ORIGINAL ARTICLE

Bedside prediction of 9-year mortality after ST-segment elevation myocardial infarction treated with primary percutaneous coronary intervention

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ABSTRACT

BACKGROUND   Despite similar underlying pathogenesis, clinical features, and management of ST-segment elevation myocardial infarction (STEMI), the long-term prognosis of patients is highly variable. The ability to stratify an individual's long-term mortality risk could facilitate development of focused interventions aimed at reducing poor long-term outcomes.

AIMS   This study aimed to develop and validate a simple risk score based on routinely collected data for all-cause and cardiovascular 9-year mortality in a homogeneous group of patients with STEMI undergoing primary percutaneous coronary intervention (pPCI).

METHODS   All consecutive patients with STEMI treated with pPCI were randomly divided into 2 groups. The first group was called the building group and was used to develop logistic regression models that were converted into a simple risk scores that estimated all-cause and cardiovascular long-term mortality risk (ANIN risk score I and II, respectively) and subsequently validated in the second group, called the validating group.

RESULTS   The 9-year follow-up data were available in 1059 out of 1064 patients with STEMI. We developed 4 independent risk scores with the highest predictive accuracy of ANIN risk score I. Validation cohorts identified 4 most important risk factors: age, renal dysfunction, Killip class, and thrombolysis in myocardial infarction flow. Low, intermediate, and high-risk subgroups were identified based on those factors with different long-term mortalities: 10%, 37%, and 71%, respectively.

CONCLUSIONS   Long-term mortality after STEMI treated with pPCI can be accurately predicted using 4-variable bedside risk score, which is ready to calculate right after pPCI. Patients in the low-risk group have an excellent prognosis despite having experienced potentially lethal disease.

INTRODUCTION   Despite the homogeneous pathogenesis of ST-segment elevation myocardial infarction (STEMI), the prognosis of patients is highly variable, even in patients treated with primary percutaneous coronary intervention (pPCI). Proper risk stratification might not only reduce the hospitalization time for patients at low long-term risk but can also help develop new and more effective treatment strategies for those at high-risk.

Previously developed risk scores estimated short- and mid-term all-cause mortality of patients with various forms of acute coronary syndromes including STEMI treated primarily with fibrinolysis.[1-3] Frequently, those scores were derived from clinical trials excluding high-risk

WHAT'S NEW?
It is the first study that developed a very long-term risk score in patients with ST-segment elevation myocardial infarction treated exclusively with primary percutaneous coronary intervention. Using only 4 clinical and angiographic variables readily available at the time of intervention, ANIN risk score has a high discriminatory power to identify patients at low, intermediate, and high risk of death of up to 9 years of follow-up. Long-term mortality rate progressively rises from 10% to 71% with increasing score value, which is of help in the individual approach to the management of each patient. In particular, ANIN risk score enables identification of low-risk patients with long-term prognosis comparable with that of general population, despite having experienced a severe and potentially lethal disease.

patients.[4,5] Most of them were complex models difficult to use in everyday practice.

Therefore, we sought to develop an easy, bedside risk score for predicting long-term all-cause and cardiovascular (CV) mortality. It may help select high-risk patients requiring especially careful outpatient management and allow for cost-effective allocation of means. Furthermore, we performed separate analyses in patients who survived the first 30 days following STEMI to avoid bias of factors influencing short--term survival.

METHODS Data from a prospective, single--center pPCI cohort and mortality data from the Polish National Census Registry were used in this study. We recruited all consecutive patients with STEMI undergoing pPCI at the Institute of Cardiology in Warsaw between February 2001 and October 2002. The rationale, methods, ethical approval, and recruitment process were fully described in previous publications.[6,7] There were no exclusion criteria. Informed consent was obtained from each patient. All patients were treated with pPCI in compliance with generally accepted standards at the time. Procedural success was defined as final thrombolysis in myocardial infarction (TIMI) grade 3 flow. Only bare metal stents were used. Major adverse cardiac and cerebrovascular events were defined according to the approved criteria. Renal dysfunction was defined as an estimated glomerular filtration rate below 60 ml/min/1.73 m². Survival data, including cause of death, were available from the Polish National Census Registry. Cardiovascular cause of death was defined according to the *International Classification of Diseases, Tenth Revision (ICD-10)* as described before.[8]

All consecutive patients were randomly divided into 2 groups with a comparable number of deaths. The first group was referred to as the building group and was used to develop a long--term logistic regression model that was converted into a simple linear risk score that estimates all-cause mortality and CV mortality (ANIN risk score I and ANIN risk score II, respectively). For each risk score, groups of patients at low, intermediate, and high risk were identified.

