What has changed in the treatment of ST-segment elevation myocardial infarction in Poland in 2003–2009? Data from the Polish Registry of Acute Coronary Syndromes (PL-ACS)

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Abstract

Background: A substantial progress has been made in Poland in the field of acute coronary syndromes (ACS) management over the last 10 years.

Aim: To present the data from the Polish Registry of Acute Coronary Syndromes (PL-ACS) collected between 2003 and 2009. Changes in treatment strategies and outcomes in ST-segment myocardial infarction (STEMI) were analysed.

Methods: We analysed patients enrolled to the PL-ACS Registry — a nationwide multicenter, prospective observational study of consecutive patients hospitalised with ACS in Poland.

Results: Overall, 284,162 patients with ACS were enrolled in 512 centres including 88 invasive cardiology centres. The STEMI was diagnosed in 35–36% of these patients in 2003–2005, and this proportion remained stable at 30% to 32% in 2006–2009. The mean age of STEMI patients increased from 62.5 years in 2003 to 64.5 in 2009. During this period, women represented 32.7% to 34.6% of the STEMI patients. Proportion of patients presenting with pulmonary oedema or cardiogenic shock decreased with time, from 15.5% in 2003 to 8% in 2009. Delays to reperfusion tended to reduce over time: pain-to--admission time was 240 min in 2005 and 229 min in 2009 and door-to-balloon time was 32 and 25 min in 2005 and 2009, respectively, with the delay being longer in the elderly population. The proportion of patients undergoing coronary angiography showed a constant increase, from 55% in 2003 to 84% in 2009. Percutaneous coronary intervention was performed in 51% and 78% of patients in 2003 and 2009, respectively. At the same time, the proportion of patients undergoing thrombolysis declined from 14% to 1%. Aspirin, beta-blocker, statin and ACE inhibitor use was constantly high, while nitrate use declined from 82% to 15%. The proportion of patients receiving clopidogrel increased from 40% to 97% over the analysed period. Significant reductions in mortality rates were observed: in-hospital mortality decreased from 11.9% to 6.4%; 30-day mortality from 13.5% to 9.6%; and 12-month mortality from 19.8% to 15.4% in 2003 and 2009, respectively. Invasive treatment strategy was associated with better in-hospital and long-term patient survival.

Conclusions: The PL-ACS Registry results demonstrate low short- and long-term mortality rates in STEMI patients, mainly due to frequent use of interventional strategy, satisfactory logistics and appropriate drug therapy used. As a consequence, hospitalisation time has shortened. However, there are several issues that need to be improved such as shortening of pre--hospital delays and increasing the rate of invasive treatment in patients presenting with cardiogenic shock.

Key words: ST-segment elevation myocardial infarction, treatment strategy, primary percutaneous coronary intervention, temporal trends, 12-month mortality

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INTRODUCTION

During the last 10 years, cardiology in Poland has made a great progress which is particularly evident in the treatment of acute coronary syndromes (ACS). In the 1990s, the most common reperfusion therapy in ST segment elevation myocardial infarction (STEMI) was thrombolytic treatment that was used in about 40–50% of STEMI patients. Mechanical reperfusion therapy, i.e. percutaneous coronary interventions (PCI), was used in only few centres, of which only the Zabrze centre provided 24-h PCI coverage. A major change occurred following a meeting of Polish cardiac catheterisation lab directors with National Health Fund managers that took place in Zabrze in February 2001. During this meeting, a strategy of financing ACS treatment in Poland was presented by Dr Andrzej Sośnierz, the director of the regional Silesian National Health Fund branch. In 2010, there were 120 cardiac catheterisation labs throughout Poland providing 24 h a day, 7 days a week coverage. As a result, all patients with STEMI in Poland can be transferred to a specialised centre within 60 min. With technological and organisational advances, Poland is now one of the countries at the European forefront of acute MI care [1]. In view of a relatively low per capita income in Poland compared to the old European Union countries, this success is even more outstanding [1]. Since 2003, the Polish Registry of Acute Coronary Syndromes (PL-ACS) is run by the Silesian Centre for Heart Diseases in Zabrze, with funds provided by the Ministry of Health of Poland and organisational support of the National Health Fund. Overall, data on nearly 300,000 patients hospitalised due to ACS have been collected.

The purpose of the study was to present the data from the PL-ACS Registry collected between 2003 and 2009 and analyse changes in patient population, treatment strategies, and in-hospital and long-term outcomes that occurred in this period.

METHODS
Polish Registry of Acute Coronary Syndromes (PL-ACS)

We used data from the PL-ACS Registry, with the methodology and the results obtained in the first 100,193 patients described previously [2]. In summary, the PL-ACS Registry is an ongoing, nationwide, multicentre, prospective, observational study of consecutively hospitalised patients among the whole spectrum of ACS in Poland. It was a joint initiative of the Silesian Centre for Heart Diseases and the Ministry of Health of Poland. Logistic support was obtained from the National Health Fund which is a nationwide public health insurance institution in Poland providing health insurance for all Polish citizens. The pilot phase of the registry commenced in October 2003 in the Silesia region. In the following months, further regions joined the registry and since June 2005, all regions in Poland contribute data for the PL-ACS Registry.

Hospitals were invited to enter the registry if they had one of the following wards: coronary care unit, cardiology, cardiac surgery, internal medicine or intensive care unit, or if they did not have any of these wards but hospitalised at least 10 ACS patients per year.

