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ORIGINAL CONTRIBUTIONS

# Development of the "OS-SEV90 Score" to Predict Severe Postoperative Complications at 90 Days Following Bariatric Surgery

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## Abstract

**Background** Bariatric surgery may be associated with severe postoperative complications (SPC). Factors associated with the risk of SPC have not been fully investigated.

**Objectives** This study aimed to identify preoperative risk factors of SPC within 90 days and to develop a risk prediction model based on these factors.

**Methods** We conducted a retrospective single-center cohort study based on a prospectively maintained database of obese patients undergoing laparoscopic bariatric surgery from October 2005 to May 2019. All SPC occurring up to the 90th postoperative day were recorded according to the Dindo-Clavien classification. Associations between potential risk factors and SPC were analyzed using a logistic regression model, and the risk prediction ("OS-SEV90 score") was computed. Based on the OS-SEV90 score, the patients were grouped into 3 categories of risk: low, intermediate, and high.

**Results** Among 1963 consecutive patients, no patient died and 82 (4.2%) experienced SPC within 90 days. History of gastric or esophageal surgery (adjusted odds ratio (aOR) 3.040, 95% confidence interval; CI 1.78–5.20, $p< 0.0001$), past of thromboembolic event aOR 2.26, 95%; CI 1.12–4.55, $p = 0.0225$), and surgery performed by a junior surgeon (aOR 1.99, 95%; CI 1.26–3.13, $p = 0.003$) were all independently associated with risk for SPC, adjusting for ASA physical status system (ASA) score ≥ 3, severe OSA, psychiatric disease, asthma, a history of abdominal surgery, alcohol, cardiac disease, and dyslipidemia. "the OS-SEV90 score" based on these factors was constructed to classify patients into 3 risk groups: low (≤2), intermediate (3–4), and high (≥5). According to "the OS-SEV90 score," SPC increased significantly from 2.9% in the low-risk group, 7.7% in the intermediate-risk group, and 23.3% in the high-risk group.

**Conclusions** A predictive model of SPC within 90 days "the OS-SEV90 score" has been developed using 9 baseline risk factors. The use of the OS-SEV90 score may help the multidisciplinary team to identify the specific risk of each patient and inform them about and optimize the comorbidities before the surgery. Further studies are warranted to validate this score in a new independent cohort before using it in clinical practice.

**Keywords** aparoscopic bariatric surgery · Severe postoperative complication · Predictive model · Gastric bypass · Sleeve gastrectomy · Morbi-mortality · Postoperative score

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## Introduction

Bariatric surgery is currently the most effective treatment for morbid obesity leading to significant both weight loss and resolution of comorbidities [1–3]. Consequently, compared to medical treatment, bariatric surgery significantly improves not only long-term survival by reducing mortality from cardiovascular disease [4] but also quality of life [5]. Despite major progress in multidisciplinary care, bariatric surgery carries a risk of potential mortality (<0.5%)

and of severe postoperative complications (SPC) up to 10%, including those leading to reintervention and even death [6–8]. It is therefore essential to determine precisely the respective predictive factors for mortality and SPC. Two models for postoperative mortality have been published [9, 10], but their usefulness no longer seems to be relevant due to the very low prevalence of mortality in the most recent series [11–15]. To date, it seems to be more relevant to identify factors that may be significantly associated with SPC. Knowledge of such risk factors makes it possible: firstly, to better inform patients of the risks of bariatric surgery; secondly, to establish a risk/benefit ratio for each patient; thirdly to optimize the patient by correcting several risk factors; and finally, either to contraindicate the patient or to propose an alternative surgical technique [16]. Numerous authors have attempted to predict the risk for adverse events after bariatric surgery either by adjusting or applying the OS-MRS to their population [17, 18], or by developing a new model based on national databases [13, 14, 19, 20]. However, a review by Geubbels has suggested that these models are not completely adequate because they did not take into account factors related to the surgeon and the care center [21]. Thus, we needed to create a novel score easy to use in practice for the risk assessment and risk stratification of each patient undergoing bariatric surgery to facilitate the adjustment of preoperative care and to improve patient outcomes after surgery. The aim of this study was to develop a preoperative score to assess the risk of severe—and so life-threatening—postoperative complications after bariatric surgery.

## Methods

### Study Design

Data were collected from a prospectively maintained database of obese patients undergoing laparoscopic Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (LSG), and revision surgery from sleeve gastrectomy to Roux-en-Y gastric bypass (LSG to RYGB) from October 2005 to May 2019 at our French tertiary referral bariatric center. The indication for bariatric surgery is assessed using the IFSO criteria [22], and all cases were endorsed in a local interdisciplinary consensus meeting. The local medical ethics committee has approved this study; no individual inform consent was necessary, as it was a retrospective analysis. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

### Surgical Technique

All procedures were standardized to be performed in the same way by all the surgeons of our center. The surgical techniques used for this study were previously described in the literature [23, 24]. Since January 2017, all patients were treated according to our Enhanced Recovery After Surgery (ERAS) protocol which has been developed with the Thorell et al.'s guidelines [25] of whom the results have been previously reported [23].