The performance of each risk score was subsequently tested on the second group, called the validation group.

A separate analysis was performed for all--cause and CV mortality for patients who were alive at day 30 (survivors of acute phase) (ANIN risk score III and ANIN risk score IV for all-cause and CV mortality, respectively).

Our study complies with the Declaration of Helsinki and the research protocol was approved by the local ethics committee (decision no. 2.6/III/2012).

Statistical analysis Typical statistical methods were used and described elsewhere.[6,7] The model incorporated baseline characteristics that could be readily identified at presentation.

The relationship between clinical factors and 9-year mortality was analyzed using a logistic regression model. A *P* value of less than 0.05 was considered significant. The results were presented as hazard ratios with 95% confidence intervals (CI).

The ANIN risk score was calculated for each patient as the simple arithmetic sum of points assigned to natural logarithm (ln) of each odds ratios (ORs), as follows: 1 point for ln of the OR (SD) of 0.5 (0.25), 2 points for 1.0 (0.25), 3 points for 1.5 (0.25), 4 points for 2.0 (0.25), etc.

We used the Hosmer–Lemeshow goodness of fit test to assess calibration,[8] in which higher *P* values indicate better calibration. The discriminatory capacity of the risk score was assessed by the area under the receiver operating characteristic curve (C statistic) as an index of model performance.[9] A model with a C statistic of 0.70 or higher was considered to have good discriminatory ability. Time--to-event data were summarized as Kaplan–Meier estimates and compared with the log-rank test. The statistical analyses were performed using the Statistical Package for Social Sciences, version 17.0 (SPSS Inc., Chicago, Illinois, United States).

RESULTS Baseline characteristics and clinical outcomes Out of 1064 patients included into ANIN Myocardial Infarction Registry, 27% were women. The mean (SD) age of patients was 60 (12) years. Angiographic success of pPCI was achieved in 83% of cases (TABLE 1). For censored observations, the duration of follow-up was 7 to 9 years with 5 patients lost to follow-up. Long--term all-cause mortality rate was 28% (N = 294), while CV mortality rate was 19% (N = 196). After random division of patients into the building and validation groups, clinical, demographic, and angiographic characteristics as well as mortality rates were comparable (TABLE 1). At day 30 of follow-up, 838 patients were alive (survivors of acute phase).

TABLE 1 Clinical and angiographic characteristics, in-hospital major adverse cardiac and cerebrovascular events, and long-term outcomes of patients in building and validation group

Parameter		All patients (n = 1059)	Building group (n = 509)	Validation group (n = 550)	P value
Clinical and angiographic characteristics	Age, y, mean (SD)	60 (12)	61 (12)	59 (11)	0.24
	Female	283 (27)	135 (27)	148 (27)	0.96
	H/O CAD	458 (43)	222 (44)	236 (43)	0.82
	H/O MI	218 (21)	111 (22)	107 (19)	0.80
	H/O hypertension	501 (48)	226 (45)	275 (50)	0.47
	Diabetes mellitus	138 (13)	66 (13)	72 (13)	0.89
	Current smokers	528 (50)	247 (49)	281 (51)	0.64
	Renal dysfunction	318 (36)	158 (31)	160 (29)	0.78
	Heart rate, bpm, mean (SD)	80 (20)	80 (20)	79 (18)	0.62
	SBP, mm Hg, mean (SD)	133 (30)	130 (30)	131 (30)	0.10
	Killip class >1	130 (12)	55 (11)	75 (13)	0.72
	Cardiogenic shock	43 (4)	18 (4)	25 (4)	0.92
	Unconscious	38 (4)	17 (3)	21 (4)	0.32
	TIT >3 hours	646 (61)	326 (64)	320 (58)	0.43
	MVD	564 (53)	282 (56)	282 (51)	0.61
	Stent implantation	815 (77)	393 (78)	422 (77)	0.89
	Planned abciximab	320 (30)	153 (30)	170 (31)	0.73
	Rescue abciximab	172 (16)	85 (17)	87 (16)	0.91
	iTIMI grade 2–3 flow	192 (18)	91 (18)	101 (18)	0.89
	fTIMI grade 3 flow	880 (83)	420 (83)	460 (84)	0.90
MACCE	re-MI	16 (2)	8 (2)	8 (1)	0.98
	Major bleeding	40 (4)	17 (3)	23 (4)	0.41
	Stroke	7 (1)	2 (0)	5 (1)	0.47
Long-term mortality	All-cause	294 (28)	146 (29)	148 (27)	0.62
	CV	196 (19)	97 (19)	99 (18)	0.86