Detailed protocol was prepared before the registry was started, with inclusion and exclusion criteria, methods and logistic issues, and definitions of all fields in the registry dataset. It was later revised twice. In May 2004, the definitions were adapted to be compatible with the Cardiology Audit and Registration Data Standards (CARDS) [3]. Nevertheless, the PL-ACS Registry case report form (CRF) covers only a part of the CARDS dataset. The second revision was distributed to the hospitals in May 2005 together with addition of new fields to the CRF which included the exact dates and times of the onset of symptoms, coronary angiography and PCI procedures.

Study population

According to the protocol, all admitted patients with suspected ACS were screened to be eligible to enter the registry but they were not enrolled until the diagnosis of ACS was confirmed. The patients were then classified as having unstable angina, non-ST-segment MI (NSTEMI) or STEMI. The STEMI was defined as the presence of both: 1) ST-segment elevation of ≥ 2 mm in contiguous chest leads consistent with infarction and/or ST-segment elevation of ≥ 1 mm in 2 or more standard leads or new left bundle branch block, and 2) positive markers of cardiac necrosis. If a patient was hospitalised during the same ACS in more than one hospital (transferred patient), all hospitals were required to complete the registry data. These hospitalisations were linked together during data management and were analysed as one ACS.

Data collection

Data were collected by skilled physicians who were in charge of particular patients. They were entered either directly into electronic CRF or printed CRF was used temporarily before putting data into electronic CRF. Internal checks for missing or conflicting data and values markedly out of the expected range were implemented by the software. Further edit checks were applied if necessary in the data management and analysis centre in the Silesian Centre for Heart Diseases.

All-cause mortality data with exact dates of deaths were obtained from the National Health Fund. Data on vital status at 12 months following STEMI were available for all patients enrolled in the study.

Statistical methods

Continuous variables are reported as means ± SD (age) or medians and interquartile ranges (pain-to-admission time, door-to-balloon time, and hospitalisation time). Categorical variables are expressed as percentages. Due to substantial differences in baseline characteristics, patients with STEMI

Figure 1. Proportions of different acute coronary syndromes diagnoses in the subsequent years; STEMI — ST-segment elevation myocardial infarction; NSTEMI — non-ST segment elevation myocardial infarction; UA — unstable angina

treated invasively were matched to patients treated non-invasively by means of the propensity score method and one-year mortalities were calculated in the matched subgroups of patients. A two-sided p value of ≤ 0.05 was considered significant. All calculations were performed using the STATISTICA 7.1 software (StatSoft, Inc., Tulsa, OK, USA).

RESULTS

In 2003–2009, data on 284,162 patients with the diagnosis of ACS were entered into the registry. These data we collected in 512 centres in Poland, including 88 invasive cardiology units and 424 non-invasive units.

The proportion of STEMI patients among all ACS patients decreased slightly in 2004–2010, while the proportion of NSTEMI increased nearly twice during the same period (Fig. 1). When we analysed data from the three voivodeships that provided the most systematic data (the śląskie, opolskie, and kujawsko-pomorskie voivodeships), verified these data using regional National Health Fund data, and extrapolated these results for the whole country, the number of patients hospitalised due to STEMI in Poland in 2004 was about 48,000, i.e. 1247/million per year, and in 2009 it was 42,000, i.e. 1091/million per year.

In the analysed period, the mean age of patients hospitalised due to STEMI increased from about 62.5 years to nearly 64.5 years in 2009, with no significant changes since 2005 (Fig. 2). The proportion of women remained constant throughout the study period (Fig. 3), while the proportion of patients diagnosed with diabetes or arterial hypertension increased. In addition, STEMI patients were more frequently previously treated with coronary angioplasty. In contrast, STEMI is less frequently diagnosed in recent years in patients with previous MI or coronary artery bypass grafting. The proportion of STEMI patients presenting with cardiogenic shock and//or pulmonary oedema decreased markedly (Fig. 4).
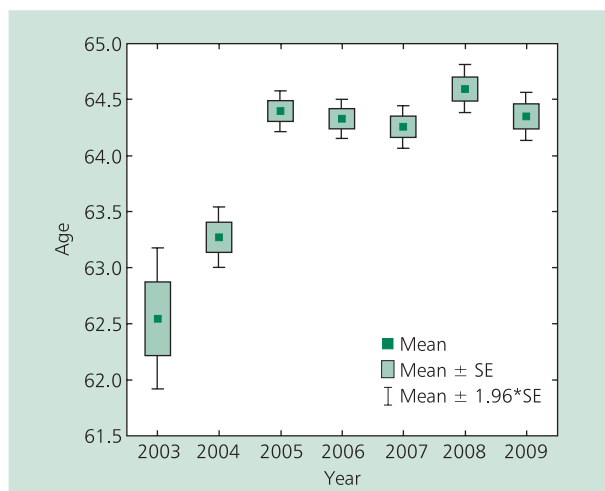

Figure 2. Mean age of patients hospitalised due to STEMI in 2003–2009

In recent years, thrombolytic therapy was virtually unused, with less than 1% of patients receiving this treatment in Poland in 2009. The most commonly used treatment is coronary angioplasty. In 2003, coronary angiography was performed in 55% of patients hospitalised with STEMI, compared to 84% of patients in 2009. The PCI was performed in 51% and 78% of patients, respectively (Fig. 5).

In 2003–2009, pain-to-arterial catheterisation time decreased by about 10 min, and overall in-hospital delay by 8 min (Fig. 6).