### Data Collection

The relevant information for each patient were prospectively collected. Patient characteristics (gender, age), biometrics values (i.e., weight, height, body mass index BMI, percentage of excess body weight), comorbidities, the ASA physical status classification system (ASA), surgical past history, medications, and habitus were retrieved. A history of gastric or esophageal surgery included patients with a history of antireflux surgery, hiatal hernia surgery, gastric band, or revision surgery from sleeve gastrectomy to Roux-en-Y gastric bypass. For each patient, the surgeon's experience was collected and was considered a junior if he performed less than 50 cases of the same procedures [26]. For the ASA score, we separated patients in two groups: one with a score $\leq 2$ and the other with a score $\geq 3$. Diabetes was divided in with or without insulin; hypertension is scored when patients used some drugs against; dyslipidemia is considered if patients used cholesterol lowering drugs or with a perturbation of their blood test. Obstructive sleep apnea (OSA) was diagnosed with a polysomnography and an Apnea/Hypopnea Index (AHI) superior to 30 defines severe OSA; a pulmonary doctor must diagnose chronic obstructive pulmonary disease (COPD); psychiatric disease was diagnosed when patients used psychiatric drugs recorded in the N05 category according to the Anatomical Therapeutic Chemical (ATCD)–Defined Daily Dose (DDD) classification [27]; a cardiac disease was defined as being diagnosed by a cardiologist. The usage of alcohol, non-steroidal anti-inflammatory drugs (NSAID's), corticosteroids, nicotine, anticoagulants, and platelet inhibitors were based on the medical past and medication history. The gastric disorders as hiatal hernia, *gastroesophageal reflux disease* (GERD), gastritis, and Barrett's esophagus were diagnosed by preoperative gastroscopy. Associated procedures during surgery were cholecystectomy, gastric band ablation, and reparation of incisional hernia or hiatal hernia.

### Outcomes

The main objective was to develop a preoperative score to assess the risk SPC within 90 days after bariatric surgery, called the "OS-SEV90 score." All the complications were stratified according to the Dindo-Clavien classification [28], and a score of three points (including grade III-a and III-b) or higher was considered a SPC. To create the "OS-SEV90 score," we analyzed the SPC that occurred within 90 postoperative days (POD90). The assessment of the outcome (SPC) was not blinded.

Such as described in the OS-MRS [9] and in the BASIC score [19], we assigned the relevant points for each patient to class them in each class of risk. We defined this class as a variable of risk factor to evaluate the efficiency of these scores to predict postoperative complications (Table 1).

### Statistical Analysis

No computation of sample size was performed. We analyzed available data. Baseline characteristics of the patients included in the cohort were described overall and by SPC group using numbers (percentages) and mean (standard deviation), as appropriate. First, we investigated potential independent risk factors associated with SPC in our overall cohort. We conducted a univariate analysis of all preoperative variables recorded in our database as possible factors associated with severe complications that occurred within 90 days postoperative (SEV90) morbidity. We used chi-square or Fisher's exact tests for categorical variables and Student's *t* test for continuous variables. All variables associated with SPC on univariate analysis ($p < 0.20$) were considered for inclusion in the multivariate logistic regression analysis. We explored collinearity among variables potentially selected in our multivariate model by calculating the variance inflation factor, with a value above 5 indicating collinearity. We used stepwise, backward, and forward procedures among qualified variables for selecting independent risk factors associated with SPC, with the threshold of $p<0.20$ to enter and remain in the model.

Second, we explored the internal validity, namely, stability and consistency, of the selected risk factors. We conducted several multivariate logistic regression models using 500 bootstrap samples to assess the distribution of an indicator variable specifying the statistical significance for each predictor variable. This was performed in the overall cohort and in random subsamples containing 90%, 80%, and 70% of the overall cohort. We considered a risk factor as robust when found significant in 50% or more of the bootstrap samples and subsamples.

Third, we explored the external validity, namely, the predictive value of the robust risk factors. We created two random samples, namely, the training cohort and the validating cohort, each containing 50% of the overall cohort. We developed a score for predicting SPC in the training cohort using robust risk factors and bootstrapped odds ratio coefficients. Subsequently, we tested the predicting value of this score in the validating cohort using the c-index representing the area under receiver operating characteristic (ROC) curves of the model.

Fourth, we described the distribution of SPC according to the two scores (derived from the two models): an exploratory score from non-parsimonious multivariate analysis (OS-SEV90_1 score) (for epidemiologic purposes) and a validated score (OS-SEV90_2 score) from multivariate analysis containing only robust risk factors (for predicting purposes). The scores which were arbitrarily grouped into 3 categories of risk: low (SPC rates <5%), intermediate (SPC rates between 5 and 10%), and high (SPC rates >10%).

Finally, we explored the time trend of SPC in our cohort by computing an univariate analysis of SPC using the year of surgery or the period (2005–2012 vs 2013–2019), as independent variable. We checked the predictive ability over time of the two models by separating the cohort according to the period (2005–2012 vs 2013–2019). Each logistic regression model was tested by Hosmer and Lemeshow test and yielded to $p>0.05$, indicating adequate goodness-of-fit.

All analyses were conducted in the complete-case analysis. Statistical analysis was performed with SAS software V9.4 (SAS institute, NC, Cary).

