

## External validation of European system for cardiac operative risk evaluation II in a Tunisian population.

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### Abstract

**Objective:** The main objective of this study is to evaluate the performance of the predictive model (EuroSCORE II) on a Tunisian population in order to validate its use in our country.

**Methods:** This is a retrospective study of data from 418 adult patients undergoing cardiac surgery with cardiopulmonary bypass between 1<sup>st</sup> January 2015 and 31 December 2016 in the department of cardiovascular and thoracic surgery of the Sahloul University Hospital of Sousse. The EuroSCORE II is calculated using the application validated on the site [www.euroscore.org](http://www.euroscore.org). The performance of the score is evaluated by analyzing its discriminative power by constructing the ROC curve and analyzing its calibration using the Hosmer-Lemeshow statistics.

**Results:** The EuroSCORE II shows good discriminative power in our population with an area under the ROC curve >0.7 in all study groups (0.864 ± 0.032 for general cardiac surgery, 0.822 ± 0.061 for coronary surgery, 0.864 ± 0.052 for valvular surgery, and 0.900 ± 0.041 for urgent cardiac surgery). The model appears to be calibrated as well by obtaining p values above the statistical significance level of 0.05 (0.638 for general cardiac surgery, 0.543 for coronary surgery, 0.179 for valvular surgery, and 0.082 for urgent cardiac surgery).

**Conclusion:** The EuroSCORE II presents acceptable performance in our population, attested by a good discriminative power and an adequate calibration.

**Keywords:** Cardiac Surgery, EuroSCORE II, Surgical Mortality, Discriminative power, Calibration

### Abbreviations:

AUC: Area Under the Curve; CABG: Coronary Artery Bypass Grafting, CI: Confidence Interval; DF: Degrees of Freedom; EuroSCORE: European System for Cardiac Operative Risk Evaluation; MI: Myocardial Infarction; MVR: Mitral Valve

Replacement; n: Number; NYHA: New York Heart Association; ROC: Receiver Operating Characteristic; SMR: Standardized Mortality Ratio; STS: Society of Thoracic Surgeons;  $\chi^2$ : Chi-Square

*Accepted on January 29, 2019*

### Introduction

In recent years, adult cardiac surgery has experienced a significant increase in operative risk due to the recruitment of an increasingly elderly population with multiple comorbidities. In addition, she benefited from improved surgical techniques and postoperative resuscitation care [1]. Despite these technical advances and accumulated knowledge, it remains a high-risk surgery, burdened with many potentially fatal complications.

The risk scores in cardiac surgery are intended to estimate the operative mortality according to the characteristics of the patient and the modalities of the surgery. They, therefore, have an important role in estimating the benefit/risk ratio of the interventions and for informing the patient, thus guiding the therapeutic choice [2]. These scores are also useful in comparing postoperative outcomes and improving the quality of care in cardiovascular facilities [3]. They have the advantage of reducing the subjectivity of the estimation of the operative risk, but must be interpreted with caution and can never be a substitute for clinical judgment.

Many predictive models have been proposed and used for cardiac surgery. The most widely used currently are the score

of the STS (Society of Thoracic Surgeons), the main score applied in North America, and EuroSCORE (European System for Cardiac Operative Risk Evaluation), which is the most used model in Europe [4]. The EuroSCORE II, published in 2012, was developed on a database of 154 centers in 43 predominantly European countries [5], it must be tested and validated in developing countries such as Tunisia before being used as a model risk stratification and serve as information for the patient seeking care or as an element of monitoring and evaluation of cardiac surgery services.

To our present knowledge, EuroSCORE II has not been validated in Tunisia. In this work, we proposed to evaluate the performance of this risk stratification model (EuroSCORE II) on a Tunisian population in order to validate its use in our country.

### Patients and Methods

This is an observational, transversal study conducted on a retrospective model in the Department of Cardiovascular and Thoracic Surgery at the Sahloul University Hospital of Sousse. This study focuses on adult patients undergoing cardiac surgery

with Cardiopulmonary Bypass (CPB), over a period of 2 years from 1<sup>st</sup> January 2015 until 31 December 2016.

