A Randomized Study Comparing Same-Day Home Discharge and Abciximab Bolus Only to Overnight Hospitalization and Abciximab Bolus and Infusion After Transradial Coronary Stent Implantation

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Background—Systematic use of coronary stents and optimized platelet aggregation inhibition has greatly improved the short-term results of percutaneous coronary interventions. Transradial percutaneous coronary interventions have been associated with a low risk of bleeding complications. It is unknown whether moderate- and high-risk patients can be discharged safely the same day after uncomplicated transradial percutaneous coronary interventions.

Methods and Results—We randomized 1005 patients after a bolus of abciximab and uncomplicated transradial percutaneous coronary stent implantation either to same-day home discharge and no infusion of abciximab (group 1, n=504) or to overnight hospitalization and a standard 12-hour infusion of abciximab (group 2, n=501). The primary composite end point of the study was the 30-day incidence of any of the following events: death, myocardial infarction, urgent revascularization, major bleeding, repeat hospitalization, access site complications, and severe thrombocytopenia. The noninferiority of same-day home discharge and bolus of abciximab only compared with overnight hospitalization and abciximab bolus and infusion was evaluated. Two thirds of patients presented with unstable angina and ≈20% presented with high-risk acute coronary syndrome prior to the procedure. The incidence of the primary end point was 20.4% in group 1 and 18.2% in group 2 (P=0.017 for noninferiority) with a troponin T–based definition of myocardial infarction; the incidence of the primary end point was 11.1% in group 1 and 9.6% in group 2 (P=0.0004 for noninferiority) with a creatinine kinase myocardial band–based definition of myocardial infarction. No death occurred. Rate of major bleeding in both groups was extremely low at 0.8% and 0.2%, respectively. From 504 patients randomized in group 1, 88% were discharged home the same day.

Conclusion—Our data suggest that same-day home discharge after uncomplicated transradial coronary stenting and bolus only of abciximab is not clinically inferior, in a wide spectrum of patients, to the standard overnight hospitalization and a bolus followed by a 12-hour infusion. This novel approach offers a safe strategy for same-day home discharge after uncomplicated coronary intervention. (Circulation. 2006;114:2636-2643.)

Key Words: angioplasty ▪ coronary disease ▪ platelets ▪ stents ▪ trials ▪ transradial

Despite significant improvements in clinical results associated with the current use of stenting and adjunctive pharmacological agents, there has been little decrease in hospitalization duration after percutaneous coronary interventions (PCI). The main reasons associated with hospitalization after PCI remain the fear of abrupt vessel closure and its associated morbidity, and the need for prolonged bed rest with femoral approach, even with closure devices. Furthermore, the use of glycoprotein IIb-IIIa inhibitors precludes same-day home discharge by requiring 12-hour infusion for abciximab and 18- to 24-hour infusion for eptifibatide and tirofiban. Therefore, overnight hospitalization remains the norm.

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The introduction of coronary stents has been associated with a dramatic decrease in vessel closure after coronary intervention. Currently, stent thrombosis occurs in \(\approx 1\%\) of the cases.\(^4\) However, stent thrombosis is associated with significant risks of morbidity and mortality.\(^4\) A few trials with no or abbreviated treatment with glycoprotein IIb-IIIa inhibitors have already demonstrated the feasibility and safety of same-day discharge after balloon angioplasty or stenting in selected low-risk patients.\(^5\)\

Transradial PCI appears safer and potentially more cost-effective than femoral PCI.\(^13\) Several randomized trials have demonstrated fewer entry site complications after transradial PCI compared with femoral approach, including when femoral artery closure devices were used.\(^14\)\(^15\)

On the basis of the Evaluation of 7E3 for the Prevention of Ischemic Complications (EPIC) study results and the suboptimal outcomes with abciximab as bolus only compared with bolus and infusion, it was recommended to prolong platelet inhibition by a 12-hour infusion of abciximab after administration of the initial bolus.\(^16\) However, worse outcomes in the EPIC bolus only group were driven entirely by rates of urgent repeat revascularization at 30 days (3.6\% bolus group versus 0.8\% bolus and infusion group, \(P<0.001\)), a complication probably related to the lack of stent use at that time (< 1\%).