## Results

### Baseline Characteristics

From October 2005 to May 2019, 1963 consecutive patients were included. Characteristics of all patients are summarized in Table 1. Most patients, 1527 (77.8%), were female; the mean age was 43.03 (SD 11.46), and the mean BMI was 42.79 kg/m$^2$ (SD 7.01). Baseline characteristics are displayed in Table 1. Primary bariatric surgery was performed in 1884 patients (96%) (i.e., LRYGB, *n*=1246 and LSG, *n*=638), followed by revisional bariatric surgery in 79 patients (4%). Two-hundred twenty-two patients (11.3%) had a past of esophageal or a gastric surgery with 79 procedures of conversion from LSG to RYGB (4%). More than half of the patients (53.7%) had already had abdominal surgery, one-fifth of them by laparotomy.

All surgical procedures were performed laparoscopically with the exception of 8 patients who required conversion to laparotomy (0.4%). Among these patients, 7 patients (87.5%) had already had a laparotomy or a past of esophageal or a gastric surgery. No death was observed at POD90.

### Follow-Up and Outcome

Overall postoperative complications occurred in 307 patients (15.6%) of whom 82 (4.2%) experienced SPC within 90 days. Sixty-two (75.6%) of them required a reintervention and 26 (31.7%) a readmission after discharge. The total hospital length of stay of these patients was 11.7 days. The most frequent SPC included severe bleeding in 28 patients (1.4%),

**Table 1** Population characteristics and univariate analysis

| | Characteristics *n* = 1963 (%) | With severe complications *n* = 82 (%) | Without severe complications *n* = 1881 (%) | *p*-value |
|---|---|---|---|---|
| Baseline characteristics | | | | |
| Age (years) (mean ± SD) | 43.03 (11.46) | 44.8 (11.1) | 43.0 (11.5) | 0.160 |
| Age > 45 years | 881 (44.9) | 39 (47.6) | 842 (44.8) | 0.621 |
| Age > 60 years | 158 (8.0) | 11 (13.4) | 147 (7.8) | 0.068 |
| Female, *n* (%) | 1527 (77.8) | 67 (81.7) | 1460 (77.6) | 0.383 |
| ASA score ≥ 3 | 508 (25.9) | 29 (35.4%) | 479 (25.5) | **0.025** |
| Inclusion in an ERAS protocol | 455 (23.2) | 10 (12.2) | 445 (23.6) | **0.016** |
| Surgery perform by a junior surgeon | 710 (36.1) | 41 (50.0) | 669 (35.6) | **0.008** |
| Associated procedure during surgery | 201 (10.2) | 12 (14.6) | 189 (10.1) | 0.181 |
| Biometrics values | | | | |
| Preoperative BMI (mean ± SD) | 42.79 (7.01) | 42.69 (7.96) | 42.79 (6.98) | 0.898 |
| Preoperative BMI > 50 kg/m$^2$ | 258 (13.1) | 12 (14.6) | 246 (13.1) | 0.683 |
| Classification of patients with others score | | | | |
| BASIC score: 1/2/3 | 1595/267/101 | 61/15/6 | 1534/252/95 | 0.209 |
| OS-MRS score: A/B/C | 1234/681/48 | 51/29/2 | 1183/652/46 | 0.968 |
| Past medical history | | | | |
| Diabetes mellitus | 480 (24.4) | 24 (29.2) | 456 (24.2) | 0.300 |
| Dyslipidemia | 425 (21.7) | 13 (15.8) | 412 (21.9) | 0.193 |
| Hypertension | 670 (34.1) | 26 (31.7) | 644 (34.2) | 0.636 |
| OSA | 755 (38.5) | 25 (30.5) | 730 (38.8) | 0.089 |
| Severe OSA (AHI ≥ 30) | 151 (7.7) | 11 (13.4) | 140 (7.4) | **0.047** |
| Psychiatric history | 268 (13.7) | 18 (21.9) | 250 (13.3) | **0.025** |
| Thromboembolic event | 120 (6.1) | 11 (13.4) | 109 (5.8) | **0.005** |
| COPD | 36 (1.8) | 1 (1.2) | 35 (1.9) | 0.672 |
| Cardiac disease | 98 (5.0) | 7 (8.5) | 91 (4.8) | 0.132 |
| Asthma | 199 (10.1) | 14 (17.1) | 185 (9.8) | **0.034** |
| Treatment and addiction | | | | |
| Nicotine | 244 (12.4) | 12 (14.6) | 232 (12.3) | 0.537 |
| Alcohol | 33 (1.7) | 3 (3.6) | 30 (1.6) | 0.155 |
| NSAID's | 65 (3.3) | 3 (3.6) | 62 (3.3) | 0.858 |
| Antiplatelet | 142 (7.2) | 4 (4.9) | 138 (7.3) | 0.403 |
| Anticoagulant | 52 (2.6) | 3 (3.6) | 49 (2.6) | 0.562 |
| Surgical history | | | | |
| Abdominal surgery | 1055 (53.7) | 57 (69.5) | 998 (53.0) | **0.003** |
| Laparotomy | 208 (10.6) | 8 (9.7) | 200 (10.6) | 0.801 |
| Esophageal or gastric surgery | 222 (11.3) | 24 (29.3) | 198 (10.5) | **<0.001** |
| Preoperative examination | | | | |
| Gastritis | 318 (16.2) | 15 (18.3) | 303 (16.1) | 0.599 |
| GERD | 519 (26.4) | 20 (24.4) | 499 (26.5) | 0.668 |
| Barrett's esophagus | 48 (2.4) | 1 (1.2) | 47 (2.5) | 0.463 |
| Hiatal hernia | 193 (9.8) | 9 (11.0) | 184 (9.8) | 0.722 |
| Ultrasonic steatosis | 425 (21.7) | 16 (19.5) | 409 (21.7) | 0.631 |

*ASA* ASA physical status classification system, *ERAS* Enhanced Recovery After Surgery, *BMI* body mass index, *OSA* obstructive sleep apnea, *COPD* chronic obstructive pulmonary disease, *NSAID's* non-steroidal anti-inflammatory drugs, *GERD* gastroesophageal reflux disease anastomotic leakage in 19 patients (0.9%), anastomotic stenosis in 15 patients (0.8%), and intense pain leading to reoperation by laparoscopy in 6 patients (0.3%).