In addition to aspirin, clopidogrel is the mainstay of antiplatelet therapy in nearly all patients undergoing invasive treatment and in more than 90% of patients managed conservatively (Figs. 7–9). A 600 mg clopidogrel dose was used in 70% of STEMI patients, most commonly several hours before PCI. Other analysed medications including beta-
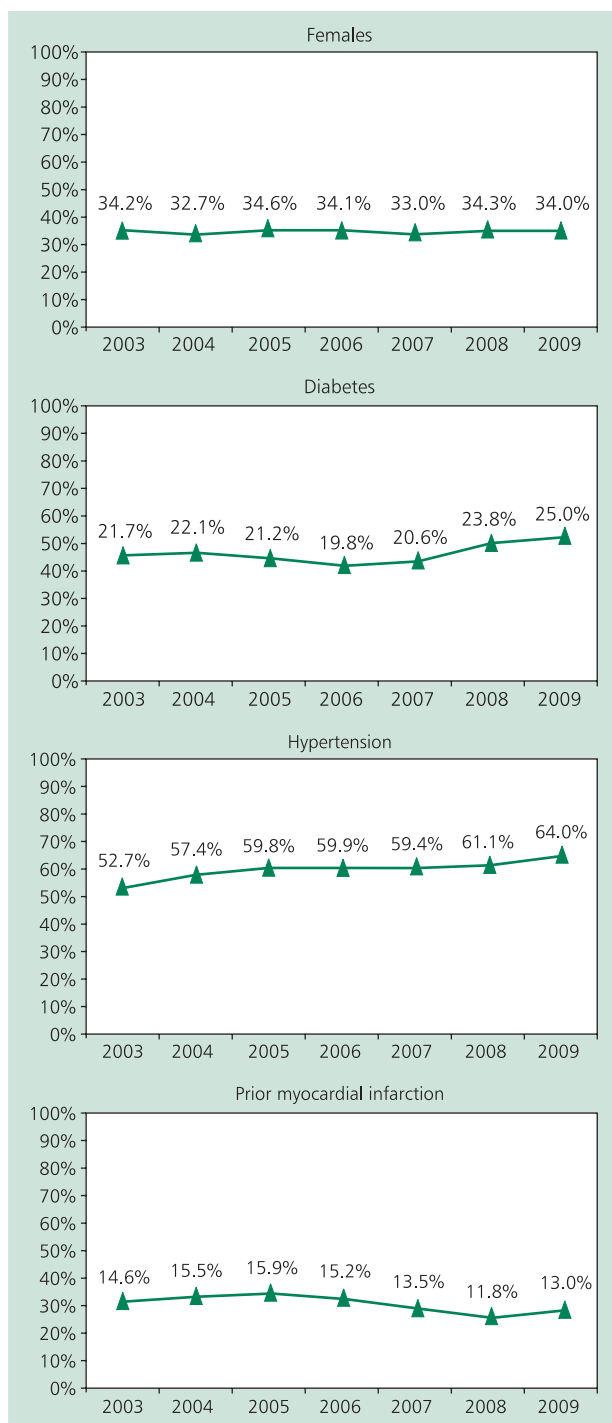
Figure 3. Characteristics of patients hospitalised due to STEMI in 2003–2009

-blockers, ACE inhibitors and statins were used in 70–80% of patients. Use of nitroglycerin shows a constant decreasing trend (Fig. 10).

Significant in-hospital, 30-day, and one-year mortality reductions were observed in 2003–2009 (Fig. 11). In-hospital mortality in the invasively treated patients did not change

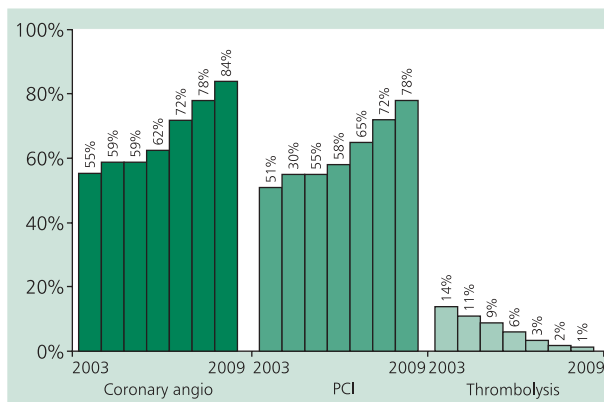Figure 4. Characteristics of patients hospitalised due to STEMI in 2003–2009

Figure 5. Reperfusion therapy in STEMI in 2003–2009; PCI — percutaneous coronary intervention
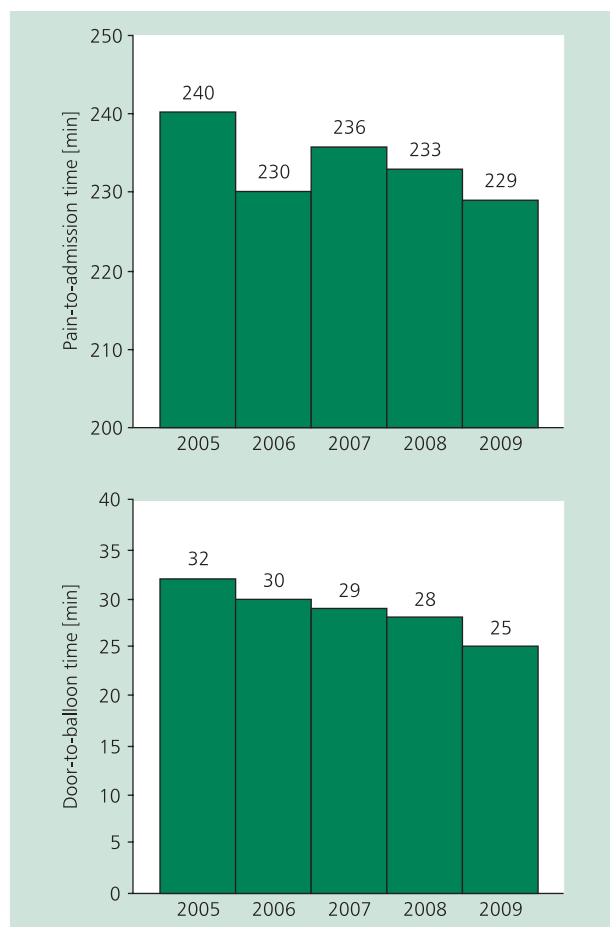
Figure 6. Delay to reperfusion therapy in 2005–2009

Figure 7. Use of aspirin in STEMI in 2003–2009

significantly in the analysed period but was markedly lower then in the conservatively treated patients (Fig. 12). Similarly, one-year mortality was lower in the invasively treated patients both in the overall study population and when propensity score-matched groups were compared (Fig. 13). Duration of hospitalisation reduced slightly regardless of the treatment strategy (Fig. 14).

