ORIGINAL REPORT

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Primary PCI for ST-elevation myocardial infarction

Background

The most recommended treatment of choice for ST-elevation myocardial infarction is primary PCI (percutaneous coronary intervention). Systematic provision of the operation requires the minimization of all possible delays and smooth cooperation at every level of the treatment chain. This follow-up study focused on the delays and results of the treatment chain aiming to deliver primary angioplasty for ST-elevation myocardial infarction patients in Pirkanmaa Hospital District.

Methods

Primary intracoronary balloon inflations have been performed in the Pirkanmaa Hospital District Heart Center since 2004. Other health care units, such as health centers, regional hospitals and ambulance services, have become links in the treatment chain as agreement on procedures has been reached and written instructions for treatment have been compiled.
The study included all the ST-elevation myocardial infarction patients who were referred for primary PCI by a cardiologist up to the end of 2007. The total number of patients was 288, of whom 78 (27%) were women. The median patient age was 68 (57–76) years.

Results

ECG was registered within approximately 1 h 58 min from the onset of the symptoms. The span from the time of diagnosis, i.e., ECG, to primary angioplasty was 90 min (71–122 min). The door-to-balloon time at the Heart Center was 29 min. The balloon inflation was successful and the coronary artery was opened in 93.7% of the cases. In-hospital mortality rate was 4.5% and the average stay in hospital lasted 3 days.

Conclusions

It is possible to minimize delays in the primary PCI treatment chain occurring at various levels of the treatment chain for ST-elevation myocardial infarction and to obtain excellent treatment results. To achieve this, efficient regional cooperation and patients' immediate transportation to a catheterization laboratory for treatment are required.

The development of invasive treatment for ST-segment elevation myocardial infarction sets special requirements for patients' early risk assessment. Using noninvasive methods, it should be possible to identify those patients who benefit from primary angioplasty and those who can be treated with intravenous thrombolytic therapy (1). International clinical guidelines always recommend primary percutaneous coronary intervention (PCI) as the treatment of choice when certain requirements are met (2). Organizing a 24-hour on-call invasive cardiology service is a major economic and logistic challenge. It is particularly demanding to construct a well-functioning treatment chain so that all of the procedures are clear to all the parties. Yet this is the only way delays in the treatment chain can be minimized and results withstanding critical review can be achieved in the treatment of ST-elevation myocardial infarction.

This article describes the construction of the treatment chain for ST-elevation myocardial infarction and the results obtained for primary PCI at Pirkanmaa Hospital District Heart Center.

Material and methods

Pirkanmaa Hospital District Heart Center began systematic primary PCI for ST-elevation myocardial infarction in October 2004. Primary PCI means balloon inflation and/or stenting (with a metal stent) of the coronary

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artery without preceding thrombolytic therapy. Other forms of angioplasty include facilitated angioplasty and so-called rescue angioplasty. In the case of facilitated angioplasty, the patient is first given thrombolytic therapy, after which a planned angioplasty of the occluded artery is performed during the next few hours. Rescue angioplasty means angioplasty performed in a situation where thrombolytic therapy has not been effective. These treatments are not discussed in this article.

Preparedness for primary PCI was gradually increased at the Heart Center. In 2004-2005 primary angioplasty was available during office hours on weekdays, and in 2006 the availability of treatment was expanded to cover weekdays from 8 a.m. to 8 p.m. and weekends from 9 a.m. to 4 p.m. At the beginning of September 2007, the services were further expanded to 24 h over the weekend (Saturday morning 8 a.m. to Monday morning 8 a.m.).

Other health care units were included in the treatment chain only after a written agreement on procedures had been reached with the Heart Center. At the same time, a training event was organized in all health care units, with the participation of two cardiologists from the Heart Center, a nurse and health care professionals from the local health center or regional hospital, and the ambulance service unit taking part in the treatment of ST-elevation myocardial infarction patients.

