Med-Score 24: A multivariable prediction model for poststernotomy mediastinitis 24 hours after admission to the intensive care unit

Mercedes Nieto-Cabrera, MD, PhD,^{a,d} Cristina Fernández-Pérez, MD, PhD,^{b,e,f}
Inés García-González, MD,^a Juan Carlos Martín-Benítez, MD, PhD,^{a,e} Justo Ferrero, MD,^a
María Bringas, MD, PhD,^{a,d} Manuel Carnero, MD, PhD,^c Luis Maroto, MD, PhD,^c and
Miguel Sánchez-García, MD, PhD^{a,e}

ABSTRACT

Objectives: Mediastinitis is a serious complication of heart surgery. In this study, we developed a bedside risk score for poststernotomy mediastinitis.

Methods: Data were prospectively collected from 4625 patients admitted to our intensive care unit after heart surgery (January 2005–June 2011). Mediastinitis was defined according to Centers for Disease Control and Prevention criteria. A logistic model was constructed in a randomly selected subgroup of 2618 patients and validated in a second cohort of 1352, as well as in a prospective cohort of 2615 (June 2011–December 2015). Model discriminatory power was assessed according to the area under the receiver operating characteristic curve (AUROC). The β coefficients of the model were used to define 3 levels of mediastinitis risk as a score designated Med-Score 24. Its performance to predict mediastinitis was compared with that of the logistic EuroSCORE and Society of Thoracic Surgeons score.

Results: Ninety-four (2.36%) patients developed mediastinitis. The risk factors identified as predictive of mediastinitis (AUROC 0.80) were 4 preoperative variables (age >70 years, chronic obstructive lung disease, obesity, and antiplatelet therapy) and 3 perioperative variables (prolonged ischemia, emergency reoperation, and prolonged intubation). AUROCs for the Society of Thoracic Surgeons score and logistic EuroSCORE were 0.63 and 0.55, respectively, both differing significantly from the area calculated for Med-Score 24 ($P < .001$).

Conclusions: The score developed showed excellent predictive power 24 hours after admission to the intensive care unit for mediastinitis risk. This simple tool helps stratify patients according to this risk, thus identifying high-risk patients for preventive measures. In our patient cohort, Med-Score 24 performed better than other scores used for this purpose. (J Thorac Cardiovasc Surg 2018;155:1041–51)

Predictive powers of mediastinitis risk scores for 3970 heart surgery patients.

Central Message

We present a new score to predict the risk of poststernotomy mediastinitis. This bedside score can be used within 24 hours after a patient undergoing major heart surgery is admitted to the ICU.

Perspective

Poststernotomy mediastinitis is a serious complication of heart surgery. Our objective was to develop and validate a simple bedside mediastinitis risk score for use within 24 hours of major heart surgery. The rationale was that if we could accurately and quickly predict this postoperative complication, we could implement appropriate prevention strategies and reduce its impacts.

See Editorial Commentary page 1052.

From the ^aCritical Care Department, ^bPreventive Medicine Service, ^cCardiac Surgery Department, and ^dInstituto de Investigación Sanitaria IdISSC, Hospital Clínico San Carlos, Madrid, Spain; ^eFaculty of Medicine, Universidad Alfonso X el Sabio, Madrid, Spain; and ^fFaculty of Medicine, Universidad Complutense de Madrid, Madrid, Spain.

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Address for reprints: Mercedes Nieto-Cabrera, MD, PhD, Martín Lagos s/n, Madrid 28040, Spain (E-mail: mernietoc@gmail.com).

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Despite advances in heart surgery and strategies for preventing surgical-site infection (SSI), poststernotomy mediastinitis (PSM) remains a major concern. The

Scanning this QR code will take you to the supplemental tables, appendix, and video for this article.

Abbreviations and Acronyms

AUROC	= area under the receiver operating characteristic curve
CABG	= coronary artery bypass grafting
CBP	= cardiopulmonary bypass pump
CI	= confidence interval
COPD	= chronic obstructive pulmonary disease
ICU	= intensive care unit
IMA	= internal mammary artery
logES	= logistic EuroSCORE
MHS	= major heart surgery
OR	= odds ratio
PSM	= poststernotomy mediastinitis
ROC	= receiver operating characteristic
SSI	= surgical-site infection
STS	= Society of Thoracic Surgeons

incidence of this serious complication has been estimated at 0.5 to 4%,¹⁻³ and it has been associated with prolonged hospital stay and increased mortality and cost.⁴⁻⁹

Risk scoring systems are useful for predicting postoperative complications and implementing appropriate prevention strategies. The impact of PSM on morbidity and mortality underscores the importance of accurately defining risk factors to identify high-risk patients both for pre- and perioperative prevention and for increased diagnostic awareness and early therapy. In numerous studies, several risk factors for developing PSM have been described.^{10,11} A recent review has also reported the variables needed for the European Association for Cardio-Thoracic Surgery

VIDEO 1. Potential impacts of Med-Score 24. Video available at: [http://www.jtcvsonline.org/article/S0022-5223\(17\)32719-8/fulltext](http://www.jtcvsonline.org/article/S0022-5223(17)32719-8/fulltext).

risk-prediction model, although this model does not include mediastinitis as an endpoint.¹² Scores predicting mediastinitis have also been developed for different regions.^{1,13-23} However, these risk scores have not always been validated or have shown suboptimal performance,^{24,25} and it is not clear how generalizable to different patient settings these scores are.²⁶

The objectives of our study were to identify independent risk factors for PSM to include in a specific predictive model for the bedside assessment of patients who undergo heart surgery 24 hours after their admission to the intensive care unit (ICU). The scoring system developed, designated Med-Score 24, was then validated in a prospective cohort and its performance compared with that of other established scores (Video 1).^{1,11}

FIGURE 1. Flow diagram of participant recruitment.