We included in our study all adult patients who had cardiac surgery under cardiopulmonary bypass, with or without aortic clamping. In the end, 418 patients were included in this study; they were enrolled and followed up to the 30<sup>th</sup> postoperative day.

Patient data were collected from department of archived records at Sahloul University Hospital referring to the factors in EuroSCORE II. EuroSCORE II was calculated for each patient using the validated application on [www.euroscore.org](http://www.euroscore.org).

The statistical analysis was done using SPSS software version 20.0. The quantitative data were represented as means  $\pm$  standard deviations and the qualitative variables in number and percentage.

The comparison between the different data made the call to Pearson's  $\chi^2$  test for proportions and Student's T-test for averages. A univariate analysis was used to identify independent predictors of hospital mortality and a value of  $p$  less than 0.05 was set as the statistical significance level.

The basic overall performance parameter was the Standardized Mortality Ratio (SMR) calculated according to the formula:

Observed mortality  $\div$  Expected mortality

The analysis of the validity of the score was carried out by two approaches:

Study of discriminative power by constructing the ROC curve, which has for abscissa the rate of false positive represented by the value (1-specificity) and for ordinate the rate of true positives represented by the value of the sensitivity. Thus, the area under the ROC curve (AUC) was obtained according to the method of Hanley and McNeal

Study of the calibration using the Hosmer-Lemeshow goodness-of-fit test, and then building the calibration plot

## Results

### Patients' characteristics

The study included 418 patients underwent cardiac surgery, 245 men (58.6%) and 173 women (41.4%), with a sex ratio of 1.4. The mean age is  $55.84 \pm 13.84$  years with extremes

**Table 2.** Distribution of risk factors and their relationship to mortality.

Variable	Frequency	$p$
Age	55.84 ( $\pm$ 13.84)	=0.361
Gender	Male	=0.697
	Female	
Diabetes on insulin	54 (12.9%)	=0.629
Extracardiac arteriopathy	48 (11.5%)	=0.063

ranging from 18 to 87 years. Women are younger ( $55 \pm 14$  years) than men ( $57 \pm 13$  years), with no significant difference ( $p=0.09$ ).

**Table 1.** Frequencies of cardiac surgical procedures and their mortalities in our population.

Type of surgery	Frequency	Mortality
Coronary surgery	160 (38.3%)	11 (6.8%)
Valvular surgery	204 (48.8%)	17 (8.3%)
Mixed valvulo-coronary surgery	16 (3.8%)	3 (18.7%)
Surgery of the thoracic aorta	26 (6.2%)	7 (36.7%)
Correction of congenital heart disease	7 (1.7%)	0 (0%)
Resection of a heart tumor	4 (1%)	1 (25%)
Removal of an endocavity PM probe	1 (0.2%)	0 (0%)

These patients have undergone different types of heart surgery. Table 1 shows the frequency of various cardiac surgical procedures and their corresponding mortalities in the validation study. Table 2 how's the distribution of risk factors in our population and their relationship to mortality (a  $p$  value  $<0.05$  is considered statistically significant).

### Mortality analysis

Of the 418 patients in our study, 39 died with a global mortality rate of 9.3%.

The mean age of the deceased patients was  $60 \pm 14$  years versus  $55 \pm 14$  years in the survivors without significant difference ( $p=0.361$ ). 61.5% of them are males, while 38.5% are females without significant difference ( $p=0.697$ ). The observed mortality is 6.8% in the coronary subgroup, 8.3% in the valvular subgroup and 23.3% in the urgency subgroup.

## Validation of EuroSCORE II

### Standardized mortality ratio

The mortality predicted by EuroSCORE II in the total population (3.25%) is significantly lower ( $p<0.001$ ) than the observed mortality (9.3%) so that the SMR is 2.86.

**Citation:** Sidi CEH, Mgarrech I, Tarmiz A, et al. External validation of European system for cardiac operative risk evaluation II in a Tunisian population. *Ann Cardiovasc Thorac Surg.* 2019;2(1):10-17.