The units included in the treatment chain came primarily from within Pirkanmaa Hospital District. Units from outside the Hospital District were also included, provided that transportation to the Heart Center took no longer than 60 min. The health care unit or ambulance service unit consulted the Heart Center cardiologist directly about treatment decisions; the ECG was sent to the cardiologist's smartphone either by fax or through the GSM network. To minimize any delays, patients were transported directly to the Heart Center for the procedure. By the end of 2007, the treatment chain included the entire hospital district as well as Forssa Hospital and the Forssa unit of the emergency service of Kanta-Häme region, Jokilaakso Hospital and ambulance services.

The study period ranged from October 1, 2004 to December 31, 2007. All patients (n = 288) referred by consulting a cardiologist to the Heart Center for primary PCI were included in the study. In addition to symptoms of a coronary artery event, the criteria of ST-elevation myocardial infarction included ST-segment elevation observed in at least two parallel leads of the ECG, either 2 mm (chest leads V1 – V3) or a minimum of 1 mm (chest leads V4 – V6 and limb leads) or what was presumed to be a new left bundle branch block (3). If the patient's general diseases, symptoms or ECG indicated primary PCI for ST-elevation myocardial infarction, the cardiologist made the decision to send the patient directly to the Heart Center and give him/her proper premedication. The premedication given to all patients was acetylsalicylic acid (ASA) 250 mg masticatory tablet, clopidogrel 600 mg orally and enoxaparin 40 mg intravenously. The Heart Center strove to prepare the patient for the procedure with a minimum of delay. The intention was to perform primary angioplasty within 90 min from the diagnosis.

The Heart Center staff has filled out a history form for all the patients coming for primary angioplasty. The details on the form include the patient identification number, gender, the referring unit, the date of the procedure, the time of pain onset, the time the ECG was recorded and sent, the time the ECG arrived at the Heart Center, and the time of the cardiologist's decision on primary angioplasty. The form also includes information about the patient's medication, events during transportation, status on admission to the Heart Center, the time of arrival, the time of puncture, the time of the first angioplasty, the time angioplasty was completed, the TIMI flow grade before and after the angiography, and possible GP IIb/IIIa receptor inhibition. TIMI flow grade 0–1 represents coronary artery occlusion, while the coronary artery is open when the TIMI flow grade is 2–3.

The patient records were used to determine the events (death, by-pass operation, hemorrhage, blood transfusion) during the hospital stay at Tampere University Hospital as well as the patient's duration of care and place of further treatment.

Statistical methods

Statistical analyses were made using the SPSS for Windows 13.0 software. As to continuous variables, the results are presented in medians

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Financial ties:
Markku Eskola has made presentations at events organized by the pharmaceutical companies AstraZeneca Oy and Novartis Finland Oy and participated in congresses abroad at the expense of pharmaceutical companies Boehringer Ingelheim Finland Ky and AstraZeneca Oy.
Kjell Nikus has made presentations at events organized by the pharmaceutical companies MSD Finland Oy, Sanofi Aventis, Novartis Finland Oy, and Bristol-Myers Squibb Finland and participated in congresses abroad at the expense of equipment and pharmaceutical companies Boston Scientific and Novartis Finland Oy.
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and quartile splits, and the Mann-Whitney U-test was used to compare them. The classified variables are presented as percentages, and the 2 test was used for their comparison. A p value of 0.05 was regarded as the limit of statistical significance.

Results

The number of patients treated (n = 288) increased gradually as new health care units were instructed and systematic operations expanded. The number of patients treated was eight in 2004, 36 in 2005, and 122 per year in 2006 and 2007. Of the patients, 3.5% had a history of coronary by-pass operation. The patients' median age was 68 (57-76) years. Of the patients, 78 (27%) were women. 55% of the male patients were aged 65 or under. The women were older; 86% of them were over 65 (Figure 1). The women's age median was 75 (69-81) years, that of the men being 64 (55-73) years. Most of the patients were transported to the Heart Center by ambulance directly from the scene of the event (32%) or from the emergency room of Tampere University Hospital (30%). The rest of the patients were referred by health centers (20%), regional hospitals (15%) or central hospitals (3%). No statistical difference was observed between the age or gender of the patients referred by different units.

