TIMI Risk Score accurately predicts risk of death in 30-day and one-year follow-up in STEMI patients treated with primary percutaneous coronary interventions

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Abstract

Background: TIMI Risk Score for ST-elevation myocardial infarction (STEMI) was developed in a cohort of patients treated with fibrinolysis. It was though to predict in-hospital and short-term prognosis. Later studies validated this approach in large cohorts of patients, regardless of the applied treatment and presented its good power to predict 30-day mortality.

Aim: We applied the TIMI Risk Score to our registry of STEMI patients treated with primary percutaneous intervention (pPCI) to validate the possibility to predict one-year survival.

Methods: Our registry comprised 494 consecutive patients (mean age 58.5±11.3 years) with STEMI treated with pPCI who were followed for approximately one year. STEMI was diagnosed based on typical criteria: chest pain, ECG changes and rise in myocardial necrosis markers. In all patients TIMI Risk Score for STEMI was calculated and they were divided into three groups: low risk (0-5 points), medium risk (6-7) and high risk (>7 points). Multivariate logistic regression analysis, Kaplan-Meier survival analysis with Cox and log-rank tests as well as c statistics from receiver-operator curves (ROC) were used for statistical analysis.

Results: TIMI 3 flow was obtained in 95.5% of patients. Median TIMI risk score was 4 (ranging from 0 to 10). During follow-up there were 47 deaths (9.5%). There was a statistically significant difference in survival between all risk groups both in 30-day and one-year follow-up ($p < 0.001$ log-rank test). TIMI Risk Score had good power to predict 30-day (c statistic 0.834, 95% CI 0.757-0.91, $p < 0.0001$) as well as one-year mortality (c statistic 0.809, 95% CI 0.739-0.878, $p < 0.0001$). Interestingly, when we excluded from the analysis all patients who died during the first 30 days, TIMI Risk score maintained its very good prognostic value. All analysed risk groups significantly differed between each other with respect to mortality ($p < 0.05$, log-rank test) and the c statistic was 0.745 (95% CI 0.612-0.879, $p < 0.0002$). In multivariate logistic regression analysis TIMI Risk Score was one of the independent risk factors of death during one-year follow-up (OR 1.59, $p < 0.001$).

Conclusions: TIMI Risk Score accurately defines the population of STEMI patients who are at high risk of death not only during the first 30 days, but also during a long-term follow-up. This simple score should be included in the discharge letters because it contains very useful information for further care.

Key words: risk stratification, STEMI, primary percutaneous intervention, TIMI Risk Score

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Introduction

Further increase of incidence of coronary artery disease has been prevented due to widespread acceptance of the principles of primary prevention. However, still approximately 50,000 patients with ST-elevation myocardial infarction (STEMI) are admitted to hospitals in Poland each year [1]. The increasing percentage of patients treated with primary percutaneous coronary intervention (pPCI) in each consecutive year must be considered a great success of interventional cardiology.

Risk stratification and identification of individuals at high risk of death remains a significant issue in patients with STEMI. When a patient is identified to be

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at high risk, he or she becomes a candidate for aggressive therapy. The most frequently used risk stratification system in Poland is the TIMI Risk Score for STEMI patients, also known as the Morrow-Antman scale (Table I). This simple method was developed on the basis of the registry of patients treated with fibrinolysis (n=14,114) in the InTIME II trial [2]. Predictive value for the first 30 days was 0.779, whereas after one--year follow-up in the group of patients who survived the first 30 days after myocardial infarction (MI) is still remained good with c statistic 0.725.

The appropriateness of interpolating a scale developed based on a registry of patients treated with fibrinolysis to individuals undergoing invasive therapy was questioned. TIMI Risk Score was validated with respect to in-hospital mortality in a group of patients with MI enrolled on the National Registry of Myocardial Infarction 3 (NRMI3, n=84,000) [3]. In this study 48% of patients underwent reperfusion therapy and in 38% of them pPCI was employed. Prognostic value of calculated risk score was found to be similar and high in patients treated with either fibrinolysis or PCI (c=0.79 vs. c=0.8) and was comparable with that in the InTIME II study. This scale however tends to underestimate the risk of death in patients not receiving reperfusion therapy (c=0.65).

Relatively low discriminating value of this scale regarding both 30-day (c=0.7) and one-year (c=0.69) follow-up was found in the patient population of the Stent-PAMI randomised trial (n=900) that involved MI patients treated with pPCI [4].

