Five-year outcome after STEMI in primary PCI era

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This review summarizes the information available from long-term follow-up after ST-elevation myocardial infarction (STEMI) in the primary percutaneous coronary intervention (p-PCI) era. The main aim of this review is to present an overview of long-term overall mortality, cardiac mortality, and major adverse cardiac events (MACE). We searched and analyzed trials with 5-year and longer follow-up periods published from January 2001 to December 2019. Only p-PCI trials were included. Overall mortality at 5-year follow-up was 9.3–23.3 % and annual overall mortality was around 2 % for the years following the first one after STEMI. Cardiac mortality at 5-year follow-up was 4.7–16.0 % and annual cardiac mortality was approximately 1.1–1.5 % for the years following the first one after STEMI. The cumulative incidences of reinfarction at 5-year follow-up, heart failure requiring admission, additional revascularization, and stroke were 5.0–18.0, 4.0–18.5 %, 19.0–37.1 %, and 2.6–8.0 %, respectively. The cumulative incidence of in-stent thrombosis was 2.6 %. The cumulative incidence of restenosis was 7.8 %. The results of the above-mentioned trials suggest a high proportion of cardiovascular deaths and MACE in the long-term follow-up period. With respect to these facts, questions arise as to how to reduce MACE and the possibility of routine use of coronary artery imaging in the follow-up.

Key words: STEMI, primary PCI, long-term, follow-up.

Pětileté výsledky po STEMI v éře primární PCI

Tento přehledový článek shrnuje informace dostupné z dlouhodobého sledování pacientů po infarktu myokardu s elevacemi ST úseku (STEMI) v éře primární perkutánní koronární intervence (p-PCI). Jeho hlavním cílem je poskytnout přehled o dlouhodobé celkové mortalitě, kardiální mortalitě a závažných nežádoucích kardiovaskulárních příhodách (MACE). Vyhledali jsme a analyzovali studie s pětiletým a delším obdobím sledování publikované od ledna 2001 do prosince 2019. Do přehledu jsme zařadili pouze studie týkající se p-PCI. Celková mortalita v pěti letech sledování byla 9,3–23,3 % a roční celková mortalita se v letech, které následovaly po uplynutí prvního roku po STEMI, pohybovala okolo 2 %. Kardiální mortalita v pěti letech sledování byla 4,7–16,0 % a roční kardiální mortalita v letech, které následovaly po uplynutí prvního roku po STEMI, byla přibližně 1,1–1,5 %. Kumulativní incidence reinfarktu v pěti letech sledování byla 5,0–18,0 %, srdečního selhání vyžadujícího hospitalizaci 4,0–18,5 %, další revaskularizace 19,0–37,1 % a cévní mozkové příhody 2,6–8,0 %. Kumulativní incidence trombózy ve stentu byla 2,6 %. Kumulativní incidence restenózy byla 7,8 %. Výsledky výše zmíněných studií svědčí o vysokém procentu kardiovaskulárních úmrtí a MACE během dlouhodobého sledování. Vzhledem k těmto skutečnostem vyvstávají otázky ohledně způsobu snížení výskytu MACE a možnosti rutinního využití zobrazování koronárních tepen v období sledování.

Klíčová slova: STEMI, primární PCI, dlouhodobý, sledování.

List of abbreviations

ACS – Acute coronary syndrome
AMI – Anterior myocardial infarction
CABG – Coronary artery bypass graft
CREDO-Kyoto AMI registry – Coronary Revascularization Demonstrating Outcome Study in Kyoto
CS – Cardiogenic shock
CSC – Czech Society of Cardiology
CVD – Cardiovascular disease
EGFR – Estimated glomerular filtration rate
IHD – Ischemic heart disease
LAD – Left anterior descending
MACE – Major adverse cardiac events
MI – Myocardial infarction
MVD – Multi-vessel disease
NSTEMI – Non-ST elevation myocardial infarction
PCI – Percutaneous coronary intervention
P-PCI – Primary percutaneous coronary intervention