Premedication was implemented well, in accordance with the instructions of the treatment chain. Eight (3%) of the 288 patients had ASA allergy. Of the remaining 280 patients, 260 (93%) were premedicated with 250 mg of ASA. Clopidogrel, 600 mg, was administered to 245 (85%) and enoxaparin, 40 mg intravenously, to 248 (86%) patients. When comparing the premedication of patients transported by ambulance, referred by the emergency room of Tampere University Hospital, by regional hospitals, and by health centers, a statistically significant difference was observed for ASA (p = 0.009), clopidogrel (p = 0.02) and enoxaparin (p = 0.004). Premedication was implemented best for patients who were transported to the Heart Center directly from the scene of the event. Of these patients, 96% were premedicated with ASA, 88% with clopidogrel and 93% with enoxaparin. Administration of a GP IIb/IIIa receptor inhibitor not included in the local treatment instructions was started in a total of 61 (21%) cases.

None of the patients died during transportation. Two patients had ventricular fibrillation and were defibrillated. None of the patients experienced ventricular tachycardia requiring treatment during transportation. During transportation, 12 (4.2%) patients had bradycardia (pulse rate below 40/min), and 28 (9.7%) patients had systolic blood pressure below 90 mmHg.

On arrival at the Heart Center, cardiogenic shock was observed in 19 (6.6%) cases. Eleven patients (3.8%) had to be resuscitated at the Heart Center.

FIGURE 1.

Distribution of patients by different age groups, %.

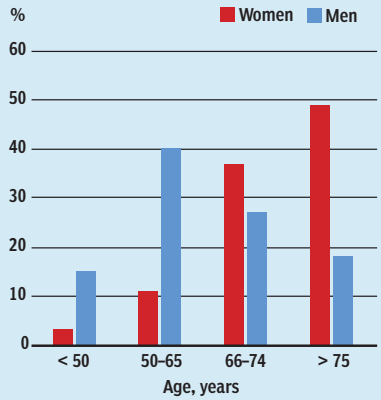

TABLE 1.

The reasons for not performing primary percutaneous coronary intervention for patients who underwent emergency angiography (n = 50, 17%).

The reason for not performing primary PCI	n	%
Arteries are open, no symptoms/no explanation for ECG	22	7.6
Diffuse disorder, not to be treated by PCI	8	2.8
Spontaneous reperfusion	7	2.4
Myocarditis	5	1.7
Pulmonary embolism	2	0.7
Takotsubo syndrome, i.e. stress-induced cardiomyopathy	2	0.7
Coronary artery dissection	1	0.3
Primary PCI presents too high a risk	1	0.3
Patient died before PCI began	1	0.3
Cytostatic-induced coronary artery spasm	1	0.3

TABLE 2.

Time delays between ECG registration and invasive procedures by the unit referring the patient for primary angioplasty: median (quartile split in brackets), times given in hours and minutes.
From ECG registration to referral (ECG → referral), from ECG registration to arrival at the Heart Center (ECG → Heart Center) and from ECG registration to primary PCI (ECG → PCI).

Time delay	Ambulance	Tampere University Hospital emergency room	Regional hospital	Health center	p-value
ECG → referral	0:05 (0:02-0:12)	0:09 (0:05-0:16)	0:15 (0:06-0:24)	0:17 (0:10-1:02)	<0.001
ECG → Heart Center	0:47 (0:39-1:00)	0:43 (0:27-1:01)	1:36 (1:21-1:45)	1:22 (0:55-2:00)	<0.001
ECG → PCI	1:17 (1:06-1:41)	1:23 (0:52-1:40)	2:08 (1:50-2:31)	1:52 (1:24-2:34)	<0.001

Emergency coronary angiography was performed for 288 patients suspected of having ST-elevation myocardial infarction. Of these, 238 (83%) patients underwent primary angioplasty. Coronary artery disease was diagnosed in 256 (89%) patients. Table 1 shows the reasons why angioplasty was not performed for all of the patients.