## Predictors of Outcome

On univariate analysis, 9 factors were significantly associated with SPC at 90 days: ASA score ≥ 3, psychiatric past history, severe OSA, past of thromboembolic event (TE event), asthma, a history of abdominal surgery, a history of gastric or esophageal surgery (HEGS), a surgery performed by a junior surgeon, and the non-inclusion in an Enhanced Recovery After Surgery (ERAS) protocol (Table 1). Seven factors had a $p$-value <0.20 but not significant: quantitative age, age group (≤60 vs >60 years), associated procedure during surgery, dyslipidemia, OSA, cardiac disease, and alcohol. The SPC at 90 days have decreased significantly over the years ($p$<0.001).

To avoid collinearity between risk factors in multivariate analysis, we did not select quantitative age and OSA, which had a higher $p$-value than age group and severe OSA, respectively. The ERAS protocol and the associated procedure during surgery were eliminated from the model because they were not baseline factors. In our multivariate model, there was no evidence of significant collinearity (Supplemental Table 1). In the multivariate analysis, past of thromboembolic event, a HEGS, and a surgery performed by a junior surgeon were the three independent risk factors of SPC at 90 days which was observed in the three selection models (Table 2).

Based on logistic regression using 500 bootstrap samples, only HEGS and a surgery performed by a junior surgeon were selected >50% in the overall and subsample cohorts (Table 3).

Forward, backward, and stepwise selection multivariate model gave the same models from full sample: HEGS (aOR = 3.61 95% CI [2.19–5.95], $p$<0.001) and surgery performed by a junior surgeon (aOR=1.87 95% CI [1.20–2.92], $p$<0.001).

From the training cohort, the bootstrapped mean trends of robust risk factors were as follows: $\beta_{HEGS}$=1.7847 and $\beta_{junior\ surgeon}$=0.8708. The score for predicting SPC was significantly associated with SPC in the training and validating cohorts ($AUC_T$=0.69 95% CI [0.61–0.78], $p$<0.001; $AUC_V$=0.58 95% CI [0.49–0.66], $p$=0.026; respectively) (Fig. 1).

## Risk Scores

Because the relative weight of each risk factor is different, we have weighted the importance of each risk factor according to its respective odds ratio (OR). We assigned 2 points for a history of gastric or esophageal surgery and 1 point for a junior surgeon. The OS-SEV90_2 robust risk score ranged from 0 to 3 points and the corresponding morbidity from 2.7 to 17.3% (Fig. 2(2.)).

In order to facilitate the use of OS-SEV90_2 robust risk score in routine practice, the study population was arbitrarily divided into 3 subgroups of risk: low, intermediate, and high risk. Thus, the low-risk group included patients with an OS-SEV90_2 score <2 and a corresponding morbidity rate of 3.3% [95% CI 2.5; 4.1]. The intermediate-risk group included patients with an OS-SEV90_2 SPC risk score equal to 2 and a corresponding morbidity rate of 7.5% [95% CI 3.2; 11.8]. The high-risk group included patient with an OS-SEV90_2 score > 2 and a corresponding morbidity rate of 17.3% [95% CI 8.7; 25.9] (Fig. 2(1.)). Each of these morbidity rates was

**Table 2** Estimates of relative odds ratio and its 95% confidence interval with its $p$-value for each selected independent predictor by automated variable selection methods. *OR* odds ratio, *95% CI* confidence interval at 95% ($N$=1963)

| Variables | Forward elimination | | Backward selection | | Stepwise selection | |
|---|---|---|---|---|---|---|
| | OR [95% CI] | $p$-value | OR [95% CI] | $p$-value | OR [95% CI] | $p$-value |
| ASA score ≥3 | 1.41 [0.86–2.30] | 0.1760 | – | – | 1.41 [0.86–2.30] | 0.1760 |
| Age >60 | – | – | – | – | – | – |
| Severe OSA | 1.95 [0.97–3.93] | 0.0624 | 2.14 [1.08–4.23] | **0.0288** | 1.95 [0.97–3.93] | 0.0624 |
| Psychiatric history | 1.48 [0.84–2.61] | 0.1691 | 1.50 [0.85–2.64] | 0.1566 | 1.48 [0.84–2.61] | 0.1691 |
| Thromboembolic event | 2.26 [1.12–4.55] | **0.0225** | 2.40 [1.19–4.79] | **0.0143** | 2.26 [1.12–4.55] | **0.0225** |
| Asthma | 1.78 [0.97–3.28] | 0.0651 | 1.80 [0.98–3.32] | 0.0585 | 1.78 [0.97–3.28] | 0.0651 |
| Abdominal surgery | 1.55 [0.93–2.61] | 0.0942 | 1.53 [0.91–2.56] | 0.1101 | 1.55 [0.93–2.61] | 0.0942 |
| Esophageal or gastric surgery | 3.04 [1.78–5.20] | **<.0001** | 3.05 [1.78–5.21] | **<.0001** | 3.04 [1.78–5.20] | **<.0001** |
| Junior surgeon | 1.99 [1.26–3.13] | **0.0031** | 2.00 [1.27–3.15] | **0.0028** | 1.99 [1.26–3.13] | **0.0031** |
| Alcohol | 2.50 [0.72–8.64] | 0.1491 | 2.43 [0.69–8.58] | 0.1666 | 2.50 [0.72–8.64] | 0.1491 |
| Cardiac disease | – | – | 1.75 [0.76–4.02] | 0.1885 | – | – |
| Dyslipidemia | – | – | – | – | – | – |

