Evaluation of European System for Cardiac Operative Risk (EuroSCORE II) in Egyptian Patients Undergoing Valvular Surgery
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ABSTRACT
Background: Models have been developed to predict a variety of outcomes, for all cardiac surgery and also for specific cardiac surgery procedures. The most broadly utilized model for anticipating mortality in cardiovascular surgery was EuroSCORE I, which has been upgraded in recent times to EuroSCORE II which was validated as a predictor for in-hospital mortality after cardiac surgery. Objective: The aim of the present study was to evaluate the accuracy of EuroSCORE II in prediction of mortality in Egyptian patients who would undergo valve surgery. Patients and methods: This retrospective cohort study evaluated the medical records of 180 adult patients who underwent valvular surgery in Departments of Cardiothoracic Surgery at Zagazig University Hospitals and Cardiac Surgery at National Heart Institute in Egypt, between January 2021 and July 2021. All studied patients were subjected to careful history taking, general examination, local cardiac examination, laboratory investigation, electrocardiogram, body mass index, and echocardiography. Results: The most common procedure done was mitral valve replacement representing (33.9%) followed by combined mitral valve replacement and tricuspid valve repair. The observed rate of in-hospital mortality was 7.8% (n = 14 patients). The real observed mortality rate was 4.4% of patients in 1st quartile, 10.9% in 2nd quartile, 14.6% of 3rd quartile and 0.0% in 4th quartile, with significant difference. Conclusion: The lower discriminative and predictive efficacy of EuroSCORE II in Egyptian patients undergoing mitral valve replacement might be explained by differences in clinical profile and the existence of additional local risk factors.
Keywords: EuroSCORE II, Mortality, Risk factor, Valvular surgery.

INTRODUCTION
Risk stratification is used during preoperative examination of patients undergoing cardiac surgery to evaluate the result of such procedures, detect curable diseases, and measure surgical risk, the number of complications, death, and severe impairment (1). EuroSCORE (European System for Cardiac Operative Risk Evaluation) is a cardiac risk model that predicts mortality following cardiac surgery. It was generated from an international European database of patients who had undergone cardiac surgery by the end of 1995 and verified in Europe, North America, and abroad before being released in 1999. The 2003 logistic EuroSCORE model was created four years later to increase predicted performance in high-risk patient categories (2). According to the patient's demographic parameters, cardiovascular and non-cardiovascular risk factors, and procedural variables, the model calculates the patient's expected 30-day mortality. It has already been verified in a range of clinical situations for its predictive accuracy (3).

Several professionals from around the world have published evidence in the last few years that the model now overpredicts risk as cardiac surgery outcomes have significantly improved with a sustained reduction in risk-adjusted mortality, suggesting that the model may now be inappropriately calibrated for current cardiac surgery (4). Changing epidemiology of cardiac surgery and improvement of surgical techniques affected the calibration of EuroSCORE. To overcome this problem, EuroSCORE II is available since October 2011, in order to maintain and optimize its role in contemporary cardiac surgical practice (5). EuroSCORE II is now widely approved and widely utilised in clinical practise in a number of countries (6). However, limitations in a risk forecasting model's inter-observer reliability necessitate additional testing of EuroSCORE II in bigger populations and in other geographic locations (7).

The aim of the present study was to evaluate the accuracy of EuroSCORE II in prediction of mortality in Egyptian patients who would undergo valve surgery.

PATIENTS AND METHODS
This retrospective cohort study evaluated the medical records of 180 adult patients who underwent valvular surgery in Departments of Cardiothoracic Surgery at Zagazig University Hospitals and Cardiac Surgery at National Heart Institute in Egypt, between January 2021 and July 2021.

