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ARTYKUŁ SPECJALNY / *STATE-OF-THE-ART REVIEW*

Risk assessment in patients with ST elevation myocardial infarction treated with primary percutaneous coronary angioplasty. Does reduced duration of hospital stay affect the prognosis?

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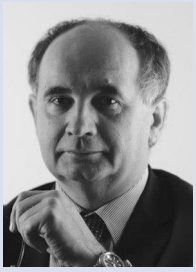

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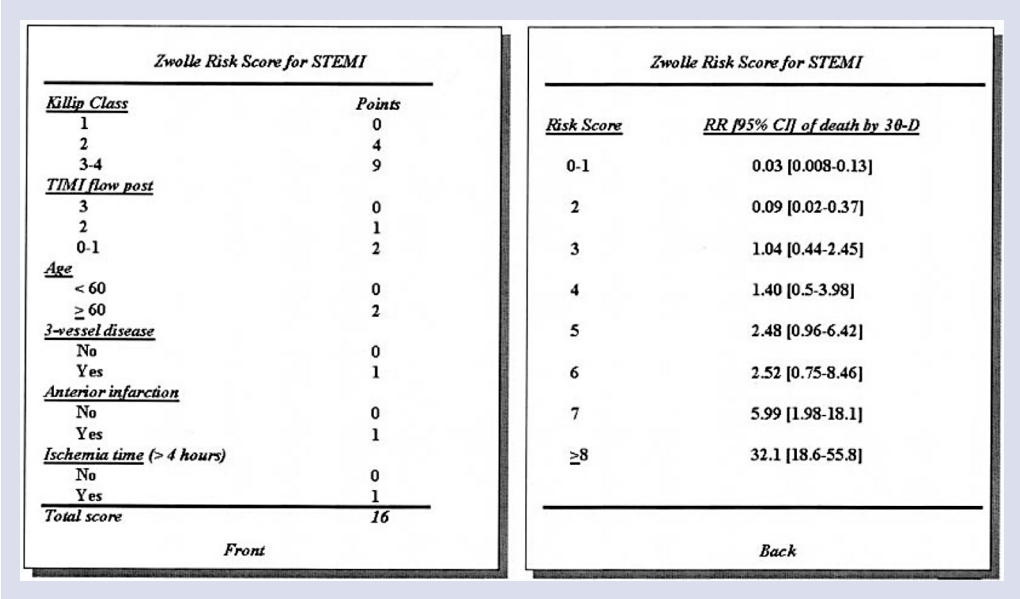

Zwolle Risk Score for STEMI

Killip Class	Points
1	0
2	4
3-4	9
TIMI flow post	
3	0
2	1
0-1	2
Age	
< 60	0
≥ 60	2
3-vessel disease	
No	0
Yes	1
Anterior infarction	
No	0
Yes	1
Ischemia time (> 4 hours)	
No	0
Yes	1
Total score	*16*

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Zwolle Risk Score for STEMI

Risk Score	RR [95% CI] of death by 30-D
0-1	0.03 [0.008-0.13]
2	0.09 [0.02-0.37]
3	1.04 [0.44-2.45]
4	1.40 [0.5-3.98]
5	2.48 [0.96-6.42]
6	2.52 [0.75-8.46]
7	5.99 [1.98-18.1]
≥8	32.1 [18.6-55.8]

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Figure 1. Zwolle scores of selected risk factors (Source: Circulation, 2004; 109: 2737–2743)

WHAT DETERMINES THE RISK FOR STEMI PATIENTS?

In-hospital mortality of ST elevation myocardial infarction (STEMI) patients observed in Europe ranges between 6% and 14% [1]. 12% of patients die within six months after infarction [2]. For that reason, attempts are made to define the group of high-risk patients who should be covered by enhanced care [3]. Studies indicate that STEMI-associated mortality depends on various factors. Several scales based on parameters that are easy to assess during the acute phase before reperfusion have been developed [4–6]. Clinical indexes of high risk during the acute phase are: advanced age, history of tachycardia, hypotension, Killip class II–IV, anterior wall infarction, past MI, coexistence of diabetes, renal failure, and heart failure. Also, delayed treatment, existence of multi-vessel coronary disease, reduced left ventricular ejection fraction (LVEF), dangerous ventricular arrhythmias, persistent chest pain, and early post-MI angina are associated with less favourable outcome.