Importantly, there was no significant difference in terms of death or myocardial infarction (MI) whether the bolus was followed by the infusion or not.

We hypothesized that with stent implantation and transradial approach, abciximab as bolus only would be as effective as bolus and 12-hour infusion therapy and that a wide spectrum of low-, moderate-, and high-risk patients treated with abciximab bolus only could be safely discharged home the same day.

Methods

Study Population

Patients referred for diagnostic catheterization and possible PCI (ad hoc procedures) were eligible if they were older than 18 years and underwent successful coronary stenting by transradial approach. Patients were excluded for clinical reasons if they had a recent (< 72 hour) ST-elevation MI; had a history of ejection fraction \(\leq 30\%\); presented transient vessel closure or hemodynamic collapse during PCI; had a femoral artery sheath or any other outside consideration precluding same-day home discharge; or had allergy, intolerance to aspirin or thienopyridines, international normalized ratio > 2.0, or contraindication to abciximab. Except for secondary branch in case of bifurcation lesion or reidilatation for in-stent restenosis, all lesions had to be stented. The protocol was approved by Health Canada and the Laval Hospital Ethics Review Board and the protocol was published on the Clinical Trials Web site. All patients signed an informed consent prior to the procedure.

Study Design and Protocol

The study was a randomized, controlled, open-label study comparing same-day home discharge and bolus only of abciximab (group 1) to overnight hospitalization and standard bolus + 12-hour infusion of abciximab after uncomplicated transradial coronary stenting (group 2). Patients with unsuccessful PCI were not randomized and entered a parallel registry (see below).

Hospitalized patients were randomized after successful PCI to either same-day home discharge or to overnight hospitalization (either at the referring center or at our institution). Outpatients were randomized after successful PCI either to same-day home discharge or to continued hospitalization at our institution until the next morning.

All patients were pretreated with aspirin and thienopyridines (minimum loading dose of 300 mg clopidogrel if \(\leq 3\) days of pretreatment) prior to diagnostic angiography. After sheath insertion, a bolus of 70 U/kg heparin was given intravenously. Before the first balloon inflation, the bolus of abciximab (0.25 mg/kg ReoPro, Centocor, Malvern, Pa) was given. After stent implantation and good angiographic results, patients were randomly assigned using sealed envelopes containing the block randomization sequence to (1) a group in which no infusion of abciximab was given and patients could be discharged home 4 to 6 hour after PCI (group 1), or (2) a group in which an infusion of abciximab (0.125 \(\mu\)g/kg per min to a maximum of 10 \(\mu\)g/min) was started for a period of 12 hours and patients remained hospitalized overnight (group 2).

Unsuccessful stenting was defined by persistent \(\equiv\) type B dissection according to Nature, Heart, Lung, and Blood Institute classification,\(^9\) compromise or loss of side-branch (\(\geq 1 \text{ mm}\)), abnormal thrombolysis in myocardial infarction (TIMI) flow or presence of thrombus. Registry patients with unsuccessful stenting received a 12-hour infusion of abciximab and remained hospitalized as decided by the operator. Vascular sheaths were removed at the end of the procedure and a hemostasis band remained in place until hemostasis was completed.

Hematology and chemistry profiles were performed before and after the procedure according to current practice. Troponin-T (Tn-T), total creatine kinase (CK), and CK-myocardial band (CK-MB) were evaluated on samples taken immediately before the procedure, after PCI (4 to 6 hours) and the next day (12 to 24 hours). For patients discharged home, next day blood samples were obtained either in our hospital, in referring centers, or in other laboratories. For patients discharged home or transferred to a referring center, all blood samples for cardiac biomarkers were forwarded to our center core laboratory for analysis. In case of repeat PCI or coronary bypass grafting, the same markers were obtained before and after the intervention and analyzed by the central core laboratory.