Ethical consent:
Approval was taken from the Research Ethical Committee and the institutional review board (IRB) of Faculty of Medicine, Zagazig University. Every patient signed an informed written consent for acceptance of the operation and participation in this study. The work was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Inclusion criteria: Age: 18-80 years, gender: both males and females, operation type: on pump valvular surgery, operation classification: elective or urgent,
New York Heart Association (NYHA) classification: I-IV, left ventricular (LV) function: good to poor, preoperative state: fair to critical, and pulmonary condition: fair to poor

Exclusion criteria: Age <18 and > 80 years, patients who underwent previous cardiac surgeries, and patients undergoing other non-valvular operations (E.g., coronary artery bypass grafting (CABG)). Operative mortality was defined as in-hospital death and death within 30 days of surgery. The EuroSCORE II was calculated using online calculator (www.euroscore.org) using the collected preoperative data. All surgical procedures were performed through conventional median sternotomy using cardiopulmonary bypass. Myocardial protection was achieved by antegrade cold cardioplegia. The EuroSCORE II was calculated for all patients and compared with actual recorded outcomes of the patients to evaluate its accuracy in prediction of surgical outcomes of our Egyptian patients.

All studied patients were subjected to:
- Careful history taking: (Personal history, present history, past history, family history).
- General examination.
- Local cardiac examination (Inspection, palpation, auscultation).
- Laboratory investigation: (CBC, INR, renal function test, liver test profile, lipid profile, CRP, ASOT, ESR, echocardiogram, body mass index (BMI), coronary angiography. Coronary angiography was done only for all patients ≥ 40 years old male patients and ≥ 45 years old female patients. Risk factor data was collected during patient’s admission as part of routine clinical practice included all the risk factors considered in the EuroSCORE II plus some additional data. Creatinine clearance was mathematically calculated using the already registered data of serum creatinine value (mg/dl), age, weight and gender. Operative mortality risk was assessed for every patient according to the EuroSCORE II version (additive and logistic). According to the risk predictions delivered using arbitrary threshold values, the patients were divided into 3 groups characterized as low (0–3), moderate (4–10), and high risk (>10).

Intraoperative data: Procedures have been performed, cardiopulmonary bypass time, cross clamp time, and complications.

Postoperative data: ICU stay, hospital stay before discharge, and complications. All our patients were followed up for 30 days in outpatient clinic after discharge and mortality, any adverse events, or complications were recorded.

Statistical Analysis:
Data were collected, revised, coded and entered to the Statistical Package for the Social Sciences (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations, ranges, and median with inter-quartile range (IQR). Also, qualitative variables were presented as number and percentages. The comparison between groups regarding qualitative data was done by using Chi-square test and/or Fisher exact test when the expected count in any cell found less than 5. P value < 0.05 was considered significant.

RESULTS
Preoperative demographic data of the studied patients are shown in table 1.

Table (1): Distribution of patients regarding preoperative demographic data

<table>
<thead>
<tr>
<th>Preoperative demographic data</th>
<th>Studied patients (n = 180)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at operative intervention (years):</td>
<td>No.</td>
</tr>
<tr>
<td>Range</td>
<td>19.0 – 73.0</td>
</tr>
<tr>
<td>Mean± SD</td>
<td>45.67 ± 12.27</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>50.0 (40.0- 56.0)</td>
</tr>
<tr>
<td>BMI (kg/M²) Mean± SD</td>
<td>27.37 ± 6.18</td>
</tr>
<tr>
<td>Female Gender</td>
<td>90</td>
</tr>
</tbody>
</table>

The most common procedure done was mitral valve replacement. Most of the patients underwent one procedure (Table 2).
AVR = Aortic valve replacement, MVR = Mitral valve replacement, TR = Tricuspid valve repair, TVR = Double valve replacement and Tricuspid valve repair (AVR + MVR + TR).

The observed rate of in-hospital mortality was 7.8%. The expected 1st quartile of EuroSCORE II was 0.96% in 2 patients, while 2nd quartile was 1.12% in another 5 patients, 3rd quartile was 1.35% in 7 patients and 4th quartile was > 1.35% in none of patients (Table 3).

