The AmBulatory Closure Device Percutaneous Intervention (ABCD-PCI) study: a single-center experience

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The AmBulatory Closure Device Percutaneous Intervention (ABCD-PCI) study is a multicenter randomized prospective controlled trial evaluating the safety of and patient satisfaction with same-day discharge following ambulatory percutaneous intervention with a closure device. This article reviews the findings from a single center, Baylor Jack and Jane Hamilton Heart and Vascular Hospital, from October 2008 through April 2010, with 23 patients in the same-day discharge group and 21 patients in the next-day discharge group. There were no differences between the groups in demographic or procedure characteristics. Outcomes were measured by a questionnaire and 7-day and 30-day follow-up phone calls. Results showed that same-day discharge after percutaneous intervention with a closure device is as safe as next-day discharge. However, there was a trend for a higher comfort level among patients in the next-day discharge group.

Historically, percutaneous intervention (PCI) was performed only on an inpatient basis. With the evolution in technology, changing patterns in reimbursement, and understanding of the relatively low risk of elective PCI in stable coronary artery disease (CAD), PCI is now primarily an outpatient procedure. The vast majority of these procedures mandate an overnight stay to observe patients for complications. However, increased adoption of direct thrombin inhibitors and vascular closure devices has made late bleeding and other adverse events associated with ambulatory PCI rare (1–4).

Same-day discharge after PCI has been shown to be safe in ambulatory PCI in two major studies, the EASY and the EPOS trials (5, 6). However, neither study evaluated the use of closure devices or patient satisfaction/anxiety about the discharge. The AmBulatory Closure Device Percutaneous Intervention (ABCD-PCI) study is a multicenter randomized prospective controlled trial looking at the safety of and patient satisfaction with same-day discharge following ambulatory PCI with a closure device. We present the data collected from a single center, Baylor Jack and Jane Hamilton Heart and Vascular Hospital, from October 2008 through April 2010.

STUDY DESIGN

Patients undergoing successful elective outpatient PCI for stable CAD who received a femoral vascular closure device

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none">• ≤ 75 years of age• Type A or B lesion• Femoral access site amenable to vascular closure device• > 2 hours since PCI	<ul style="list-style-type: none">• Life expectancy < 12 months• Acute myocardial infarction• Anticoagulants besides heparin or bivalirudin used during procedure• PCI to nonnative vessel• Evidence of thrombus• Implantation of > 3 stents• INR ≥ 2, platelets $\leq 100,000/\mu\text{L}$, or hematocrit $\leq 25\%$• Occlusion of side branch during PCI• Ejection fraction $\leq 30\%$• Residence > 30 minutes from a hospital• Occurrence of dissection, hematoma, or abnormal bleeding during the procedure• Pregnancy• Presence of infection• Chronic renal insufficiency (creatinine ≥ 1.5 mg/dL)

PCI indicates percutaneous intervention; INR, international normalized ratio.

followed by a 2-hour recovery period were eligible for this study. Inclusion and exclusion criteria are listed in Table 1. Once the 2-hour recovery period was completed, subjects were randomly assigned in a 1:1 fashion into the intervention arm (same-day discharge) and usual-care arm (next-day discharge). Patients in the intervention arm were discharged 1 hour after randomization. Prior to leaving the hospital, they completed a questionnaire assessing their pain, satisfaction, anxiety, and readiness for discharge. This same questionnaire was completed by the

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patients in the next-day discharge group prior to leaving the hospital. One part of the questionnaire evaluated patients' pain and discomfort. The scoring system ranged from 0 to 5, with 0 representing "none" and 5 "a lot." The next set of questions evaluated patients' feelings about their discharge. This scoring ranged from 0 to 10 and assessed patients' stress, strength, energy, and emotions about the discharge. Patients in both groups received follow-up phone calls on day 7 and 30. The primary endpoints were patient pain, adverse events related to the procedure, and patient satisfaction regarding discharge based on questionnaire and phone interview follow-up. Adverse events were defined as any event that occurred within 1 month of discharge and included cardiac death, myocardial infarction, stroke, readmission due to chest pain, pseudoaneurysm, severe pain at groin site, and repeat PCI.

RESULTS

A total of 48 patients from Baylor Heart and Vascular Hospital were enrolled in the trial, 25 patients in the same-day discharge arm and 23 in the next-day discharge arm. Two patients from each arm were excluded after randomization: three patients did not fill out the survey and one patient left against medical advice. There were no differences between the groups with regard to gender, past medical history (diabetes, hypertension, hyperlipidemia, peripheral vascular disease, and previous PCI), medications prior to enrollment, number of diseased vessels by angiography, and number of stents used during the procedure (*Table 2*). Three closure devices were used: the Mynx, Angioseal, and Perclose.