*ASA* ASA physical status classification system, *OSA* obstructive sleep apnea

**Table 3** Relative frequency (%) with which each candidate variable (13) was selected in 500 bootstrap samples drawn from the original cohort (full sample; 90%, 80%, 70% subsamples)

| Variables | Full sample | 90% sample | 80% sample | 70% sample |
|---|---|---|---|---|
| ASA score ≥3 | 16.8 | 5.4 | 5.4 | 6.6 |
| Age >60 | 12.6 | 9.0 | 18.6 | 15.4 |
| Severe OSA | 47.2 | **55.0** | **58.8** | **53.6** |
| Psychiatric history | 29.8 | 9.6 | 8.2 | 11.2 |
| Thromboembolic event | **54.6** | **54.6** | 37.2 | 39.6 |
| Asthma | 39.6 | 48.8 | 23.6 | 23.6 |
| Abdominal surgery | 33.4 | 37.0 | 44.8 | 21.6 |
| Esophageal or gastric surgery | **95.2** | **93.0** | **93.4** | **89.8** |
| Junior surgeon | **80.2** | **74.8** | **56.4** | **71.8** |
| Alcohol | 25.0 | 27.8 | 30.6 | 30.6 |
| Cardiac disease | 19.0 | 28.4 | 31.8 | 45.0 |
| Dyslipidemia | 23.2 | 11.4 | 5.2 | 11.2 |

*ASA* ASA physical status classification system, *OSA* obstructive sleep apnea

significantly different from the two others using a chi$^2$ test with a *p*-value < 0.0001.

The exploratory score was calculated with slopes of risk factors from non-parsimonious multivariate analysis (in our cohort): SPC risk score = 0.1704*ASA group + 0.6671*severe OSA + 0.3952*psychiatric past history + 0.8148*TE event + 0.5760*asthma + 0.4418* a history of abdominal surgery + 1.1126*HEGS + 0.6866*junior surgeon + 0.9144*alcohol. Then, this score was changed to an OS-SEV90_1 score round out of 10. The OS-SEV90_1 score ranged from 0 to 6 points and the corresponding morbidity from 1.0 to 42.9% (Fig. 2(2.)). The very high rate of OS-SEV90_1 for the patients with a score of 6 can be explained by the small number of patients in these groups (7 patients, respectively). As for validated score, we divided into 3 subgroups of risk: low, intermediate, and high risk. Thus, the low-risk group included patients with an OS-SEV90_1 score ≤ 2 and a corresponding morbidity rate of 2.9% [95% CI 2.1; 3.7]. The intermediate-risk group included patients with an OS-SEV90_1 score ranging from 3 to 4 and a corresponding morbidity rate of 7.7% [95% CI 4.8; 10.6]. The high-risk group included patient with an OS-SEV90_1 score ≥ 5 and a corresponding morbidity rate of 23.3% [95% CI 10.7; 35.9] (Fig. 2(1.)). Each of these morbidity rates was significantly different from the two others using a Fisher exact test with a *p*-value < 0.0001.

We compared the predictive value of the two SPC risk scores (OS-SEV90_1 and OS-SEV90_2). The non-

