The Feasibility and Safety of Early Discharge for Low Risk Patients with Acute Myocardial Infarction after Successful Direct Percutaneous Coronary Intervention

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SUMMARY

There is a lack of consensus among cardiologists regarding the length of time patients should be hospitalized after an uncomplicated acute myocardial infarction (AMI) and successful direct percutaneous coronary intervention (d-PCI). The purpose of this study was to evaluate the feasibility and safety of early discharge (discharge <4 days after the procedure) for low risk patients with AMI who underwent successful d-PCI.

From May 1996 through December 2001, d-PCI was performed in 898 consecutive patients with AMI. Of these 898 patients, 463 (51.6%) were stratified to be at low risk. Lower risk was defined as: (1) Killip classification ≤2 on admission; (2) the infarct-related artery achieved normal blood flow without recurrent ischemia or reinfarction in the first 24 hours; (3) no mechanical or electrical complications after d-PCI, (4) no acute renal failure, acute stroke, or major bleeding complication; (5) no advanced congestive heart failure (defined as ≥New York Heart Association functional class 3); and (6) no sepsis. Patients who were discharged <4 days after undergoing the procedure were enrolled in group 1 (*n*=266). Patients who were discharged ≥4 days after undergoing the procedure were enrolled in group 2 (*n*=197). Univariate analysis demonstrated that group 2 patients had a significantly longer hospital stay (*P*=0.0001) than group 1 patients. At the first 30-day follow-up examination, there were no significant differences in the combined major cardiac events (death, recurrent ischemia, reinfarction, revascularization, or advanced congestive heart failure) between the group 1 and group 2 patients (1.50% vs 1.52%, *P*=0.92). There were also no significant differences in the combined major noncardiac complications (acute stroke, acute renal failure, bleeding complications requiring blood transfusion, vascular sequelae, or sepsis) between the group 1 and group 2 patients (1.13% vs 0.51%, *P*=0.89).

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Received for publication May 9, 2002.

Revised and accepted July 4, 2002.
Early discharge was feasible in a majority of the patients who experienced AMI and were at lower risk 24 hours after successful d-PCI. Thus, the patients had a shortened hospital stay and no increased risk. (Jpn Heart J 2003; 44: 41-49)

**Key words:** Acute myocardial infarction, Direct percutaneous coronary intervention, Early discharge, Low risk patients

Because of the continuous development of new devices,1-3) technical refinements,3-6) increasing operator experience, and new developments in preprocedural, intraprocedural, and postprocedural regimens,6-9) early discharge has been shown to be safe and cost-effective for patients who underwent outpatient diagnostic cardiac catheterization and elective coronary angioplasty.10-12) While primary angioplasty,13) especially primary stenting,14) has been demonstrated to be superior to thrombolytic therapy for re-establishing normal flow in the infarct-related artery (IRA), the safety and the benefits of early discharge for low risk patients with acute myocardial infarction (AMI) who underwent successful direct percutaneous coronary intervention (d-PCI) have seldom been evaluated.15)

The purpose of this study was to provide further information as to whether shortening the length of the hospital stay for patients with uncomplicated AMI who underwent successful d-PCI was indeed safe and feasible and without increasing patient risk.

**Patients and Methods**

**Patient population:** In our hospital, all patients with AMI underwent d-PCI after informed consent was obtained. For the purpose of study, all patients undergoing d-PCI were prospectively identified and entered into a computerized database. From May 1996 through December 2001, d-PCI was performed in 898 consecutive patients of all ages who presented with an AMI of <12 hours’ duration in our hospital.

**Patient selection and entry criteria:** In order to explore the feasibility and safety of early discharge (defined as <4 days of hospital stay) for low risk patients who experienced AMI and underwent successful d-PCI, only patients who met the following criteria at 24 hours after d-PCI were included. The criteria were (1) Killip classification on admission \(\leq 2\); (2) the IRA achieved normal coronary flow without recurrent ischemia or reinfarction during the first 24 hours; (3) no mechanical or electrical complications after d-PCI, (4) no acute renal failure, acute stroke, or major bleeding complication (defined as requiring a blood transfusion); (5) no advanced congestive heart failure (defined as \(\geq \) New York Heart Association functional class 3); and (6) no sepsis. Patients were also excluded if: (1) revasculariza-
tion of non-IRA (either coronary artery bypass surgery or stage PCI to other vessel) was performed during hospitalization; or (2) intra-aortic balloon pump support due to distal embolization of IRA was required. A total of 463 (51.6%) of the 898 patients met the inclusion criteria and were divided into two groups. Patients who were discharged <4 days after undergoing the procedure were enrolled in group 1 (n=266; 57.5%) and patients who were discharged 4 days after undergoing the procedure were enrolled in group 2 (n=197; 42.5%).