On the other hand, definition of low-risk patients is important, because those patients could be monitored for shorter periods of time, earlier mobilised, their hospital stay duration could be reduced, and soon after MI they could return to normal physical, social, and professional activity. Identification of those patients may be facilitated by the criteria of the Primary Angioplasty in Myocardial Infarction II study (PAMI-II) or Zwolle primary percutaneous coronary intervention (PCI) index [7, 8]. According to the PAMI-II criteria, the group of low-risk patients involves individuals under the age of 70 years, with LVEF over 45%, with a single- or double-vessel disease, post successful primary PCI, and with no persistent arrhythmia. The Zwolle risk index was developed based on the 30-day mortality in a group of 1791 STEMI patients treated with primary PCI. The following risk factors were selected: age, Killip class, MI of the anterior wall, duration of ischaemia, multi-vessel coronary disease, and thrombolysis in myocardial infarction (TIMI) flow (Fig. 1). Patients with a Zwolle index score of 3 or less are qualified as low-risk patients.

ABORTED MYOCARDIAL INFARCTION — A DEFINITION

The basic aim of treatment of STEMI is reperfusion, i.e. restoration of blood flow in the occluded coronary artery, as early and as completely, as possible. An effective reperfusion allows avoidance of necrosis of the myocardium, or limiting of its extent, to improve the prognosis in both the acute phase and in long-term follow-up. During the era of pharmacological fibrinolysis, as a standard reperfusion treatment, it was noted that in approximately 10% of patients biochemical markers of myocardial necrosis are not released, despite the existence of a typical evolution of changes in the electrocardiogram (ECG). To describe that group of patients a definition of aborted myocardial infarction (abMI) was proposed. It was observed that the ratio of abMI patients was increasing with reduced time of ischaemia and shorter time to introduction of fibrinolytic treatment. Studies indicate that the ratio of abMI cases in the first hour of ischaemia may be as high as 25%. Moreover, patients with diagnosed abMI were characterised by a much more favourable prognosis compared to other MI patients [9–12]. The definition of abMI was based on studies completed in times when pharmacotherapy was the standard method of reperfusion treatment, and it is applicable to fibrinolytic treated patients only. Considering the

fact that at present the majority of STEMI patients are treated with mechanical reperfusion using primary PCI techniques, development of a definition of abMI for that group of patients should be considered. During the fibrinolytic treatment era, abMI was diagnosed in those cases, where reperfusion treatment caused a significant reduction (by at least 50%) of ST elevations, suggesting transmural ischaemia, with the level of released myocardium necrosis markers below the double upper reference limit (URL) for creatine kinase. As determinations of cardiac creatine kinase MB isoenzyme (CK-MB) and troponins were not available at that time, they were not used in the definition. Considering the fact that currently CK-MB and cardiac troponins tests are commonly applied, they should be considered in the definition of abMI for the primary PCI. Although cardiac troponins are a good marker of myocyte necrosis (in that respect they are superior to CK-MB), their other features, including release kinetics and low specificity level, disqualify cardiac troponins as a good marker of a course of MI treated with PCI. According to the third universal definition of MI, a PCI-associated MI is arbitrarily defined as an increase in the biochemical index of myocyte damage (in that case of cardiac troponin) above the level of five times more than normal ($> 5 \times 99^{th}$ percentile of URL) in patients with normal baseline values ($< 99^{th}$ percentile of URL) or an increase in the index by more than 20%, if baseline values were elevated, stable, or dropping [13]. Summing up, we believe that the modern definition of abMI could be the following: abMI is a clinical situation in which, in a STEMI patient treated with mechanical reperfusion, TIMI 3 flow is achieved, there is at least 50% reduction of ST elevations, and no new pathological Q waves appear in post-procedural ECG, with the level of myocardium damage remaining below the level of five times the URL for CK-MB.