An ECG was obtained before, after (4 to 6 hours), the day after PCI (12 to 24 hours), and at 30 days (\(\leq 7\) days). All ECGs were sent to our central core laboratory and were reviewed by an independent cardiologist (P.P.), who was blinded to patient group assignment.

Study personnel contacted all patients the day after PCI and at 30 to 17 days and recorded any clinically relevant adverse events, including repeat hospitalization and unsolicited medical visits. A blinded data safety monitoring board reviewed summary data during the study enrolment. All major events were adjudicated by a clinical event committee, which remained blinded to treatment assignment.

Study End Points

The primary composite end point included any of the following 7 events at 30 days: death from any cause, Q and non-Q wave MI, any unplanned revascularization (PCI or coronary artery bypass graft) for ischemia, major bleeding according to Randomized Evaluation in PCI Linking Angiogram to Reduced Clinical Events (REPLACE-2) study criteria,\(^8\) repeat hospitalization for any cause related to the index procedure, severe thrombocytopenia (platelet count \(\leq 50,000/\mu\text{L}\)), and access site complications (such as fistulas, pseudo-aneurysms, complication requiring surgery, local infection requiring antibiotics, and moderate to severe [\(\geq\) grade II] local hematomas). The secondary composite end point included death, MI, and repeat target vessel revascularization at 30 days. Major bleeding included intracranial, intraocular, or retroperitoneal hemorrhage, clinically overt blood loss resulting in a decrease in hemoglobin of \(> 3 \text{ g/dL}\), any decrease in hemoglobin of \(> 4 \text{ g/dL}\), or transfusion of \(\equiv 2 \text{ U}\) of packed red blood cells or whole blood.\(^18\) Local hematomas were graded according to a specific scale: type I, \(\leq 5 \text{ cm diameter}\); type II, \(\leq 10 \text{ cm diameter}\); type III, \(> 10 \text{ cm but not above the} \text{; type IV, extending above the} \text{; type V, anywhere with ischemic threat of the} \text{. Q wave MIs were graded according to the Minnesota code. For non-Q wave MI, both troponin-T (Tn-T) and CK-MB–based definitions were applied. According to Tn-T values, non-Q wave MI were recognized when}
any value post-PCI was ≥3 times baseline value and >0.1 ng/mL. According to CK-MB values, non–Q wave MI were recognized when any value post-PCI was 3x upper limit normal value, ie, >30 μg/mL in our laboratory. In case of elevated value of cardiac biomarkers prior to PCI, non–Q wave MI was adjudicated when elevation post-PCI was ≥50% higher than the pre-PCI value. The number of unsolicited medical visits defined as any unplanned medical visit related to the index procedure was also recorded.

### Sample Size and Data Analysis

The study was designed as a noninferiority trial. On the basis of our previous clinical experience and serial troponin assessment, we hypothesized an event rate of 23% for the primary composite end point (using TnT-based MI definition) in overnight hospitalization and the bolus + infusion group, and we estimated an absolute upper margin for noninferiority of 8%. Using the Blackwelder equation with a power of 90% and a 1-sided α value of 5%, we calculated a sample size of 948 patients. To account for possible crossover, we further expanded randomization to include 1005 patients. Data were collected in dedicated case-report forms and data entry was performed through secure Internet link into a database located at Gestion Recherche Quebec (GEREQ; Montreal, Canada). High-quality data acquisition was performed by double-checking with 100% of source documents.

Categorical variables were expressed as numbers and percentages and continuous variables as mean±SD. Baseline and procedural characteristics were compared between the 2 groups using χ² tests for categorical variables and Student t tests for continuous variables.