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PTCA – Percutaneous transluminal coronary angioplasty
Re-PCI – Recurrent percutaneous coronary intervention
SCAAR – Swedish Coronary Angiography and Angioplasty Registry
SD – Standard deviation
STEMI – ST-elevation myocardial infarction
SVD – Single-vessel disease

Introduction

Cardiovascular diseases (CVD) are a leading cause of death worldwide. It is estimated that 17.9 million people died of CVD in 2016, which accounts for 31 % of all global deaths. Of these deaths, 85 % are due to myocardial infarction and stroke. Over three quarters of CVD deaths take place in low – and middle-income countries. Coronary artery disease and acute coronary syndromes can be partially prevented by a healthy lifestyle (2). With regard to the high level of standard of living, the issue of obesity as one of the crucial factors influencing CVD risk is increasing. This problem goes hand in hand with the prolonging life expectancy, which increases the risk of CVD. It is estimated that 23.6 million people worldwide will die of CVD by 2030 (4). In terms of CVD, ischemic heart disease is the most common cause of death worldwide. It causes more than 20 % of all deaths in Europe (1). Of major concern is the current trend of decreasing age at manifestation of the first cardiovascular event. Based on recent trials, patients with ST-elevation myocardial infarction (STEMI) are getting younger (5, 12) and have more comorbidities (12). If we focus on the Czech Republic, results from the CZECH-2 registry demonstrate that the estimated incidence of confirmed acute coronary syndromes (ACS) was 2,149 cases per one million population per year. The estimated incidence of confirmed myocardial infarction (MI) was 1,680 cases per one million population per year, and the estimated incidence of STEMI was 661 cases per one million population per year (3). Due to better diagnostic tools and treatment options, increasingly more patients survive the first episode of acute coronary syndrome. Given the high incidence among people of productive age, there are not only medical, but also severe socioeconomic consequences.

There has been a major progress in the treatment of STEMI in the last few decades. Percutaneous transluminal coronary angioplasty (PTCA) was carried out for the first time in 1977 by Andreas Gruentzig in Zurich, Switzerland. This was the beginning of interventional cardiology as we know it now.

According to the recent recommendations of the Czech Society of Cardiology (CSC) (2017), primary percutaneous coronary intervention (p-PCI) is the first-line therapy for acute STEMI, if possible (1A) (13). Percutaneous coronary intervention (PCI) is commonly used as a measure in secondary prevention of adverse cardiac events due to significant stenosis of coronary arteries. With respect to the facts above, recurrence of CVD might be partially preventable with timely intervention, and close follow-up of patients after STEMI is necessary. At the moment, there is plenty of information on major adverse cardiac events (MACE) in short-term follow-up, but lack of information on long-term follow-up five years and more after STEMI. An evaluation of the endpoints of this review may open a discussion on leading to optimization of care in these high-risk post-STEMI patients.

In this review article, we would like to summarize the results of the studies focused on the long-term outcome five or more years after primary PCI for STEMI, and assess the current follow-up strategy in patients after STEMI.

Methods

Data source

We searched the PubMed and Cochrane Library databases for articles published from 1 January 2001 to 31 December 2019 using the key words „STEMI", „long-term follow-up", „5 years", and „primary PCI". All the articles were published in English. Disagreements were solved through discussion.

Review selection and eligibility criteria

We included all trials with at least a 5-year follow-up after p-PCI for STEMI, while the other ACS were excluded. Trials with a shorter follow-up period were excluded. The primary endpoint was the overall mortality at 5-year follow-up. The secondary endpoint was the cardiac or cardiovascular mortality at 5-year follow-up. A tertiary endpoint was MACE at 5-year follow-up. MACE of interest were reinfarctions, additional revascularization (repeat percutaneous coronary intervention (re-PCI)), coronary artery bypass graft (CABG), heart