Previous cardiac Surgery		20 (4.8%)	=0.916
Poor mobility		10 (2.4%)	=0.305
Chronic lung disease		12 (2.9%)	=0.058
Recent MI		38 (9.1%)	=0.043
Angina at rest		50 (12%)	=0.025
NYHA	Grade I	20 (4.8%)	<0.001
	Grade II	212 (50.7%)	
	Grade III	168 (40.2%)	
	Grade IV	18 (4.3%)	
Creatinine clearance	>85 ml/min	204 (48.8%)	<0.001
	51-85 ml/min	156 (37.3%)	
	<51 ml/min	54 (12.9%)	
	Dialysis	4 (1.0%)	
Critical preoperative state		12 (2.9%)	<0.001
Ejection fraction	>50%		<0.001
	31-50%	84 (20.1%)	
	30%	5 (1.2%)	
Pulmonary hypertension	<3155 mmHg		=0.008
	31-55 mmHg	124 (29.9%)	
	>55 mmHg	60 (14.1%)	
Active endocarditis		25 (6.0%)	=0.009
Urgency	Elective	315 (75.4%)	<0.001
	Urgent	66 (15.8%)	
	Emergent	26 (6.2%)	
	Salvage	11 (2.6%)	
Weight of the intervention	Isolated CABG	159 (38.0%)	=0.379
	Single non CABG	151 (36.1%)	
	2 procedures	92 (22.1%)	
	3 or more	16 (3.8%)	
Surgery on thoracic aorta		26 (6.2%)	=0.001

In the coronary subgroup, the mortality predicted by EuroSCORE II (2.32%) is lower than the observed mortality (6.8%) without statistical significance ( $p=0.052$ ), so that the SMR is 2.93. whereas in the valvular subgroup this predicted mortality (3.39%) is significantly ( $p<0.001$ ) lower than the observed mortality (8.3%) with an SMR of 2.44.

The mortality predicted in the urgency sub-group (6.99%) is lower than the observed mortality (23.3%), but in a non-significant way ( $p=0.335$ ) the SMR is 3.33.

The discriminative power of EuroSCORE II was estimated by the area under the ROC curve (AUC). It seems to have good discrimination in the total population as well as in all subgroups studied, the area under the curve is  $0.864 \pm 0.032$  (between 0.801 and 0.927 with CI=95% and  $p<0.001$ ) for the total population,  $0.822 \pm 0.061$  (between 0.703 and 0.941 with CI=95% and  $p=0.001$ ) for the coronary subgroup,  $0.864 \pm 0.052$  (between 0.762 and 0.967 with CI=95% and  $p<0.001$ ) for the valvular subgroup, and  $0.900 \pm 0.041$  (between 0.819

and 0.981 with CI=95% and  $\rho < 0.001$ ) for the urgency subgroup (Figure 1).