Procedure and protocol: A percutaneous femoral approach with an 8 French arterial sheath was used in 98.0% of our patients, while a transradial artery approach with a 6 French arterial sheath was used in 2.0%. The radial artery sheath was immediately removed after the procedure and the femoral arterial sheath was removed when the activated clotting time was <150 seconds after the procedure. Patients who received primary balloon angioplasty were given heparin infusion for 18 to 24 hours. Patients who achieved successful primary stenting did not receive additional heparin infusion and were treated with ticlopidine (250 mg PO twice a day) for two weeks. Patients who received adjunctive tirofiban therapy were given continuous tirofiban infusion for 18 hours after loading (loading dose was given before d-PCI: 10 µg/kg; maintenance dose: 0.15 µg/min) without additional heparin use. Aspirin (100 mg PO once a day) was administered to each patient indefinitely.

Definitions: Standard 12-lead electrocardiograms were performed in all patients. AMI was defined as 1) typical chest pain lasting for more than 30 minutes with ST-segment elevation >1 mm in at least two consecutive precordial or inferior leads, 2) typical chest pain lasting for more than 30 minutes with a new onset of complete left bundle branch block, or 3) typical chest pain lasting for more than 30 minutes with ST-segment depression ≥1 mm or definite T-wave inversion or both and an elevation of creatine phosphokinase (CPK) with CK-MB fraction >4.0% on at least one occasion. Procedural success was defined as a reduction to residual stenosis of <40% by balloon angioplasty or successful stent deployment at the desired position with a residual stenosis <20% followed by Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow in the IRA. Recurrent ischemia was defined as recurrent chest pain with or without a new electrocardiographic change. If these findings were associated with at least a 50% increase in the previous CK-MB trough, reinfarction was diagnosed. Multi-vessel disease was defined by a stenosis of >50% in ≥2 major epicardial coronary arteries.

Data collection: Detailed in-hospital and follow-up data, including age, sex, coronary risk factors, Killip score on admission, reperfusion time, pre- and post-TIMI flow grades, angiographic results, number of diseased vessels, and 30-day
follow-up adverse events, were obtained. These data were collected prospectively and entered into a computerized database. 

**Study end points:** The primary end point was the composite of death, reinfarction, recurrent ischemia, repeated revascularization, or advanced congestive heart failure at 30 days after stratification. The secondary endpoint was the combined major noncardiac complications (defined as stroke, acute renal failure, bleeding complications requiring blood transfusion, or sepsis beyond 24 hours after d-PCI)

**Outpatient care and follow-up:** Noninvasive stress testing was not routinely performed and optimal medical treatment was continuously conducted in all survival patients after discharge. Patients had to return to the outpatient department at the end of the first and third weeks after hospital discharge. Patients were advised to return to the outpatient clinic or phone our staff immediately if recurrent chest pain, palpitations, or a new onset of dyspnea developed.

**Statistical analysis:** Data are expressed as mean±SD. Continuous variables were compared using the Student t test or Mann-Whitney test. Categorical variables were compared using the chi-square or Fisher's exact test. All statistical analyses were performed using an SAS system. A P value <0.05 was considered statistically significant.

**RESULTS**

**Baseline clinical characteristics and angiographic findings:** The relevant patient characteristics for both groups are shown in Tables I and II. There were no significant differences in the baseline characteristics in terms of age, gender, coronary artery disease risk factors, previous myocardial infarction, previous stroke, infarction location, Killip classification upon presentation, or time to reperfusion. However, group 1 patients had a significantly shorter hospital stay than group 2 patients. Furthermore, group 1 patients had significantly lower requirements for intensive care (without admission to the coronary care unit) than group 2 patients. Angiographic findings demonstrated that there were no significant differences in terms of mean left ventricular function, number of diseased vessels, target vessel involvement, reperfusion methods, percentage of patients receiving tirofiban therapy, or post d-PCI residual stenosis between the 2 groups. Nearly 60% of the patients in group 1 and over 56% of the patients in group 2 underwent stent implantation (P=NS).