Primary and secondary composite end points were calculated as cumulative incidence of events. The primary and secondary end points were analyzed using the test statistic described by Blackwelder for a 1-sided null hypothesis stating that overnight hospitalization and bolus abciximab and 12-hour infusion is better than same-day home discharge and abciximab bolus only. The χ² test was used to compare the event rates in the randomized groups and the registry. For the components of the primary and secondary end points, 95% confidence intervals are presented for the difference (event rate in group 1 minus event rate in group 2). The upper bound of this confidence interval indicates the maximal amount by which the event rate in group 1 could exceed the event rate in group 2. Event-free survival curves for the primary end point were constructed according to Kaplan-Meier techniques. All analyses were conducted according to the intent-to-treat principle, and a probability value <0.05 was considered significant. Statistical tests were performed with SAS software, version 8.2 (SAS Institute, Cary, NC). The authors had full access to and take responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

### Results

Study recruitment was conducted at Laval Hospital from October 2003 to April 2005 (Figure 1). There were no significant differences between the 2 groups in baseline characteristics (Table 1). The overall population was at moderate and high risk, as two thirds of patients presented with unstable angina and 20% presented with high-risk acute coronary syndrome with a Tn-T value ≥0.1 ng/mL prior to the procedure. Five hundred ten patients (38%) originated from home, 120 (9%) were hospitalized in our institution prior to PCI, and 718 (53%) were transferred from referring centers. No significant differences in procedural characteristics existed between the 2 groups (Table 2). Clinical follow-up at 30 days was 100%.

The primary end point was equivalent in both groups, whether the definition for MI was Tn-T–based (20.4% in group 1 versus 18.2% in group 2, P=0.017 for noninferiority) or CK-MB–based (11.1% in group 1 and 9.6% in group 2, P=0.0004 for noninferiority) (Figure 2A and 2B). The registry patients with unsuccessful stenting had more events as compared with both

TABLE 1. Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (n=504)</th>
<th>Group 2 (n=501)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>60±10</td>
<td>61±10</td>
</tr>
<tr>
<td>Male</td>
<td>395 (78)</td>
<td>395 (79)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>83 (16)</td>
<td>82 (16)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>424 (84)</td>
<td>441 (88)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>263 (52)</td>
<td>276 (55)</td>
</tr>
<tr>
<td>Family history</td>
<td>354 (70)</td>
<td>372 (74)</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>169 (33)</td>
<td>171 (34)</td>
</tr>
<tr>
<td>Previous MI</td>
<td>219 (43)</td>
<td>224 (45)</td>
</tr>
<tr>
<td>Previous PCI</td>
<td>107 (21)</td>
<td>93 (19)</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>334 (66)</td>
<td>335 (67)</td>
</tr>
<tr>
<td>MI &lt;7 days</td>
<td>167 (33)</td>
<td>168 (34)</td>
</tr>
<tr>
<td>Tn-T &gt;0.1 ng/ml</td>
<td>93 (18)</td>
<td>95 (19)</td>
</tr>
<tr>
<td>Clopidogrel &gt;12 hours</td>
<td>463 (92)</td>
<td>452 (90)</td>
</tr>
</tbody>
</table>

Group 1: bolus only + same-day home discharge. Group 2: bolus and 12 hours infusion + overnight hospitalization. Data are mean±SD or No. of patients (%).
vealed distal vessel occlusion and repeat angioplasty was performed. This was the only patient with target vessel revascularization; 4 others underwent repeat PCI in vessels other than the initial target vessel.

To evaluate myocardial necrosis and the safety of same-day home discharge after abciximab bolus without infusion, we assessed serial Tn-T changes after PCI. In the bolus only group, TnT was 0.457 ng/mL pre-PCI, 0.178 ng/mL 4 to 6 hour later, and 0.176 ng/mL the next day. In the bolus + infusion group, Tn-T was 0.475 ng/mL pre-PCI, 0.174 ng/mL 4 to 6 hour later, and 0.176 ng/mL the next day. The mean baseline Tn-T values in both groups highlight the fact that the study population was at moderate and high risk prior to the procedure. Changes in Tn-T were similar in both groups. It is noteworthy that the majority of patients were safely discharged home despite elevated Tn-T post-PCI. Furthermore, even assessing minimal myonecrosis induced by PCI, there was no penalty of withholding abciximab infusion in our population. Overall, results with patients at higher risk were consistent with those at lower risk.