DISCUSSION

The proportion of STEMI among all ACS in Poland has remained stable at about 30–32% for the last 5 years. In the same time, however, the proportion of NSTEMI increased twice, particularly in the oldest age groups. In the NRMI Registry in United States, STEMI patients comprised 47%, and NSTEMI patients comprised 53% of all patients in 1990–2006 [4]. In the Euro Heart Survey ACS III Registry, STEMI was diagnosed in 7,655 (40%) among 19,205 included patients [5]. In the GRACE Registry, run from April 1999 to December 2000, STEMI patients comprised 30% of all ACS patients. Similarly to the PL-ACS Registry, the proportion of NSTEMI patients increased in the oldest age groups [6]. In all these registries, the population of STEMI patients becomes older [4–6], with
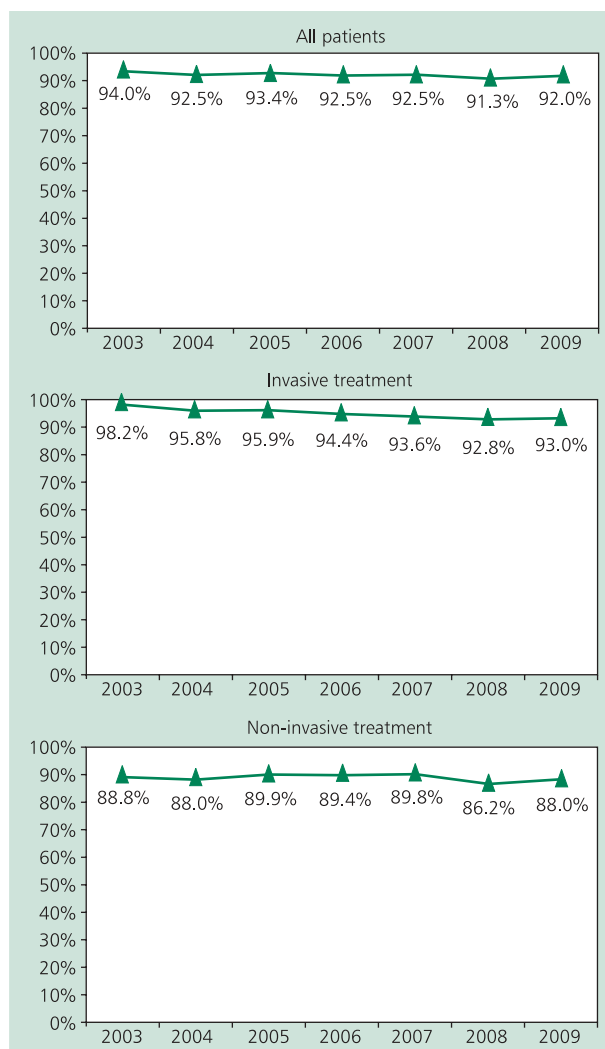
the median age of about 64–66 years, very similar to the PL-ACS Registry findings. More effective reperfusion therapy has presumably resulted in a significant reduction of the proportion of STEMI patients with pulmonary oedema or cardiogenic shock. This is one of the causes of the observed improvement in MI treatment outcomes in Poland.