Another important issue with respect to prognosis assessment in patients after MI is usefulness of the analysed scale in outpatient clinics, i.e. whether scoring calculated during hospitalisation of STEMI patients will be suitable for risk stratification in patients continuing their treatment in outpatient facilities.

Published reports on the use of TIMI Risk Score in patients with STEMI undergoing pPCI are based on the populations of randomised trials. However, the results of NRMI3 registry data analysis are valid only for in-hospital mortality. The purpose of our study was to analyse TIMI Risk Score usefulness with respect to prediction of 30-day and one-year mortality in an unselected group of STEMI patients treated with pPCI.

Methods

Patients

Our analysis involved 494 consecutive patients diagnosed with STEMI treated with pPCI. Criteria of STEMI diagnosis were as follows: clinical presentation, ECG abnormalities (ST elevation in two adjacent leads by 0.1 mV or left bundle branch block) and an increased level of the serum markers of myocardial necrosis. All patients underwent pPCI within 12 hours after the onset of symptoms.

Table I. TIMI Risk Score in the STEMI patients (Morrow-Antman Scale)

History
☐ age 65-74 (2 points)
☐ age ≥75 (3 points)
☐ DM, HA or angina (1 point)
Exam
☐ SBP <100 (3 points)
☐ HR >100 (2 points)
☐ Killip II-IV (2 points)
☐ weight <67 kg (1 point)
Clinical presentation
☐ anterior STE or LBBB (1 point)
☐ time to treatment >4 h (1 point)
Sum of points: 0-14

Abbreviations: DM – diabetes mellitus, HA – arterial hypertension, CAD – coronary artery disease, SBP – systolic blood pressure, HR – heart rate, LV – left ventricle, LBBB – left bundle branch block STE – ST elevation

Outcome

Primary endpoint of the study was cardiac-related death within 30 days and one year of follow-up. Additional one-year follow-up mortality analysis was carried out on the group of patients who survived the first 30 days following MI.

Statistical methods

To compare the general characteristic parameters of survivors vs. non-survivors, χ^2 and Mann-Whitney tests were used. A TIMI Risk Score value was calculated retrospectively for every patient. Based on analysis of death rates according to scoring result patients were divided into three risk groups: high (≥8 points), moderate (6-7 points) and low (0-5 points) risk. To analyse survival in selected risk groups, Kaplan-Meier curve log-rank test was performed. Predictive value (c) of TIMI Risk Score was estimated based on the ROC curve [5] (Analyse-it Software Ltd.), which illustrate a correlation between percentage of true positive (sensitivity) and percentage of false positive (1-specificity) results. Area under the ROC curve (c value) delineates index prognostic power. C statistic value between 0.8 and 0.9 features excellent discriminating power, between 0.7 to 0.8 acceptable predictive value, while c=0.5 means a lack of power [5]. Univariate analysis of categorical variables with the log-rank test was also performed. Cox's regression model (Statistica) was employed for

Table II. Comparison of demographic and clinical parameters between survivors and those who died during one-year follow-up

Parameter	Overall	Patients who survived one year	Patients who died within one year of follow-up	p
Age [years]	58.5±11.3	58±11.1	61.5±12.5	0.035
Female gender [%]	24	25.5	19.1	NS
Body weight [kg]	79.5±13.6	79.7±13.7	77.3±11.1	NS
Blood pressure [mmHg]				
Systolic	141.6±27.1	142.8±25.5	128.8±37.2	0.008
Diastolic	87.4±18.8	88.6±16.7	76±31.3	0.017
Heart rate [beats/min]	78.11±17.26	76.67±15.88	92.22±23.19	<0.0001
Assessment according to Killip scale	1.6±0.76	1.5±0.62	2.6±1.17	<0.0001
Myocardial infarction location [%]				
Anterior	44.1	40.7	75.6	<0.0001
Inferior	52.6	55.4	25.5	0.0001
Time to intervention >4 h [%]	45.3	45.1	46.8	0.83
TIMI 3 flow after pPCI [%]	95.5	97.3	78.7	0.0001
Risk factors [%]				
Hypertension	41.7	41.6	42.5	NS
Diabetes mellitus	15.5	14.9	21.2	NS
History of ischaemic heart disease [%]				
Myocardial infarction	10.7	10	17	NS
Exertional angina	39	37.8	51	0.07
TIMI Risk Score	3.7±2.3	3.5±2	6.3±2.3	<0.000001

both non-categorical variable univariate and multivariate analyses.