**Reasons for delayed hospital discharge in group 2 patients (Table III):** The reasons for delayed hospital discharge for group 2 patients included waiting for a bed in the emergency department after d-PCI, need for a test (including echocardiography, Holter electrocardiogram), a bed in the step-down unit was not available, patient reluctance to be discharged earlier or the physician's discretion, fever due
### Table I. Baseline Clinical Characteristics of the 463 Patients

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (n=266)</th>
<th>Group 2 (n=197)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>58.6±11.7</td>
<td>60.1±12.1</td>
<td>0.19</td>
</tr>
<tr>
<td>Male: female</td>
<td>243:23</td>
<td>170:27</td>
<td>0.08</td>
</tr>
<tr>
<td>Hypertension</td>
<td>41.4% (110)</td>
<td>49.2% (97)</td>
<td>0.09</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>24.8% (66)</td>
<td>24.4% (48)</td>
<td>0.91</td>
</tr>
<tr>
<td>Current smoking</td>
<td>59.8% (159)</td>
<td>63.5% (125)</td>
<td>0.42</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>50.0% (133)</td>
<td>45.7% (90)</td>
<td>0.36</td>
</tr>
<tr>
<td>Previous MI</td>
<td>9.4% (25)</td>
<td>9.6% (19)</td>
<td>0.93</td>
</tr>
<tr>
<td>Previous stroke</td>
<td>4.5% (12)</td>
<td>4.1% (8)</td>
<td>0.81</td>
</tr>
<tr>
<td>Infarction location by electrocardiogram</td>
<td></td>
<td></td>
<td>0.95</td>
</tr>
<tr>
<td>Anterior wall</td>
<td>59.0% (157)</td>
<td>61.4% (121)</td>
<td></td>
</tr>
<tr>
<td>Inferior wall</td>
<td>36.8% (98)</td>
<td>34.5% (68)</td>
<td></td>
</tr>
<tr>
<td>Lateral wall</td>
<td>1.9% (5)</td>
<td>2.0% (4)</td>
<td></td>
</tr>
<tr>
<td>Non-Q wave MI</td>
<td>2.3% (6)</td>
<td>2.0% (4)</td>
<td></td>
</tr>
<tr>
<td>Killip classification</td>
<td></td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Killip I</td>
<td>78.2% (208)</td>
<td>79.2% (156)</td>
<td></td>
</tr>
<tr>
<td>Killip II</td>
<td>21.8% (58)</td>
<td>20.8% (41)</td>
<td></td>
</tr>
<tr>
<td>Time to reperfusion (minutes)</td>
<td>287±122</td>
<td>293±113</td>
<td>0.86</td>
</tr>
<tr>
<td>Duration of hospital stay (days)</td>
<td>3.37±0.77</td>
<td>5.98±0.93</td>
<td>0.0001</td>
</tr>
<tr>
<td>Without admission to coronary care unit</td>
<td>17.3% (46)</td>
<td>0% (0)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Data are expressed as mean±SD or % (number) of patients. MI=myocardial infarction.