The PL-ACS Registry data indicate a significant improvement in both STEMI treatment strategies and outcomes in Poland in 2003–2009. In 2009, reperfusion therapy was used in 79% of patients, including invasive therapy, which is the most effective strategy, in 78% of patients. The remaining patients were not offered reperfusion therapy mostly due to an excessively large delay in hospital presentation, i.e. more than 12 h from the onset of the pain. Of note, a very small and decreasing proportion of patients is offered thrombolytic treatment (only 1% of patients in 2009), which is in some disagreement with the current guidelines. Time to reperfusion in Poland is still too long and despite a dense network of
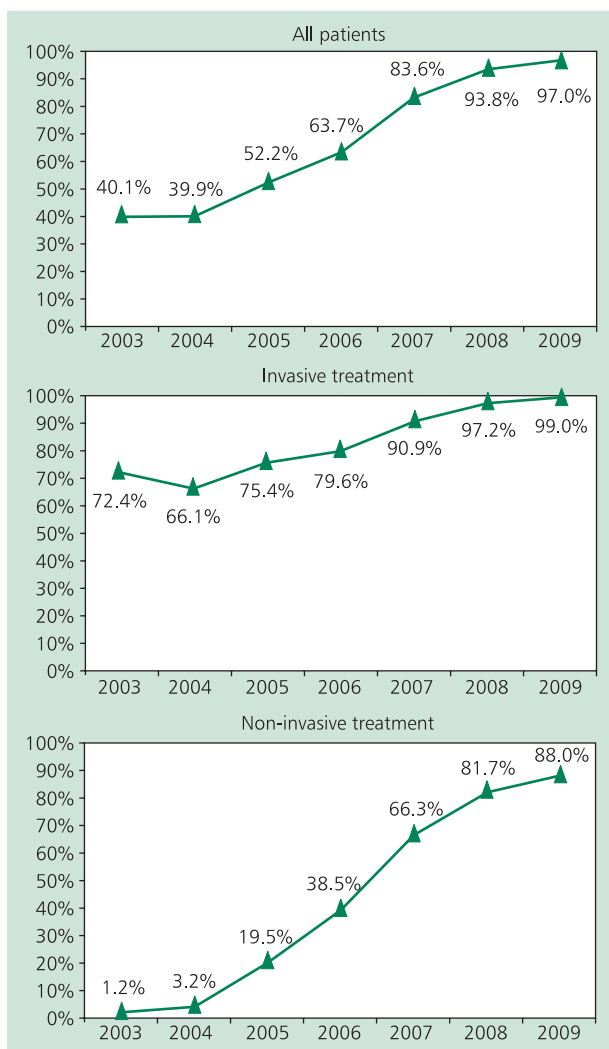
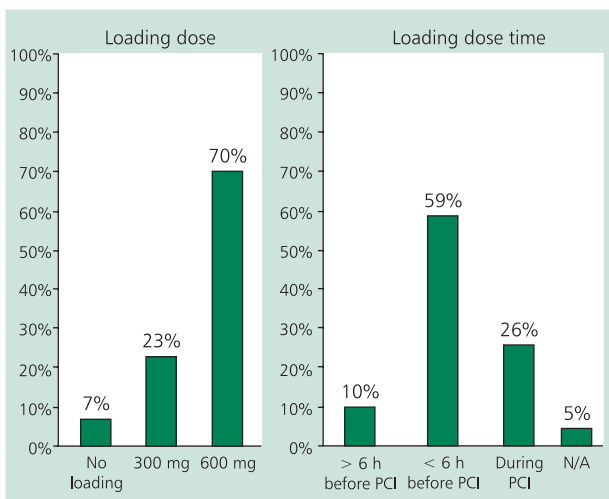**Figure 8.** Use of clopidogrel in STEMI in 2003–2009

Figure 9. Clopidogrel dosage in STEMI — loading dose of clopidogrel and the time of the loading dose; N/A — not available; PCI — percutaneous coronary intervention

cardiac catheterisation labs in Poland, it has been only slightly reduced during the last 7 years. Time to reperfusion consists of prehospital delay which includes decision delay and patient transport time, and in-hospital delay. Too large prehospital delay remains a problem in Poland. Ostrzycki et al. [7] found that only 18% of STEMI patients presented to a hospital within the first 2 h. In Cracow experience, the mean time from the first contact with the patient to reperfusion ranged from 93 min if the patient was referred directly to a cardiac catheterisation lab to 193 min if the patient was transferred from a local non-PCI-capable hospital [8]. The PL-ACS Registry data indicate that about 20% patients present to a hospital within the first 2 h from the onset of the pain. Decision delay comprises about 60% of the total pre-hospital delay, and transport time comprises the remaining 40% [9]. In Poland, the decision delay is about 100 min (based on the data collected in 146 patients hospitalised in the Silesian Centre for Heart Diseases in 2009–2010) and is definitely the major cause of a prolonged time from the onset of the pain to the first patient contact with a physician (median of 118 min in Poland). However, there is no fully effective method that would reduce this delay. Literature data indicate a very limited effectiveness of educational media campaigns which are practically the only way to increase public awareness of dangers related to a delayed treatment of MI [10, 11]. In contrast, in-hospital delay ("door-to-artery time") is very short in Poland, indicating good work organisation in cardiac catheterisation labs.

Another problem is too long patient transport time to a PCI-capable hospital. This results from a practice of transporting patients first to a local hospital emergency department and then to a PCI-capable hospital, which prolongs transport time by about 60–100 min and increases both the risk of complications and costs [8]. Wider use of ECG teletransmission systems and increased awareness of ambulance teams result in an increased proportion of patients referred directly to a PCI-capable hospital [9]. In this situation, further efforts should be directed at providing more opportunities to transmit ECG from the ambulance to the referral centre before logistic and therapeutic decisions are made. It is clear that the time from the onset of pain to reperfusion, particularly with thrombolytic treatment but also with PCI strategy, remains a major factor determining the degree of myocardial damage and treatment outcomes [12–14]. It seems, however, that any significant reduction of reperfusion delay in the coming years would be difficult. As noted above, public educational media campaigns are of limited value, and on the other hand, as indicated by the PL-ACS Registry data, the proportion of older patients increases, and these patients tend to present to hospitals significantly later in the course of the disease and include more women who generally fare worse compared to men.