THE VALUE OF ENZYMATIC MONITORING IN STEMI PATIENTS TREATED WITH PRIMARY PCI

2012 European Society of Cardiology (ESC) guidelines regarding the treatment of STEMI patients state that 'blood is routinely collected during the acute phase of MI for determination of myocardial necrosis, but introduction of reperfusion treatment should not be delayed up to the point of availability of results of those determinations. Troponin (T or I) is a marker of choice, considering its high sensitivity for myocardial necrosis'. The guidelines say nothing about necessary subsequent routine determinations, except for repeated tests of troponin T or I within 3–6 h, if the first determination gave a negative result. So, according to the guidelines, troponins are an important marker used for confirmation of MI, but not for monitoring its course [14]. Additionally, ESC recommendations regarding myocardial revascularisation, published in 2014, do not change the position presented previously [15]. Current guidelines lack any information concerning necessary constant monitoring of markers of MI necrosis, including troponin and

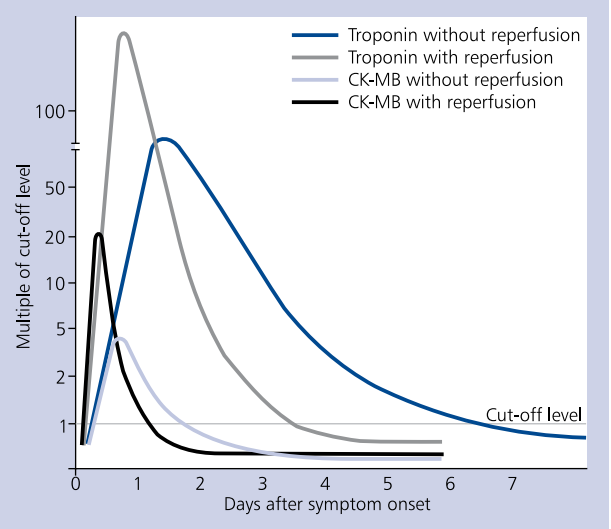

Figure 2. The dynamics of myocardial infarction markers depending on reperfusion (Source: J. Heuser. Self-modified from ACC/AHA Practice Guidelines 2005 p. E52); CK-MB — creatine kinase MB isoenzyme

CK-MB, during patient hospitalisation. Moreover, taking the level of marker enzymes as a basis for hospital discharge has no practical justification. Specifically, a low dynamic of release and normalisation of troponin does not make it suitable for the risk assessment of patients with confirmed STEMI, and it is not included in any risk assessment scales used as a basis for the decision on reduced in-patient time. It is also worth noting that, in the era of routine treatment of STEMI patients with primary PCI, serial CK-MB measurements have also lost their significance. Determination of the level of that enzyme can be still used for the assessment of efficacy and persistence of reperfusion during fibrinolytic treatment (high risk of re-occlusion). In case of mechanical reperfusion, the assessment of its efficacy is made by angiography, and the risk of re-occlusion associated with that therapeutic method is very low (below 3–5%). Considering the fact that an effective mechanical reperfusion with primary PCI causes rapid washout of CK-MB markers of MI necrosis and occurrence of maximum levels of the enzyme within 12 h with subsequent drop within 24 h, repeating the measurement 2–3 times is usually sufficient (Fig. 2).

The use of troponins for monitoring of the course of MI is futile, considering the very slow rate of reduction of the marker's blood level (positive values may persist for as long as two weeks post MI) and its low specificity (high levels noted in case of, e.g., renal failure, lung diseases, cerebral injury, and other conditions). Hence, there are no ESC or Polish Society of Cardiology recommendations regarding extended monitoring of markers after a successful primary PCI, or the decision on early mobilisation and discharge of a patient depending on the measurement. Moreover, there is no basis for associating levels of those markers with the length of hospital stay and

time of discharge. According to the ESC guidelines, increased troponin level is used for confirmation of the diagnosis of MI, and not for the assessment of efficacy of treatment. Determination of maximum levels of marker enzymes is important for the diagnosis, and for the assessment of extensiveness of MI, particularly in scientific clinical trials. In common practice, echocardiographic assessment of the function of left and right ventricle and assessments based on regional contractility disorders are recommended instead of less precise and non-specific enzymatic methods. In cases of complicated MI and the existence of any doubts in the clinical assessment, additional determinations of troponin levels, as well as other markers, including CK-MB, may be performed, but that would depend on the clinical status of the patient and should be ordered for individual patients at the physician's discretion.

IS REDUCTION OF IN-HOSPITAL TIME BELOW 72 H SAFE FOR LOW-RISK STEMI PATIENTS WITH ABORTED MI?