Data are presented as number (percentage) unless indicated otherwise.

Abbreviations: CAD, coronary artery disease; CV, cardiovascular; eGFR, estimated glomerular filtration rate; bpm, beats per minute; fTIMI, final thrombolysis in myocardial infarction flow; H/O, history of; iTIMI, initial thrombolysis in myocardial infarction flow; MACCE, major adverse cardiac and cerebrovascular events; MI, myocardial infarction; MVD, multivessel disease; re-MI, reinfarction; SBP, systolic blood pressure; TIT, total ischemic time

Long-term mortality risk scores Four independent risk scores for 9-year all-cause and CV mortality, both for the entire building group and survivors of acute phase, were developed.

All-cause mortality risk score (ANIN risk score I) Four independent risk factors for all-cause mortality were identified: age above 60 years, Killip class higher than 1, renal dysfunction, and procedural failure (TABLE 2). Data necessary to calculate ANIN risk score I were incomplete for 79 patients (16%), and therefore they were excluded from further analysis. ANIN risk score I demonstrated excellent prognostic accuracy for the following time points: 30-day mortality (area under the curve [AUC], 0.83),

1-month mortality (AUC, 0.82), 5-year mortality (AUC, 0.81), and 9-year mortality (AUC, 0.79).

Cardiovascular mortality risk score (ANIN risk score II) The same set of 4 independent risk factors for CV mortality as in ANIN risk score I was identified; however, different point values were attributed (TABLE 2). ANIN risk score II was a predictor of long-term CV mortality (Supplementary material, *Table S1*).

All-cause mortality risk score for survivors of acute phase of ST-segment elevation myocardial infarction (ANIN risk score III) Independent risk factors that formed ANIN risk score III for survivors of the acute phase are presented in TABLE 2. Data

TABLE 2 Multivariate analysis of the whole cohort of patients and survivors of acute phase of ST-segment elevation myocardial infarction with corresponding points

Parameter	All patients						Survivors of acute phase of STEMI					
	All-cause mortality		RS	CV mortality		RS	All-cause mortality		RS	CV mortality		RS
	OR (95% CI)	P value	PT	OR (95% CI)	P value	PT	OR (95% CI)	P value	PT	OR (95% CI)	P value	PT
Age >60 years	3.9 (2.1–5.9)	<0.001	3	2.3 (1.3–4.1)	0.03	2	3.6 (1.6–5.3)	<0.001	3	2.2 (1.1–4.1)	0.02	2
Renal dysfunction	1.9 (1.3–2.8)	0.001	1	2.5 (1.5–4.0)	<0.001	2	2.2 (1.6–3.4)	<0.001	1	2.2 (1.2–3.7)	0.006	2
Killip class >1	3.6 (1.9–4.6)	<0.001	3	2.7 (1.6–4.4)	0.01	2	2.5 (1.2–3.9)	0.003	2	3.1 (1.4–7.1)	0.006	2
fTIMI <3	2.2 (1.5–3.3)	<0.001	2	2.3 (1.2–4.2)	<0.001	2	2.0 (1.3–3.2)	0.02	1	2.2 (1.2–3.9)	0.007	2
Diabetes mellitus	–	–	–	–	–	–	2.0 (1.2–4.0)	0.01	1	–	–	–
Hypertension	–	–	–	–	–	–	1.8 (1.2–2.9)	0.005	1	–	–	–