TABLE 1. Patient pre-, intra-, and postoperative characteristics by study cohort

Variables	Whole N = 3970	Model development n = 2618	Model validation n = 1352
Preoperative			
Age, y, mean (SD)	66.4 (11.7)	66.4 (11.9)	66.5 (11.8)
Female sex, n (%)	1458 (36.7)	968 (37)	490 (36.2)
BMI, kg/m ² , mean (SD)	27.1 (4.0)	27.02 (4.2)	27.2 (3.9)
Diabetes mellitus, n (%)	1138 (28.9)	738 (28.5)	800 (29.8)
COPD, n (%)	380 (9.6)	260 (10)	120 (8.9)
Antiplatelets, n (%)	1538 (38.7)	1013 (38.7)	525 (38.8)
AdES, mean (IQR)	6 (4-8)	6 (4-8)	6 (4-8)
logES, mean (IQR)	5.0 (2.4-9.8)	4.9 (2.4-9.7)	5.1 (2.3-9.8)
Urgent/emergent, n (%)	347 (8.8)	225 (8.6)	122 (9.1)
Intraoperative			
CBP, n (%)	2585 (65.1)	1700 (64.9)	885 (65.5)
CABG, n (%)	1360 (34.3)	894 (34.1)	466 (34.5)
Valve, n (%)	1693 (42.6)	1101 (42.1)	592 (43.8)
Ascending aorta, n (%)	391 (9.8)	258 (9.9)	133 (9.8)
Combined, n (%)	300 (7.6)	209 (8)	91 (6.7)
Other, n (%)	226 (5.7)	156 (6)	70 (5.2)
IMA, n (%)	1618 (40.8)	1069 (40.8)	549 (40.6)
Bilateral IMA, n (%)	269 (6.8)	160 (6.1)	109 (8.1)
Postoperative			
Emergency reoperation (first 24 h)	233 (6)	140 (5.3)	93 (6.9)
Prolonged intubation (>24 h)	338 (9)	219 (8.4)	119 (8.8)
Status at discharge: dead, n (%)	202 (5.1)	136 (5.2)	66 (4.9)
Days of ICU stay, median (IQR)	1 (1-3)	1 (1-3)	1 (1-3)
Days of hospital stay, median (IQR)	8 (6-12)	8 (6-12)	8 (6-12)

SD, Standard deviation; BMI, body mass index; COPD, chronic obstructive pulmonary disease; AdES, additive EuroSCORE; IQR, interquartile range; logES, logistic EuroSCORE; CBP, cardiopulmonary bypass pump; CABG, coronary artery bypass graft; IMA, internal mammary artery; ICU, intensive care unit; IQR, interquartile range.

METHODS

Data Source

The cardiovascular ICU of the Hospital Clínico San Carlos in Madrid, Spain, provides care for patients who have undergone cardiovascular surgery or suffered a critical cardiac event. The unit's database collects data on 242 variables for all patients who undergo heart surgery. For the present study, we identified data for all patients who had undergone major heart surgery (MHS) from January 2005 to June 2011 and combined these data with those of the patients' clinical records to construct a predictive model for PSM.

Participants

All consecutive patients admitted to the ICU after MHS aged older than 17 years were included in this study. We excluded patients who died within 4 days of surgery, were operated on without sternotomy, or who were admitted after reoperation for complications during the same admission (Figure 1). The bundle of practices used to prevent SSI in our Cardiovascular Program can be found in Appendix E1. We selected 48 variables from the literature, including demographic, preoperative, intraoperative, and postoperative factors as potential mediastinitis risk factors. The definitions of categorical and continuous variables are those reported for the EuroSCORE.¹³

Outcome

The outcome of interest was mediastinitis. This was defined as described by the Centers for Disease Control and Prevention as an infection involving tissues and spaces underneath the subcutaneous tissue fulfilling at least 1 of the following criteria: (1) positive culture of mediastinal tissue

or fluid; (2) evidence of mediastinitis during operation or histology; and (3) 1 of the following: fever (38.8°C), chest pain, or sternal instability, as well as either purulent drainage from the mediastinum or mediastinal widening on imaging tests. SSI was monitored during hospital stay and readmissions over 1 year.

Predictors

The following variables were examined: age, sex, body mass index, hypertension, diabetes, smoking, dyslipidemia, extracardiac arteriopathy, kidney failure, chronic obstructive pulmonary disease (COPD), New York Heart Association classification, left ventricular ejection fraction, recent myocardial infarction, pulmonary hypertension, cardiogenic shock, surgical risk estimated by the logistic EuroSCORE (logES), previous interventions, preoperative stay, antiplatelet and/or anticoagulant agents, type of cardiac surgery (valve, coronary artery bypass grafting [CABG], mixed [CABG plus valve], aortic, other MHS), surgical priority (elective, urgent, or emergent), use of cardiopulmonary bypass (CBP) pump, duration of CBP, ischemia or aortic crossclamping, use of internal mammary artery (IMA) or double IMA, surgical drainage at 24 hours postsurgery, emergent reoperation for bleeding and/or tamponade at 24 hours, duration of mechanical ventilation, prolonged endotracheal intubation (>24 hours), vasopressor support, and length of ICU stay.