Table (3): Distribution of patients regarding outcomes

<table>
<thead>
<tr>
<th>Operative data</th>
<th>Studied patients (n = 180)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
</tr>
<tr>
<td>Predicted mortality by EuroSCORE II:</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td></td>
</tr>
<tr>
<td>Observed rate of in-hospital mortality:</td>
<td></td>
</tr>
<tr>
<td>Alive</td>
<td></td>
</tr>
<tr>
<td>Died</td>
<td></td>
</tr>
</tbody>
</table>

Table (4) distributes observed in-hospital mortality in relation to expected quartiles estimated by EuroSCORE II. The real observed mortality rate was 4.4% of patients in 1st quartile, 10.9% in 2nd quartile, 14.6% of 3rd quartile and 0.0% in 4th quartile, with significant difference.

Table (4): Observed in-hospital mortality in relation to expected quartiles of mortality estimated by EuroSCORE II

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Quartiles of EuroSCORE II</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0- 0.96</td>
<td>0.97- 1.12</td>
</tr>
<tr>
<td>Alive</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Died</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Total</td>
<td>No.</td>
<td>%</td>
</tr>
</tbody>
</table>

The area under the ROC curve (AUC) for the EuroSCORE II was 0.517 (95% CI= 0.442 - 0.592) with no statistical significance, indicating that EuroSCORE II had low discriminative power to distinguish between incidences of mortality in our group of Egyptian patients (Figure 1).
The Hosmer-Lemeshow (HL) goodness-of-fit test showed a significant difference between expected and observed mortality in our series of patients according to EuroSCORE II model (Chi square = 128.4, P = <0.001), indicating poor calibration of this model in predicting the overall in-hospital mortality among our Egyptian patients (Figure 2).
DISCUSSION

Regarding the demographic data of the studied cases, we found that the age of the patients at time of operative intervention ranged from 19 to 73 years with mean age was 45.67±12.27 years. There were 90 (50%) males and 90 (50%) females with a male to female ratio of 1:1. Khan et al., (8) compared the European system for cardiac operative risk evaluation (EuroSCORE) II with the postoperative outcomes in patients undergoing cardiac surgery, they enrolled 101 cardiac surgery patients, the majority (75.2%) of the patients were male and reported mostly (61.4%) from urban area. Out of 101 patients, 4 (4.0%) were less than 20 years old, 21 (20.8%) were between 20-40 years, 56 (55.4%) were between 41 to 60 years and 20 (19.8%) were above 60 years old. Whereas El Hadj Sidi et al., (9) studied the external validation of the European System for Cardiac Operative Risk Evaluation II in a Tunisian population, they enrolled 418 adult patients undergoing cardiac surgery, 245 men (58.6%) and 173 women (41.4%), with a sex ratio of 1.4, with mean age is 55.84 ± 13.84 years with extremes ranging from 18 to 87 years.

Regarding the operative data of the studied cohorts, our results showed that the most common procedure done was mitral valve replacement representing (46.11%) followed by combine mitral valve replacement and tricuspid valves repair (31.11%). In terms of weight of intervention, there are 64 (35.55%) patients who underwent a combination of two procedures, 20 (11.11%) patients underwent three procedures and 96 (53.33%) patients underwent one procedure. While Khan et al., (8) showed that the majority of the patients were with Coronary Artery Bypass Grafting (CABG) 66 (65.3%), valve repair or replacement procedure in 33 (32.7%) or replacement of part of aorta in 2 (2.0%) patients. Regarding weight of the intervention El Hadj Sidi et al., (9) revealed that isolated CABG (38.0%), single non-CABG (36.1%), two procedures (22.1%), three or more (3.8%) and surgery on thoracic aorta (6.2%).

Regarding the outcome between the studied group, we found that the observed rate of in-hospital mortality was 7.8% (n = 14 patients). The predicted mortality by EuroSCORE II ranged from 0.55 to 27.2% with mean of 1.60%. The expected 1st quartile of EuroSCORE II was 0.67% in 145 patients, while 2nd was 0.80% in another 145 patients, 3rd quartile was 1.13% in 150 patients and 4th quartile was >1.13% in 140 patients. They also revealed that the real observed mortality rate was 2.1% of patients in 1st quartile, 4.1% in 2nd quartile, 1.3% of 3rd quartile and 2.9% in 4th quartile, with non-significant difference (P = 0.47).

