Next Day Discharge After Successful Primary Angioplasty for Acute ST Elevation Myocardial Infarction

An Open Randomized Study “Prague-5”

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SUMMARY

This study tested the feasibility and safety of next day hospital discharge after successful primary PCI for uncomplicated STEMI. Twenty-three p-PCI patients (out of 271 consecutive patients) who fulfilled the study inclusion criteria were enrolled in the pilot nonrandomized phase (transfer of patients from the coronary unit to a standard ward within 24 hours after their admission) of the study. The randomized phase of the study screened a total of 1946 consecutive STEMI patients undergoing p-PCI in the two participating centers. Only 56 (ie, 2.9% from all p-PCI) very low risk patients residing less than 20 km from the PCI center were selected. They were randomized 1:2 to either a standard hospital stay (group A, $n = 19$, age, 58 ± 8) or first day discharge (group B, $n = 37$, age, 56 ± 10 ; NS). There were no serious complications among 79 study patients within 30 days. The duration of hospital stay was 105 ± 45 hours (group A) and 29 ± 3 hours ($P < 0.0001$) in group B. Ejection fraction after 30 days was $56.8 \pm 6.5\%$ in group A versus $57.3 \pm 7\%$ in group B (NS). A patient comfort questionnaire showed a clear preference of first day discharge in all patients randomized into group B.

The results indicate that next day discharge after successful p-PCI is feasible and safe in selected uncomplicated STEMI patients. (Int Heart J 2008; 49: 653-659)

Key words: Myocardial infarction, Angioplasty, Early hospital discharge

THE early mobilization of patients following an acute myocardial infarction (AMI) has gradually shortened the hospital stay over the last 40 years. The average hospital stay for AMI patients was 4-6 weeks in the 1970s, 2-3 weeks in the 1980s, and 1-2 weeks at the beginning of the 1990s. In recent years, several studies¹⁻⁴⁾ showing the possibility of an even further reduction in the hospital stay

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in a group of low-risk acute coronary syndrome patients were published. Efforts to reduce the treatment costs played a certain role when these studies were started. The Cardiocenter Kralovské Vinohrady in Prague has been engaged in the routine p-PCI treatment of all STEMI patients since October 1995. Our experience of more than 10 years with primary PCI led us to investigate whether selected uncomplicated STEMI patients treated by successful p-PCI could be discharged within a few hours.

METHODS

Inclusion and exclusion criteria: A set of strict inclusion and exclusion criteria was predefined after discussion with the hospital ethics committee to allow enrollment of only the lowest risk patients who were unlikely to suffer from any serious complications. The committee suggested that the permanent residence of these patients should be close to the PCI center and they should be visited shortly after discharge at home by a physician. These criteria are listed in Table I.

Screened STEMI patients: A total of 2217 consecutive patients with acute STEMI were treated by primary PCI in the two participating centers during the study period (2003 - 2006). Only 79 of these (3.6%) fulfilled the strict inclusion/

Table I. Inclusion and Exclusion Criteria for the Study

Inclusion criteria	Exclusion criteria
1. Signed informed consent and subsequent written agreement of a family member (confirming good social background).	1. Previous Q-MI in other location.
2. Acute STEMI (ST elevation in 2 leads) treated by p-PCI within 6 hours after the onset of symptoms.	2. Signs of heart failure (Killip II-IV).
3. Optimal result of p-PCI (TIMI-3 flow and < 20% residual stenosis)	3. Hypotension (< 100 mmHg SBP) persisting after p-PCI.
4. Single-vessel disease: the infarct-related artery is the only major coronary artery with significant (> 70%) stenosis.	4. Chest pain recurrence.
5. Patient permanent residence < 20 km from PCI center.	5. Clinically significant arrhythmia (requiring treatment) occurring > 6 hours after PCI.
6. Left ventricular ejection fraction > 40% (echocardiography 12-24 hours after admission).	6. Serious clinical/laboratory findings requiring additional evaluation.
7. Age < 75 years.	7. Need for anticoagulation therapy.
8. Telephone contact between the patient and PCI center after discharge is available 24 hours daily.	8. Patient enrolled in other research project during this STEMI.

exclusion criteria. The most frequent reasons for exclusion of a patient from the study were a residence more than 20 km from the hospital (48% of excluded patients), significant multivessel disease (16%), and age > 75 years (11%).