Statistical Analysis

A required sample size of 3529 consecutive patients was calculated for a 95% confidence interval (95% CI) and accuracy of 0.5% for a 2.4% probability of mediastinitis. To adjust the multivariate model, we estimated that approximately 10 variables would need to be considered, ie, 100 events

TABLE 2. Univariate analysis of data from the model development cohort (n = 2618)

Variable	Mediastinitis probability % (n/N)	OR (95% CI)	P value
Age, y			
<55	1.42 (6/416)	1	.063
55-64	1.80 (11/599)	1.27 (0.47-3.47)	
65-70	1.97 (9/448)	1.39 (0.49-3.95)	
71-74	2.28 (10/429)	1.62 (0.58-4.49)	
75-80	3.65 (19/501)	2.63 (1.04-6.64)	
>80	2.94 (5/165)	2.1 (0.63-6.98)	
Age >70 y			
Yes	3.0 (36/1216)	1.75 (1.03-2.95)	.033
No	1.7 (24/1402)		
Sex			
Female	2.5 (24/968)	0.88 (0.52-1.48)	.623
Male	2.2 (36/1650)	1	
BMI >30, kg/m ²			
Yes	3.9 (22/567)	1.7 (1.22-3.54)	.006
No	1.9 (38/1991)		
Diabetes mellitus			
Insulin	3.1 (7/227)	0.67 (0.30-1.53)	.544
OAD	3.0 (13/436)	0.42 (0.05-3.51)	
Diet	1.3 (1/75)	0.97 (0.38-2.46)	
No diabetes mellitus	2.1 (39/1855)	1	
Hypertension			
Yes	2.8 (44/1585)	1.91 (1.06-3.46)	.029
No	1.5 (15/1021)		
Peripheral vascular disease			
Yes	2.6 (9/349)	1.21 (0.55-2.31)	.744
No	2.3 (51/2222)		
COPD			
Yes	4.6 (12/960)	2.32 (1.21-4.42)	.009
No	2.0 (45/2350)		
Endocarditis			
Yes	4.7 (4/85)	2.15 (0.77-6.19)	.131
No	2.2 (56/2533)		
Antiplatelets			
Yes	3.0 (30/1013)	1.6 (0.96-2.67)	.069
No	1.9 (30/1605)		
Kidney failure			
Yes	3.4 (32/930)	2.10 (1.25-3.51)	.004
No	1.7 (28/1680)		
MI <90 d			
Yes	1.9 (7/368)	0.78 (0.35-1.73)	.53
No	2.4 (51/2099)		
Cardiogenic shock			
Yes	1.7 (1/58)	0.75 (0.10-5.53)	1
No	2.3 (58/2547)		
Intra-aortic balloon pump			
Yes	2.2 (4/179)	0.94 (0.33-2.62)	.903
No	2.4 (54/2270)		
Ejection fraction <35			

(Continued)

TABLE 2. Continued

Variable	Mediastinitis probability % (n/N)	OR (95% CI)	P value
Yes	2.4 (11/454)	1.06 (0.55-2.07)	.847
No	2.3 (49/2155)		
Severe PHT			
Yes	1.0 (3/287)	0.42 (0.13-1.35)	.133
No	2.5 (57/2321)		
NYHA			
I-II	2.3 (19/831)	1	.701
III	2.6 (39/1490)	1.15 (0.66-2.0)	
IV	1.6 (2/128)	0.68 (0.16-2.95)	
Involvement of ascending aorta			
Yes	1.5 (3/214)	0.58 (0.18-1.88)	.364
No	2.4 (57/2404)	1	
Previous cardiac surgery			
Yes	2.5 (8/314)	1.11 (0.52-2.36)	.783
No	2.3 (52/2263)	1	
Surgery status			
Urgent/emergent	4.0 (9/225)	0.71 (0.39-1.29)	.114
Inpatient	1.7 (16/928)	1.68 (0.80-3.55)	
Elective outpatient	2.4 (35/1449)	1	
CPB on-pump			
Yes	2.4 (41/1700)	1.16 (0.67-2.02)	.577
No	2.1 (19/918)		
Perfusion time quartiles, min			
0 (off-pump)	2.0 (19/938)	1	.019
<55	0.8 (3/355)	0.39 (0.11-1.33)	
56-83	2.0 (14/642)	1.11 (0.55-2.23)	
>83	3.8 (24/640)	1.88 (1.02-3.47)	
Prolonged perfusion time (Q3)			
Yes	3.8 (24/640)	2.01 (1.22-3.47)	.006
No	1.9 (36/1936)		
Ischemia or aortic crossclamp time, quartiles, min			
0	2.0 (20/1000)	1	.037
<40	1.3 (4/317)	0.68 (0.22-1.95)	
41-63	1.8 (12/658)	1.04 (0.51-2.12)	
>64	3.7 (24/643)	2 (1.09-3.68)	
Prolonged ischemia time (Q3)			
Yes	3.8 (24/640)	2.08 (1.23-3.52)	.005
No	1.9 (36/1936)		
Procedure			
CABG	2.0 (18/894)	1.04 (0.38-2.83)	.050
Valve	2.2 (24/1101)	1.13 (0.43-2.98)	
Aorta	1.9 (5/258)	1	
Combined	5.3 (11/209)	2.81 (0.96-8.22)	
Others	1.3 (2/156)	0.66 (0.13-3.43)	
No CABG surgery			
Yes	2.4 (42/1724)	1.21 (0.69-2.12)	.493
No	2.0 (18/894)		
Valve surgery			

(Continued)

TABLE 2. Continued

Variable	Mediastinitis probability % (n/N)	OR (95% CI)	P value
Yes	2.6 (39/1513)	1.36 (0.79-2.33)	.253
No	1.9 (21/1105)		
Aorta surgery			
Yes	1.4 (3/214)	0.58 (0.18-1.88)	.364
No	2.4 (57/2404)		
IMA use			
Yes	2.8 (30/1069)	1.46 (0.87-2.44)	.144
No	1.9 (30/1549)		
IMA bilateral use			
Yes	2.5 (4/160)	1.10 (0.39-3.07)	.859
No	2.3 (56/2458)		
Urgent reoperation			
Yes	9.3 (13/140)	5.29 (2.79-10.03)	<.01
No	1.9 (47/2478)		
Reoperation for bleeding			
Yes	8.9 (9/101)	4.73 (2.26-9.90)	<.001
No	2.0 (51/2517)		
Reoperation for tamponade			
Yes	11.1 (5/45)	5.72 (2.17-15.05)	.003
No	2.1 (55/2573)		
Vasopressors >24 h			
Yes	4.7 (6/129)	2.20 (0.93-5.21)	.066
No	2.2 (54/2489)		
Intubation >24 h			
Yes	11.0 (24/219)	8.0 (4.72-13.81)	<.001
No	1.5 (36/2399)		

OR, Odds ratio; CI, confidence interval; BMI, body mass index; OAD, oral antidiabetics; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PHT, pulmonary hypertension; NYHA, New York Heart Association; CPB, cardiopulmonary bypass; Q, quartile; CABG, coronary artery bypass graft; IMA, internal mammary artery.

needed to avoid overdispersion. All available data were included without applying criteria for missing data.