Major bleeding was extremely low in both groups (0.8% and 0.2%), representing a total of 5 out of 1005 patients (Table 3). Furthermore, among these 5 patients, 2 were adjudicated as major bleeding according to a drop in hemoglobin without external bleeding; the other 3 patients were rectal bleeding. Transfusions were given to 2 patients in each group. Although the only access site complication was local hematoma, most were transient and resolved after local compression without preventing same-day home discharge. Importantly, same-day home discharge did not lead to increased repeat hospitalization (5% in group 1 versus 3% in group 2) or to more unsolicited medical visits (6% in both groups).

Among the 504 patients randomized to group 1, 88% were discharged home the same day. For the 61 patients who remained hospitalized, the reasons were: physician preference in 25 cases; delayed hemostasis/local bleeding or thrombocytopenia in 18 cases; patient preference in 10 cases; and persisting chest pain in 8 cases. In group 2, only 1 patient did not receive abciximab infusion. Therefore, our results analyzed as per-protocol assigned are consistent with the intent-to-treat analysis.

### Discussion

The increasing demand for PCI has created a significant burden on hospital bed availability. Moreover, the increasing use of drug-eluting stents and pharmacological therapies such as glycoprotein IIb–IIIa inhibitors have added clinical benefit but have also caused a significant increase in PCI costs. Therefore, we intended to demonstrate that the use of transradial coronary stenting with abciximab bolus only would allow a majority of moderate- and high-risk patients to be discharged home safely the same day. Indeed, the primary composite end point, including ischemic and bleeding events, likely to lead to a change of practice was similar in the 2 randomized groups. After successful transradial coronary stenting with a bolus only of abciximab, even patients at higher risk can be safely discharged home the same day. Both randomized groups had significantly lower events at 30 days than in the registry. This indicates that the strategy we propose allows accurate identification of those patients who can safely be discharged early. It should be noted that, from 1348 enrolled patients, 1005 were successfully randomized and 343 (25%) entered the registry. This suggests that our novel strategy could be applied to a majority of the study population (≈75%) who undergo transradial PCI (Figure 1).

The clinical equivalence between abciximab as bolus only and the bolus followed by a 12-hour infusion rests on some unique properties of abciximab. The bolus of abciximab represents ≈75% of the total dose. Pharmacological data have shown that a single bolus (0.25 mg/kg) of abciximab induces >80% of platelet aggregation inhibition and this effect is prolonged for several hours. It is also currently recommended to administer clopidogrel before catheterization, and the sooner the better. A minimal loading dose of 300 mg provides maximal ADP-induced platelet aggregation inhibition within a few hours. Recent data have suggested that higher loading dose of clopidogrel could produce more rapid and higher ADP-induced platelet aggregation inhibition. This is most relevant when PCI is performed within a few hours (≈6 hour) after clopidogrel inhibition. In our study, efforts were maximized to initiate clopidogrel as soon as possible, most often in the referring centers. More than 90% of patients received their loading dose at least 12 hour prior to the procedure, which seems as important as the dose itself. It should be acknowledged that this delay cannot be obtained in all patients and in this setting larger loading doses provide a significant benefit.