Tab. 1. *Five-year outcome after STEMI in p-PCI era*

Title	Author		Trial characteristics					MACE – non-fatal cumulative incidence					Mortality	
		Number of patients	Age	Length of follow-up (months)	Symptom to p-PCI (mean)	AMI	CS	Women	Recurrent infarction	Heart failure	Additional revascularization	Stroke	5-year overall	5-year cardiac
7	Parodi, G.	1009	63.0	51.0	3.2 hours	52.0 %	13.0 %	23.0 %	5.0 %	4.0 %	19.0 %	NA	20.0 %	16.0 %
8	Wang, F.	2346	64.3	74.4	6.3 hours	40.8 %	NA	29.3 %	NA	10.6 %	NA	NA	18.8 %	5.6 %
9	Fokkema, M. L. (STEMI only)	22126	66.8	39.0	NA	NA	NA	29.3 %	18.0 %	18.5 %	NA	NA	20.0 %	NA
10	Pedersen, F.	2804	62.7	56.4	3.8 hours	46.4 %	5.0 %	28.5 %	NA	NA	NA	NA	23.3 %	13.8 %
11	Yamashita, Y.	3942	67.6	60.5	4.2 hours	46.0 %	15.0 %	26.0 %	6.2 %	8.5 %	37.1 % total 3.1 % CABG 34.0% re-PCI	6.1%	20.4 %	12.2 %
14	Widimsky, P. (P-PCI only)	429	65.0	60.0	NA	41.0 %	NA	30.0	12.0 %	NA	34.0 % total 12.0 % CABG 22.0 % re-PCI	8.0%	19.0 %	NA
15	Kozieradska, A.	505	58.6	63.6	NA	42.9 %	NA	24.5 %	NA	NA	NA	NA	21.0 %	NA
17	Cui, K.	1205	60.0	60.1	5.0 hours	38.2 %	10.0 %	20.7 %	V	NA	22.8 %	2.6 %	9.3 %	4.7 %

failure, and stroke as significant factors influencing patient prognosis. The definition of anterior myocardial infarction (AMI) included patients with both anterior lead ST-elevations and left anterior descending (LAD) artery occlusion. Cardiogenic shock (CS) and Killip class IV heart failure were evaluated together. The length of follow-up was converted to months for all trials. All results were reported to the first decimal place, if possible.

Endpoints were extracted from different studies as their common targets. Endpoints were focused on 5-year outcome. The overall mortality, cardiac mortality, recurrent infarction, revascularization, and stroke were defined individually in each trial. Heart failure was defined as cardiac decompensation requiring admission to hospital. Restenosis was defined as a > 50 % stenosis of a previously stented segment.

The statistical analysis was as follows. Continuous variables were presented as mean or median. Categorical variables were presented as counts and percentages. The weighted arithmetic mean was calculated for individual endpoints.

Results

The following are the results of trials with a reported ***5-year outcome after STEMI in the primary PCI era***. A summary of these trials is presented in Table 1.

Parodi et al. reported one of the first results of long-term outcome after p-PCI for STEMI. Their prospective trial included 1,009 patients treated with p-PCI who were followed for 51.0 months as the mean period. The mean age of this cohort was 63.0 years and 23.0 % were women. The symptom-to-PCI time was 3.2 hours. Anterior myocardial infarction (AMI) occurred in 52.0 %, and 13.0 % of patients suffered from cardiogenic shock (CS). The overall mortality at 51.0 months in this trial was 20 %, and cardiac mortality was 16.0 %. Non-fatal reinfarction rate during this period was 5.0 %, and additional revascularization procedure rate was 19.0 %. Hospitalization for heart failure was required in 4.0 % of patients during the 5-year follow-up (7).

Wang et al. evaluated the impact of cancer on long-term overall mortality and cardiovascular outcome. This retrospective study enrolled 2,346 patients along with a cohort of 263 patients with a history of cancer; we present the overall results. For the purpose of this review, the data mentioned are computed from the cohort of 2,346 patients. For a better overview, the weighted arithmetic mean was calculated for individual endpoints. The median of the clinical follow-up was 74.4 months, and the mean age was 64.3 years. Women accounted for 29.3 %. The symptom-to-PCI time was 6.3 hours. Patients suffering from AMI accounted for 40.8 %. No data regarding patients in CS were reported. The overall mortality at 5-year follow-up was 18.8 %, and cardiac mortality was 5.6 %. The cumulative incidence of heart failure was 10.6 %. The overall mortality at 5-year follow-up in patients after primary PCI for STEMI with a history of cancer was approximately twice as high as that in the control group when compared to cardiac mortality, which was similar in the two groups (8).