Qualitative variables are presented as their frequencies and quantitative data as the mean and standard deviation or median and interquartile range, as appropriate. The study cohort was randomly divided into 2 groups: two thirds to develop the predictive model (development cohort) and one third for its validation (validation cohort).

The homogeneous distribution of both cohorts was assessed with the χ^2 test and Student *t* test under the assumption of normality, and the median test for variables showing a skewed distribution. Univariate analysis was performed for qualitative variables and reported as odds ratios (OR) with 95% CI. For quantitative variables, ORs were estimated using a univariate logistic regression model, and receiver operating characteristic (ROC) curves were constructed and divided by quartiles to check for linearity and for categorization. Logistic regression models were adjusted for pre-, intra-, and postoperative variables by backward stepwise regression based on the maximum likelihood estimators. The likelihood ratio and its significance were calculated for each variable according to criteria for entry ($P < .05$) and removal ($P > .10$). We selected risk factors showing a $P < .10$ in the univariate analysis or that were clinically relevant. Possible interactions were evaluated with the introduction of multiplicative terms. Discriminative capacity was assessed by the area under the ROC curve

(AUROC) and its 95% CI. Sensitivity was defined as the capacity of the model to detect infection and specificity as its capacity to rule out infection. The model was calibrated by comparing predicted versus observed probabilities after their calculation from the adjusted model coefficients. The Hosmer–Lemeshow test was used for model goodness-of-fit. The model with the greatest discriminative power, good calibration, viable capacity, and meeting the principle of parsimony (explaining the maximum variability outcome variable with the smallest number of parameters included) was selected.

Med-Score 24 was obtained from the point estimate for each variable using the beta-exponents of the final model. Predicted and observed probabilities were compared. We calculated the AUROC predicted by Med-Score 24 in the validation population and then applied Med-Score 24 and the selected scores to the whole cohort. Agreement of risk stratification was evaluated with the weighted Kappa index. AUROCs of the scores were compared with the nonparametric ROC Mann–Whitney *U* test.²⁷ Lastly, Med-Score 24 was validated in a prospective cohort from June 2011 to December 2015.

In all cases, the distribution of the variable was checked against theoretical models and the assumption of homogeneity of variance tested. In all hypothesis tests the null hypothesis with a type I error or α error <0.05 was rejected. The statistical packages used for all tests were SPSS 15.0 (SPSS Inc, Chicago, Ill) and STATA 11.0 (StataCorp LLC, College Station, Tex). The study protocol was approved by our local Ethics Committee. The manuscript was drafted following the TRIPOD statement.²⁸

RESULTS

Participants

In total, 4625 surgeries were performed from January 2005 to June 2011, 3970 of which fulfilled our inclusion criteria. Of the 3970 heart surgery patients, two thirds were randomly assigned to the predictive model development group ($n = 2618$) and the remaining one third ($n = 1352$) to the model validation group (Figure 1).

Mediastinitis developed after 94 surgical interventions (2.36%). The main characteristics of the study participants (Table 1) were homogeneous in those developing PSM and those not, and no significant period effect was detected (Tables E1 and E2). Patients developing mediastinitis showed a complicated clinical course with a significantly greater incidence of complications requiring readmission to the ICU in some cases associated with a prolonged median (interquartile range) ICU length of stay of 5 (2-31) versus 1 (1-3) days and hospital length of stay of 50.5 (34.2-75.2) versus 5.5 (2-31) days, compared with patients not developing mediastinitis, respectively. These patients also more frequently needed early hospital readmission within 30 days than patients not developing mediastinitis (22.4% of patients vs 1.7%). Mortality was also significantly greater in patients developing mediastinitis: 27.7% versus 5.4% (Table E3) ($P < .001$).

Model Development

Univariate analysis of the model development cohort is provided in Table 2. The following risk factors were included in the models adjusted for the development cohort: the preoperative factors age >70 years, hypertension, COPD, kidney failure, antiplatelet therapy, body mass index

TABLE 3. Logistic regression models adjusted for each defined period in the model development cohort and final predictive model and scoring system (n = 2618)

Risk factor	Preoperative model	Pre + intraoperative model	Overall model	Scoring system	
	OR (95% CI)	OR (95% CI)	OR (95% CI)	β	Points
Age >70 y	1.02 (1.00-1.05)	1.02 (0.99-1.05)	2.26 (1.25-4.08)	0.81	2
COPD	2.01 (1.05-3.87)	2.07 (1.07-4.00)	2.41 (1.18-4.89)	0.88	2
Kidney failure	1.85 (1.08-3.16)	1.79 (1.05-3.07)			
Antiplatelets	1.56 (0.93-2.62)	2.00 (1.15-3.46)	2.13 (1.17-3.89)	0.81	2
BMI >30, kg/m ²	1.96 (1.14-3.35)	2.05 (1.19-3.53)	2.26 (1.23-4.15)	0.7	2
Perfusion time Q3		2.68 (1.53-4.71)			
Ischemia time Q3			2.92 (1.59-5.38)	1.29	3
Emergent reoperation			3.85 (1.83-8.11)	1.34	4
Prolonged intubation			3.63 (1.90-6.94)	1.29	4
Constant				-5.69	
AUROC OR (95% CI)	0.67 (0.60-0.74)	0.72 (0.65-0.80)	0.80 (0.74-0.86)	0.77 (0.70-0.83)	
Sensitivity (%)	76	68	77		
Specificity (%)	52	58	72		

OR, Odds ratio; CI, confidence interval; β , beta-exponents; COPD, chronic obstructive pulmonary disease; BMI, body mass index; Q, quartile; AUROC, area under the receiver operating characteristic curve.