Abbreviations: CI, confidence interval; OR, odds ratio; PT, point; RS, risk score; STEMI, ST-segment elevation myocardial infarction; others, see TABLE 1

necessary to calculate risk score were incomplete for 105 patients (21%), and therefore they were excluded from the further analysis. Mortality rate increased with higher risk scores (Supplementary material, *Figure S1*); however, discriminatory capacity of that model was suboptimal (AUC, 0.69). In order to find a better model, we performed additional analysis, which demonstrated the highest accuracy (AUC, 0.74) for the model created for all-cause mortality of the entire cohort of patients (ANIN risk score I). Applying ANIN risk score I, univariate analysis for that group of patients showed significantly higher mortality for the intermediate- and high-risk patients in comparison with low-risk patients (OR, 5.2; 95% CI, 2.8–9.4; *P* <0.001 and OR, 18.9; 95% CI, 8.2–43.5; *P* <0.001; respectively).

Cardiovascular mortality risk score for survivors of acute phase of ST-segment elevation myocardial infarction (ANIN risk score IV) The same set of four independent risk factors for CV mortality with same point values as in ANIN risk score II was identified (Table 2). Univariate analysis showed higher mortality of intermediate- and high-risk patients in comparison with low-risk patients (Supplementary material, *Table S1*).

For all 4 risk scores, mortality rates increased with higher scores (Supplementary material, *Figure S1*).

All scores but ANIN risk score III included the same set of 4 variables (age >60 years, Killip class >1, renal dysfunction, and procedural failure). Beside the ANIN risk score III, all scores were highly predictive of long-term death or CV death, respectively, with very good discrimination capacity in the building group (Supplementary material, *Table S1*). Kaplan–Meier curves for the 4 risk scores are shown in FIGURE 1. A univariate analysis of the validation group confirmed strong association between ANIN risk scores and long-term mortality (Figure 2 and Supplementary material, *Table S2*).

DISCUSSION The pivotal findings of the current study, in which a simple, bedside STEMI risk score was created and validated, are: 1) both all-cause and CV long-term mortality following STEMI treated with pPCI may be accurately predicted using only 4 clinical and angiographic variables readily available at the time of intervention (age >60 years, Killip class >1, renal dysfunction, and procedural failure); 2) ANIN risk score I has the highest discriminatory power to identify patients at low (10%), intermediate (37%), and high (71%) risk of death up to 9-year of follow-up with all 3 groups including a large numbers of patients; 3) patients in the low risk group according to ANIN risk score I have an excellent prognosis despite having experienced a severe and potentially lethal disease.