Results

Data on 494 STEMI patients treated with pPCI were analysed. Mean age was 58.5±11.3 years, and 24% of the studied subjects were females. Angiographic success of pPCI, defined as TIMI 3 flow following intervention, was achieved in 95.5% of cases. During one-year follow-up 47 (9.5%) patients died. General characteristics of individuals who survived or died within the first year following procedure are outlined in Table II.

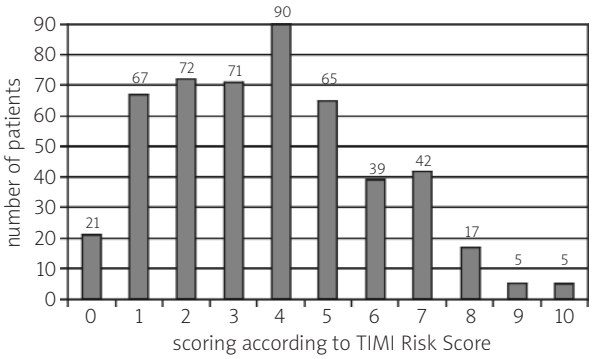

Figure 1. A number of the patients according to scoring with the use of TIMI Risk Score method

In our group TIMI Risk Score on a 14-point scale ranged between 0 and 10 (median 4 points). Figure 1 shows the distribution of scores and Figure 2 mortality in each scoring result category. As mentioned before, based on mortality analysis the patient population was split into 3 groups of low (0-5 points), moderate (6-7) and high (≥8) risk.

Thirty-day mortality in the individual groups was 2.07% (n=8), 13.58% (n=11) and 44.4% (n=12), respectively. One-year mortality in each risk group was 3.8% (n=15), 19.75% (n=16) and 59.25% (n=16), respectively. Analysis of 30-day and one-year survival revealed significant differences between all the groups (p <0.001 in the log--rank test). Kaplan-Meier survival curves up to one year are shown in Figure 3. Analysis of ROC curves revealed that the c statistic value for TIMI Risk Score referring to 30-day prognosis was 0.834 (95%CI 0.757-0.91; p <0.0001). Discrimination power with respect to one-year

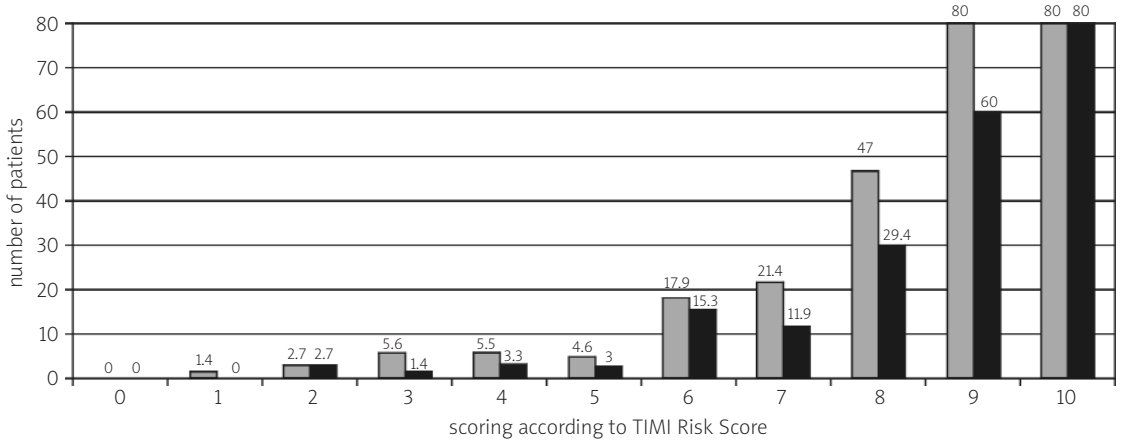

Figure 2. Thirty-day (black bars) and one-year (gray bars) mortality according to scoring with the use of TIMI Risk Score