Pilot nonrandomized phase (suggested by the ethics committee prior to the randomized phase) means the transfer of patients from the coronary care unit to a cardiology ward with free regimen within 24 hours after their admission. In this phase, 23 p-PCI patients (age, 58 ± 10 years) who fulfilled the study inclusion criteria were enrolled. There were no complications during standard hospital stay in these patients.

The randomized phase of the study was approved by the ethics committee based on the encouraging outcomes of the pilot phase. Fifty-six very suitable patients were randomized to either a standard hospital stay group (group A, $n = 19$, age, 58 ± 8) or first day discharge group (group B, $n = 37$, age, 56 ± 10 ; NS). The baseline data of all 79 study patients are presented in Table II.

Randomization: Patients fulfilling the inclusion and exclusion criteria were randomized by the envelope method into two groups: A (standard hospital stay) and B (discharge within 24-30 hours after admission). The randomization ratio was 1:2. Patients randomized into the early discharge group were given detailed instructions concerning the physical load, and dietary and regimen steps for each individual day until the seventh day after discharge from hospital. The member of the family who helped with the home care was informed about the patient's condition in detail and was briefed on the basic symptoms that might point to the recurrence of a coronary event or heart failure.

Follow-up: Patients were carefully followed during the first month (clinical check up on the 1st, 2nd, 3rd, 7th and 30th day, laboratory examinations on the 1st and 7th day, and echocardiography on 1st and 30th day). The patients were contacted by phone on day 2, while on day 3 a physician visited the patient at home (group B) and on days 7 and 30 the patients visited the PCI center.

Study duration and endpoints: As this study was designed as a feasibility and safety study and the pilot phase showed a low proportion (among all p-PCI

Table II. Baseline Clinical Data of the Study Patients

	Pilot phase patients	Group A patients	Group B patients
<i>n</i>	23	19	37
Mean age $\pm$ SD	58 ± 10	58 ± 8	56 ± 10
Females	13%	32%	46%
Diabetes mellitus	22%	32%	19%
Hypertension	39%	32%	46%
Smokers (incl. past)	70%	68%	57%
Hypercholesterolemia	30%	37%	24%
Anterior location of MI	57%	21%	32%

patients) of patients fulfilling the strict inclusion criteria, our intention was to randomize at least 50 patients who fulfilled the study criteria. The following end-points were followed within 30 days: death, reinfarction, stroke, unstable angina pectoris, rehospitalization, repeat target vessel revascularization, local groin complications requiring treatment, and left ventricular ejection fraction.

Catheterization and arterial access site care after intervention: The coronary angiography and subsequent primary PCI were performed with 5-6 F catheters. Heparin was not applied any further after PCI was completed. When the APTT fell below 50 seconds, the inguinal sheath was removed, followed by manual compression and 6 to 8-hour application of circular compression.

Antithrombotic therapy: After the initial treatment with acetylsalicylic acid 250-500 mg i.v. and heparin 130 IU/kg i.v., the patients received acetylsalicylic acid 200 mg per day, and a clopidogrel loading dose of 300 mg (during the later study course 600 mg) with a subsequent daily dose of 75 mg.

Additional medication: Additional medication was left to the discretion of the attending physician. Beta-blockers, ACE inhibitors, and statins were given to all patients unless contraindicated.

Approval of the study: Informed consent was obtained from each patient. The study was approved by the Ethics Committees/Institutional Review Boards of both participating hospitals. Some changes suggested by these bodies prior to the start of the study are described above. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki as reflected in a priori approval by the hospital human research committee.

Statistical analysis: The data are presented as the mean value $\pm$ SD or percentage. The unpaired *t*-test was used for continuous variables between groups, while Fisher's exact test was used for categorical variables and the Mann-Whitney test for independent two samples. A *P* value < 0.05 was considered to indicate statistical significance.