To the best of our knowledge, this is the first study that developed a very long-term risk score for STEMI patients treated exclusively with pPCI. Our results confirmed that risk factors already established at the time of intervention for short- and midterm mortality were still decisive after 9 years of follow-up in a homogenous group of patients.[10] As expected, age was found to be the strongest predictor of long-term mortality due to the aging process itself and major rate of comorbidities. It should be kept in mind that patients older than 60 years of age were at least at intermediate risk of death, which makes them potential beneficiaries of intensive postdischarge therapy. The second most powerful risk factor was heart failure. It was previously proven that even class Killip class II increased mortality in patients after myocardial infarction undergoing pPCI.[11] Renal dysfunction was also confirmed as a powerful risk factor of mortality and CV events, especially in patients undergoing mechanical reperfusion.[12] In the GUSTO-IIb (Global Use of Strategies To Open Occluded Arteries in Acute Coronary Syndromes) trial, patients with STEMI and renal dysfunction at
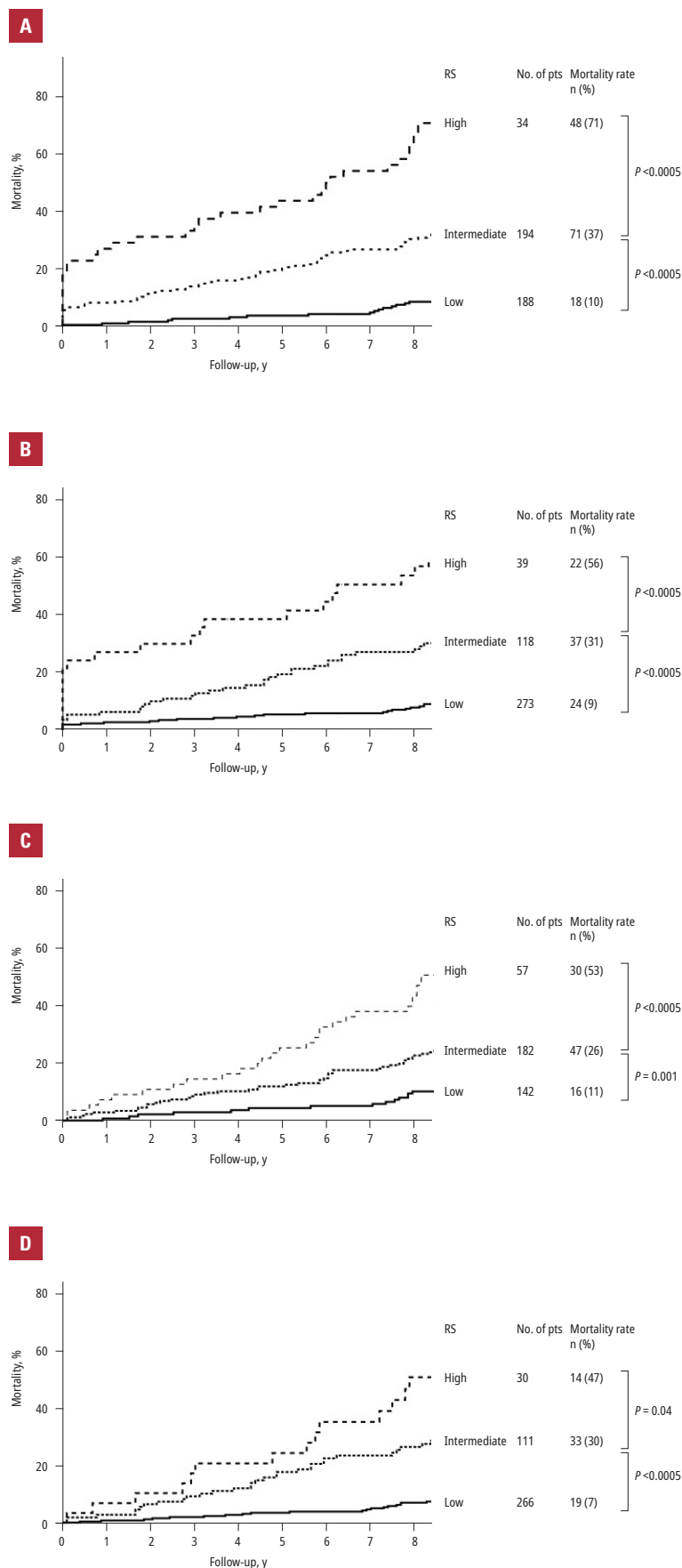
FIGURE 1 Kaplan–Meier curves in the building group: **A** – ANIN risk score I; **B** – ANIN risk score II; **C** – ANIN risk score III; **D** – ANIN risk score IV

Abbreviations: pts, patients; RS, risk score

admission had a 6-fold higher 6-month mortality than those with normal renal function. Final TIMI flow was found to be a strong independent predictor of death after pPCI, which is consistent with previous reports. It was also included in both the CADILLAC score and Angiographic Perfusion Score (a combination of TIMI flow grade and TIMI myocardial perfusion grade).[4,13]