Fokkema et al. evaluated the largest dataset from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR). This registry gathers information from all catheterization laboratories in Sweden. Data were collected prospectively, offering us a possibility of multicenter evaluation of cardiovascular outcome. With respect to these facts, a clinical outcome of up to 6 years was evaluated from the SCAAR. Out of a total of 70,479 patients, 22,126 (31.4 %) were treated for STEMI, and this subgroup was included in our analysis. The median follow-up was 39.0 months. The mean age was 66.8 years and women accounted for 29.3 %. No data regarding patients with AMI and CS were reported. The overall mortality rate at 5-year follow-up was 20.0 %. The cumulative incidences at 5-year follow-up of myocardial infarction, in-stent-thrombosis, restenosis, and heart failure were 18.0 %, 2.6 %, 7.8 %, and 18.5 %, respectively (9).

Pedersen et al. published the results of a long-term prospective trial from Denmark's registries. This trial enrolled 2,804 patients treated with p-PCI for STEMI. The median of the clinical follow-up was 56.4 months, and the mean age was 62.7 years. Women accounted for 28.5 %. The symptom-to-PCI time was 3.8 hours. The occurrences of AMI and CS were 46.3 % and 5.0 %, respectively. Beyond 30 days, the annual cardiac mortality rate was < 1.5 %; the weighted mean was 1.35 %. The causes of death that occurred after 30 days were non-cardiac in 65 % of cases (mainly malignancies and pulmonary diseases). The 5-year all-cause and cardiac mortality rates were 23.3 % and 13.8 %, respectively. The patients who survived the first month after STEMI treated with primary PCI had an excellent prognosis. Non-cardiac causes were responsible for the majority of later deaths in these patients (10).

Yamashita et al. published the results of a retrospective trial from the CREDO-Kyoto AMI registry and assessed the 5-year outcome of 3,942 patients enrolled. The median of the clinical follow-up of this cohort was 60.5 months, and the mean age was 67.6 years. Women accounted for 26.0 %. The symptom-to-PCI time was 4.2 hours. The occurrences of AMI and CS IV were 46 % and 15 %, respectively. The CREDO-Kyoto AMI registry evaluated both short-term (within 6 months) and long-term (beyond 6 months) incidences and causes of deaths. Non-fatal reinfarction rate at 5-year follow-up was 6.2 %, heart failure rate was 8.5%, additional revascularization procedure rate was 37.1 %, and stroke rate was 6.1 %. The cumulative 5-year incidence of all-cause death in the current study population was 20.4 %, cardiac death occurred in 12.2 %, and non-cardiac death in 9.4 %. The independent risk factors of all-cause death were advanced age, previous heart failure, renal dysfunction, and liver cirrhosis beyond 6 months after STEMI. In STEMI patients who underwent primary percutaneous coronary intervention, the long-term risk for cardiac death was relatively low compared to that for non-cardiac death, which was responsible for nearly two-thirds of all-cause deaths beyond 6 months (11).

Widimsky et al. in the PRAGUE-2 trial compared the outcomes in patients after p-PCI with those after thrombolytic therapy. The data published clearly demonstrated the superiority of p-PCI in STEMI patients to thrombolytic therapy. This prospective trial enrolled 850 patients, and 429 of them were in the p-PCI cohort and were included in our review. The patients were followed for 60.0 months as the mean period. The mean age of this cohort was 65 years and 30.0 % were women. AMI occurred in 41.0 %. No data regarding patients

in CS were reported. During the follow-up, the cumulative incidence of the composite endpoint (death from any cause or recurrent infarction or stroke or revascularization) was 40.0 % in p-PCI patients. The respective cumulative incidence of death from any cause was 19.0 %, recurrent infarction was 12.0 %, stroke was 8.0 %, and revascularization was 34.0 % (14).