Success of the procedure

Coronary angiography showed an occluded coronary artery (TIMI 0-1) in 166 (69.7%) of the patients (n = 238) treated with primary angioplasty. Occlusion of the artery was the more common the younger the patient (p = 0.03). The age median of patients in TIMI 0–1 class was 66 years (quartile range 56–75) and that of patients in TIMI class 2–3 was 72 years (quartile range 60–79). Comparison of the sufficiency of coronary artery circulation among the patients (TIMI 0–1 vs. TIMI 2–3) revealed that the patient's gender or the unit referring the patient had no effect on the TIMI flow class. The TIMI flow class at admission also had no effect on mortality in hospital.

When using TIMI flow class 2–3 as an indicator of a successful angioplasty, the coronary artery was open in 223 (93.7%) cases. The patient's gender or the referring unit had no effect on the success of the procedure. When studying the effect of age on the post-angioplasty TIMI flow class, it was observed that there were more unsuccessful procedures in the older patients. However, the difference was not statistically significant.

Delays

An electrocardiogram (ECG) was recorded on average 1 h 58 min (52 min–3 h 57 min) after the onset of pain. The ECG was sent to the Heart Center cardiologist for evaluation within 10 min (4–19 min) of its registration. Ambulances had the shortest delay, 5 min (2–12 min), between taking and sending the ECG, followed by 9 min (5–16 min) for the emergency room of Tampere University Hospital, 15 min (6–24 min) for the regional hospitals, and 17 min (10 min–1 h 2 min) for the health centers; p < 0.01.

The time span between taking the ECG and the decision on performing angioplasty was 18 min (10–35 min). The cardiologist made the treatment decision in 2 min (1–5 min) from the arrival of the ECG to the Heart Center. The time span between taking the ECG and primary angioplasty was 1 h 30 min (1 h 11 min–2 h 2 min). Transportation of the patients to the Heart Center took 58 min (40 min–1 h 26 min) from the ECG and 35 min (25–57 min) from the decision on the procedure. Table 2 shows the delays by the place referring the patients for primary angioplasty.

After arrival at the Heart Center, the patients underwent arterial puncture within 12 min (10–15 min) and primary angioplasty in 29 min (24–37 min), and the procedure was finished in 57 min (44 min– 1 h 10 min). The time span between the arterial puncture and primary angioplasty was 16 min (13–21 min). The time span between the decision on the procedure to primary angioplasty was 1 h 7 min (51 min–1 h 30 min).

Terminal events during the hospital stay

Mortality during the hospital stay was 4.5%. Table 3 shows the mortality by the type of treat-

TABLE 3.

In-hospital mortality of patients admitted for primary percutaneous coronary intervention by treatment type. The mortality figures were divided into groups by whether or not the patient was in cardiogenic shock at arrival.

Treatment	All		No cardiogenic shock		Cardiogenic shock	
	n	%	n	%	n	%
Conservative, PCI or by-pass operation (n = 288)	13	4.5	5	1.9	8	42.1
Primary PCI (n = 238)	11	5.0	4	1.8	7	46.7
By-pass operation (n = 13)	2	15.4	14	10.0	1	33.3

ment and the patient's condition on admission in greater detail. None of the patients had cerebral hemorrhage; however, intestinal hemorrhage was observed in one patient. Other hemorrhages requiring blood transfusion were observed in 4.9% of the patients: Of the hemorrhages, 29% were related to a by-pass operation.

A by-pass operation was performed for 4.5% of the patients during the hospital stay. Excluding the patients suffering from cardiogenic shock on admission from the analysis, a by-pass operation was performed for 3.7% of the patients during the hospital stay. Of the 19 patients with cardiogenic shock on admission, primary angioplasty was performed for 15 (79%), by-pass operation for three patients (16%), and one patient was treated conservatively.

In all, 95 patients (33%) were discharged directly from the Heart Center and 180 (62.5%) were transferred to another health care unit for further treatment. The average duration of care in the Heart Center was 3 (1–5) days.