>30 kg/m², and logES; the intraoperative factors mixed procedures, emergency surgery, use of IMA, third quartile of CPB time (>83 minutes) and third quartile of ischemia time (>64 minutes); and the postoperative factors vasopressors, emergency reoperation for bleeding or tamponade, and intubation >24 hours. Three models were constructed sequentially. We then selected the model with the greatest discriminative capacity (AUROC 0.80; 95% CI, 0.74-0.86), sensitivity, and specificity as a potentially feasible model. Thus, the final model used to develop the risk score consisted of 7 variables with independent predictive capacity (4 preoperative, 1 intraoperative, and 2 postoperative).

Risk Score

The scoring system was based on the relative weights obtained by rounding ORs assigning: 2 points for age >70 years, COPD, obesity, and antiplatelet therapy; 3 points for ischemia duration >60 minutes; and 4 points for emergency reoperation and prolonged intubation to give a range of 0 to 19 points (Table 3). Goodness-of-fit determined in the Hosmer-Lemeshow test was $P = .46$.

We also defined 3 risk levels according to individual scores: low (0-5 points), intermediate (6-9 points) (OR, 7.24; 95% CI, 4.05-12.93), and high (≥ 10 points) (OR, 17.58; 95% CI, 7.84-39.40). Mediastinitis risk levels in the model development cohort were low in 2057 patients (78.5%), intermediate in 490 (18.7%), and high in 71 (2.7%). The predicted and observed incidences of the 3 risk levels were not significantly different (Figure 2, A). The discriminatory power of Med-Score 24 (AUROC, 0.77; 95% CI, 0.70-0.83) was lower than in the final model. This difference was not significant ($P = .715$). Figure 3 and

Tables E4 to E6, show score correlations with predicted risk.

Score Validation

In the model validation cohort, Med-Score 24 classified 1050 patients (77.6%) as having a low risk, 257 (19%) an intermediate risk, and 45 (3%) a high risk of developing mediastinitis. Figure 2, B, shows Med-Score 24 predicted and observed incidences of mediastinitis among patients in the 3 risk groups.

Med-Score 24 was also validated prospectively in a cohort of 2516 patients (June 2011-December 2015). Forty-three of these patients developed mediastinitis (1.7%). The discriminative and stratification capacity of Med-Score 24 proved excellent. The AUROC was 0.76 (95% CI, 0.69-0.82), and the numbers of patients developing mediastinitis were 12 (0.7%) of 1798 patients (71.5%) classified as showing a low risk (used as reference), 21 (3.5%) of 598 patients (23%) showing an intermediate risk (relative risk, 5.4; 95% CI, 2.6-11.1), and 10 (8.5%) of 120 patients (4.7%) showing a high risk (relative risk, 13.5; 95% CI, 5.7-32.2). Hosmer-Lemeshow goodness-of-fit was $P = .999$.

Other Risk Scores

To compare the discriminatory power of Med-Score 24 with those of the scores of logES and Society of Thoracic Surgeons (STS),¹ the scoring systems were applied to the whole patient cohort. Poor risk stratification agreement with Med-Score 24 was detected: κ 0.12 (95% CI, 0.11-0.13) for preoperative STS score, κ 0.13 (95% CI, 0.12-0.15) for the combined STS score, and κ 0.121 (95% CI,

FIGURE 2. Med-Score 24 observed and predicted probability distributions in the model development (A) ($n = 2658$) and model validation (B) ($n = 1352$) cohorts.

0.10-0.14) for the logES. The AUROCs for STS (0.63; 95% CI, 0.551-0.695) and logES (0.55; 95% CI, 0.492-0.623) indicated the significantly lower discriminative power of these scores ($P = .014$ and $P < .001$, respectively) than Med-Score 24 (0.79; 95% CI, 0.73-0.86) (Figure 4).

DISCUSSION

The findings of this study indicate that a risk level for PSM can be obtained in a patient undergoing heart surgery within 24 hours of admission to the ICU on the basis of routinely collected and easily available clinical information. The scoring system developed, Med-Score 24, emerged as a simple tool for classifying patients undergoing MHS according to their risk—low, intermediate, or high—of subsequently developing mediastinitis. The predictive power of Med-Score 24 was significantly greater than those of the well-established risk scoring systems STS and logES.

The patient cohorts used here to develop and validate our model were homogeneous and sufficiently large to provide

adequate statistical power. The final model was validated, confirming its good discriminatory power in both a historical and prospective cohort. The lower AUROC observed in the model validation cohort is likely explained by the low incidence of the outcome measure, although the model still showed good stratification capacity. The risk of selection bias due to confounders was minimized by including all consecutive patients undergoing heart surgery over a 7-year period.

As in our study, models including only preoperative variables seem to show less discriminatory power than those also based on perioperative variables.^{21,29-32} Preoperative variables, like age, obesity, and COPD, have been identified as risk factors for PSM in other surgical risk scores.^{3,4,22,25,33,34} In contrast, the use of antiplatelet agents has been rarely assessed as a risk factor for mediastinitis.³³ In our study, the use of any preoperative antiplatelet drug emerged as an independent risk factor, doubling the risk of a patient developing mediastinitis. In

FIGURE 3. Score correlations with predicted risk.

line with our findings, antiplatelet agents not only prevent hemostasis but also cause immune response alterations.³⁴

In contrast, other frequently identified risk factors such as diabetes mellitus, preoperative length of stay, or use of IMA could not be confirmed in our study. We hypothesize that our perioperative protocol for glycemic control could reduce the risk of SSI in patients with diabetes as also suggested by others.³⁵ Although preoperative length of stay did not emerge as an independent risk factor for mediastinitis in our study, our analysis of this variable may have been biased because the database used only collects admission data for our hospital, and some patients were referred from other centers for surgery.