A tendency for reduced in-hospital stay of patients invasively diagnosed and treated for cardiovascular diseases has been observed in recent decades. Some hospitals successfully apply same-day discharge hospitalisation protocols for patients electively treated with coronary or peripheral procedures [16–18]. In Poland, in 2001 newly-formed centres of the American Heart of Poland introduced a model of invasive procedures based on short-term hospital stays. The model was initially opposed by both cardiologists and the insurer (The Silesian Sick Fund). Some very interesting observations may be drawn from the analysis of early and late outcomes of such procedures, compared to the standard of care used at that time [19]. After analysing the population of 5327 patients with stable coronary disease treated invasively with coronary angiography and possibly PCI in Silesian centres of invasive cardiology between January and September 2002, patients were divided into the so-called short hospitalisation group of 1435 patients, who stayed in a hospital for 1.06–1.07 days, and the so-called standard group of 3892 patients with hospital stay of 6.30–7.13 days. Both groups were not different in terms of demographic features, coexisting diseases, and risk factors. Favourable early outcomes confirmed safety of procedures in the short hospitalisation group. Comparison of 180-day data revealed no differences in mortality rate, incidence of MI, cerebral stroke, or repeated revascularisation between groups. Also, patients in the short hospitalisation group were less often re-hospitalised compared to the standard group. It should also be mentioned that patients in the short hospitalisation group were subject to higher risk procedures, concerning a higher rate of multi-vessel PCI (30.7% vs. 15%) and necessary use of platelet blocker IIb/IIIa (29% vs. 13%). The overall analysis, including direct and delayed costs, demonstrated a final positive financial outcome of short hospitalisation for the insurer, totalling 1,190,187 PLN for the nine-month period. In time, the model of the same-day discharge hospitalisation for patients with stable coronary disease, subject to invasive procedures was accepted, copied, and is currently used by many centres all over the country.

That trend applies also to STEMI patients who had been previously hospitalised for several weeks because of MI, and currently their hospital stay has lasted for several days. That is associated with progress in PCI techniques, allowing effective, permanent, and safe reperfusion. Miniaturisation of equipment, modern anti-platelet and anti-thrombotic drugs, and application of the radial access, are associated with reduced risk of bleeding and haemorrhagic complications, with simultaneous reduction of the risk of early in-stent thrombosis. We also possess hard scientific evidence from numerous clinical trials completed in that group of patients, based on which we are currently able to identify high- and low-risk patients and apply an appropriate therapeutic strategy.

However, current ESC guidelines present no clear position regarding the length of hospital stay for STEMI patients. Guidelines provide the following provisions related to the discussed problem: "Patients subjected to successful uncomplicated primary revascularisation should remain in the Intensive Cardiology Care Unit for at least 24 h, and then they may be transferred to a monitored site in a less restrictive care unit for another 24–48 h. The length of hospital stay should be determined individually, considering the medical and social situation of the patient, including his/her health before MI." Therefore, according to the ESC guidelines, duration of hospitalisation for a STEMI patient with low risk of complications (estimated according to clinical parameters using the Zwolle index or PAMI-II) may be less than 72 h. According to the referenced literature, the stay may be within 72 h or approximately 72 h. Therefore, guidelines state clearly the possible discharge of a patient after a time shorter than 72 h (on the second or third day). Moreover, guidelines do not state if reduction of the in-hospital time to less than 48–72 h could be harmful for patients (which would correspond to the recommendation class III) [14].

Recently published study results indicate that the duration of hospital stay of an MI patient has gradually reduced, with no associated rise in mortality rate in later periods, which confirms that early discharge is not associated with higher mortality [20, 21]. Moreover, PAMI-II trial demonstrated that low-risk patients, post successful primary PCI, can be safely discharged on post-procedure day 3, without any non-invasive tests [7]. Generally, early discharge of low-risk patients (within 72 h) is both practically possible and safe in the case of patients with uncomplicated STEMI, post successful primary PCI [7, 8, 20]. Moreover, some publications suggest that in-hospital time may be reduced to less than 48 h. That suggestion is confirmed by clinical practice in leading centres. The CathPCI registry, held in the United States of America, indicates that in 45% of classified hospitals at least half of the patients admitted

because of STEMI are discharged within 48 h from admission [22]. According to the cited publications, referenced also by ESC guidelines, the mean in-hospital time of patients with similar clinical characteristics and STEMI treatment was just 55 h [23]. Reduction of hospitalisation time for patients after a successful primary PCI and with low risk of complications to less than 48–72 h has no negative impact on early or late outcome. Some authors claim that it is even an independent factor increasing the chance for late survival free from cardiovascular events [24, 25].

