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Clinical Research

Accuracy of Dedicated Risk Scores in Patients Undergoing Primary Percutaneous Coronary Intervention in Daily Clinical Practice

Anibal P. Abelin, MD, Renato B. David, MD, Carlos A. Gottschall, MD, PhD,

and Alexandre S. Quadros, MD, PhD

Instituto de Cardiologia/Fundação Universitária de Cardiologia (IC/FUC), Programa de Pós Graduação em Ciências da Saúde: Cardiologia, Porto Alegre, Brazil

ABSTRACT

Background: Comparisons between dedicated risk scores in patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (pPCI) in real-world clinical practice are scarce. The aim of this study was to assess the diagnostic performance of the Global Registry of Acute Coronary Events (GRACE), Primary Angioplasty in Myocardial Infarction (PAMI), Thrombolysis in Myocardial Infarction (TIMI), and Zwolle scores in STEMI patients undergoing pPCI in contemporary clinical practice.

Methods: This was a prospective cohort study of consecutive patients with STEMI undergoing pPCI between December 2009 and November 2010 in a high-volume tertiary referral centre. The outcomes assessed were major cardiovascular events (MACEs) and death within 30 days. The diagnostic accuracy of the scores was assessed using receiver operating characteristic curves, and scores were compared using the DeLong method.

Results: During the study period, 501 patients were included. Within 30 days, 62 patients (12.4%) presented a MACE and 39 individuals (7.8%) died. All scores were statistically associated with death and MACE within 30 days (P < 0.01). The c-statistic and 95% confidence intervals for 30-day mortality were: GRACE, 0.84 (0.78-0.90); TIMI, 0.81 (0.74-0.87); Zwolle, 0.80 (0.73-0.87); and PAMI, 0.75 (0.68-0.82) (P < 0.01). There was no statistically significant difference regarding the accuracy of the TIMI, GRACE, and Zwolle scores for 30-day mortality, but the GRACE score was superior to the PAMI score (P < 0.01).

In recent years, significant advances have been made in the treatment of ST-segment elevation acute myocardial infarction (STEMI).¹⁻⁵ In current daily clinical practice there are patients with very low predicted mortality. These patients

E-mail: alesq@terra.com.br

RÉSUMÉ

Introduction : Les comparaisons entre les scores de risque des patients ayant eu un infarctus du myocarde avec sus-décalage du segment ST (IM avec sus-décalage du segment ST) qui subissent une intervention coronarienne percutanée primaire (ICPP) dans la pratique clinique réelle sont peu nombreuses. Le but de cette étude était d'évaluer la performance diagnostique du registre global GRACE (Global Registry of Acute Coronary Events), de l'étude PAMI (*Primary Angioplasty in Myocardial Infarction*), de l'étude TIMI (*Thrombolysis in Myocardial Infarction*) et des scores Zwolle chez les patients subissant une ICPP dans la pratique clinique actuelle.

Méthodes : Il s'agissait d'une étude de cohorte prospective de patients consécutifs ayant eu un IM avec sus-décalage du segment ST qui ont subi une ICPP entre décembre 2009 et novembre 2010 dans un centre de référence tertiaire à volume élevé. Les résultats cliniques évalués ont été les événements cardiovasculaires indésirables majeurs (ÉCIM) et la mortalité dans les 30 jours. L'exactitude diagnostique des scores a été évaluée à l'aide de la courbe caractéristique d'efficacité du récepteur (ROC : *receiver operating characteristic*), et les scores ont été comparés à l'aide de la méthode de DeLong.

Résultats : Durant la période étudiée, 501 patients ont été inclus. En 30 jours, 62 patients (12,4 %) ont subi un ÉCIM et 39 individus (7,8 %) sont morts. Tous les scores ont été statistiquement associés à la mortalité et l'ÉCIM dans les 30 jours (P < 0,01). La statistique C et l'intervalle de confiance à 95 % de la mortalité dans les 30 jours a été : registre global GRACE, 0,84 (0,78-0,90); étude TIMI, 0,81 (0,74-0,87);

could benefit from early discharge from the intensive care unit and from the hospital, resulting in better clinical care and optimization of health resources.⁶⁻⁹ In contrast, morbidity and mortality after STEMI are still high in other subgroups.¹⁰⁻¹³ With the aim of identifying these patients, dedicated risk scores have been developed, which might allow individualized management and treatment of patients with STEMI.¹⁴⁻¹⁷ A comparison among these scores is available in Supplemental Table S1.