Approved risk factors for atherosclerosis, such as hypertension, smoking, dyslipidemia, diabetes mellitus, and family history of coronary heart disease were not included in our model. However, the inverse association between the number of those factors and in-hospital mortality was previously demonstrated.[14] One of the possible explanations is a high incidence of those factors in up to 98% of patients with myocardial infarction,[15] which makes them inutile in discriminating high-risk patients. Moreover, in the same paper it was shown that patients with no or few traditional risk factors were higher Killip class, had higher TIMI risk score, and finally higher mortality. That observation was confirmed in another study where the presence of at least 1 modifiable coronary heart disease risk factor was associated with improved outcome after myocardial infarction.[16] The prognostic value of diabetes mellitus is controversial in patients with STEMI. Some studies have shown that it is an independent predictor of mortality,[17] while a 5-year follow-up of patients with STEMI treated with PCI did not show the predictive role of diabetes.[18] The protective role of all those features might be due to conscious control of health status or high prevalence of proper treatment.

Several previous studies have developed risk prediction scores for patients with acute coronary syndrome. TIMI score for STEMI was derived from fibrinolytic therapy trials, and therefore included weight, which was a known risk factor for bleeding but is no longer significant in the era of pPCI. Moreover, TIMI risk score did not include Killip class, leading to an inferior discriminative accuracy as compared with the GRACE risk score. The GRACE score, derived from a large cohort of patients with various forms of acute coronary syndromes, involved risk factors irrelevant for STEMI risk stratification such as presence of ST-segment deviation or increased cardiac enzymes, which are present by definition in every STEMI. It also excluded high-risk patients with recent stroke, known renal dysfunction, cardiogenic shock, or complex coronary anatomy. In contrast to previous studies, our registry did not exclude any patients, which resulted in a higher number of patients in intermediate risk and high-risk groups. Thus, the developed risk scores reflect real-life setting.

Considering the very long follow-up, we performed separate analysis for all-cause and CV mortality in the whole cohort of patients and subgroup of survivors of acute phase of STEMI.
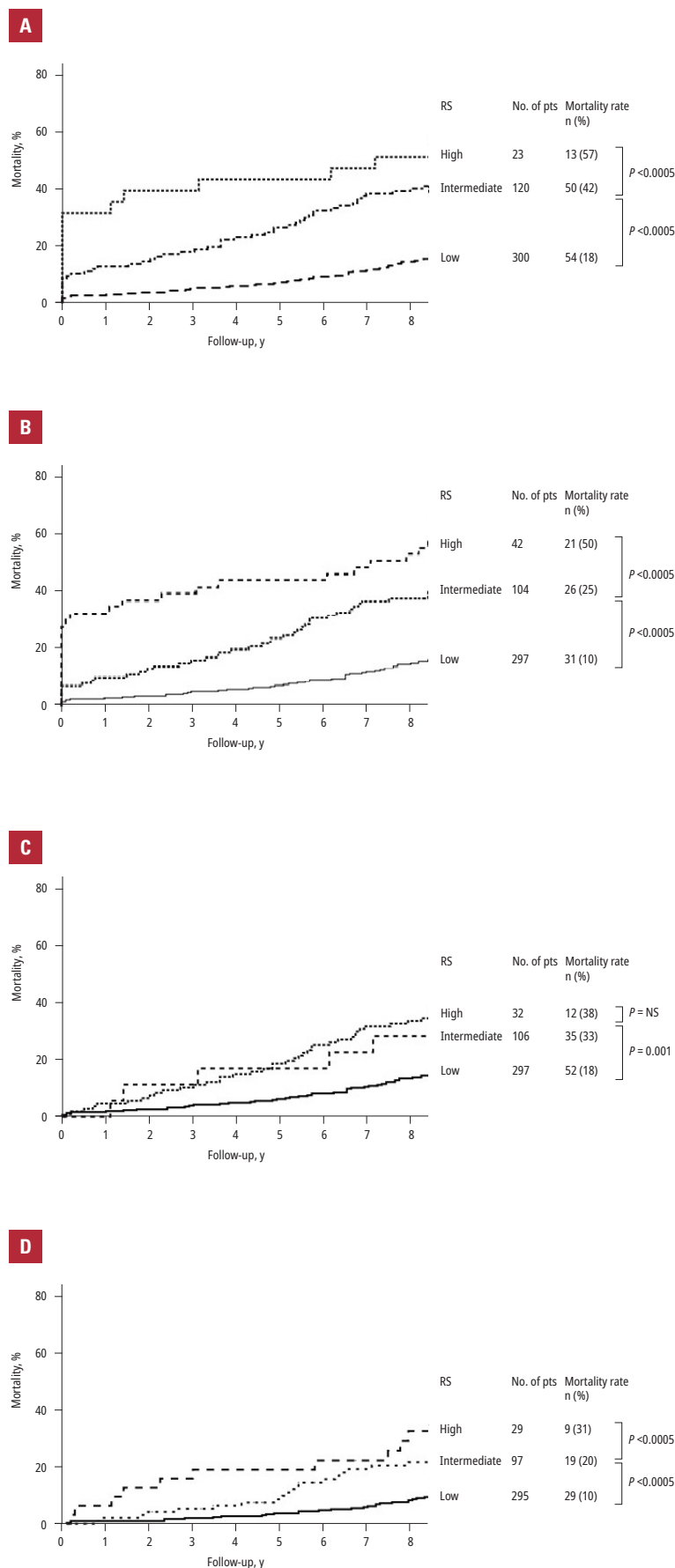
FIGURE 2 Kaplan–Meier curves in the validation group: **A** – ANIN risk score I; **B** – ANIN risk score II; **C** – ANIN risk score III; **D** – ANIN risk score IV