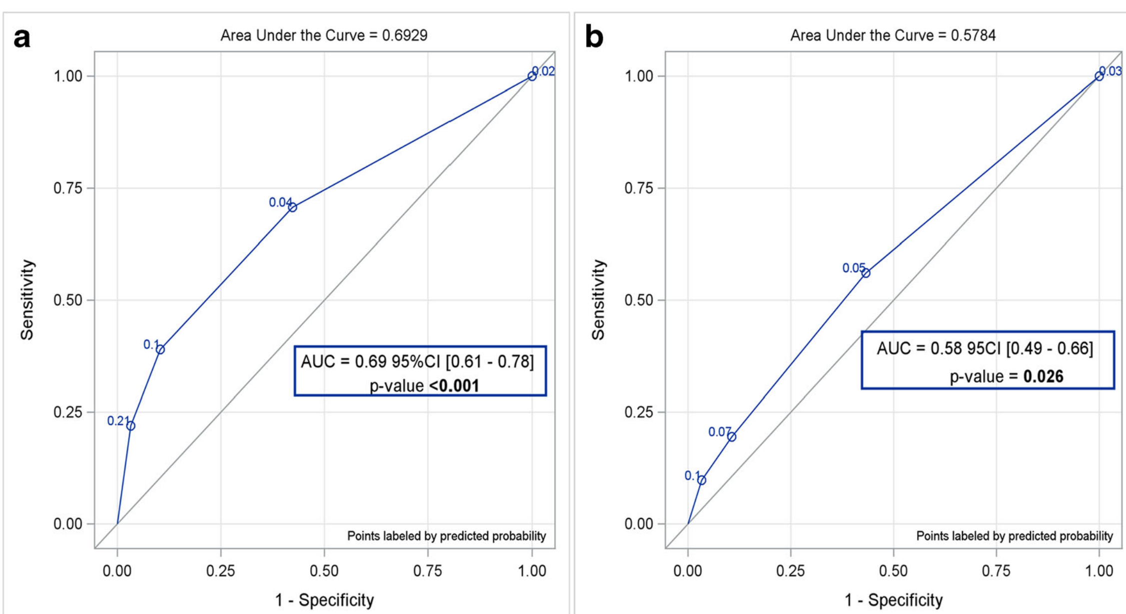
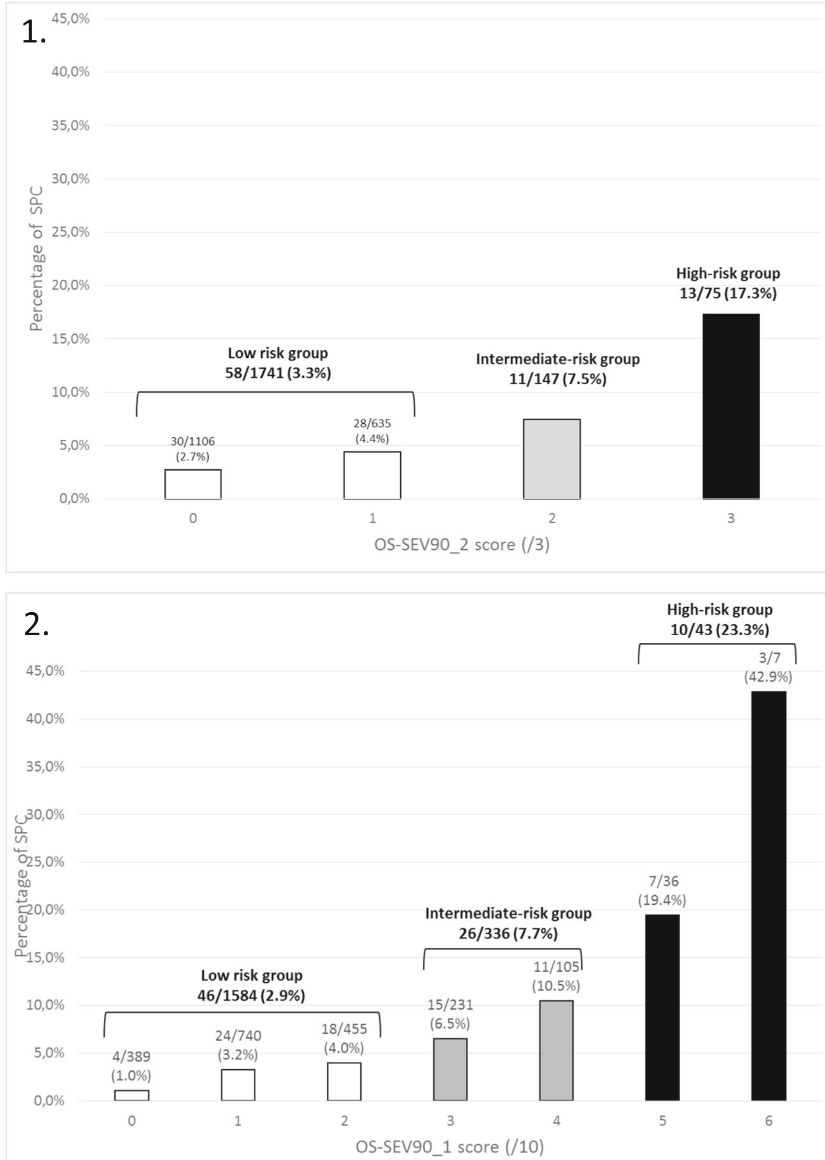



**Fig. 1** ROC curves for the two robust risk factors in (**a**) training (*n*=982) and (**b**) validating cohort (*n*=981) (Hosmer and Lemeshow goodness-of-fit test: *p*=0.686 and *p*=0.8911, respectively). AUC, area under the curve

**Fig. 2** Severe morbidity rates in each subgroups of (1.) the OS-SEV90_2 robust risk score of SPC in validating model (0 point for 0 risk factors; 1 point for junior surgeon; 2 points for esophageal or gastric surgery; and 3 points for two risk factors present) and (2.) the OS-SEV90_1 score (/10) in non-parsimonious model ($N$=1963). The risk category of patients can be computed in the calculator available in Supplemental appendix




parsimonious OS-SEV90_1 score was significantly better than the robust risk factor OS-SEV90_2 score in our overall cohort ($AUC_{OS\text{-}SEV90\_1}$=0.70 95% CI [0.64–0.76]; $AUC_{OS\text{-}SEV90\_2}$=0.63 95% CI [0.57–0.70], p=0.003) (Supplemental Figure 1).