The combination of abciximab and clopidogrel provides optimal platelet aggregation inhibition considering the almost
Figure 2. Event-free survival curves for primary end points with Tn-T and CK-MB at 30 days. Kaplan-Meier event curves for the primary end point (death, MI, urgent revascularization, major bleeding, repeat hospitalization, access site complication, and severe thrombocytopenia) using Tn-T–based MI definition (A) and CK-MB–based MI definition (B). Note that most events occurred during the first 24 hours.
immediate and profound platelet aggregation inhibition obtained with abciximab together with the more selective, less potent, and delayed inhibition of platelet activation obtained with clopidogrel. In the Do Tirofiban and ReoPro Give Similar Efficacy Outcome (TARGET) trial, patients with triple therapy had better clinical outcomes at 1 year. In contrast, in the Intracoronary Stenting and Antithrombotic Regimen: Rapid Early Action for Coronary Treatment (ISAR-REACT) trial, it was shown that abciximab failed to demonstrate additional clinical benefit after 6 hour pretreatment with 600 mg of clopidogrel. Very recently, in ISAR-REACT 2, Kastrati et al suggested that, the benefit of abciximab was confined to patients at higher risk with troponin positive before PCI. Our study population included a majority of patients for whom current guidelines for PCI still recommend glycoprotein IIb-IIIa inhibitors. In accordance with today’s practices, our study involved a majority of moderate- and high-risk patients with two thirds with unstable angina, 35% having presented an acute MI in the previous 7 days, and 20% having Tn-T >0.1 ng/mL at the time of the procedure. Furthermore, it should be noted that, in ISAR-REACT and ISAR-REACT-2, troponin changes after PCI were not assessed. Gurbel et al showed higher platelet aggregation inhibition with triple therapy compared with aspirin + 300 mg or 600 mg clopidogrel at 8 hour and at 18 to 24 hours after stenting; this was correlated with statistically lower CK-MB, Tn-I, and myoglobin release. Given the higher sensitivity and specificity of troponin-T, we elected to monitor troponin-T changes as an optimal marker of myocardial infarction. Because the combination of clopidogrel and glycoprotein IIb-IIIa inhibitors has been shown to further reduce troponin release after PCI, we felt it important to exclude a possible harm of withholding abciximab infusion in moderate- and high-risk patients, especially with a strategy of same-day home discharge. Using troponin-T–based and CK-MB–based MI definition, our results demonstrate no penalty at 30 days to the use of abciximab bolus only, in cases of uncomplicated PCI. It will be important to evaluate whether clinical equivalence is maintained at longer clinical follow-up.

A recent meta-analysis has shown that the rate of vascular complications and the risk of bleeding were consistently lower after transradial approach compared with the traditional femoral approach. Although its use is increasing, transradial PCI is performed less frequently than the femoral approach. Reasons advanced for this include a steeper learning curve for practitioners and the impossibility of using certain larger devices. Indeed, our study reported an overall rate of major bleeding of 0.5% (1.4% when the registry is included). This contrasts favorably with reports from recent studies using the femoral approach such as REPLACE-2, which reported rates of major bleeding of 4.1% with heparin and glycoprotein IIb-IIIa inhibitors and 2.4% after bivalirudin and provisional glycoprotein IIb-IIIa inhibitors. Same-day home discharge after uncomplicated transradial stenting imposes a dramatic change of practice. Beyond the

### TABLE 3. Thirty-Day Results

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (n=504)</th>
<th>Group 2 (n=501)</th>
<th>One-Sided Upper Bound, 95% CI*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tn-T primary end point</td>
<td>103 (20.4)</td>
<td>91 (18.2)</td>
<td>6.4</td>
</tr>
<tr>
<td>Tn-T secondary end point</td>
<td>63 (12.5)</td>
<td>52 (10.4)</td>
<td>5.4</td>
</tr>
<tr>
<td>CK-MB primary end point</td>
<td>56 (11.1)</td>
<td>48 (9.6)</td>
<td>4.7</td>
</tr>
<tr>
<td>CK-MB secondary end point</td>
<td>7 (1.4)</td>
<td>9 (1.8)</td>
<td>0.9</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>⋯</td>
</tr>
<tr>
<td>Q wave MI</td>
<td>2 (0.4)</td>
<td>0</td>
<td>⋯</td>
</tr>
<tr>
<td>Tn-T non-Q wave MI</td>
<td>63 (12.5)</td>
<td>52 (10.4)</td>
<td>5.4</td>
</tr>
<tr>
<td>CK-MB Non-Q wave MI</td>
<td>5 (1.0)</td>
<td>9 (1.8)</td>
<td>0.9</td>
</tr>
<tr>
<td>Urgent revascularization</td>
<td>5 (1.0)</td>
<td>0</td>
<td>⋯</td>
</tr>
<tr>
<td>Urgent PCI</td>
<td>5 (1.0)</td>
<td>0</td>
<td>⋯</td>
</tr>
<tr>
<td>Urgent CABG</td>
<td>0</td>
<td>0</td>
<td>⋯</td>
</tr>
<tr>
<td>Repeat hospitalization</td>
<td>24 (4.8)</td>
<td>17 (3.4)</td>
<td>3.4</td>
</tr>
<tr>
<td>Unsolicited medical visit</td>
<td>30 (6)</td>
<td>32 (6)</td>
<td>⋯</td>
</tr>
<tr>
<td>Access site complication</td>
<td>24 (4.8)</td>
<td>21 (4.2)</td>
<td>2.7</td>
</tr>
<tr>
<td>Major bleeding</td>
<td>4 (0.8)</td>
<td>1 (0.2)</td>
<td>1.3</td>
</tr>
<tr>
<td>Thrombocytopenia &lt;50 000/µL</td>
<td>3 (0.6)</td>
<td>3 (0.6)</td>
<td>⋯</td>
</tr>
<tr>
<td>Transfusion</td>
<td>2 (0.4%)</td>
<td>2 (0.4%)</td>
<td>⋯</td>
</tr>
</tbody>
</table>