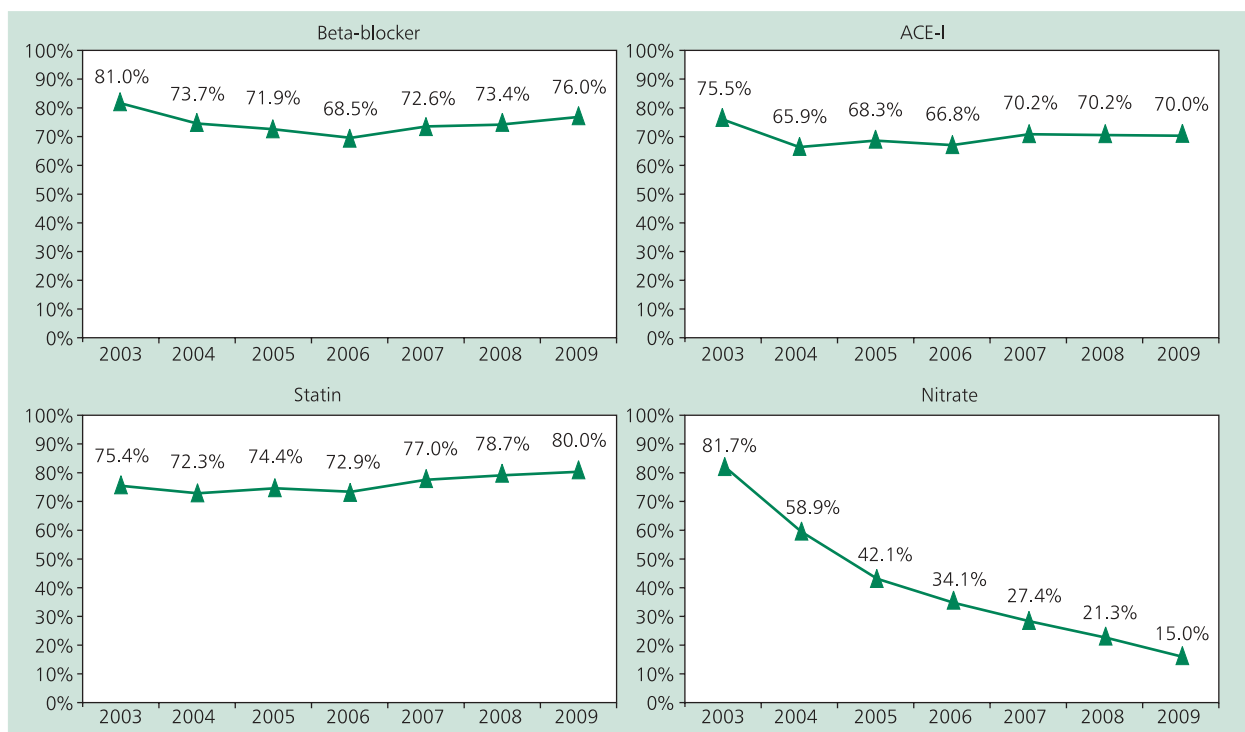Schiele et al. [5] analysed data from 21 European countries and found a significant reduction of the "door-to-artery"

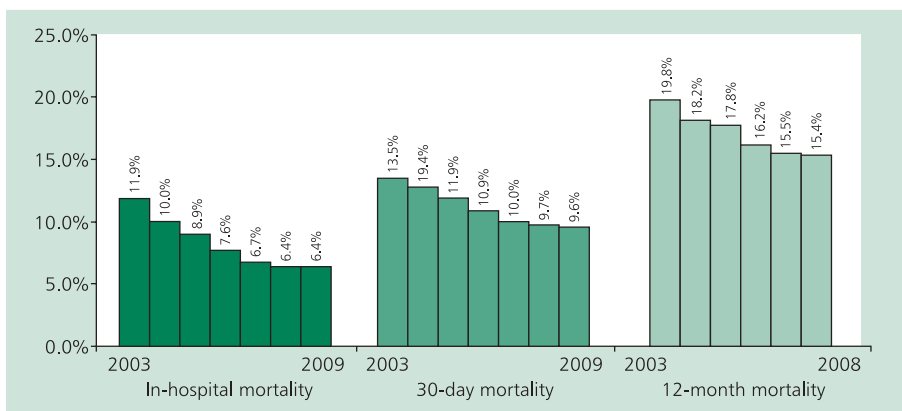**Figure 10.** Drug treatment of STEMI during hospitalisation

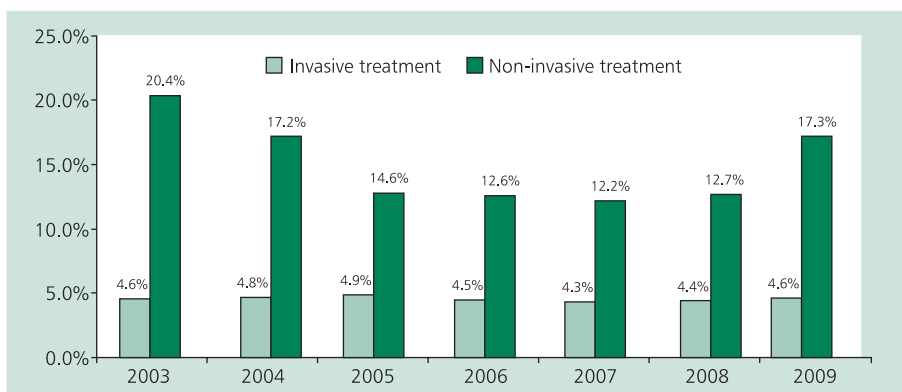**Figure 11.** Mortality in STEMI in 2003–2009