## Time Trend

As shown in supplemental figure 2, we observed a decrease of SPC over time. The year of surgery ($\beta_{surgery\ years}$= −0.161, p<0.001) and the period (2005–2012 vs 2013–2019; $\beta_{period}$= −0.905, $p$<0.001) were significantly associated with a decrease of SPC over time. The predictive ability over time of the two models by separating the cohort according to the period (2005–2012 vs 2013–2019) was the same: for OS-SEV90_1 score, $AUC_{[2005\text{-}2012]}$=0.70 95% CI [0.60–0.79] and $AUC_{[2013\text{-}2019]}$=0.68 95% CI [0.60–0.76]; for OS-SEV90_2, $AUC_{[2005\text{-}2012]}$=0.68 95% CI [0.58–0.78] and $AUC_{[2013\text{-}2019]}$=0.68 95% CI [0.60–0.76] (Supplemental Figure 3).

## Discussion

In the present study, 2 factors known at the time of surgery (a history of gastric or esophageal surgery and a bariatric surgery performed by a junior surgeon) were identified as independent risk factors for the occurrence of SPC at day 90. A validated prediction model, "the OS-SEV90_2 score," based on these factors and a non-parsimonious prediction model, "the OS-SEV90_1 score," based on all multivariate risk factors was constructed and allows to classify patients into 3 risk groups: low, intermediate, and high.

According to validated score value, severe morbidity rates increased significantly from 3.3 to 17.3%. According to “the OS-SEV90_1 score” value, severe morbidity rates increased significantly from 2.9 to 23.3%.

In our study, no death were observed at 90 days postoperatively. This mortality rate is within the lower bounds of the figures in the literature and confirms the safe nature of bariatric surgery reported in recent studies [13, 29].

Contrary to previous studies [10, 12, 14, 17, 19, 20], we did not asses morbidity rate at 30 days but at 90 days postoperatively because this time period appears insufficient to correctly predict surgical outcomes [30], even if 30-day complications reflect direct postoperative complications. Modern postoperative intensive care and perioperative management of surgical patients may reduce or postpone death from complications beyond 30 days, making 90-day outcomes more relevant in the modern era [31]. In the present study, overall postoperative complication rate was 15.6% within 90 days postoperatively, and 82 patients (4.2%) experienced SPC according to the Dindo-Clavien classification [28]. This observed rate of SPC is consistent with those in the literature [19, 20]. Unlike two registry studies [12, 14], we chose to assess the severity of complications according to the Dindo-Clavien in order to homogenize our results by reference to the literature.

In our study cohort, a past of thromboembolic event, a history of gastric or esophageal surgery, and a surgery performed by a junior surgeon were the three independent risk factors of SPC at 90 days with an odds ratio ranging from 1.99 to 3.04. With modern bariatric surgery, thromboembolic events are rare, but they remain an important cause of mortality (together with cardiac events and infectious complications/leaks) more than morbidity. A history of gastric or esophageal surgery including the revisional bariatric surgery and a past of antireflux surgery is the factor with the greatest OR. Revisional surgery is one of the predictors of the BASIC score [19] with an OR of 1.498 and has also been reported recently as a predictive factor in the Scandinavian Obesity Surgery Registry (SOReg) study [20]. At present, the significant impact of revision surgery on morbidity is debated [32] as shown by the contradictory results of different studies [33–36]. In literature, a past of antireflux surgery seems to be a more consensual risk factor of morbidity [37, 38]. The inflammatory changes due to the first surgery can make the second one technically more difficult which can explain the implication of this factor in the occurrence of complications.

In the present study, a past of thromboembolic event is the predictive factor of morbidity with the second higher odds ratio. Thromboembolic event remains one of the most life-threatening complications after bariatric surgery [39, 40] either from pulmonary embolism or from bleeding complications induced by anticoagulant treatment. Moreover, it is one of the factors predictive of mortality of the OS-MRS score [9]. Furthermore, a past of TE event is an identified risk factor of new TE event not only in overall population [41] but also in patients with bariatric surgery [42]. In our cohort, no 90-day mortality relative to TE event was observed, but 5 patients (0.25%) developed a postoperative TE event (Dindo-Clavien = 2 for all of them): 3 pulmonary embolisms and 2 deep venous thrombosis. Among the 120 patients of our cohort with a past of TE event, 38 (31.7%) had a preoperative treatment by anti-platelets or anticoagulants, and 6 of them developed a postoperative hemorrhagic complication in which 3 were severe ones. The low level of TE event in our cohort can be explained by the systematic postoperative thromboprophylaxis applied since the beginning of bariatric surgery in our center. Some authors do not recommend thromboprophylaxis since the establishment of ERAS protocol [43], but we still applied the recommendations of guidelines for ERAS after bariatric surgery [25] and use a systematic postoperative dose of low molecular weight heparins (LMWH) adjusted to BMI (i.e., 8000 u of enoxaparin for BMI >35 $kg/m^2$ and 10,000 u for BMI >50 $kg/m^2$).

As suggested by the review published by Geubbels et al., surgeon-related factor predicted adverse outcome with an OR of 1.99, especially when surgery is performed by a junior surgeon. It was already identified in numerous studies [26, 44, 45]. The lack of experience can be the source of technical difficulties which may be the origin of postoperative complications. Some studies tried to find some solutions to reduce the impact of the learning curve in bariatric surgery like Buchwald et al. who suggested a rigorous mentoring program and supervised training by a senior surgeon [46]. Robotic bariatric surgery seems easier to learn and so can be a solution too [47] even if the impact of the robotic approach on morbidity is very discussed on the literature [48, 49]. Thus, further studies and analysis are needed to determine the safety of the robotic approach. Finally, another possible solution could be the implementation of a surgical simulation care pathway [50], but it is not studied yet for bariatric surgery.

