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Same-day discharge after coronary stenting and femoral artery device closure: A randomized study in stable and low-risk acute coronary syndrome patients☆

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ABSTRACT

Objective: To compare same-day (SD) vs. delayed hospital discharge (DD) after single and multivessel coronary stenting facilitated by femoral closure device in patients with stable angina and low-risk acute coronary syndrome (ACS).
Methods: University of Southern California patients were screened and coronary stenting was performed in 2480 patients. Four hundred ninety-three patients met screening criteria and consented. Four hours after percutaneous coronary intervention, 100 were randomized to SD (n = 50) or DD (n = 50). Patients were followed for one year; outcomes-, patient satisfaction-, and cost analyses were performed.
Results: Groups were well distributed, with similar baseline demographic and angiographic characteristics. Mean age was 58.1 ± 8.8 years and 86% were male. Non-ST-elevation myocardial infarction and unstable angina were the clinical presentations in 30% and 44% of the SD and DD groups, respectively (p = 0.2). Multivessel stenting was performed in 36% and 30% of SD and DD groups, respectively (p = 0.14). At one year, two patients from each group (4%) required unplanned revascularization and one patient in the SD group had a gastrointestinal bleed that required a blood transfusion. Six SD and four DD patients required repeat hospitalization (p = 0.74). There were no femoral artery vascular complications in either group. Patient satisfaction scores were equivalent. SD discharge was associated with $1200 savings per patient.
Conclusions: SD discharge after uncomplicated single and multivessel coronary stenting of patients with stable, low-risk ACS, via the femoral approach facilitated by a closure device, is associated with similar clinical outcomes, patient satisfaction, and cost savings compared to overnight (DD) hospital stay.

1. Introduction

Despite advances in the field of interventional cardiology, including effective oral antiplatelet regimens, better anticoagulation regimes, lower profile equipment, improved hemostatic devices, and increased safety and feasibility of outpatient percutaneous coronary intervention (PCI), overnight stay after uncomplicated coronary stenting still remains standard of care in the United States [1–16]. Here we compare clinical outcomes, patient satisfaction, and cost of same-day (SD) vs. delayed hospital discharge (DD) after single and multivessel coronary artery stenting and femoral arterial device closure in patients with stable angina (SA) and low-risk acute coronary syndrome (ACS).

2. Materials and methods

This is a single-institution (two hospitals), prospective, randomized study. Patients undergoing diagnostic coronary angiography (n = 5627) were screened from October 2011 to April 2014. Patients were stratified on the basis of their initial clinical presentation. This included patients with SA and unstable angina (UA) and non-ST-elevation myocardial infarction (NSTEMI) with a troponin T <1 ng/mL.

Based on inclusion (Table 1) and exclusion criteria (Table 2), 493 eligible patients consented prior to coronary angiography; 103 patients met inclusion criteria immediately after PCI and 100 patients were randomized four hours after uncomplicated PCI (Fig. 1). Patients received an oral loading dose of clopidogrel (300–600 mg) as pre-treatment or immediately after stent implantation and were anticoagulated with bivalirudin (0.75 mg/kg intravenous loading dose and 1.75 mg/kg/h infusion for the duration of the PCI) or heparin (70 units/kg intravenous loading dose and additional doses to an activated clotting time goal of ~250 s) (Table 3). Common femoral angiography was performed at the end of the procedure via the side arm of the sheath. Hemostasis of

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Table 1
General inclusion criteria.

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Patients undergoing single and multivessel stenting of type A, B, and C de novo lesion(s) for the treatment of stable angina, unstable angina or non-ST-elevation myocardial infarction with a troponin T of <1 ng/mL.
Patients treated with P2Y12 inhibitor oral loading dose, either as a pre-treatment or immediately after stenting, and recommended to be continued daily.
Patients anticoagulated with intravenous heparin or bivalirudin during the procedure and stopped immediately after procedure completion.
Arterial access via the femoral artery (sheath size 5, 6, 7 or 8 Fr) and an arteriotomy site suitable for hemostatic device closure (puncture in the common femoral artery at least 5 mm from femoral artery bifurcation).
Thrombolysis In Myocardial Infarction III coronary flow upon completion of the intervention.
Left ventricular ejection fraction ≥30%.
Patients who live less than an hour away from the hospital.

the femoral-arteriotomy access site was facilitated by deployment of a hemostatic closure device (StarClose® or ProGlide®, Abbott Vascular, Temecula, CA). The ultimate choice of closure device used was at the discretion of the interventional cardiologist.

Table 2
General exclusion criteria.