Kozieradska et al. evaluated the long-term outcome in a retrospective trial in a cohort of 505 patients treated with p-PCI for STEMI. The median of the clinical follow-up of this cohort was 63.6 months; the mean age was 58.6 years. Women accounted for 24.5 %. AMI occurred in 42.9 %. No data regarding patients in CS were reported. The primary aim of this analysis was to assess the usefulness of the GRACE, TIMI, Zwolle, and CADILLAC risk scores for predicting 5-year mortality in patients after p-PCI for STEMI. The GRACE, TIMI, and Zwolle scoring systems had a good predictive value for mortality during a 5-year follow-up in patients treated with p-PCI for STEMI. For the purpose of this review article, only long-term outcome was of interest. The 5-year overall mortality was 21 % (15).

Cui et al. focused their trial on a significant proportion of patients suffering from multivessel disease (MVD). The strategies of staged p-PCI and culprit-only p-PCI were compared in this retrospective trial. This trial enrolled a total of 1,205 patients; 576 of them had staged p-PCI and 629 had culprit-only p-PCI. For the purpose of this review article, the weighted mean was calculated for all analyzed endpoints. The mean of the clinical follow-up was 60.1 months; the mean age was 60.0 years. Women accounted for 20.7 %. The symptom-to-PCI time was 5.0 hours. The occurrence of AMI was 38.2 %. The occurrence of CS was 10.0 %. Overall, staged complete revascularization was associated with a lower risk of MACE. The cumulative incidence of reinfarction was 6.7 %, additional revascularization was 22.8%, stroke was 2.6 %, overall mortality was 9.3%, and cardiac mortality was 4.7 %, all at 5-year follow-up (17).

Discussion

The long-term outcome at five and more years in patients who experienced STEMI has not yet been evaluated widely. Only a limited number of studies are available at the moment, the results of which are summarized from the perspective of individual endpoints below.

Reinfarction

The incidence of reinfarction was observed in a wide range from 5.0 % to 18.0 % (7, 9, 11, 14, 17). Recurrent infarction was defined individually in each trial. The wide range of results was probably caused by different definitions and laboratory examinations used (creatine kinase, troponin, different sensitivity levels of troponin testing in time, etc.). The facts above confirm that a significant portion of patients underwent re-PCI or CABG at 5-year follow-up after STEMI. With respect to the facts observed, we suppose that a closer follow-up with routine or selective use of coronary imaging has the potential to reduce the incidence of adverse cardiac events.

Heart failure

Heart failure was defined as cardiac decompensation, requiring admission to hospital. The incidence of heart failure was observed in a wide range from 4.0 % to 18.5 % (7, 8, 9, 11). A detailed assessment of this MACE was, in fact, problematic: 1) further details of echocardiographic follow-up were not available; 2) we were unable to evaluate what was responsible for cardiac decompensation – whether it was a higher demand on cardiac output (infectious diseases, etc.) or worsening of ejection fraction as a result of CAD progression, or valvular heart disease; 3) simultaneously, we had no data on the severity of heart failure. We suppose that clinical follow-up did include echocardiography, but no data are reported.

Additional revascularization

Revascularization was defined individually in each trial. The total amount of additional revascularization was also observed in a wide range from 19.0 % to 37.1 % (7, 11, 14, 17). When CABG and PCI are compared, re-PCI is a more common method of revascularization ranging from 22.0 % to 34.0 % (11, 14), opposed to CABG with a range from 3.1 % to 12.0 % [11, 14]. It is probably partially caused by older age in this cohort of patients. We suppose that they were less frequently indicated for CABG due to characteristics of culprit lesions suitable for PCI, comorbidities, and a lower chance to benefit from open cardiac surgery.

Stroke

Stroke was also observed in a wide range from 2.6 % to 8.0 % of patients [11, 14, 17]. Ischemic stroke is related to atherosclerotic progression in the arteries. Patients with diffuse atherosclerotic disease of cerebral arteries may benefit from secondary prevention focused on decreased hypertension treatment and aggressive hypolipidemic treatment. Due to a similar pathologic cause, intensive and well up-titrated drug treatment of CVD may lead to minimization of ischemic stroke. Simultaneously, we have no data for a proportion of cerebrovascular adverse events based on cardioembolism and hemorrhage.