RESULTS

There were no serious complications among the 79 study patients within 30 days (Table III). The duration of hospital stay was 105 ± 45 hours (group A) and 29 ± 3 hours ($P < 0.0001$) in group B. Ejection fraction after 30 days was $56.8 \pm 6.5\%$ in group A versus $57.3 \pm 7\%$ in group B (NS). The patient comfort questionnaire filled in on day 7 showed a clear preference for first day discharge; all patients randomized into group B were satisfied with the first day discharge, while only 37% of patients in group A were satisfied with their standard length of hospital stay. One patient in the pilot nonrandomized phase suffered from a groin arterial pseudo-aneurysm after catheterization that required surgery. One patient

Table III. Clinical Endpoints Within 30 Days

	Pilot phase patients	Group A patients	Group B patients
<i>n</i>	23	19	37
Duration of hospital stay (hours)	119 ± 47	105 ± 45	29 ± 3
Death	0	0	0
Reinfarction	0	0	0
Stroke	0	0	0
Recurrent ischemia	0	0	0
Repeat target vessel revascularization	0	0	0
Arterial access site complications requiring treatment	1	0	0
Rehospitalization	0	0	1
30 days left ventricular ejection fraction (%)	50.6 ± 5.4	56.8 ± 6.5	57.3 ± 7.0

in group B was rehospitalized due to dizziness of noncardiac origin during the first week after MI. The participating Coronary Care Units did not receive any telephone calls, the aim of which was consultation concerning the health condition of the patient, from B group patients (early discharge from hospital).

DISCUSSION

Primary PCI is a method of acute STEMI treatment, which has proved to be safe and effective.⁵⁾ In comparison with intravenous thrombolysis, it leads to a significantly greater reduction in the risk of ischemia recurrence, new myocardial infarction, and to a greater reduction in the risk of cardiac death in some groups of STEMI patients.^{6,7)} Compared with thrombolysis, it brings a lower risk of stroke and hemorrhagic complications. The knowledge of anatomy of the whole coronary bed enables an exact stratification of patients with regard to the risk of another coronary event in the early postinfarction period. Stent indwelling into the affected part of the coronary artery considerably reduces the risk of reocclusion in the early period after AMI.⁸⁾ The aim of our study was to identify a very low risk group of patients who would have no cardiac complications in the early postinfarction period. Considering the above mentioned details and our previous experience with treating STEMI patients, we concluded it would be sufficient to stratify the patients on the basis of physical examination, coronary angiography and coronary intervention, 24-hour ECG monitoring, and echocardiography examination. Exercise test performance was not considered beneficial in our STEMI patients who were randomized into the very early discharge group in this study. Strictly defined criteria and their observance led to the fact that only 3% of acute STEMI patients from the catchment zones of the study centers were randomized in our study. For safety and organizational reasons, the patients whose

transfer distance was greater than 20 km from the facility did not participate in the project. This caused another reduction in the number of suitable patients who could be included in our study.

We determined there were only a few foreign studies dealing with the problems of early discharge from hospital into home care after AMI.^{2,3,4,9)} There was no study in which the average time of hospitalization was less than 72 hours. The majority of these studies dealt with patients treated with intravenous thrombolysis,^{2,4)} and most investigated patients who underwent coronary angiography or exercise testing before discharge from the hospital. This approach, however, did not enable “very early discharge”. The authors of these studies came to the conclusion that organizational problems concerning the early discharge from hospital and the low socioeconomic background of the patients had been the most common reasons the duration of hospitalization could not be reduced below the limit of 72 hours. These problems were unimportant in our patients; very early discharge could not be realized in only a few as they lived on upper floors and there were no elevators in their houses. Our study may be considered as unique with regard to the average time of hospitalization achieved, which did not exceed 30 hours in the very early discharge group of patients. The patients’ evaluation and views of very early discharge from hospital are also important (the reaction of 100% of group B patients was favorable, 60% of group A patients preferred very early discharge to standard length of hospitalization). Our primary goal was not to evaluate the economic benefits of very early discharge in comparison with the standard time of hospitalization in STEMI patients. Emphasis was placed on the possibility and safety of very early discharge into home care and the comfort of the patient.

Study limitations: Our study is limited by the small number of patients (very strict inclusion and exclusion criteria, two participating centers only), so the reproducibility in a large-scale multicenter trial is needed prior to application of this management strategy in clinical practice. Further studies are also needed to verify whether this policy is safe for patients with multivessel disease, elderly patients, and patients who reside far from a PCI center.

Conclusion: Successful primary PCI performed within 6 hours of symptom onset in highly selected low-risk STEMI patients with single vessel disease enables next day discharge from the hospital. However, only a small number of patients fulfilled our criteria for this very early discharge.

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