Clinical
Age <30 or >80 years
Acute ST-elevation myocardial infarction (STEMI)
Non-STEMI with documented troponin T >1 ng/mL at presentation to the catheterization laboratory
Severe valvular heart disease
Cardiogenic shock or hemodynamic instability
Any contraindication to anticoagulation
Pregnancy
Patients with bleeding diathesis, including thrombocytopenia (platelets <100,000), thrombasthenia, Von Willebrand's disease, or anemia (hemoglobin <10 mg/dl, hematocrit <30) or coagulopathy
Patients with a creatinine >1.5 mg/ml not on hemodialysis
Patients with an international normalized ratio (INR) >1.5
Patients unable to consent or follow-up
Patients with inadequate social or home support (homeless, lives alone, etc.)
Patients with cancer or autoimmune disease with life expectancy of <1 year
Pharmacological
Patients who received a IIb/IIIa inhibitor or thrombolytics within 24 h of the procedure
Patients who received low molecular weight heparin within 12 h of the procedure
Patients on or planned coumadin therapy post angioplasty
Angiographic and procedural
Treatment of >2 lesions in >2 vessels
Major site branch occlusion
Target lesion is a total occlusion, located in the left main coronary artery or a vein graft with friable lesions
Significant left main diameter stenosis (>50%)
Intra-coronary thrombus
Dissection type C–F not stented
Target lesion is >55 mm in length, heavily calcified, or with visible thrombus
Access site-related
Closure device non-deployment (including morbidly obese patients)
Uncontrolled hypertension (>160 mm Hg systolic)
Target artery closed (with any method) within 48 h of study closure
Ipsilateral arterial puncture
Patients with hematoma, pseudoaneurysm, or arteriovenous fistula present prior to sheath removal
Patients with severe common femoral calcification visualized by fluoroscopy
Patients with small femoral arteries (<5 mm in diameter)
Patients with femoral artery stenosis >50%
Patients with brachial or radial puncture sites
Patients with puncture sites in vascular grafts
Patients with antegrade punctures

If the stenting procedure was performed without complications and the closure device was successfully deployed, the patient was observed for four hours. If there were no complications, the electrocardiogram remained unchanged, and the patient was asymptomatic, with stable vital signs, and able to ambulate, he/she was then enrolled in the study ($n = 100$) and randomized to either the SD ($n = 50$) or the DD ($n = 50$) group. Patients were not considered enrolled until they were successfully randomized. During the observation period, patients received risk factor modification education and were informed about continued pharmacotherapy, especially dual antiplatelet therapy.

Patients in the SD group were discharged from the hospital six hours after hemostatic closure device deployment, only if they remained stable. Patients in the DD group were discharged from the hospital at the discretion of the attending cardiologist no sooner than 24 h after PCI. Patients with an indication for extended hospital stay were not discharged from the hospital regardless of randomization.

Detailed screening information was recorded to track the number of patients screened and consented, and included the reason for screening failure (exclusion criteria, procedure-related complications, closure device failure, access complication, chest pain, arrhythmias, hemodynamic instability, etc.) (Tables 4 and 5).

The primary end point was major adverse cardiac events (MACE) defined as a composite of events at 30 days, including death from any cause, myocardial infarction (MI), unplanned coronary revascularization, or vascular complication. MI was defined based on clinical presentation, troponin elevation and ECG. PCI-related, procedural MI was defined as a troponin increase >3 times the upper limit of normal. Vascular complication was defined as the cumulative occurrence of intracranial or intraocular bleeding, hemorrhage at the access site requiring intervention, hematoma with a diameter >5 cm, a reduction in hemoglobin >4 g per deciliter without an overt bleeding source, or ≥3 g per deciliter with a source and vascular injury requiring repair (defined as any vascular injury requiring open surgery or ultrasound guided intervention), or transfusion of a blood product.

The secondary end points at 30 days included major bleeding not related to coronary artery bypass surgery (CABG) and recurrent hospitalization. The safety end point was a composite of major bleeding or vascular complication. Patients were followed through the hospital course: at 24–72 h, 7–14 days post-discharge in the clinic, and at 30–45 days via telephone contact or office visit. Follow-up at one year was performed via telephone contact, office visit, or medical record review. Patient satisfaction surveys were conducted at pre-specified intervals at 30–45 days after discharge. To estimate potential savings, an allocated model of hospital costs was used, and the unit cost for the interventional cardiac procedure was estimated. This cost model was estimated based on current Medicare hospital rates and based on an allocation model. Prices per unit were based on actual costs or estimated based on current hospital cost. This cost model was specific for the University of Southern California Hospital and LA County Hospital [6].

2.1. Statistical analysis

Categorical variables were reported as numbers and frequencies and were compared using chi-square statistics or Fisher exact test. Continuous variables were reported as mean ± standard deviation. For continuous data, measurement differences were compared using the Student's t-test; while the Mann–Whitney U test was used for the nonparametric continuous data. One-way analysis of variance and a post hoc multiple comparisons test (Scheffe) were used for comparison of continuous data between the SD and DD patient groups. A two-tailed probability value of <0.05 was considered statistically significant.

2.2. Patient satisfaction analysis

Patient satisfaction surveys were provided in person or via telephone interviews 24–72 h, 7–14 days, and 30–45 days after the