Discussion

Compared with intravenous thrombolytic therapy, primary angioplasty for ST-elevation myocardial infarction improves patients' prognosis (4). Rapid commencement of reperfusion therapy reduces patient mortality (5). Consequently, it is extremely important to minimize delays at every level of the treatment chain. According to European clinical guidelines, primary angioplasty is the treatment of choice if it can be performed by experienced staff within two hours after the first contact with a health care unit. The delay can be at most 90 minutes, provided that less than two hours has passed since the symptoms started, the threatening infarction is expected to be extensive, and there is minor risk of hemorrhage (2). A national registry study in the USA showed that the time delay was less than two hours in only 4% of the PCI procedures (6). Our own study showed minor delays at all levels of the treatment chain. The average time delay from the diagnosis to angioplasty was 90 minutes. This is very much affected by the distance separating the health care units included in the treatment chain. Despite the long time delay for patients referred to primary angioplasty by the emergency department of Tampere University Hospital, the delay of 83 minutes was among the best results reported (7).

Other time delays, such as the time span from arrival at the catheterization laboratory to primary angioplasty, were also important factors in the comparison of the treatment results (8). According to one study, there were rather considerable differences between different hospitals. That study involved 340 hospitals, which were divided into different classes on the basis of the time delays. The delay was 28 minutes for the best hospitals, 35 minutes for the average hospitals, and 42 minutes for the worst hospitals. Of all the hospitals, 25% achieved the under 30 minute limit from arrival at the catheterization laboratory to primary angioplasty. The results are similar to

our own results (time delay 29 min).

The time delays can be reduced by means of experienced staff, when each staff member is given exact, predetermined tasks already at the time the patient is reported to arrive for primary angioplasty. The delays can also be minimized by other, minor factors. One example is determining the approach in advance. In 8% of cases, primary PCI cannot be performed through a wrist artery, which causes unnecessarily increases the delay of primary angioplasty (61 min for unsuccessful radial approach vs. 39 min femoral approach) (9). The Heart Center has preliminarily agreed on using femoral approach for the procedure. Despite the relatively abundant antithrombotic medication, only been minor hemorrhages have occurred.

Instruction and training of the primary care units is of the utmost importance in optimizing the treatment results for acute myocardial infarction. Thrombolytic therapy given at the scene of the event reduces mortality compared against a situation where the patient is transported to hospital for the commencement of fibrinolytic therapy (10). In our study, the place of referral for primary angioplasty revealed no differences in events during the hospital stay. Nevertheless, the patient transportation units had the shortest time delays between registration and sending of the ECG, and even the times from taking the ECG to arrival at the Heart Center were at the same level as within the hospital. This indicates that the in-hospital logistics need to be made more efficient.

A normal finding in coronary angiography is rare in cases of myocardial infarction confirmed with a biochemical marker test. The randomized PRAGUE study showed that coronary arteries were open among 2.6% of the patients who had undergone coronary angiographies for chest pain and ST-elevation (11). In an unselected material, coronary arteries were observed to be open in 13% of the patients referred for primary PCI (12). This corresponds with the finding of our own study which showed that 11% had no coronary artery disease diagnosed in angiography. In borderline cases, the threshold for emergency-type angiography should be kept low, in order to avoid serious hemorrhagic complications caused by thrombolytic therapy in cases of false positive ECG findings.

According to the meta-analysis of randomized treatment studies, 30-day mortality in connection with primary PCI was 7–9% (4). In-hospital mortality of the ST-elevation myocardial infarction patients treated with primary percutaneous coronary intervention was 4.5% in this study. This corresponds to with the reported in-hospital mortality of 4.5% obtained in a study of 259 consecutive ST-elevation myocardial infarction patients in one referral center (13). In that study, the door-to-balloon time was 98 minutes, compared to 29 minutes in our own study. These mortality rates are considerably lower than the mortality rates previously presented for unselected materials in the era of thrombolytic therapy. In our hospital, mortality during the hospital stay before the introduction of primary percutaneous coronary intervention was 9.6% (14). On the basis of this, it can be concluded that primary angioplasty can improve the prognosis for patients with ST-elevation myocardial infarction as long as activities are well planned and have proper guidelines.