Those results are consistent with the experience of the authors of this paper. In the group of 127 patients with acute coronary syndrome, who had PCI performed in 2012–2013 in the American Heart of Poland 3rd Cardiology Department in Dabrowa Gornicza and who were discharged to home within less than 72 h, STEMI was diagnosed in 26 individuals (20.5%). In that group of patients, the mean in-hospital time was 50 h and 56 min (similar to data presented in available literature) [23]. Those patients were qualified as low risk according to the Zwolle scale (three points or less), and all of them met the definition of aborted MI proposed by the authors. All patients in the discussed group survived for 30 days, and none of them died because of cardiovascular reasons. A single reported case of death was noted on day 54 after discharge, and was caused by complications of ischaemic cerebral stroke that occurred in week six after MI. Throughout the whole follow-up period, lasting for an average of 30.3 months, survival in the followed group of patients was 96.1%, and major adverse cardiovascular event-free survival was 67.0% (Figs. 3, 4). Serious adverse events, defined as death, MI, cerebral stroke, and repeated revascularisation, occurred eight times. Observed serious adverse events included repeated PCI (four cases), including two cases caused by in-stent restenosis, one case of progression of atheromatous lesions in coronary arteries, and one case of scheduled next stage of revascularisation. Also, one case of coronary artery bypass grafting, one case of vascular surgery on peripheral arteries, and two cases of ischaemic cerebral stroke were observed (Figs. 3, 4).

It is currently believed that reduction of in-hospital time of patients with STEMI successfully treated with PCI to less than 72 h is a positive trend, providing a highly favourable cost-effective index. Low-risk patients, who should be discharged sooner, may be identified using existing tools, including the Zwolle and PAMI-II scales, based on clinical characteristics. Additionally, the authors suggest the definition of patients with abMI successfully treated with primary PCI, who should be qualified as low-risk patients. Extended hospitalisation of low-risk patients is not recommended and is not cost effective, and in some cases it may even translate into worse long-term prognosis. Continued treatment in the home setting is associated with better effects, compared to long-term hospitalisation. The important role of continuous and integrated cardiovascular care should be mentioned, involving a complete revascularisation of the myocardium, electrotherapy, treatment of peripheral atherosclerosis, and cardiology rehabilitation. Coordinated medical care ensures the continuous character of the diagnostic and therapeutic process and improves prognosis for patients post MI. In that context, it is more important than unnecessary extension of hospital stay during the acute phase of myocardial infarction.

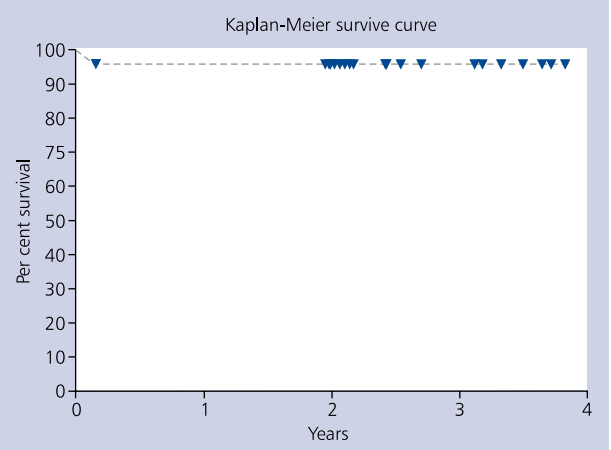

Figure 3. Kaplan-Meier survival (96.1%) in long-term follow-up

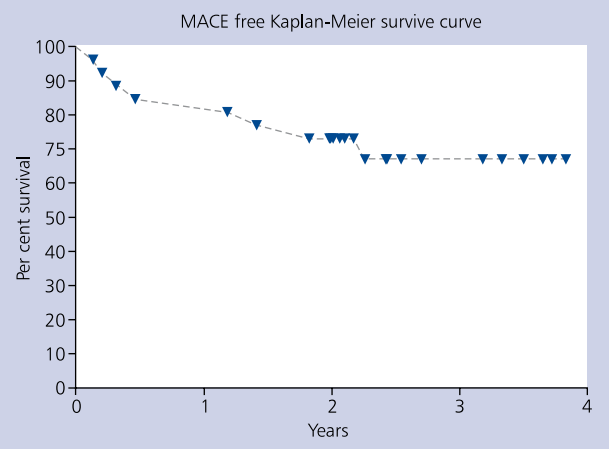

Figure 4. Major adverse cardiovascular event (MACE)-free survival (67%) in long-term follow-up

Conflict of interest: *none declared*

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