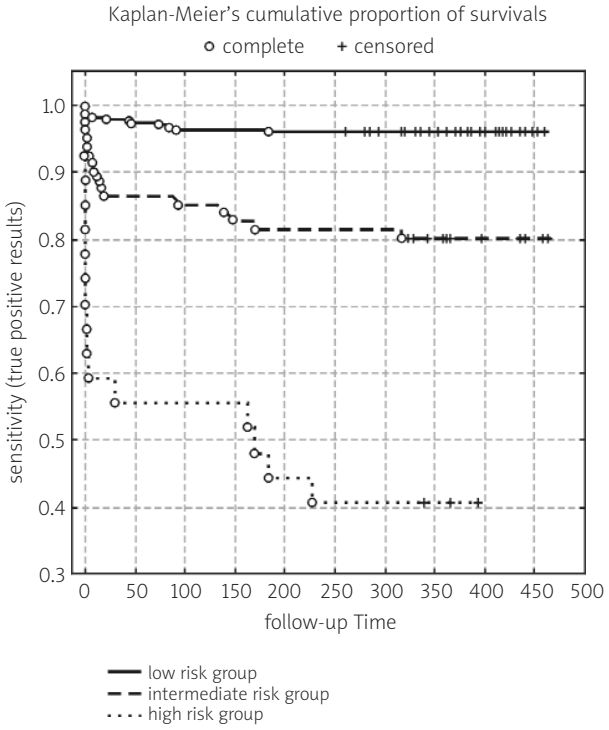

Figure 3. Kaplan-Meier's survival curve for one--year follow-up. Differences between individual groups are statistically significant (p <0.001 in the log-rank test)

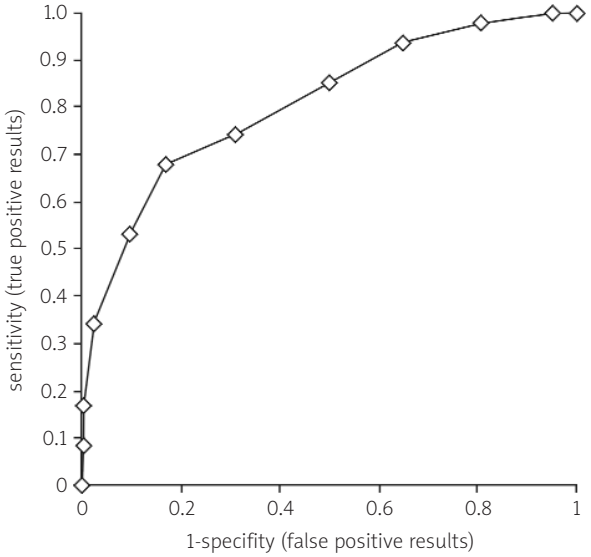

Figure 4. ROC curve for one-year follow-up mortality. Predictive value (c) of TIMI Risk Score was 0.809

follow-up was 0.809 (95% CI 0.739-0.878; p <0.0001). The ROC curve for one-year follow-up mortality is presented in Figure 4.

In the group of patients who survived the first 30 days following MI (n=447), differences regarding one--year survival between the individual risk groups remained statistically significant (p <0.05 in the log-rank test). Predictive value of the c index was maintained at the level of 0.745 (95% CI 0.612-0.879; p=0.0002).

Among categorical variables, the following were significantly associated with prognosis of one-year survival: anterior location of MI, TIMI flow <3 after percutaneous angioplasty and the age ≥65 years (Table III). The results of univariate analysis of non--categorical variables potentially related to death within one-year are outlined in Table IV. In the multivariate analysis (see Table V) TIMI Risk Score was independently associated with one-year mortality (relative risk 1.59; p <0.00001).

Table III. Univariate analysis of one-year mortality – categorical variables

Parameter	Interception value	N	Mortality [%]	p
Age	≥65 years	174	14.37 (n=25)	0.0072
	<65 years	320	6.88 (n=22)	
Anterior myocardial infarction	Yes	218	16.51 (n=36)	<0.0001
	No	276	3.99 (n=11)	
TIMI flow <3	Yes	22	45.5 (n=10)	0.0072
	No	460	6.96 (n=32)	

Table IV. Univariate analysis of one-year mortality – non-categorical variables

Parameter	Relative risk	p
Heart rate	1.035	<0.001
Age	1.02	0.06
Systolic blood pressure	0.98	0.0004
Diastolic blood pressure	0.97	<0.0001
Assessment according to Killip scale	2.21	<0.0001
TIMI Risk Score	1.72	<0.0001
Ejection fraction	0.9	<0.0001