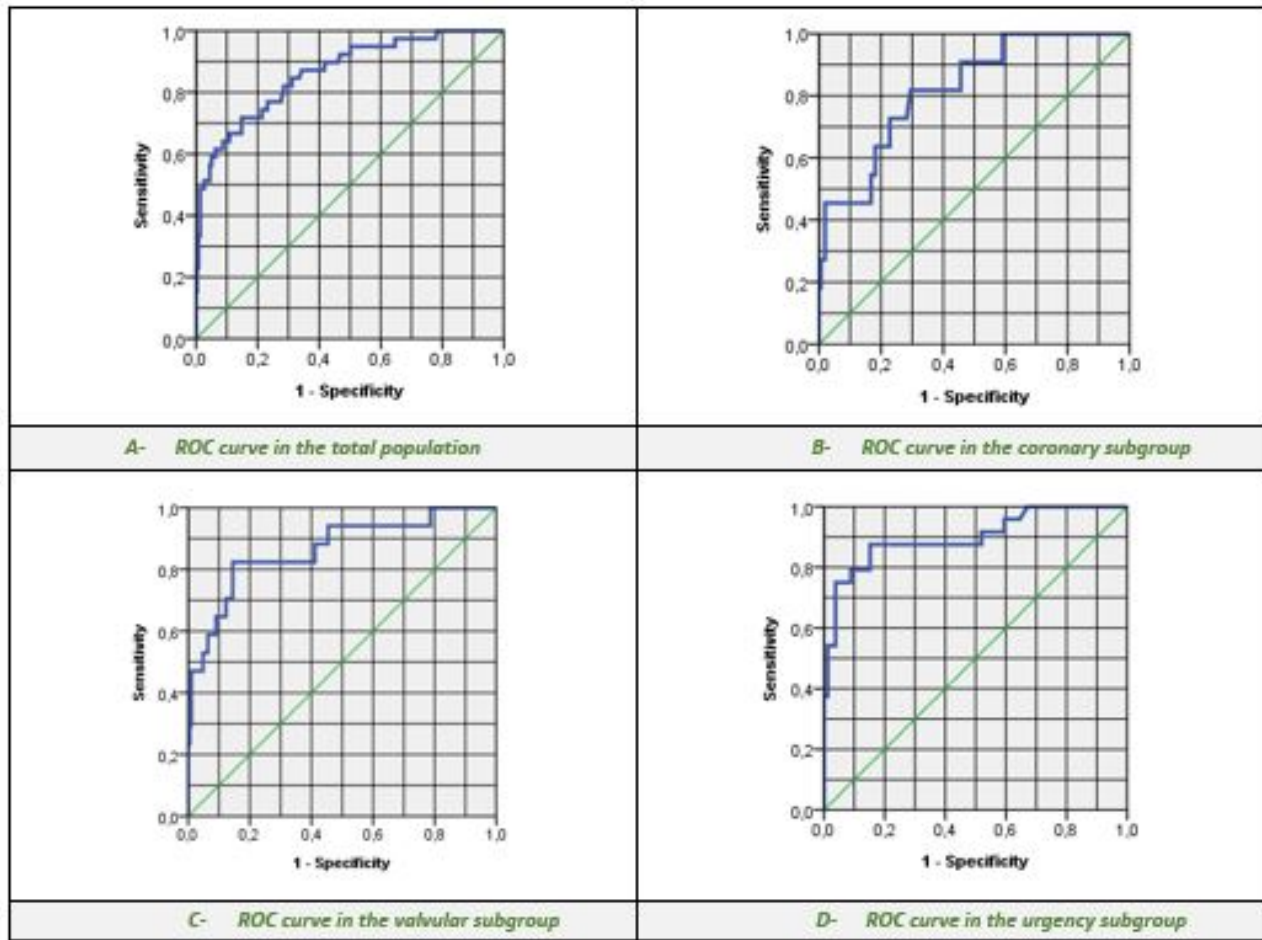


Figure 1. Shows the ROC curves for the total population and for the different subgroups studied.

**Calibration analysis**

To this extent, we performed a Hosmer-Lemeshow goodness-of-fit test that gives a  $\chi^2$  value of 4.28, with a df of 6 and a  $\rho$  value of 0.638 in the total population. This test gives a  $\chi^2$  value of 2.14 with a df of 3 and a  $\rho$  value of 0.543 for the coronary subgroup, a  $\chi^2$  value of 4.90 with a df of 3 and a  $\rho$  value of 0.179 for the valvular subgroup, and a  $\chi^2$  value of 6.70 with a df of 3 and a  $\rho$  value of 0.082 for the urgency subgroup.

The EuroSCORE II also seems to have a good calibration in the total population and the coronary subgroup, but less good in the other two subgroups ( $\rho$  value remains greater than 0.05

Tables 3 correspond to the contingency table of the Hosmer-Lemeshow goodness-of-fit test in the total population, while Figure 2 illustrates the calibration plots in the total population and the coronary, valvular, and urgency subgroups.