Despite their frequent use, some scores present the limitations of having been developed more than a decade ago. The inclusion of patients of randomized clinical trials

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Corresponding author: Dr Alexandre S. Quadros, Instituto de Cardiologia / Fundação Universitária de Cardiologia (IC/FUC), Av. Princesa Isabel 395, Santana 90.620-001, Porto Alegre, Rio Grande do Sul, Brazil. Tel.: +55-51-3230-3600; fax: +55-51-3217-2035.

See page 130 for disclosure information.

Conclusions: The TIMI, GRACE, and Zwolle scores performed equally well as predictors of mortality in patients who underwent pPCI in current practice. These results suggest that these scores are suitable options for risk assessment in a real-world setting.

might also limit their use in current real-world practice. Evaluations of those scores in populations within contemporary interventional practice are scarce, as are comparative studies of several scores.^{18,19} The aim of this study was to assess the diagnostic performance of the Global Registry of Acute Coronary Events (GRACE), Primary Angioplasty in Myocardial Infarction (PAMI), Thrombolysis in Myocardial Infarction (TIMI), and Zwolle risk scores in STEMI patients undergoing primary percutaneous coronary intervention (pPCI) in contemporary daily clinical practice.

Methods

Patients

This was a prospective cohort study that consecutively included patients with STEMI who underwent pPCI at the Instituto de Cardiologia do Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil, from December 2009 to November 2010. Our facility is a tertiary referral centre that performs approximately 3000 percutaneous coronary interventions per year. pPCI is the routine STEMI treatment at our institution, and the catheterization laboratory is open 24 hours per day, 7 days per week. The project was approved by the local Research Ethics Committee, and all patients received information regarding the study and provided written informed consent. The authors are responsible for the design and conduction of the study, analysis, writing and editing, and final content of the manuscript. No extramural funding was used to support this work.

The inclusion criterion was STEMI submitted to pPCI as the initial reperfusion strategy, determined by the assisting physician. STEMI was defined as typical chest pain at rest associated with ST-segment elevation of at least 1 mm in 2 contiguous leads in the frontal plane or 2 mm in the horizontal plane, or typical pain at rest in patients with a new, or presumably new, left bundle-branch block. The exclusion criteria were delta T greater than 12 hours, use of lytic therapy as the primary reperfusion therapy for the index event, age younger than 18 years, or refusal to participate. Delta T was defined as the time from the onset of chest pain to hospital arrival.

pPCI procedures

The medications used in the patient's initial care and the indications for pPCI were at the discretion of the medical scores Zwolle, 0,80 (0,73-0,87); étude PAMI, 0,75 (0,68-0,82) (P < 0,01). Il n'y a eu aucune différence statistiquement significative concernant l'exactitude de l'étude TIMI, du registre global GRACE et des scores Zwolle pour la mortalité dans les 30 jours, mais le score du registre global GRACE a été supérieur au score de l'étude PAMI (P < 0,01).

Conclusions : L'étude TIMI, le registre global GRACE et les scores Zwolle ont montré une performance aussi bonne que les prédicteurs de la mortalité chez les patients qui avaient subi une ICPP dans la pratique actuelle. Ces résultats suggèrent que ces scores sont des options qui conviennent à l'évaluation des risques dans un contexte réel.

team. Patients received a bolus dose of acetylsalicylic acid (300 mg) and clopidogrel (300-600 mg). After conventional coronary angiography, unfractionated heparin was administered at a dose of 60 U/kg to 100 U/kg and pPCI was performed as previously described.²⁰ Aspects related to the procedure, such as access site, administration of glycoprotein IIb/IIIa inhibitors and adjunctive aspiration thrombectomy, were left to the operators' discretion. An intra-aortic balloon was used only in patients with cardiogenic shock.