Abbreviations: NS, nonsignificant; others, see FIGURE 1

Therefore, we developed 4 risk scores, 3 of which included the same set of 4 simple variables (age >60 years, Killip class >1, renal dysfunction, and procedural failure) and showed a strong prognostic capacity in patients treated with pPCI (ANIN risk scores I, II, and IV). ANIN risk score III designed for all-cause mortality of survivors, including additional variables such as history of hypertension and diabetes mellitus, was suboptimal at risk discrimination but could be successfully replaced by ANIN risk score I.

ANIN risk score I had the highest predictive value for all-cause mortality, both in the whole cohort of patients and in the survivors of acute phase, with an excellent prognostic accuracy at consecutive time points up to 9 years. This model yielded outstanding performance in discriminating patients at intermediate- and high-risk of death. Of note, each of the 3 risk groups included considerable number of patients and risk of death varied widely (10%, 37%, and 71%). The Kaplan–Meier analysis presented a late mortality curves divergence confirming persistent poor prognosis of high-risk patients. Patients older than 60 years with heart failure or combined renal dysfunction and procedural failure were classified as high and had mortality rate of 71%. All patients older than 60 years of age or having signs of heart failure on admission or combination of renal dysfunction and procedural failure were at least at intermediate risk of death in the long-term follow-up. On the contrary, patients with STEMI classified as being at low risk based on ANIN risk score (up to 60 years of age and either no additional risk factors or only 1 of the following: renal dysfunction or procedural failure) had an excellent 9-year outcome, with 10% mortality rate similar to that reported for a general population cohort matched for age.

Finally, ANIN risk score showed a predictive value for the estimation of long-term mortality that was comparable with the CADILLAC, TIMI, and PAMI risk scores for 30-day and 1-year mortality rates.[19]

Limitations The risk model is based on data from a single center; however, this approach helps avoid bias in conducting the study. Our study was conducted between 2001 and 2002 according to the guidelines current at that time. An inevitable consequence of long-term follow-up studies are changes in the methods of treatment, both conservative and interventional. The ANIN risk score was not validated on an external group of patients; however, internal validation was successful.

Conclusions ANIN risk score provides a good long-term risk stratification of real-life patients with STEMI treated with pPCI based on 4 simple clinical and angiographic variables. Patients can be accurately reevaluated at day 30. The 9-year

risk of death progressively rises from 10% to 71% with increasing score value, which is of help in the individual management of each patient. ANIN risk score also enables identification of low-risk patients with long-term prognosis comparable with that of general population.

SUPPLEMENTARY MATERIAL

Supplementary material is available at www.mp.pl/kardiologiapolska.

ARTICLE INFORMATION

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