**Discussion**

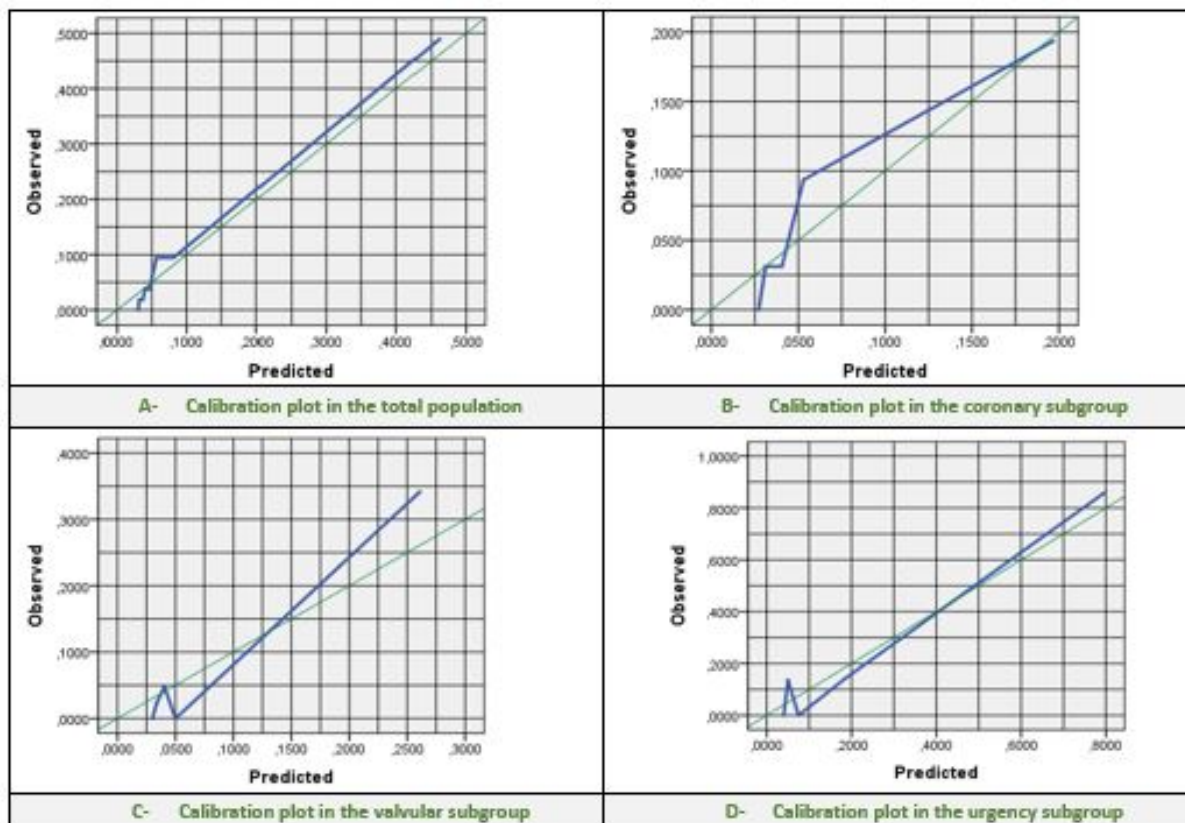
Table 4 presents the distribution of the variables designed for the development of EuroSCORE II in our study as well as in the initial study conducted by Nashef et al.

The average age of our population was 55.84 years, while women accounted for 41.4%, against an average of 64.6 years and a female representing nearly a third of the population of EuroSCORE II [5].

Table 3. Contingency table of the Hosmer-Lemeshow test in the total population.

Groups	n	Expected mortality	Observed mortality
1	53	1.6	0
2	53	1.7	1
3	54	2.0	1
4	52	2.1	2
5	54	2.5	2
6	53	3.0	5
7	52	4.3	5
8	47	21.7	23

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**Figure 2.** Calibration plots.

**Table 4.** Comparison of patients' characteristics between the original EuroSCORE II population and our population.

Variable	Our population (n=418)	Nashef [5] (n=22381)	p
Age	55.84 (± 13.84)	64.6 ( ± 12.5)	<0.001
Female gender	173 (41.4%)	6919 (30.9%)	<0.001
Diabetes on insulin	54 (12.9%)	1705 (7.6%)	<0.001
Extracardiac arteriopathy	48 (11.5%)	NA	
Previous cardiac Surgery	20 (4.8%)	NA	
Poor mobility	10 (2.4%)	713 (3.2%)	=0.359
Chronic lung disease	12 (2.9%)	2384 (10.7%)	<0.001
Recent MI	38 (9.1%)	NA	
Angina at rest	50 (12%)	NA	
NYHA	Grade II	212 (50.7%)	NA
	Grade III	168 (40.2%)	NA
	Grade IV	18 (4.3%)	NA
Creatinine clearance	51-85 ml / min	156 (37.3%)	NA
	<51ml / min	54 (12.9%)	NA
	Dialysis	4 (1%)	244 (1.1%)
Critical preoperative state	12 (2.9%)	924 (4.1%)	=0.199
Ejection fraction	31-50%	84 (20.1%)	NA