Figure 12. In-hospital mortality in STEMI in 2003–2009 depending on the treatment strategy
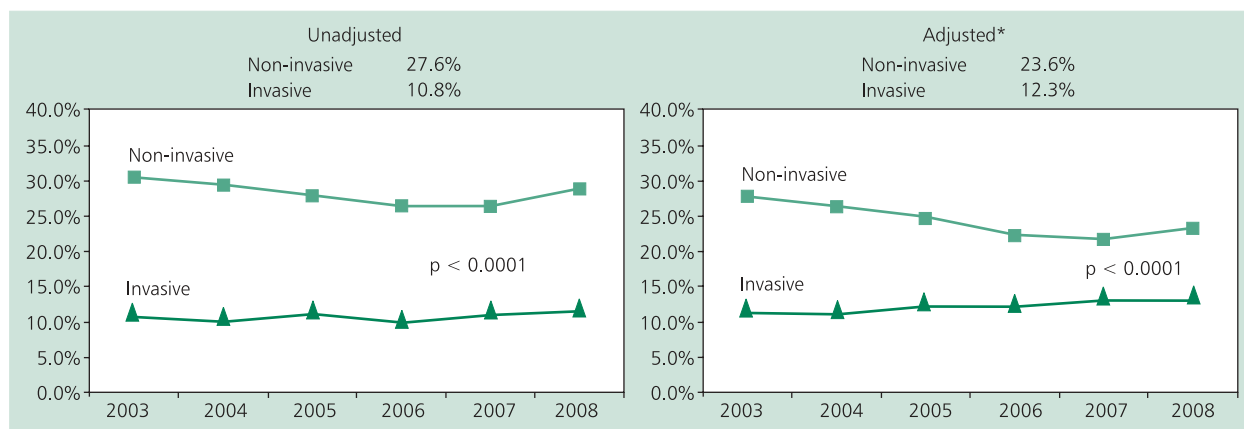
Figure 13. Propensity score-adjusted one-year mortality in STEMI in 2003–2008 depending on the treatment strategy; *adjusted for differences in baseline characteristics with the propensity score method
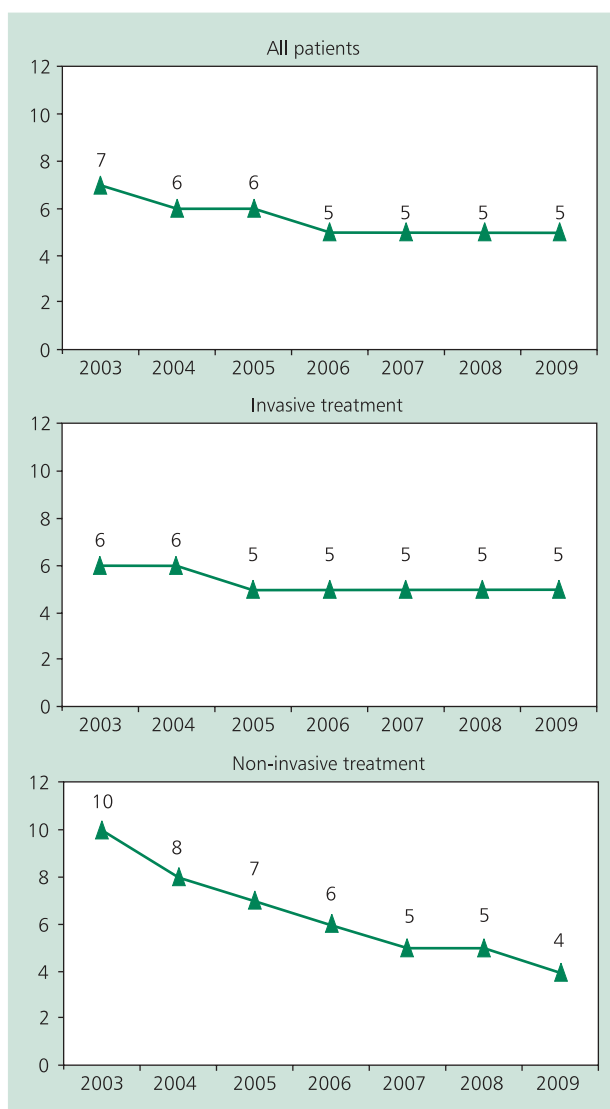

Figure 14. Duration of hospitalisation of STEMI patients

time from 60 to 45 min in 2006–2008, although similarly to the Polish data, the proportion of patients presenting within the first 2 h remained low, and the "pain-to-artery" time remained relatively long.

In Europe, reperfusion therapy was used in 77.2% of patients in 2006 and in 81.3% of patients in 2008 (p = = 0.0007), with a significant increase in PCI use from 51.7% in 2006 to 64% in 2008 [5]. When comparing European data and the PL-ACS Registry finding, the most striking difference is related to the use of fibrinolytic treatment, which is virtually unused in Poland while still administered in more than 17% of STEMI patients in Europe [5]. Similar observations have been made in the United States. From 1990 to 2006, the rate of primary angioplasty in STEMI increased steadily from about 38% to 72%, with concomitant reduction in the number of patients undergoing fibrinolytic treatment [4].

In-hospital drug therapy in Poland is generally in agreement with the current guidelines, with dual antiplatelet therapy used in virtually all patients, and beta-blockers, statins and ACE inhibitors in about 80% of patients. These findings are comparable with the Euro Heart Survey III results, 2006 NRMI data, and GRACE Registry findings [4–6].

Data collected in the PL-ACS Registry in 2007–2008 indicate that in majority of STEMI patients, the loading dose of clopidogrel is administered before PCI and less frequently during PCI. Our findings are very similar to results reported by Schiele et al. [5].

In the analysed period, STEMI outcomes in Poland systematically improved, with in-hospital mortality reduction from 11.9% to 6.4% (p < 0.001), 30-day mortality reduction from 13.5% to 9.6% (p < 0.001), and one-year mortality reduction from 19.8% to 15.4% (p < 0.001). In contrast, outcomes in patients treated invasively did not change, likely resulting from an influence of two concomitant mutually counteracting factors: technological advances in cardiac cathe-

terisation labs and increased skills and experience of invasive cardiologists that might result in improved outcomes, and a trend to treat more older patients with significant comorbidities in whom outcomes may be worse. In this situation, any further improvement in outcomes in the coming years seems difficult. Our registry has also contributed to the growing evidence documenting the value of invasive STEMI that was showed both in the overall study population and in propensity score-matched patients.

In-hospital mortality was 7.1% in the Euro Heart Survey III [5], 8% in the US data from 2006 [4], and 6.2% in the GRACE Registry [15]. In an Italian BLITZ Registry in 2001, in-hospital mortality was 7.5%, and 30-day mortality was 9.5% [16]. Outcomes in Poland are thus very good, and the registry data indicate continuous improvement in 2003–2010, most likely due to a wider availability of invasive treatment, increasing experience of invasive cardiologist, and implementation of guideline-based drug treatment. This effective treatment has resulted in a small but sustained reduction of the duration of hospitalisation, an important parameter in cost considerations for hospitals.