*One-sided upper bound 95% confidence interval (CI) for the difference (event rate with early discharge — event rate with overnight hospitalization). Data are No. of patients (%).
safety aspects, many hurdles need to be recognized that will likely influence the acceptance of this practice. For hospital management, there may be little financial incentive, as rates of reimbursement involve at least 1 or 2 nights spent at the hospital. However, in the interest of patients and from the societal point of view, it would be more appropriate to allocate maximum resources to the procedure and shift to outpatient practice when feasible and safe. Furthermore, the development of multidisciplinary PCI clinics to ensure management of short-term logistics and patient follow-up, as well as cardiovascular risk factor counseling, appears of paramount importance.

A few concerns need to be addressed: First, the event rates at 20.4% in group 1 and 18.2% in group 2 were lower than surmised at 23% as the reference rate. However, the proposed novel strategy for group 1 was highly statistically noninferior to the current practice (group 2) using both MI definitions.21 Furthermore, our study population, >1000 moderate- and high-risk patients recruited over a period of 16 months, is representative of today’s practice in a typical high-volume catheterization laboratory. The study design imposed that abciximab infusion be initiated at the end of uncomplicated PCI, and therefore there was a delay (<1 hour) between bolus administration and the initiation of the infusion. Given that the majority of the dose is included in the bolus, and given abciximab pharmacodynamics, the delay was considered to be without clinical impact. Finally, this study was performed in a single center with a large experience in transradial PCI. Whether these results can be replicated in other centers with less experience in the transradial approach will require validation in a large multicenter study.

In conclusion, same-day home discharge is a safe strategy after uncomplicated transradial stenting with a bolus only of abciximab in a wide spectrum of patients, including patients presenting with moderate- to high-risk acute coronary syndromes.

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Results have been presented in part at the American Heart Association Meeting (Late breaking clinical trials session, November 13, 2005, Dallas, TX) and published in abstract form (Circulation. 2005;112:3362).

The EASY study was organized as follows: Principal Investigator: O.F. Bertrand; Co-Principal Investigators: R. De Larochellière and L. Roy. Data and Safety Monitoring Board: W. O’Neill (chair), V. Dzavik, and L. Title. Clinical Event Adjudication Committee: R. Bonan (chair), M. De Grâce, M.C. Vandal, A. Facta, and A. Dana. ECG Core Laboratory; P. Poirier. Cardiac Biomarkers Core Laboratory: R. Lavoie, F. Bertrand. Biostatistics: S. Simard and M.C. Guertin.

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Disclosures

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A Randomized Study Comparing Same-Day Home Discharge and Abciximab Bolus Only to Overnight Hospitalization and Abciximab Bolus and Infusion After Transradial Coronary Stent Implantation

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