariatric surgery during the ongoing COVID-19 pandemic. The patients included representing a broad spectrum of bariatric surgery patients in terms of demographics, geographical distribution, stage of COVID-19 pandemic severity in the host population, and surgeons' and centers' experiences.

4.3. Strengths and Limitations of the Study

This study only included data from participating centers and might therefore not represent the complete global picture. Furthermore, although we ensured that our collaborators knew the importance of submitting all consecutive patients during the study period, we cannot be certain that all contributors followed this instruction. Finally, this is an observational study. So, results are very likely to have been influenced by other confounding variables such as procedure choice.

The study's strengths include the large sample size, the global reach of the study, the high data completion rate, and extensive data profiling. Additionally, the data represented different phases of the COVID-19 pandemic across the 42 included countries (before, during, or after the COVID-19 peak).

5. Conclusion

The 30-day mortality rate after bariatric surgery is significantly higher in patients with BMI > 60 kg/m² compared to patients with BMI < 50 kg/m² and BMI 50–60 kg/m². There was no significant difference amongst the three groups with regards to complications rate. This may

be due to differences in procedure selection. The patient group of BMI \geq 70 kg/m² represents a particularly high-risk group with significantly higher postoperative morbidity and mortality. The preoperative obesity-related comorbidities were more prevalent in patients with BMI > 60 kg/m².

Declarations of interest

none.

CRedit authorship contribution statement

RS and IO contributed equally to this work and shared the first authorship. RS: Conceptualization, Methodology, Investigation, Formal analysis. IO: Formal analysis, Writing- Original draft preparation, Writing - Review & Editing. BM: Investigation, Data Curation. AAT: Investigation, Data Curation. CL: Investigation, Data Curation. KM: Conceptualization, Methodology, Writing - Review & Editing, Supervision. All authors have seen the final manuscript and approved it.

Institutional research committee approval number

This project was registered as a multinational audit (number: 5197) at the University Hospitals Birmingham NHS Foundation Trust, UK. Each site project lead was responsible for obtaining local governance approvals and data sharing agreements before entering data into the registry.

Statement of informed consent

Patient's approval to share their anonymized data was obtained by the individual collaborators. It was the responsibility of the site leads to ensure that patient approval was in place and documented in the notes before entering data into the registry.

Statement of human and animal rights

Not Applicable.

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Data Availability

The data used to support the findings of this study can be released upon request.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.orcp.2022.06.003](https://doi.org/10.1016/j.orcp.2022.06.003).

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