Table V. Multivariate analysis (Cox's regression model) of one-year mortality (χ^2=74.41; df=3; p <0.0001)

Parameter	Relative risk	p
TIMI Risk Score	1.59	<0.0001
TIMI flow after pPCI	0.6	0.0002
Heart rate	1.017	0.007

Discussion

In our group of STEMI patients treated with pPCI the TIMI Risk Score was shown to be a reliable system of mortality prediction. It featured excellent discrimination power regarding both 30-day and one--year follow-up. Predictive value of the c index remained at a satisfying level with respect to one-year follow-up of patients who survived the first 30 days after MI. TIMI Risk Score assessment also identified a relatively small group of patients (5.4%, n=27) at high risk of death.

In our study, no exclusion criteria were used. Thus, we did not confine the scope of scale employment, although the precision of our analysis was limited. It was assumed that this scale must be suitable for wide use and its applicability should not be limited only to selected patients. In the InTIME II study many exclusion criteria were used, resulting in a marked decrease in the percentage of patients in both moderate and high risk subgroups. In our study 21.8% of patients scored ≥6 points, while in the InTIME II trial only 12% did so (p <0.0001).

Validating TIMI Risk Score in the NRMI3 registry [3], the only exclusion criterion was cardiogenic shock. The discriminating value achieved in our study regarding 30 days was higher than in-hospital mortality of patients in the NRMI3 study. This might have been influenced by the mean age of patients, 58.5±11.3 and 63±13 years respectively. According to Rathore et al. [6], TIMI Risk Score has low predictive value (c=0.69) for the assessment of 30-day mortality in elderly patients (≥65 years) with STEMI who underwent reperfusion therapy. In general, the results of the published reports suggest limited accuracy of survival prediction in elderly patients.

In a registry of subjects with STEMI in Olmsted County (n=562, 43% underwent reperfusion therapy, follow-up 6.3±4.7 years) prognostic value of the c parameter was c=0.73 regarding 28-day and one-year follow-up [7].

In the population of the GUSTO V study (16,256 STEMI patients randomised to therapy with r-PA alone or with abciximab and r-PA) a relationship between TIMI Risk Score and mortality was analysed [8]. In the period of 30 days hazard ratio (HR) was 1.51 (95% CI 1.47-1.56; p <0.001) while for one year it was 1.52 (95% CI 1.47-1.55; p <0.001).

The use of TIMI Risk Score when qualifying patients with STEMI to either fibrinolysis or pPCI was assessed in the randomised DANAMI-2 study (n=1527) [9]. In the low risk group (0-4 points) no statistically significant differences were observed within 3-year follow-up (pPCI 8.0% vs. fibrinolysis 5.6%; p=0.11), while in the high risk group a significant difference was found (25.3 vs. 36.2%; p=0.02).

A unique feature of our study is that TIMI Risk Score was applied for risk stratification among STEMI patients treated in outpatient facilities after discharge from hospital. The scale maintains good one-year follow-up predictive value in a population of patients who survived the first 30 days after MI, who thus are potential outpatients. It seems that inclusion of TIMI Risk Score results in the hospital discharge forms may be helpful for clinicians responsible for outpatient treatment of individuals after MI.

TIMI Risk Score is a very simple scale and it is possible to use it at the time of admission to hospital. It does not include any biochemical markers. Grabowski et al. found that inclusion of BNP assessment in the risk stratification model increased the area under the ROC curve from 0.852 to 0.918 [10].

The efficacy of PCI must be taken into account when analysing patients treated with such interventions. Zwolle Risk Score for STEMI, unlike TIMI Risk Score, includes new parameters associated with invasive treatment: PCI efficacy (blood flow according to TIMI scale) and presence of multi-vessel disease [11]. It also includes the age of the patient, anterior location of MI, result of the assessment according to Killip scale and onset of pain-to-treatment time. Zwolle Risk Score was designed to predict 30-day mortality and was based on a registry of STEMI patients treated with pPCI. Based on the aforementioned parameters a scale with exceptionally high prognostic value of c=0.907 was eventually developed.