Data collection

Patients were interviewed by 1 of the investigators (A.P.A., R.B.D.) on hospital admission, and clinical, angiographic, and laboratory data were collected using a standard questionnaire. Blood samples for laboratory tests were collected from all patients at admission. Angiography was performed in at least 2 different views by experienced operators using a previously validated digital electronic system (Siemens Axiom Artis, Munich, Germany). Intracoronary nitroglycerin was routinely administered at a dose of 200 μ g before measurements. Coronary flow before and after the procedures was assessed and described according to the TIMI criteria.²¹

Outcomes and follow-up

All patients were visited daily during the in-hospital period by 1 of the investigators (A.P.A., R.B.D.) to assess in-hospital events. The occurrence of events 1 month after the index event was evaluated in a telephone call and by review of medical records. All-cause mortality and major cardiovascular events (MACEs) were assessed and registered by 1 of the study investigators. MACEs were defined as a combination of allcause mortality, new acute myocardial infarction (MI), or stroke. New MI was defined by recurrent chest pain with new elevation of serum biomarkers, after the initial decline of the natural curve, with ST-segment elevation or new Q waves, according to the universal definition of MI.²² Stroke was defined as a new, sudden-onset focal neurological deficit, of presumably cerebrovascular cause, irreversible (or resulting in death) within 24 hours, and not caused by another readily identifiable cause. Stroke was classified as ischemic or hemorrhagic.



Figure 1. Study flow chart. pPCI, primary percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

Statistical analysis

Data were collected in a Microsoft Access database and statistical analysis was performed using SPSS for Windows 17.0. Results are expressed as mean \pm SD, median (interquartile range), or absolute and relative frequencies as appropriate. Sample size calculation was performed considering the smallest area under the receiver operating characteristic (ROC) curve between the original scores (0.78) and a 30-day mortality rate of 8%. The minimum sample size for 80% statistical power and a significance level of 0.05 was estimated at 400 patients.

The individual risk scores were calculated as previously published (Supplemental Table S2).¹⁴⁻¹⁷ The accuracy of the GRACE, PAMI, TIMI, and Zwolle scores for predicting MACE and 30-day mortality was assessed according to the area below the ROC curve.²³ Comparison between the ROC curves was performed with the nonparametric DeLong test, using MedCalc software for Windows, version 12.1.4.0 (MedCalc Software, Mariakerke, Belgium).²⁴ Statistical significance was defined as a 2-tailed *P* value < 0.05.

Results

Patients

During the study period, 501 patients with STEMI who underwent pPCI were included, according to the flow chart in Figure 1. In the study period, no patient received lytic therapy as the primary reperfusion therapy at our hospital. The baseline sample profile is shown in Table 1. Total ischemic time was 5.2 \pm 2.9 hours, with a delta T of 3.6 \pm 2.8 hours. The median door-to-balloon time was 76 (56-105) minutes, and 71% of the patients were treated within 90 minutes of hospital arrival.

Outcomes and risk scores

All patients were available for 30-day follow-up. MACEs occurred in 62 patients (12.4%), new MI in 32 cases (6.4%),

Table 1.	Characteristics	of the	study	sample	(n = 5)	501)
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Characteristic	Value
Clinical	
Age, y	60.5 ± 11.8
CAD risk factors	
Male	342 (68)
Hypertension	335 (67)
Dyslipidemia	185 (37)
Smoking	212 (42)
Family history of CAD	158 (32)
Diabetes mellitus	94 (19)
Medical history	
MI	119 (24)
PCI	37 (7)
CABG	17 (3)
Anterior MI	212 (42)
Systolic blood pressure, mm Hg	135 ± 31
Diastolic blood pressure, mm Hg	82 ± 19
Heart rate, bpm	79 ± 20
Killip class III/IV	27 (5)
Ischemic time, h	5.2 ± 2.9
Delta T, h	3.6 ± 2.8
Angiographic and procedural variables	
Door-to-balloon time, min	76 (56-105)
Three-vessel disease	96 (19)
LAD involvement	214 (43)
Direct-stent placement	165 (33)
Glycoprotein IIb/IIIa	147 (30)
Aspiration thrombectomy	154 (31)
Reference vessel diameter, mm	3.2 ± 0.49
Lesion length, mm	17.3 ± 8.5
Stenosis	
Before	97 ± 6
After	2.9 ± 14
TIMI grade 2/3 flow	
Before	135 (27)
After	468 (93)

Results are expressed as mean \pm SD or n (%); door-to-balloon time is expressed as median (interquartile range).

CABG, coronary artery bypass graft; CAD, coronary artery disease; LAD, left anterior descending artery; MI, myocardial infarction; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction.

and the 30-day mortality rate was 7.8% (n = 39). All risk scores were significantly associated with MACE, and the diagnostic accuracy assessment for combined events is presented in Figure 2. The Zwolle, GRACE, and TIMI scores presented higher accuracy than the PAMI score for MACE (P < 0.05 for all comparisons). There were no significant differences between scores on any other comparisons.