The use of IMA has also been shown to be a risk factor for mediastinitis. In these studies, however, MHS was conducted under CBP, whereas in our cohort CABG was mostly off-pump, possibly reducing ischemia time. Our low incidence of mediastinitis in patients undergoing IMA grafting could be explained by artery harvesting by skeletonization. This technique serves to preserve the rest of the vascular bundle, thus maintaining sternal irrigation and reducing the risk of infection.^{10,12}

The sensitivity of the model for the outcome variable was high, since all SSIs developing during hospital stay, as well as those diagnosed after discharge, were recorded. The homogeneous diagnostic criteria defined determined that the model's specificity was also good. We used Centers for Disease Control and Prevention criteria to define PSM. In some studies, mediastinitis is not clearly defined or the authors' own criteria are used. Further, sometimes both superficial and deep wound infections are included in prediction models.^{4,17,25,26} Besides their different incidence, these 2 infections differ in their morbidity and mortality. In the 2005 STS score,¹ the main outcome was SSI or sepsis of any origin, implying that the risk of developing mediastinitis is similar to that of developing other postoperative infections.

The limitations of our study are mainly those related to its single-center nature. Thus, although the predictive model developed showed excellent discriminatory power, it was only validated at our center. Risk factors identified at 1 institution may play a different role in another patient setting due to differences in preoperative management, surgical

FIGURE 4. Discriminating power of risk scoring systems in the whole cohort (n = 3970). STS, Society of Thoracic Surgeons; ES, EuroSCORE; AUROC, area under the receiver operating characteristic curve; CI, confidence interval.

protocols, and postoperative care. Also, our patient population was relatively homogenous compared with cohorts in other regions of the world, ie, those showing greater variation in terms of patient race and ethnicity or prevalence of obesity. The Med-Score 24 thus requires external validation. Our predictive model is based on well-defined, measurable, and easily accessible variables and this will allow for its easy validation at other centers. Effectively, the good predictive power of the model suggests its results may be fairly generalizable. Moreover, its 7 variables can be obtained at the patient’s bedside without the need for further tests, calculations, or subjective interpretation. Further, we should mention that our model shows the characteristic features of a reliable and easily extrapolatable predictive model, as we included all variables potentially associated with mediastinitis reported in the literature.

Another potential limitation of our study is that other contributing risk factors for SSI such as noncompliance with preventive strategies were not considered. However,

we can nevertheless assume a stable and good measure of compliance because of the existence of detailed protocols for the prevention of mediastinitis, an experienced surgical team, and well-established perioperative care measures.

Finally, when STS and logES scores were assigned to our whole patient cohort, a different distribution of risk levels was observed compared with the use of Med-Score 24. Resultant AUROCs indicated a significantly lower predictive power for mediastinitis of these established scoring systems. In other studies, these models have shown suboptimal performance as they only consider preoperative variables,^{17-20,23-26} as noted here for our preoperative model. The logES model has proved its good discriminatory capacity for superficial SSI, but this capacity was found to be suboptimal for deep SSI,²⁶ as when used in our cohort. In contrast, a greater cumulative EuroSCORE has been linked to a greater risk of SSI.³⁵ Such contrasting findings could be related to differences in definitions, follow-up duration, missing data, surgical procedures, geographic

location, and study period (30 days, 60 days, or 1 year after surgery as in our study).

Our results are in agreement with the opinions expressed by some authors, who consider that EuroSCORE—a well-validated score for predicting mortality after cardiac surgery—is not a good predictor of mediastinitis.³⁵ Although comparing the validity and predictive power of large databases is challenging, we used the robust ROC analysis method to confirm the better performance of Med-Score 24 over STS and logES for this purpose. We did not compare our scoring system to more recent scores, for instance EuroSCORE II and the latest STS scores,¹⁷⁻²⁰ because they use variables not prospectively collected in our historical database.

CONCLUSIONS

The predictive model proposed here emerged as a valid, simple tool to detect within 24 hours of ICU admission the risk of PSM. In our cohort, Med-Score 24 served to stratify patients according to their risk level such that moderate- to high-risk patients could be subjected to prevention measures and increased alertness during their postoperative care. Med-Score 24 requires external validation at different centers. Future work should also be targeted at assessing the clinical impacts of implementing Med-Score 24.

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Key Words: poststernotomy mediastinitis, risk score, surgical site infection, postoperative cardiac surgery complications, predictive model

APPENDIX E1. SURGICAL-SITE INFECTION PREVENTION BUNDLE CURRENTLY USED IN THE CARDIOVASCULAR PROGRAM AT THE HOSPITAL CLINICO SAN CARLOS, MADRID, SPAIN

- Chlorhexidine bathing or showering of the patient the night before surgery
- Hospital-wide hand hygiene campaign with regular auditing
- Perioperative decolonization with a combination of oral chlorhexidine and nasal mupirocin
- Hair removal outside the operating room using an electric razor
- Antimicrobial prophylaxis: cefazolin 30 to 60 minutes or vancomycin + levofloxacin (allergic or high risk of methicillin-resistant *Staphylococcus aureus*) 2 hours before incision. Discontinue agent within 24 hours after surgery
- Perioperative control of blood glucose (<180 mg/dL)
- Bone wax should be avoided
- External chest support vest
- Surveillance for surgical-site infection

TABLE E1. Patient pre-, intra-, and postoperative characteristics by study cohort