Limitations of the study
Although the PL-ACS Registry is a prospective observational study, not all hospitals treating ACS patients in Poland contributed to data collection, with differences in this proportion between the voivodeships and between the years of data collection. Thus, the data averaged for Poland may not necessarily reflect the actual situation in different regions of the country.

CONCLUSIONS
In summary, analysis of the presented data indicates some areas of potential further improvement in STEMI treatment outcomes:
— reduction of the time from the onset of the pain to revascularisation, which might be helped by a wider use of thrombolytic treatment in agreement with the guidelines;
— more frequent use of invasive treatment in patients presenting with cardiogenic shock (currently in 43% of such patients aged < 75 years and in only 26% of the elderly patients in cardiogenic shock [17]);
— optimisation of further treatment following hospital discharge, with a wider use of cardiac rehabilitation.

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Co się zmieniło w leczeniu zawału serca z uniesieniem odcinka ST w Polsce w latach 2003–2009? Dane z Ogólnopolskiego Rejestru Ostrych Zespołów Wieńcowych (PL-ACS)

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Streszczenie

Wstęp: W ciągu ostatnich 10 lat w polskiej kardiologii osiągnięto bardzo duży postęp, szczególnie wyraźny w zakresie leczenia ostrych zespołów wieńcowych (OZW).

Cel: Celem niniejszej pracy jest prezentacja wyników rejestru dotyczących chorych z zawałem serca z uniesieniem odcinka ST (STEMI) i analiza zmian, jakie dokonały się w latach 2003–2009 w populacji chorych z zawałem, a także sposobu leczenia oraz wyników wewnątrzszpitalnych i odległych.

Metody: W analizie wykorzystano dane pochodzące z Ogólnopolskiego Rejestru Ostrych Zespołów Wieńcowych (PL-ACS), który od 2003 r. prowadzi zespół Śląskiego Centrum Chorób Serca w Zabrzu. Rejestr PL-ACS jest finansowany przez Ministerstwo Zdrowia przy organizacyjnej pomocy Narodowego Funduszu Zdrowia. Zebrano dane prawie 300 000 hospitalizowanych chorych z rozpoznaniem OZW.

Wyniki: W latach 2003–2009 włączono do rejestru PL-ACS łącznie 284 162 osób z OZW hospitalizowanych w 512 szpitalach, w tym 88 ośrodkach kardiologii interwencyjnej. Odsetek pacjentów z STEMI wynosił 35–36% w latach 2003–2005 i zmniejszył się do poziomu 30–32% w latach 2006–2009. Średni wiek chorych wzrósł z 62,5 w 2003 r. do 64,5 roku w 2009 r. Odsetek kobiet w ciągu lat wynosił 32,7–34,6%. W ciągu lat zmniejszył się również odsetek chorych przyjmowanych z obrzękiem płuc lub wstrząsem kardiogennym: 15,5% w 2003 r. i 8% w 2009 r. Opóźnienie do momentu wdrożenia leczenia reperfuzyjnego układało się w trend malejący: czas ból–przyjęcie wynosił 240 min w 2005 r. i 229 min w 2009 r., a czas opóźnienia wewnątrzszpitalnego wynosił odpowiednio 32 min i 25 min. Odsetek chorych leczonych inwazyjnie znacząco wzrósł z 55% w 2003 r. do 84% w 2009 r. Przezskórne interwencje wieńcowe również były częściej wykonywane w 2009 r. (78%) niż w 2003 r. (51%). W tym samym czasie odsetek pacjentów leczonych trombolitycznie zmniejszył się z 14% do 1% w 2009 r. Kwas acetylosalicylowy, beta-adrenolityki, statyny oraz inhibitory receptora angiotensyny stosowano u wysokiego odsetka chorych. W ciągu lat zmniejszyła się natomiast częstość stosowania azotanów — z 82% do 15%. Znacząco więcej chorych otrzymywało klopidogrel w 2009 r. (97%) niż w 2003 r. (40%). Zaobserwowano istotne zmniejszenie śmiertelności, zarówno wewnątrzszpitalnej (11,9% w 2003 r. *v.* 6,4% w 2009 r.), jak i 30-dniowej (13,5% w 2003 r. *v.* 9,6% w 2009 r.) oraz rocznej (19,8% w 2003 r. *v.* 15,4% w 2009 r.). Leczenie inwazyjne istotnie poprawiało rokowanie zarówno krótko-, jak i średnioterminowe u chorych z STEMI.

Wnioski: Wyniki leczenia STEMI w Polsce w latach 2003–2010 ulegały stałej poprawie. To niewątpliwie efekt rosnącej dostępności do pracowni hemodynamiki, coraz większego doświadczenia zespołów leczących i wreszcie farmakoterapii coraz bliższej wytycznym ESC. Konsekwencją tak efektywnej terapii jest niewielkie, ale stałe skracanie się czasu hospitalizacji, ważnego elementu decydującego o opłacalności procedury dla szpitala. Jednocześnie można wskazać obszary, w których istnieje jeszcze możliwość poprawy rokowania dla chorych z STEMI, takich jak skrócenie czasu od początku bólu do udrożnienia tętnicy i częstsze wykorzystanie procedur inwazyjnych u chorych we wstrząsie kardiogennym.

Słowa kluczowe: zawał serca z uniesieniem odcinka ST, strategia leczenia, pierwotna przezskórna interwencja wieńcowa, trendy czasowe, śmiertelność 12-miesięczna

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