	<30%	5 (1.2%)	NA	
Pulmonary hypertension	31-55 mmHg	124 (29.9%)	NA	
	>55 mmHg	60 (14.1%)	NA	
Active endocarditis		25 (6%)	497 (2.2%)	<0.001
Urgency	Urgent	66 (15.8%)	4135 (18.5%)	=0.160
	Emergent	26 (6.2%)	972 (4.3%)	=0.063
	Salvage	11 (2.6%)	109 (0.5%)	<0.001
The weight of the intervention	Single non CABG	151 (36.1%)	NA	
	2 procedures	92 (22.1%)	NA	
	3 or more	16 (3.8%)	NA	
Surgery on thoracic aorta		26 (6.2%)	1636 (7.3%)	=0.396

These differences may be related to longer life expectancy and a lower incidence of rheumatic heart disease (more common among women in our country) than in European countries. The external validation studies of EuroSCORE II in different Western European countries [6-8] and Eastern Europe [3,9,10] gave results similar to those of the initial study, as well as than that conducted by Borraacci et al. [11].

To obtain results comparable to those of our study, we can consult the Asian series like that of Atashi et al. [12], that of kar et al. [13], or that of Pillai et al. [14].

Since the population of EuroSCORE II is 9 years older than our population, there should be more comorbidities, but paradoxically, we found that diabetes on insulin was more common in our population while chronic lung disease was more common in the population of the original study. Better management of diabetes mellitus and a spread of smoking (the leading risk factor for lung diseases) in developed countries can explain these facts.

Although early surgery improves the vital prognosis in the active phase of infective endocarditis as indicated by the work of Nagai et al. [15], we found that the presence of this pathology is an independent factor of mortality after cardiovascular surgery.

A higher percentage of patients with active infectious endocarditis in our population, compared to the population of EuroSCORE II, can also be explained by the prevalence of valvular and infectious diseases in our country.

This factor has undoubtedly contributed to increasing our mortality.

With regard to emergency cardiac surgery, we found no significant difference between our results and those provided by the original study, with the exception of the rescue category, which is more common in our study. We can assume that this difference can seriously affect our results while taking into account that the notion of urgency is subjective and not yet codified.

**Table 5.** Review of the main results of the EuroSCORE II validation studies compared with our results.

Author	Country	Procedure	n	SMR	ROC		Hosmer-Lemeshow statistics	
					AUC	CI	$\chi^2$	p
Our study	Tunisia	All	418	2.86	0.864	0.801-0.927	4.28	=0.638
		Coronary	160	2.93	0.822	0.703-0.941	2.14	=0.543
		Valvular	204	2.44	0.864	0.762-0.967	4.90	=0.179
		Urgency	103	3.33	0.900	0.819-0.981	6.70	=0.082
Nashef [5]	international	All	22381	1.05	0.809	0.782-0.836	15.48	=0.0505
Kosztá [3]	Hungary	All	2287	1.19	0.817	0.778-0.856	23.70	=0.0084
		Coronary	1038	0.75	0.811	0.713-0.910	8.52	=0.5789
		Urgency	593	1.28	0.791	0.737-0.844	14.18	=0.0145
Garcia-Valentin [4]	Spain	All	4034	NA	0.79	0.76-0.82	38.98	<0.001
Carnero-Alcázar [7]	Spain	All	3798	1.27	0.851	0.827-0.874	86.69	<0.001