Variables	Whole cohort		Model development		Model validation	
	N = 3970		n = 2618		n = 1352	
	n	%	n	%	n	%
Preoperative variables						
Age, y, mean (SD)	66.4 (11.7)		66.4 (11.9)		66.5 (11.8)	
Age, y, range						
<55	634	16	422	16.1	212	15.7
55-64	934	23.5	610	23.3	324	24
65-70	704	17.7	457	17.5	247	18.3
71-74	638	16.1	439	16.8	199	14.7
75-80	803	20.2	520	19.9	283	20.9
>80	257	6.5	170	6.5	87	6.4
Sex						
Female	1458	36.7	968	37	490	36.2
BMI, kg/m ² , mean (SD)	27.1 (4.0)		27.02 (4.2)		27.2 (3.9)	
BMI range						
<20	108	2.8	87	2.8	21	1.6
20-29	2903	74.7	1905	74.7	998	75.1
30-35	803	20.7	519	20.7	284	21.4
>35	74	1.9	48	1.9	26	2
Smoking						
No	2293	58.3	1529	59.0	764	57.1
Previous history	1164	29.6	754	29.1	410	30.6
Current	473	12	308	11.9	165	12.3
Diabetes mellitus						
No	2799	71.1	1855	71.5	944	70.2
Diet only	115	2.9	75	2.9	40	3
Oral antidiabetics	666	16.9	436	16.8	230	17.1
Insulin	357	9.1	227	8.8	130	9.7
Hypertension	2448	61.9	1585	60.8	863	63.9
Dyslipidemia	2060	52.8	1337	51.9	723	54.3
Peripheral vascular disease	528	13.5	349	13.6	179	13.4
COPD	380	9.6	260	10	120	8.9
Kidney failure	1456	36.8	930	35.6	526	38.9
Preoperative Hb, g/dL, mean (SD)	13.4 (3.1)		13.4 (3.2)		13.3 (2.7)	
Ejection fraction (%), mean (SD)	60.7 (13.7)		60.8 (13.6)		60.5 (13.6)	
Depressed EF	690	17.4	454	17.4	236	17.5
NYHA class						
I-II	1288	34.5	831	33.9	457	35.6
III	2246	60.2	1490	60.8	756	59
IV	197	5.3	128	5.2	69	5.4
Severe PHT	414	10.5	287	11	127	9.4
Involvement ascending aortic	327	8.2	214	8.2	113	8.4
MI <30 d	573	15.3	368	14.9	205	16.2
Cardiogenic shock	76	1.9	58	2.2	18	1.3
IABP preoperative/intraoperative	279	7.5	179	7.3	100	8
Endocarditis	120	3	85	3.2	35	2.6
Heparin	190	4.8	129	4.9	61	4.5
Coumarin	635	16	428	16.3	207	15.3
Antiplatelets	1538	38.7	1013	38.7	525	38.8
AdES quartile						
<4	952	24.1	616	23.6	336	24.9
4-5	830	21	569	21.8	261	19.3
6-7	1362	34.4	893	34.3	469	34.7
>7	812	20.5	528	20.3	284	21

(Continued)

TABLE E1. Continued

Variables	Whole cohort		Model development		Model validation	
	N = 3970		n = 2618		n = 1352	
	n	%	n	%	n	%
logES quartile						
<2.5	989	25	637	24.4	352	26.1
2.5-4.9	989	25	674	25.9	315	23.3
5.0-9.9	992	25.1	648	24.9	344	25.5
>9.9	986	24.9	647	24.8	339	25.1
Preop stay, d, median (IQR)	2 (1-3)		2 (1-3)		2 (1-2)	
Priority						
Elective	2199	55.7	1449	55.7	750	55.6
Inpatient	1404	35.5	928	35.7	476	35.3
Urgent/emergent	347	8.8	225	8.6	122	9.1
Previous cardiac surgery	474	12.1	314	12.2	160	12
Intraoperative variables						
CBP	2585	65.1	1700	64.9	885	65.5
CPB time, min, mean (SD)	54 (51.3)		53.8 (51.7)		54.1 (50.4)	
CBP time range, min, in quartiles						
0	1408	36.1	938	36.4	470	35.4
1-55	555	14.2	375	14.6	180	13.5
56-83	970	24.8	623	24.2	347	26.1
>83	972	24.9	640	24.8	332	25
Ischemia or aortic crossclamp time, min, mean (SD)	39.7 (38.3)		39.4 (38.3)		39.9 (38.2)	
Crossclamp time, min, in quartiles						
0	1499	37.8	999	38.2	500	37.1
1-40	484	12.2	317	12.1	167	12.4
41-63	1007	25.4	659	25.2	348	25.8
>64	977	24.6	643	24.6	334	24.8
Procedures						
CABG	1360	34.3	894	34.1	466	34.5
Valve	1693	42.6	1101	42.1	592	43.8
Ascending aortic	391	9.8	258	9.9	133	9.8
Combined	300	7.6	209	8	91	6.7
Other	226	5.7	156	6	70	5.2
No CABG	2610	65.7	1724	65.9	886	65.5
Bilateral IMA	269	6.8	160	6.1	109	8.1
IMA	1618	40.8	1069	40.8	549	40.6
Valve	2299	57.9	1513	57.8	786	58.1
Postoperative variables						
Reoperation for bleeding or for tamponade	233	6	140	5.3	93	6.9
Reoperation for bleeding	165	4.16	101	3.86	64	4.7
Surgical drainage, cc 24 h, mean (SD)	546.8 (390.3)		549.8 (381.5)		540.9 (406.8)	
Reoperation for tamponade	77	2	45	1.7	32	2.4
Vasopressors >24 h	201	5	129	4.9	72	5.3
Intubation >24 h	338	9	219	8.4	119	8.8
Duration of intubation						
6-12 h	1495	40.5	1003	41.5	492	38.7
12-24 h	1850	50.2	1199	49.6	651	51.3
24-48 h	196	5.3	127	5.3	69	5.4
48-72 h	51	1.4	32	1.3	19	1.5
3-7 d	42	1.1	24	1	18	1.4
>7 d	54	1.5	33	1.4	21	1.7
Status at discharge, dead	202	5.1	136	5.2	66	4.9
Days of ICU stay, median (IQR)	1 (1-3)		1 (1-3)		1 (1-3)	
Days of hospital stay, median (IQR)	8 (6-12)		8 (6-12)		8 (6-12)	

SD, Standard deviation; BMI, body mass index; COPD, chronic obstructive pulmonary disease; Hb, hemoglobin; EF, ejection fraction; NYHA, New York Heart Association; PHT, pulmonary hypertension; MI, myocardial infarction; IABP, intra-aortic balloon pump; AdES, additive EuroSCORE; logES, logistic EuroSCORE; IQR, interquartile range; CBP, cardiopulmonary bypass pump; CPB, cardiopulmonary bypass; CABG, coronary artery bypass graft; IMA, internal mammary artery; ICU, intensive care unit.