### Table II. Angiographic Results and Reperfusion Methods for the 463 Patients

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (n=266)</th>
<th>Group 2 (n=197)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEF (%)</td>
<td>53.6±10.9</td>
<td>55.3±12.1</td>
<td>0.63</td>
</tr>
<tr>
<td>No. of diseased vessels</td>
<td></td>
<td>0.54</td>
<td></td>
</tr>
<tr>
<td>Single vessel</td>
<td>54.1% (144)</td>
<td>51.3% (101)</td>
<td></td>
</tr>
<tr>
<td>Multivessel</td>
<td>45.9% (122)</td>
<td>48.7% (96)</td>
<td></td>
</tr>
<tr>
<td>LMCA disease</td>
<td>1.9% (5)</td>
<td>1.5% (3)</td>
<td>1.00</td>
</tr>
<tr>
<td>Target vessel involvement</td>
<td></td>
<td>0.51</td>
<td></td>
</tr>
<tr>
<td>LAD</td>
<td>60.9% (162)</td>
<td>62.9% (124)</td>
<td></td>
</tr>
<tr>
<td>RCA</td>
<td>30.1% (80)</td>
<td>31.0% (61)</td>
<td></td>
</tr>
<tr>
<td>LCX</td>
<td>9.0% (24)</td>
<td>6.1% (12)</td>
<td></td>
</tr>
<tr>
<td>Reperfusion methods</td>
<td></td>
<td>0.56</td>
<td></td>
</tr>
<tr>
<td>Stent</td>
<td>59.0% (157)</td>
<td>56.3% (111)</td>
<td></td>
</tr>
<tr>
<td>Balloon</td>
<td>41.0% (109)</td>
<td>43.7% (86)</td>
<td></td>
</tr>
<tr>
<td>Adjunctive tirofiban therapy</td>
<td>24.8% (66)</td>
<td>19.8% (39)</td>
<td>0.20</td>
</tr>
<tr>
<td>Post d-PCI residue stenosis (%)</td>
<td>12.45±9.8</td>
<td>13.55±12</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Data are expressed as mean±SD or % (number) of patients. d-PCI=direct percutaneous coronary intervention; LAD=left anterior descending artery; LCX=left circumflex artery; LMCA=left main coronary artery; LVEF=left ventricular ejection fraction; RCA=right coronary artery.
to upper respiratory infection and others. The majority of the reasons for delayed hospital discharge were patient reluctance to be discharged earlier or the physician's discretion (51.3%), followed by waiting for a bed in the emergency department after d-PCI. Further analysis demonstrated that the physician's discretion was the most common reason for delayed hospital discharge.

**Comparison of untoward events during the first 30 day follow-up between the 2 groups (Table IV):** Risk evaluation was performed again before hospital discharge. There was no major cardiac or noncardiac complication in group 1 patients before hospital discharge. At the 30-day follow-up examination, the overall combined major cardiac events and combined major noncardiac complications in our patients were 1.5% and 0.9%, respectively. There were no significant differences in combined major cardiac events ($P=0.92$) or combined major

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**Table III.** Reasons for Delayed Discharge in 197 Patients

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waiting for bed in emergency room after the procedure</td>
<td>15.2%</td>
</tr>
<tr>
<td>Need for a test (echocardiography, Holter electrocardiogram)</td>
<td>6.1%</td>
</tr>
<tr>
<td>Step-down unit bed not available</td>
<td>14.7%</td>
</tr>
<tr>
<td>Physician's discretion</td>
<td>37.1%</td>
</tr>
<tr>
<td>Request by patient and family</td>
<td>14.2%</td>
</tr>
<tr>
<td>Fever due to upper respiratory tract infection</td>
<td>7.1%</td>
</tr>
<tr>
<td>Others</td>
<td>5.6%</td>
</tr>
</tbody>
</table>

**Table IV.** Untoward Events of First 30 Days of Follow-up for 463 Patients

<table>
<thead>
<tr>
<th></th>
<th>Group 1 ($n=266$)</th>
<th>Group 2 ($n=197$)</th>
<th>$P$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined major cardiac events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0 (0%)</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Reinfarction</td>
<td>1 (0.4%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Recurrent ischemia</td>
<td>1 (0.4%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>IRA revascularization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>1 (0.4%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>CABG</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Advanced CHF</td>
<td>1 (0.4%)</td>
<td>2 (1.0%)</td>
<td></td>
</tr>
<tr>
<td>Combined major noncardiac complications</td>
<td></td>
<td></td>
<td>0.89</td>
</tr>
<tr>
<td>Acute stroke</td>
<td>1 (0.4%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Acute renal failure</td>
<td>1 (0.4%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>UGI bleeding</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>0 (0%)</td>
<td>1 (0.5%)</td>
<td></td>
</tr>
<tr>
<td>Late vascular sequelae</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) pseudoaneurysm</td>
<td>1 (0.4%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>2) arteriovenous fistular formation</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
</tbody>
</table>

Data are expressed as number (%) of patients. CABG=coronary artery bypass graft surgery; CHF=congestive heart failure; IRA=infarct-related artery; PTCA=percutaneous coronary intervention; UGI=upper gastrointestinal tract.
noncardiac complications ($P=0.89$) between group 1 and group 2 patients.