Another interesting alternative is the CADILLAC Risk Score [4], intended for MI patients treated with pPCI. It was designed and underwent validation in a registry of randomised clinical trials (CADILLAC and Stent-PAMI). The analysis of mortality risk involves age, Killip class, left ventricular ejection fraction, concomitant anaemia, renal failure, TIMI flow after coronary intervention and number of significant coronary lesions. The CADILLAC Risk Score was found to have high predictive value with respect to 30-day (c=0.83) as well as one-year (c=0.79) follow-up. Based on validation in the patient population of the Stent-PAMI trial, its high discrimination power was confirmed (c=0.81 for 30-day and c=0.78 for one--year follow-up, respectively). In this group of patients the CADILLAC Score appeared to have higher c values than the Zwolle Risk Score (c=0.74 for either 30-day or one-year follow-up) as well as TIMI Risk Score (0.7 and 0.69, respectively). Its efficiency in the population of unselected patients with MI should also be analysed.

Another scale, GRACE, is applicable to all forms of acute coronary syndromes and is used for prediction of survival within 6 months after discharge from hospital [12]. It takes into account age, history of either heart failure or MI, heart rate (HR) and systolic blood pressure (SBP) on admission to hospital, ST-segment depression, creatinine level expressed as mg/dl, elevated level of myocardial necrosis biochemical markers and also additional risk in patients who did not undergo PCI. The discrimination value of c reached in this model was 0.81. During 4-year follow-up this value was maintained at a comparable level, i.e. 0.8 [13].

The dynamic risk evaluation proposed by Chang et al. may represent a chance for more appropriate prediction of survival [14]. The patients are scored on admission, after 3 hours and on the 2nd and 5th hospitalisation days. This method takes into consideration variables such as age, Killip class, HR, SBP, cumulative ST-segment elevation, ST-segment normalisation and occurrence of adverse events during hospitalisation. Prognostic value of the tests carried out at 4 time-points ranged between 0.82 and 0.87.

All these scales are based on categorisation of several variables. An alternative approach to risk stratification is a simple risk index [15] calculated according to the following formula: simple risk index = = HR × $(age/10)^2$/SBP. Three parameters are analysed but this formula takes into consideration their precise values. The c statistic value was 0.79 with respect to prognosis of 30-day follow-up mortality. Meanwhile, in the population of NRMI-3 c value regarding in-hospital mortality among patients treated with the reperfusion method was 0.81 [16].

Most presented risk classifications require assessment of many parameters that are not available at the time of first contact with a patient, e.g. ejection fraction. It seems unlikely that all patients will undergo echocardiographic evaluation at the time of hospital admission. Thus retrospective validation of scales such as CADILLAC likely excludes patients who died before echocardiography was performed.

There is a theoretical background to question if risk stratification scales designed primarily for patients treated with fibrinolysis may be suitable for those undergoing pPCI. Stent use and method of successful reperfusion (fibrinolysis or intervention) also have an impact on patient prognosis. In the TIMI Risk Score scale, the onset of pain-to-intervention time, identified as injection of fibrinolytic drug or angioplasty, is also considered. However, the real times between the onset of pain and reperfusion of the infarct-related artery may vary with different treatments used.

The TIMI Risk Score system does not include a parameter of paramount importance, i.e. angioplasty efficiency. On the other hand, in the case of fibrinolysis (i.e. in the InTIME II trial) efficiency of reperfusion therapy is also unknown.

Several parameters may improve predictive value of the TIMI scale, although they require additional examinations and prolong the process of patient risk stratification. One must ensure that such a scale is simple and suitable for application at the time of patient admission to hospital even at the cost of some limitations. It is possible due to a lower number of analysed parameters limited to medical history, physical examination and MI location according to ECG. Such a risk scale was developed and it may even be used retrospectively, with calculations based on data from hospital discharge forms.

Conclusions

TIMI Risk Score is a simple, easy and useful tool of risk stratification in STEMI patients treated with pPCI. It accurately identifies patients at high risk of death during both 30-day and one-year follow-up.

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TIMI Risk Score dobrze prognozuje śmiertelność 30-dniową i roczną w grupie pacjentów z zawałem serca z uniesieniem odcinka ST leczonych pierwotną przezskórną interwencją wieńcową

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Streszczenie

Wstęp: Ocena rokowania pacjentów z zawałem z uniesieniem odcinka ST (STEMI) jest ważnym elementem postępowania diagnostyczno-terapeutycznego. Jedną z najczęściej opisywanych skal ryzyka jest TIMI Risk Score, opracowana na podstawie kohorty pacjentów z badania InTIME II do szybkiego prognozowania śmiertelności 30-dniowej w populacji pacjentów leczonych fibrynolitycznie. Jednak jej przydatność do oceny ryzyka zgonu w odległej obserwacji w grupie chorych leczonych interwencyjnie budzi kontrowersje. Istotnym z punktu widzenia praktyki klinicznej zadaniem byłoby znalezienie skali ryzyka, która wyliczona w momencie hospitalizacji mogłaby być użyteczna również w późniejszej opiece ambulatoryjnej.