Whereas the study by El Hadj Sidi et al., (9) revealed that the mortality predicted by EuroSCORE II in the total population (3.25%) was significantly lower (P < 0.001) than the observed mortality (9.3%), so that the standardized mortality ratio (SMR) was 2.86. In the coronary subgroup, the mortality predicted by EuroSCORE II (2.32%) was lower than the observed mortality (6.8%) without statistical significance (P = 0.052), so that the SMR was 2.93, whereas in the valvular subgroup this predicted mortality (3.39%) was significantly (P < 0.001) lower than the observed mortality (8.3%) with a SMR of 2.44. The mortality predicted in the urgency subgroup (6.99%) was lower than the observed mortality (23.3%), but in a non-significant way (P = 0.335), the SMR was 3.33.

Using the area under the ROC curve (AUC) (or C-statistic) for the EuroSCORE II was 0.517 (95% CI= 0.442 - 0.592) with no statistical significance, indicating that EuroSCORE II had low discriminative power to distinguish between incidences of died and alive patients. In agreement with our results the study by Amr and El-shorbagy (10) concluded that the area under the ROC curve (AUC) for the EuroSCORE II was 0.52 (95% CI, 0.38-0.66) with no statistical significance (P = 0.77), indicating that EuroSCORE II had low discriminative power to distinguish between incidences of died and alive patients. In contrast the study by El Hadj Sidi et al., (9) revealed that the EuroSCORE II shows good discriminative power in their population with an area under the ROC curve more than 0.7 in all studied 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).

Our results showed that the Hosmer-Lemeshow (HL) goodness-of-fit test showed a significant difference between expected and observed mortality according to EuroSCORE II model (Chi square = 128.4, P <0.001), indicating poor calibration of this model in predicting the overall in-hospital mortality. In agreement with our results the study by Amr and El-shorbagy (10) concluded that the HL goodness-of-fit test showed a significant difference between expected and observed mortality according to EuroSCORE II model (Chi-square = 16.2, P = 0.02), indicating poor calibration of this model in predicting the overall in-hospital mortality. While, the study by Elsayad et al. (11) revealed that the area under receiver operating characteristics curve (AUROC) was 0.792 with a 95% confidence interval 0.73 to 0.84, and a Hosmer-Lemeshow test for goodness of fit statistic P value of
0.614. HL test p value of 0.748, the AUROC was 0.564.

In contrast the study by Yamaoka et al. (12) revealed that Hosmer–Lemeshow p-value was 0.089. As well El Hadj Sidi et al. (9) reported that Hosmer-Lemeshow goodness-of-fit test gives a $X^2$ value of 4.28 (df = 6; $P = 0.638$) in the total population. $X^2$ value of 2.14 (df = 3; $P = 0.543$) for the coronary subgroup, a $X^2$ value of 4.90 (df = 3; $P = 0.179$) for the valvular subgroup, and a $X^2$ value of 6.70 (df = 3; $P = 0.082$) for the urgency subgroup. They also concluded that 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 ($P > 0.05$).

EuroSCORE II has poor calibration and low discriminative power in our surgical population, with significant differences in preoperative demographics and risk factors when compared to European population on whom EuroSCORE II was developed and validated. In addition, there are significant predictors of in-hospital mortality, which are not involved in EuroSCORE II such as hypercholesterolemia and chronic liver disease. These findings may be explained by the differences in the clinical base of two different surgical populations. In countries where EuroSCORE was developed and validated, more patients underwent heart valve surgery for degenerative causes; however, this profile is different from developing countries where valve surgery is more frequent mainly for rheumatic causes (13).

CONCLUSION
The lower discriminative and predictive efficacy of EuroSCORE II in Egyptian patients undergoing mitral valve replacement might be explained by differences in clinical profile and the existence of additional local risk factors.

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Conflict of interest: Nil.

REFERENCES