**DISCUSSION**

**Feasibility and safety of early discharge for low risk AMI patients:** In the present study, we found that 463 (51.6%) of the 898 patients who experienced uncomplicated AMI and underwent successful d-PCI were ready for early discharge with very low 30-day combined major cardiac (1.5%) or major noncardiac events (0.9%). Group 1 patients who were discharged in <4 days had a significantly shorter duration of hospital stay than Group 2 patients ($P=0.0001$). Therefore, early discharge was safe and feasible.

Of the 463 patients, over 57% received stent implantation. In our previous study, we demonstrated that combination therapy with ticlopidine and aspirin without further heparin infusion after successful primary stenting in patients with uncomplicated AMI was feasible and safe. Our findings suggested that with the worldwide increase in the use of stent-supported direct coronary angioplasty, there should be an increase in the number of low risk AMI patients who undergo successful d-PCI and can be discharged earlier than normal without increasing the risk of an unfavorable clinical outcome.

**Comparison with previous studies:** While primary angioplasty, especially primary stenting, has been demonstrated to be superior to thrombolytic therapy for re-establishing normal flow in the IRA, the safety and potential benefit of early discharge after successful d-PCI in low risk patients has seldom been discussed. To the best of our knowledge, only one prospective randomized study, the PAMI-II trial, has evaluated the hypothesis that primary percutaneous transluminal coronary angioplasty (PTCA), with subsequent discharge from the hospital 3 days after undergoing the procedure, is safe and cost-effective in low risk patients. In the PAMI-II trial, the risk stratification and randomization were performed immediately after primary PTCA. In their study, 471 (51.9%) of 908 patients were low risk and 237 (50.3%) of the 471 patients were randomized to receive accelerated care and early discharge (admission to a nonintensive care unit and day 3 discharge without a noninvasive test). However, 25% (59 patients) of the 237 patients were found to have protocol-designated contraindications for early discharge. These contraindications included death (0.4%), transient ischemic attack (0.4%), chest pain (7.7%), congestive heart failure (1.7%), arrhythmia (8.5%), bleeding (3.0%) and fever (3.4%), all of which developed within the first 72 hours after undergoing the procedure. In addition, 10% of the combined adverse events were noted early after PTCA in both the study and control groups. In our study, the risk stratification was performed 24 hours after the successful d-PCI and our results demonstrated that, for low risk patients, only
very few combined untoward events occurred within 30 days after d-PCI. Previous studies have demonstrated that serious complications, including death, usually occur within 48 hours after AMI. Therefore, it would be more appropriate to perform risk stratification at least 24 hours after d-PCI for patients with AMI in order to safely discharge patients earlier.

In the PAMI-II study, it is interesting to note that of the 178 who were eligible for early hospital discharge, only 142 (79.8%) were discharged on day 3 of hospitalization. This finding suggests that more than 20% of the patients were reluctant to be discharged earlier. In our study, we found that more than 42% of the patients had delayed hospital discharge. The reasons for delayed hospital discharge included waiting for a bed in the emergency department after the procedure for 15.2%, the need for further tests for 6.1%, a step-down unit bed was not available for 14.7%, reluctance to be discharged early for 51.3%, fever due to upper respiratory infection for 7.1%, and other reasons for 5.4%. It was surprising to find that for more than one-third the reason for the delayed discharge was attributed to a decision by the physician. Therefore, based on the PAMI-II and our data, substantial numbers of low risk patients could be discharged earlier if physicians were confident in risk stratification.

Our study had several limitations. First, it was not designed to evaluate the incidence of low risk patients with AMI undergoing d-PCI. Therefore, the true incidence of low risk patients in the AMI population might have been underestimated. Second, this was a retrospective and nonrandomized study. Therefore, the potential risk of bias could not be completely excluded. However, this prospective manner might provide a more truthful representation for our understanding of the incidence and different reasons for delayed hospital discharge in low risk patients after successful d-PCI. Third, our study was not designed to evaluate the clinical outcomes in terms of recurrent ischemia or recurrence of infarction between primary stenting and balloon angioplasty. Therefore, we could not provide information as to whether more patients who received primary stenting could be discharged earlier than patients who received primary balloon angioplasty. Finally, this was a retrospective study. Therefore, regarding the time to risk stratification, there was no comparison in this study. However, there were no major cardiac or noncardiac complications in group 1 patients before hospital discharge.

In conclusion, patients who experienced AMI and were stratified as low risk 24 hours after d-PCI could be safely discharged early. Thus, the patients experienced a shorter hospital stay without an increase in risk.
REFERENCES