All scores were also statistically associated with 30-day mortality (Fig. 3). The GRACE, TIMI, and Zwolle scores presented similar diagnostic accuracy for death within 30 days, and the diagnostic accuracy of the GRACE score was higher than that of the PAMI score (Table 2). There was no statistically significant difference in any other comparisons.

We also addressed the influence of age on the accuracy of the risk scores. The study population was stratified according to the cut point of 65 years, and 162 patients were identified (32% of the total). In patients aged 65 years or younger, all risk scores presented statistical significance (P < 0.001) to the 30-day mortality outcome, but c-statistics were lower than in the total cohort. In patients older than 65 years, the GRACE and TIMI risk scores maintained statistical significance (P < 0.01), and the Zwolle and PAMI risk scores did not. In this



Figure 2. ROC curves: Major adverse cardiovascular events at 30 days. GRACE, Global Registry of Acute Coronary Events; PAMI, Primary Angioplasty in Myocardial Infarction; ROC, receiver-operator characteristic; TIMI, Thrombolysis in Myocardial Infarction.

subgroup, c-statistics were lower than in those aged 65 years or younger for all scores.

Risk of death according to score stratification

Aiming to explore the ability of the scores to identify very low- and high-risk patients, we assessed 30-day death rates according to quartiles of risk in each score (Fig. 4). All scores showed a statistically significant linear relationship with this outcome (P < 0.001). Of note, this stratification identified a subgroup of patients with a 30-day mortality of 1% or less in patients within the first quartile of risk in all the scores. Those in the highest quartile of risk showed mortality rates of 17%-25%.

Discussion

In this study, we demonstrated that dedicated risk scores for STEMI present adequate accuracy for prediction of 30-day mortality in patients undergoing pPCI in a contemporary, real-world clinical setting. Our report can be considered representative of current pPCI practice in tertiary centres, demonstrated by the in-hospital mortality rate, door-toballoon time, and percent of patients treated within 90 minutes of hospital arrival. The GRACE, TIMI, and Zwolle scores presented similar c-statistics for the mortality and MACE outcomes, but the PAMI score performed comparatively poorly. The European Society of Cardiology Guidelines for the Management of Acute Myocardial Infarction in Patients Presenting with ST-segment Elevation suggest the use of schemes such as the PAMI-II criteria or the Zwolle risk score to identify low-risk patients with the goal of early discharge.²⁵ In contrast, specific recommendations regarding the use of risk scores in STEMI patients were not addressed in the latest American College of Cardiology/American Heart Association Guidelines for the Management of Patients with ST-Elevation Myocardial Infarction.²⁶ The present study shows that the Zwolle, TIMI, and GRACE scores can be used to identify high-risk patients with STEMI undergoing pPCI. Besides, our results also support the notion that the risk scores should be used to identify very low risk patients. The subgroup within the lower quartile of risk presented a mortality rate of 1% or less in any of the scores.

In the context of STEMI, the most appropriate risk score should adequately stratify patients to support therapeutic decisions and the length of hospital stay, including stay in intensive care units. This approach is associated with lower costs, and has already proved to be safe and effective.⁶⁻⁸ The use of validated scoring systems allows the physician to obtain a numerical prediction for an outcome, which is a valuable tool in the clinical decision-making process. Most variables included in these models are known to clinicians to be associated with poorer outcomes, but the integration in a risk score provides a more reliable perspective; incorporating the use of risk scores will also make clinicians more familiar with



Figure 3. ROC curves: death at 30 days. GRACE, Global Registry of Acute Coronary Events; PAMI, Primary Angioplasty in Myocardial Infarction; ROC, receiver-operator characteristic; TIMI, Thrombolysis in Myocardial Infarction.

those variables. The use of novel internet portable devices might also facilitate the use of risk scores at the bedside. Another important use of risk scores is as a research tool, to adjust for different baseline patient characteristics in quality of care assessment initiatives comparing outcomes among institutions or operators.