Cel: Ocena przydatności TIMI Risk Score w określaniu śmiertelności 30-dniowej i rocznej w rejestrze pacjentów ze STEMI leczonych pierwotną przezskórną interwencją wieńcową (pPCI).

Metodyka: Badaniem objęto 494 kolejnych chorych z ostrym STEMI (średni wiek 58,5±11,3 lat), z czego 118 (24%) to kobiety, leczonych pPCI w ciągu pierwszych 12 godz. od wystąpienia objawów, poddanych następnie rocznej obserwacji, w której oceniano wystąpienie zgonu z przyczyn sercowo-naczyniowych. Każdemu pacjentowi obliczano wartość TIMI Risk Score. Na podstawie analizy odsetków zgonów w zależności od liczby punktów, arbitralnie podzielono badanych na 3 grupy ryzyka: niskiego (0–5 punktów), średniego (6–7) i wysokiego (≥8). W analizie statystycznej użyto analizy przeżycia Kaplana-Meiera, testu log-rank, oceny krzywych ROC oraz modelu regresji Coksa.

Wyniki: Wartości 14-punktowego TIMI Risk Score w grupie badanej wahały się w granicach 0–10 (mediana 4). Pierwotna PCI była skuteczna angiograficznie (przepływ TIMI 3 po zabiegu) u 472 (95,5%) pacjentów. W rocznej obserwacji zanotowano 47 (9,5%) zgonów. Śmiertelność 30-dniowa w poszczególnych grupach ryzyka wynosiła odpowiednio: 2,07% (n=8), 13,58% (n=11) i 44,4% (n=12). Śmiertelność roczna kształtowała się odpowiednio na poziomie: 3,8% (n=15), 19,75% (n=16) i 59,25% (n=16). W analizie przeżycia 30-dniowego i rocznego różnice między poszczególnymi grupami były istotne statystycznie ($p < 0,001$; log-rank test). Wartość prognostyczna TIMI Risk Score w okresie 30 dni wyniosła c=0,834 (95% CI 0,757–0,91; $p < 0,0001$), w skali roku c=0,809 (95% CI 0,739–0,878; $p < 0,0001$). Również w grupie chorych, którzy przeżyli pierwsze 30 dni po zawale (n=447), obserwowano istotne statystycznie różnice w śmiertelności pomiędzy trzema zdefiniowanymi grupami ryzyka ($p < 0,05$; log-rank test), a wartość c dla TIMI Risk Score w obserwacji rocznej wyniosła c=0,745 (95% CI 0,612–0,879; p=0,0002). W analizie jednoczynnikowej wykazano, że istotny wpływ na śmiertelność mają następujące parametry: częstotliwość akcji serca przy przyjęciu, wiek, ciśnienie skurczowe krwi, ciśnienia rozkurczowe krwi, ocena w skali Killipa, TIMI Risk Score, frakcja wyrzutowa, przednia lokalizacja zawału oraz nieskuteczna interwencja. W analizie wieloczynnikowej TIMI Risk Score, podobnie jak skuteczność angiograficzna zabiegu oraz częstotliwość pracy serca przy przyjęciu, był niezależnie związany z wystąpieniem zgonu w rocznej obserwacji (ryzyko względne 1,59; $p < 0,001$).

Wnioski: Z uwagi na wysoką wartość diagnostyczną TIMI Risk Score oceniany przy przyjęciu może mieć zastosowanie w ocenie ryzyka chorych ze STEMI leczonych pPCI, zarówno w warunkach wewnątrzszpitalnych, jak i w późniejszej opiece ambulatoryjnej. Jest to nieskomplikowane, poręczne i użyteczne narzędzie stratyfikacji ryzyka, które doskonale identyfikuje chorych z wysokim ryzykiem zgonu zarówno w ciągu 30-dniowej, jak i rocznej obserwacji.

Słowa kluczowe: stratyfikacja ryzyka, zawał mięśnia sercowego, pierwotne interwencje wieńcowe, skala ryzyka

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