Overall mortality

The primary endpoint of this article is all-cause mortality at 5-year follow-up. The overall mortality ranged from 9.3 % to 23.3 % in our review (7, 8, 10, 11, 14, 15, 17). Mortality data are consistently around 20.0 % in all studies except the trial by Cui et al., with no obvious explanation (17). The annual risk of mortality beyond 1 year after STEMI was around 2.0 % per year (11, 16). Five trials reported a cause-of-death analysis (7, 8, 10, 11, 17), and cardiovascular mortality was the most important cause of death in the first year after STEMI. The cause of death beyond 1 year after STEMI was mostly non-cardiac, predominantly cancer and pneumonia. The 1-year all-cause mortality after STEMI ranged from 7.3 % to 11.4 % (7, 10, 11, 16), and 1-year cardiovascular mortality after STEMI was from 5.6 % to 9.3 % (7, 10, 11, 16).

Cardiac mortality

Cardiac mortality at 5-year follow-up was observed in a wide range from 4.7 % to 16.0 %. Similar results were found in trials (7, 10, 11) opposed to (8, 17). With respect to the methods of research, for example, trials (8, 17) included only cardiac mortality opposed to trial (7). Parodi et al. defined cardiac death as a death considered to be of cardiac origin unless a non-cardiac cause was established

clinically or at necropsy. The annual cardiac mortality in patients who experienced STEMI was approximately from 1.1 % to 1.5 % (10, 11). It demonstrates that close follow-up in patients with STEMI is effective and leads to a decrease in significant cardiac damage. The results above imply a significant proportion of cardiovascular complications and deaths in the long-term outcome.

Predictors of long-term mortality

The important risk factors are advanced age ≥ 75 years, previous heart failure, diabetes mellitus, renal dysfunction with eGFR < 60 ml/s, prior PCI, cardiogenic shock, delayed treatment of STEMI < 360 minutes, and liver cirrhosis [11, 16]. Patients with cancer have a 5-year cardiac mortality similar to that of the non-cancer control group (8).

The time from symptom to p-PCI

The time delay from symptom onset to p-PCI was observed in a wide range from 3.2 to 6.3 hours (7, 8, 10, 11, 17). It may have been caused by different education of patients during the emergency call and by a different density of the network of heart centers with catheterization laboratories in each country. The issue of health insurance may also play a significant role. Uninsured or poorly insured patients may try to delay the emergency call. No obvious correlation between long-term mortality and the time from symptom to p-PCI was observed.

Areas of possible further research

A really long-term follow-up beyond 5 years after STEMI treated with p-PCI is poorly described. No intervention studies of high-risk patients have been performed, and especially no repeat information regarding the status of coronary arteries several years post p-PCI has been reported. This information may provide us with the possibility to focus on long-term follow-up more intensively in high-risk groups of patients with the aim of achieving a further reduction in mortality and MACE.

Limitations

The most obvious limitation of our review is the lack of uniform definitions among the studies included. Different inclusion periods may affect the standard of medical care, and the use of cardioprotective medication was not included in our analysis. Similarly, different stents were likely used in different studies with a potential to affect the rate of restenosis (bare-metal versus drug-eluting stents) as well as the rate of reinfarction/stent thrombosis (first-generation versus second – or third-generation drug-eluting stents). However, the data from the SCAAR registry are relatively recent (patient inclusion period from 2006 till 2010) and the overall mortality in this large and well-conducted trial is remarkably similar to most other studies included.

Conclusion

The overall long-term mortality after STEMI remains high, around 20.0 % at 5-year follow-up, even in the current era of primary PCI. Cardiovascular morbidity (re-infarction, heart failure, additional revascularization or stroke) is also significant. Further effort aimed at this high-risk population is required.

Conflict of interest: Dr. Kočka reports consulting for Medtronic, Abbott Vascular, B Braun, Philips.

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