TABLE E2. Characteristics of the whole patient cohort during the study period (n = 3970)

Variable	2005		2006		2007		2008		2009		2010		2011	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Sex (male)	449	63.2	376	65.4	392	63.7	329	59.6	348	64.0	341	63.9	277	63.0
Age >70 y	309	43.5	271	47.2	276	44.9	249	45.1	257	47.2	254	47.6	211	48.0
DM	198	28.4	158	27.8	172	28.2	172	31.4	151	27.8	153	28.7	134	30.5
COPD	72	10.2	60	10.4	66	10.8	42	7.6	51	9.4	49	9.2	41	9.3
Antiplatelets	303	42.7	225	39.1	236	38.4	205	37.1	207	38.1	189	35.4	173	39.3
Urgent/emergent priority	62	8.7	60	10.4	45	7.3	47	8.6	55	10.1	43	8.1	35	8.2
CABG	324	45.6	271	47.1	264	42.9	252	45.7	217	39.9	205	38.4	168	38.2
No CABG surgery	443	62.4	359	62.4	404	65.7	339	61.4	375	68.9	375	70.2	315	71.6
CPB	443	62.4	352	61.2	403	65.5	340	61.6	376	69.1	369	69.1	302	68.6
Intubation >24 h	39	5.5	48	8.3	49	8.0	49	8.9	71	13.1	46	8.6	36	8.2
Emergency reoperation <24 h	40	5.6	40	7.0	34	5.5	26	4.7	36	6.6	36	6.7	21	4.8
BMI median (IQR)	26.6 (24.4-29.2)		26.2 (24.2-29.3)		26.8 (24.4-29.3)		26.8 (24.4-29.7)		26.6 (24.2-29.4)		26.8 (24.4-29.7)		27.4 (24.2-30.3)	
AdES median (IQR)	6 (3-7)		6 (3-8)		6 (4-8)		6 (4-8)		6 (4-9)		6 (4-8)		6 (4-8)	
logES median (IQR)	4.6 (2.3-8.6)		5.1 (2.4-10)		5.5 (2.6-10.2)		5.1 (2.5-9.8)		5.5 (2.7-11.8)		4.7 (2.4-9.3)		5.1 (2.5-9.1)	
CPB time median (IQR)	47 (0-70)		50 (0-74)		56 (0-80)		55 (0-89)		66 (0-96)		65 (0-92)		61 (0-93)	
Ischemia time median (IQR)	35 (0-53)		36.5 (0-59)		40 (0-60)		41 (0-64)		49 (0-74)		48 (0-72)		46 (0-73)	

DM, Diabetes mellitus; COPD, chronic obstructive pulmonary disease; CABG, coronary artery bypass graft; CPB, cardiopulmonary bypass; BMI, body mass index; IQR, interquartile range; AdES, additive EuroSCORE; logES, logistic EuroSCORE.

TABLE E3. Impact of mediastinitis in the global cohort (n = 3970)

	Mediastinitis % (n/N)	No mediastinitis % (n/N)	OR (95% CI)	P value
Readmission to ICU	71.3 (67/94)	2.1 (81/3876)	116.3 (70.7-191.3)	<.001
Readmission to hospital <30 d	22.4 (21/94)	1.7 (66/3876)	16.6 (9.6-28.6)	<.001
ICU length of stay, median (IQR)	5 (2-31)	1 (1-3)	1.04 (1.03-1.05)	<.001
Hospital length of stay, median (IQR)	50.5 (34.2-75.2)	5.5 (2-31)	1.04 (1.03-1.05)	<.001
Mortality, 30 d	27.7 (26/94)	4.5 (202/3876)	8.0 (5.0-12.9)	<.001

OR, Odds ratio; CI, confidence interval; ICU, intensive care unit; IQR, interquartile range.

TABLE E4. Poststernotomy mediastinitis risk categories defined for our model development patient cohort (n = 2618)

Risk level	Score	OR (95% CI)	P value
Low	0-5	1	<.001
Intermediate	6-9	7.24 (4.05-12.93)	<.001
High	≥10	17.58 (7.84-39.40)	<.001

OR, Odds ratio; CI, confidence interval.

TABLE E5. Correlation between Med-Score 24 scores and mediastinitis probability in the whole and model development cohorts

Whole cohort		Model development cohort	
Score (%)	n/N	Score (%)	n/N
0 (0.7)	4/596	0 (0.5)	2/400
2 (1.2)	13/1064	2 (1)	7/688
3 (0.4)	1/280	3 (0.5)	1/198
4 (1.4)	12/846	4 (1.2)	7/568
5 (0.9)	3/321	5 (1)	2/203
6 (5.4)	18/331	6 (5.6)	12/215
7 (6.7)	14/210	7 (8)	11/137
8 (5.8)	6/103	8 (4.1)	3/73
9 (5.8)	6/103	9 (7.7)	5/65
10 (18.4)	7/38	10 (11.5)	3/26
11 (12.2)	5/41	11 (14.3)	4/28
12 (10)	1/10	12 (0)	0/3
13 (5.6)	1/18	13 (10)	1/10
14 (40)	2/5	14 (100)	2/2
15 (33.3)	1/3	15 (0)	0/2
17 (0)	0/1	17 (0)	0/0

TABLE E6. Score ranges according to number of risk factors in a patient

No. of risk factors	Med-Score 24	
	Minimum	Maximum
0	0.00	0.00
1	2.00	4.00
2	4.00	8.00
3	6.00	11.00
4	8.00	13.00
5	11.00	15.00
6	15.00	17.00