Finally, the ASA score stratified the gravity of comorbidities of each patient and was identified as a morbidity and mortality risk factor in numerous studies [51–54].

Contrary to our study, other independent risk factors for SPC have been reported in the literature [9, 16, 19]. First, elderly is considered a risk factor of mortality OS-MRS score [9]. However, bariatric surgery in the elderly population continues to be a controversial issue. As a matter of fact, elderly seems to be a risk factor of overall morbidity [55, 56] but not of SPC [31, 57–59]. In our study, we found the same results because patients ≥ 60 years old had a significantly higher occurrence of overall morbidity in POD90 (25.3% vs 14.8%, *p*-value = 0.0005) but not of severe morbidity which is the purpose of this score (5.7% vs 4%, *p*-value = 0.304). These results may be explained by the existence of confounding factors that are more frequent in older subjects, such as higher ASA score and major comorbidities (i.e., hypertension, diabetes, OSA, past of cardiac disease, and use of anticoagulants).

Super-obesity (BMI ≥50 kg/m$^2$) remains the risk factor of the OS-MRS score with the highest odds ratio and was also reported as a predictive factor of morbidity. Surprisingly, we did not report any significant statistical result. This result may be explained by several reasons. First super-obese patients represent a small sample of our population (*n*= 13.1%). Secondly, our policy with super-obese patients is to perform bariatric surgery in two stages: an easier and less morbid LSG and in a second stage a bypass or a SADI-S [60] as previously published [61, 62].

Male gender had a morbidity odds ratio of 2.795 in the OS-MRS score, and a recent study with a large effectiveness found a higher rate of SPC for men [63]. However, in this study, some confounding factors could exist because men were significantly older, with a higher BMI and with more comorbidities than women.

The last risk factor in the OS-MRS score was primary hypertension. The implication of this specific factor on the postoperative morbidity is poorly studied in the literature. Moreover, DeMaria et al. did not clearly explain the mechanism by which hypertension contributes to increase mortality risk [9]. They supposed that it would be more the cardiovascular disease—which hypertension is a marker—which can be responsible for this increase.

Unlike the BASIC score, we did not find any significant association between adverse events and the use of anticoagulants, a mild-to-moderate COPD (GOLD II), and a past of psychiatric history. The impact of anticoagulants on morbidity in bariatric surgery is controversial, as evidenced by the results of the series [64] [65]. Currently, there are no guidelines for the management of preoperative chronic anticoagulation, but in our center, we did a systematic bridging therapy: cessation of anticoagulants 5 days before the procedures and switch by LMWH up to 15 postoperative days like suggested in some studies [66, 67]. This protocol and the few numbers of severe events can explain the difference between our study and the results of the registry data study [64]. Accordingly a recent NSQIP dataset-based study has suggested that only severe-to-very severe COPD (GOLD III and IV) increase the postoperative morbidity after bariatric surgery [68]. In our cohort, the rate of COPD was very low (1.8%), and the great majority was classified mild-to-moderate (69.4%) that can explain the absence of this factor in our score. Finally, the impacts of psychiatric history on morbidity and on specific complications are actually poorly studied in bariatric surgery, and further studies are needed to evaluate bariatric surgery in patients with a psychiatric history. In any case, the management of these patients is very specific, and the adaptation of their treatment and dosage must to be carefully to avoid decompensation of psychiatric problems [69].

However, the results of this study must be treated with caution due to its limitations. One of the main limitations was the relatively small sample size (*n*=1963) combined with low event marker (82 patients with SPC). Consequently, detecting inter-patient variability requires larger study populations. For example, older age was not identified as a risk factor for SPC possibly due to a lack of statistical power. Another limitation is that the studied parameters were determined before the study and some can be involved in the occurrence of complications and not included in our analysis. Finally, because it is known that the original article overestimated the predictive values of its score, it is required, before to be used in clinical decision, to validate it in a completely independent cohort which is the next step for this work. Thus, the clinical validity of the prognosis score can be established like for the OS-MRS score [70]. The OS-SEV90 score was associated with the risk for serious postoperative complications, and if validated in other materials, it could potentially be used to guide preoperative risk evaluation.

## Conclusions

In the present study, severe postoperative complications following modern bariatric surgery were rare (<5%) and decreased over time. A history of gastric or esophageal and a bariatric surgery performed by a junior surgeon who performed fewer than 50 cases and past history of VTE were independent risk factors for SPC at 90 days. Application of the OS-SEV90 score might permit to predict the risk of SPC after bariatric surgery, although the performance of this score to discriminate the risk of SPC was low (AUC=0.70, a value at the limit between poor and acceptable). With the OS-SEV90, the multidisciplinary team will be able to inform the patient of his specific risk, try to optimize the comorbidities before the surgery, and refer him to a center with an adapted technical platform (intensive care, tertiary referral bariatric center, interventional radiology). However, it should be validated in a new independent cohort of patients. Further research in this area involving large multi-center databases with robust, standardized, and well-validated measurements of risk factors and outcomes are warranted.

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## Declarations

**Conflict of Interest** The authors declare no competing interests.

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