		Coronary	1231	0.94	0.900	0.866-0.934	26.58	=0.001
		Valvular	1727	1.39	0.827	0.788-0.865	50.43	<0.001
<b>Chalmers [8]</b>	UK	All	5576	1.10	0.79	0.77-0.83	NA	<0.001
		Coronary	2913	1.12	0.79	0.73-0.85	NA	=0.052
<b>Stavridis [9]</b>	Greece	All	621	NA	0.848	0.75-0.94	10.9	=0.21
<b>Nezic [10]</b>	Serbia	All	1864	1.05	0.85	0.81-0.89	22.916	=0.003
		Coronary	1039	0.96	0.81	0.72-0.91	16.333	=0.038
		Valvular	410	1.07	0.91	0.86-0.96	10.065	=0.260
<b>Borracci [11]</b>	Argentina	All	503	1.31	0.856	0.792-0.920	NA	=0.082
<b>Atashi [12]</b>	Iran	All	2581	NA	0.667	0.648- 0.685	936.66	<0.01
<b>Amr [21]</b>	Egypt	MVR	580	NA	0.52	0.38-0.66	16.2	=0.02

Table 5 summarizes the results of the EuroSCORE II performance analysis (SMR, discriminative power and calibration) in our study compared to those provided by the literature. By analyzing the overall performance of the model in our population, we found a generally high SMR (2.86 for the total population, 2.93 for the coronary subgroup, 2.44 for the valvular subgroup and 3.33 for the urgency subgroup), which is very different from the results published by most cardiac surgery centers in recent years, with numbers approaching 1 indicating a good performance.

Only a few series offer results comparable to ours, such as that of Stavridis et al. [9] (2.23) or that of Kar et al. [13] (1.94) for any type of cardiac surgery included, or that of Laurent et al. [16] for aortic valve replacement or that of Kalender et al. [17] (6.77) for emergency coronary surgery or that of De Oliveira et al. [18] and that of Taamallah et al. [19] for Surgery of infectious endocarditis.

Calculating the area under the ROC curve (AUC) according to the Hanley and McNeal method finds acceptable figures (0.864 for the total population, 0.822 for the coronary subgroup, 0.864 for the valve subgroup, and 0.900 for the urgency subgroup) with confidence intervals whose lower limits always greater than 0.7, which defines the threshold for the model to be discriminating [20]. These results are comparable to the statement made by the authors of the original EuroSCORE II article, which was 0.809 (0.782-0.836) [5].

The majority of the external validation studies also showed results similar to those of the initial study, while that carried out in Egypt by Amr et al. [21] in Egypt found disappointing results with an AUC of 0.52. In light of these findings, the results of our work show that the discriminating power of EuroSCORE II is adapted to our population for all groups studied: general cardiac surgery, coronary surgery, valvular surgery, and urgent cardiac surgery.

The results obtained by the Hosmer-Lemeshow goodness-of-fit test for evaluating the calibration of EuroSCORE II in our population require careful analysis. This test is currently under discussion because of its sensitivity to the number of groups

and the size of the sample [22]. It was used for this study because it was used in the internal validation of the model.

The Hosmer-Lemeshow goodness-of-fit test in our population shows small  $\chi^2$  values with  $p$  values always above the limit for statistical significance determination which is 0.05 and this for all the subgroups studied except for the urgency subgroup whose value is approaching (0.638 for the total population, 0.543 for the coronary subgroup, 0.179 for the valvular subgroup and 0.082 for the urgency subgroup). Therefore, there is no statistically significant difference between expected mortality and observed mortality.

These results are in contradiction with those provided in the literature, which is generally in favor of a bad calibration of EuroSCORE II in parallel with the results published in the initial article [5], which shows a  $p$  value (0.0505) very close to the limit of determination of statistical significance.

Other series show disappointing results with values of  $p$  less than 0.05, like that of Amr et al. [21] in Egypt and that of Wang et al. [23] in China, both of which are studied in patients undergoing valvular surgery, or as the multicentric study by Grant et al. [24] made on the largest number of patients undergoing cardiac surgery in emergency (3342). These authors conclude that there is a significant difference between their observed mortality and their expected mortality.

In general, we can say that the EuroSCORE II shows a good calibration in our population subject to the small sample size.

## Conclusion

Despite the differences in the profile of risk factors between the Tunisian population and the population constituting the database used for the development of EuroSCORE II, we can say that this risk model presents acceptable performances in our population, as evidenced by adequate discrimination and calibration.

However, we reproach him with an underestimation of the mortality especially in the patients supposed to be low risk.

At the end of this work, we proclaim the need to start prospective and especially multicentric studies on larger samples before concluding definitively on the performance of this model in our country, or even to develop an adapted version.

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