In previous studies, the assessment of the accuracy of dedicated risk scores for STEMI in the daily practice has provided mixed results. A recent meta-analysis showed a pooled c-statistic of 0.77 for the TIMI score and 0.82 for the GRACE score for short-term outcomes.²⁷ Kozieradzka et al. found that the TIMI, GRACE, and Zwolle scores had similar results for a 30-day mortality outcome.¹⁹ This study included patients treated in the 2000-2002 period, and is limited by the lack of a statistical comparison among the ROC curves. Aragam and colleagues found similar accuracy of the TIMI and GRACE scores for in-hospital mortality (0.84 vs 0.83) and mortality at 6-month follow-up (0.72 vs 0.71), but these

patients were also treated more than a decade ago.¹⁸ Other studies were limited by exclusion of higher-risk patients, low number of scores analyzed, and retrospective design.²⁸⁻³¹

The Zwolle score is the only model using angiographic variables, taking into account the outcome of pPCI and the presence of multivessel disease (Supplemental Table S1).¹⁷ Risk scores are generally used by cardiologists, and the need to evaluate angiographic data might explain why this score has not become as popular as others, despite similar diagnostic accuracy.^{14,16,27} In our study, the c-statistic of the TIMI score was not statistically different from the GRACE score. Considering that the TIMI score is simpler and easier to apply, this finding might favour its use in daily clinical practice. The worst performer among the scores was the PAMI score,¹⁵ and the restrictive selection criteria used to develop this model might explain this lower accuracy.

Another practical challenge in risk stratification refers to the elderly patients, and all the risk scores performed worse in

Table 2. Comparison of ROC curves between scores for prediction of death at 30 days

	TIMI vs PAMI	TIMI vs GRACE	TIMI vs Zwolle	PAMI vs GRACE	PAMI vs Zwolle	GRACE vs Zwolle
Difference between areas	0.05	0.03	0.01	0.09	0.05	0.04
Standard error	0.03	0.03	0.04	0.03	0.04	0.04
95% CI	0.00 to 0.11	-0.03 to 0.09	-0.06 to 0.08	0.02 to 0.15	-0.04 to 0.13	-0.04 to 0.12
z statistic	1.84	1.07	0.20	2.59	1.11	0.94
Р	0.07	0.28	0.84	< 0.01	0.27	0.34

CI, confidence interval; GRACE, Global Registry of Acute Coronary Events; PAMI, Primary Angioplasty in Myocardial Infarction; ROC, receiver-operator characteristic; TIMI, Thrombolysis in Myocardial Infarction.



Figure 4. Risk of death at 30 days (%) according to quartiles of risk. GRACE, Global Registry of Acute Coronary Events; PAMI, Primary Angioplasty in Myocardial Infarction; TIMI, Thrombolysis in Myocardial Infarction.

patients older than 65 years. It is important to note that age is the only variable contemplated in all of the scores, but computed differently in each of them (Supplemental Table S2). We believe that an accurate assessment of the influence of age in the performance of these risk scores will have to be addressed by further studies with larger numbers of patients.

Strengths and limitations

Some strengths and limitations of this study are worthy of note. No data were available from longer-term follow-up, which could have influenced the accuracy of the scores. However, 30-day mortality is a clinically relevant end point that has been used in several previous studies. Despite a priori sample size calculation, the present study included a relatively small number of patients. Our institution is a high-volume centre (approximately 500 pPCIs per year), and we chose to focus this analysis within a 1-year time frame to keep results representative of contemporary pPCI practice. Because of insufficient statistical power, we were not able to consistently assess the diagnostic accuracy of the risk scores in the elderly (older than 65 years) and very elderly (older than 75 years). When comparing the results of original score development studies with those of the present study, the different risk profile of the patient populations must be taken into account. Finally, our study excluded patients who underwent pPCI with a delta T symptom time greater than 12 hours, who would benefit less from a primary reperfusion strategy.

Conclusions

The TIMI, GRACE, and Zwolle scores performed similarly as predictors of 30-day mortality, suggesting that these scores can be used to assess prognosis in this setting. The PAMI risk score presented significantly worse diagnostic accuracy than the other 3 scores, and we suggest that this score should not be used in contemporary practice. Patients within the lower quartile of risk had an estimated 30-day mortality of 1% or less estimated according to all the scores, suggesting that a very low risk subgroup can be identified. The GRACE, PAMI, TIMI, and Zwolle scores were not adequately accurate as predictors of MACE within 30 days. Our results reinforce the importance of periodic evaluations of the diagnostic accuracy of risk scores in daily clinical practice.

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Disclosures

The authors have no conflicts of interest to disclose.

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Supplementary Material

To access the supplementary material accompanying this article, visit the online version of the *Canadian Journal of Cardiology* at www.onlinecjc.ca and at http://dx.doi.org/10. 1016/j.cjca.2013.07.673.