Our results are similar to those obtained by the Swedish study Register of Information and Knowledge about Swedish Heart Intensive Care Admission, or RIKS-HIA study, which focused on patients treated in the years 1999-2004 (15). The RIKS-HIA patients treated with primary percutaneous coronary interven-

What was known before

- Compared to thrombolytic therapy, primary PCI for correctly selected ST-elevation myocardial infarction patients improves patients' prognosis.
- Rapid commencement of procedures is associated with reduced mortality.
- International register studies show that only a few centers are able to provide primary PCI within the time limits given in clinical guidelines. The issue has not been studies previously in Finland.

What the study taught

- A regional treatment chain should gradually be created in cooperation with all parties participating in the treatment of ST-elevation myocardial infarction patients.
- Primary PCI for ST-elevation myocardial infarction can be implemented in a well-organized treatment chain with minor delays and within the time limits specified in clinical guidelines.
- Excellent results have been achieved with primary PCI for ST-elevation myocardial infarction.

tion were younger than those treated in the Heart Center (64 vs. 68 years). In both studies, 27% of the patients were women. In the Swedish material, the time delay from the onset of symptoms to angioplasty was 3 hours and 30 minutes, i.e., 6 minutes shorter than in our own study. Of the RIKS-HIA patients, 8.8% (Killip IV) had cardiogenic shock on admission, compared to 6.6% in our study. In Sweden, the average duration in hospital was four days, i.e., one day longer than in the Heart Center. In-hospital mortality was 3.5% in the Swedish study and 4.5% in our study.

This study showed that delays during different stages of the treatment chain can be minimized by careful and systematic planning of logistics and by local agreements on clinical guidelines. Excellent results and reduced in-hospital mortality can be obtained as long as the availability of experienced professionals at different stages of the treatment can be assured. It is particularly important to transport the patients directly to a cardiology unit, which makes it possible to avoid the additional delays caused by stopping at emergency rooms. In consequence of the excellent results, at the beginning of 2008, treatment by primary percutaneous coronary intervention in the Heart Center expanded to 24-hour treatment provided every day of the week.

Limitations of the study

During the follow-up study, information was not collected about patients not suspected of having ST-elevation myocardial infarction on the basis of a cardiologist's consultation. Therefore, no information is available with regard to events among this patient group. Data concerning the anatomic location of myocardial infarction were not collected. Over 60% of the patients who underwent primary PCI were transferred from the Heart Center to another health care unit for further treatment. The care period and in-hospital mortality presented in our article refers to the previous care period in the Heart Center and mortality during this care period. Patients for whom the functionality of the treatment chain and results of the PCI were tested at night represent only a small proportion of the present material. This must be taken into account when comparing the results against reports from abroad. ■

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ENGLISH SUMMARY

Primary PCI for ST-elevation myocardial infarction

Current ST-elevation myocardial infarction (STEMI) guidelines recommend primary percutaneous coronary intervention (PCI) as the treatment of choice whenever feasible. Establishing around-the-clock availability of invasive procedures is a considerable logistic and economic challenge. This study evaluated the first years' results of the Pirkanmaa Hospital District Heart Center primary PCI programme. The ECG from the pre-hospital interaction site was transmitted to the on-call cardiologist with authority to activate the catheterization suite with the patient bypassing the emergency room. Over a 3-year period, 288 patients were diagnosed with STEMI and accepted for primary PCI. Median door-to-balloon time was 29 minutes. The success rate, the proportion of patients with a TIMI flow of 2 or 3 at the end of the procedure, was 93.7%. In-hospital mortality was 4.5%, which was reduced from the 9.6% previously reported by our hospital in the fibrinolysis era. Median length of stay in the Heart Center was 3 days. In conclusion, primary PCI can be delivered with only short delays and low mortality if the logistics are well organized and the catheterization laboratory can be activated by a single call from the paramedics in the field.