There were no significant differences between the study groups when comparing scores for pain, tenderness, numbness, bruising, and concern about the appearance of bruising. For each component of this portion of the questionnaire, the average score was <1 in both arms of the trial. Based on patient satisfaction and anxiety, there appeared to be a trend, though not statistically significant, for patients in the next-day discharge arm to be more physically and emotionally ready to go home. As ascertained at 7-day and 30-day follow-up phone calls, the rate of complications was similar among the two groups. In the same-day discharge group, there were three adverse events: two incidents of pain at the groin site and one rehospitalization due to exacerbation of heart failure. In the next-day discharge arm, there were also three adverse events: one instance of a pseudoaneurysm treated with thrombin injection and two incidents of severe pain at the groin site. The questions, results, and adverse events are summarized in *Table 3*.

DISCUSSION

Ambulatory PCI is a common procedure and represents a potential area where efficiency for both the patient and the hospital can be improved without compromising patient safety. Previous trials have shown the safety of same-day discharge after ambulatory PCI (5, 6). In the EPOS study, 403 patients undergoing elective PCI were assigned to the same-day discharge group and 397 were assigned to the next-day discharge group. This trial showed no difference between cardiac events or complications

Table 2. Demographic and procedure characteristics

Characteristic	Same-day discharge group (n = 23)*	Next-day discharge group (n = 21)*
Age (years)	60.56	57.04
Sex: male	15	16
Smoking history	15	18
Currently smoking	7	6
Alcohol intake	13	9
Past medical history		
Diabetes	11	9
Hypertension	20	20
Hyperlipidemia	20	20
Myocardial infarction	4	7
Cerebrovascular accident	0	0
Peripheral vascular disease	1	1
Gastrointestinal bleed	0	0
PTCA	2	1
Percutaneous intervention	8	9
Medications prior to enrollment		
Antiplatelet	20	19
Anticoagulant	3	5
Antianginal	18	15
Lipid-lowering	20	18
Diabetes mellitus	10	10
Number of vessels with plaques		
1	21	21
2	0	0
3	2	0
Number of stents		
0	0	1
1	18	13
2	4	7
3	1	0
Closure device		
Mynx	12	12
Angioseal	11	8
Perclose	0	1

*Included 4 who were randomized but did not participate: 2 in the same-day group and 2 in the next-day group.

PTCA indicates percutaneous transluminal coronary angioplasty.

at the femoral access site between the two study groups, with the conclusion that same-day discharge is feasible and safe in a majority of patients undergoing elective PCI. The EASY trial enrolled 1005 patients randomized to receive PCI with a transradial approach, either with a bolus of abciximab and same-day discharge or overnight hospitalization with a bolus and then a standard 12-hour infusion of abciximab. The primary composite

Table 3. Study outcomes

Outcomes	Same-day discharge group (n = 23)	Next-day discharge group (n = 21)
Questions about patients' pain and discomfort (average score, with scale of 0–5)		
Pain in your groin?	0.826	0.476
Tenderness around groin?	0.826	0.809
Numbness in groin area?	0.043	0.047
Bruising around groin or thigh?	0.391	0.523
Problems in groin where catheter was inserted?	0.130	0.142
Concern over the appearance of your bruise?	0.087	0.047
Questions about how patients felt about going home (average score, with scale of 0–10)		
Do you believe you are ready for discharge? (Yes)	21	19
How physically ready are you to go home?	8.65	9.27
How would you describe your pain or discomfort?	2.13	0.857
How would you describe your strength?	6.73	8.42
How do you feel about your energy?	6.52	7.95
How emotionally ready are you to go home?	8.78	9.52
Distance to hospital (miles)	42.3	43
Adverse events at 30 days (n)*	3	3

*In same-day group: 1 heart failure exacerbation, 2 cases of severe pain at groin site. In next-day group: 1 pseudoaneurysm, 2 cases of severe pain at groin site.

endpoint—30-day incidence of death, myocardial infarction, revascularization, major bleeding, repeat hospitalization, access site complication, and thrombocytopenia—was equivalent in both groups. This study also showed that same-day discharge is a safe alternative to overnight hospitalization.

In our study, the use of a vascular closure device was evaluated with regard to patient satisfaction and safety with same-day discharge versus next-day discharge in a single high-volume

medical center. Our single-center data revealed no difference in safety between the two strategies, but there was a nonsignificant trend for patients to feel more comfortable with staying overnight after PCI. This difference did not correlate to any clinical or demographic variable. The number of adverse events was the same in the two study groups, showing that both approaches are safe. The distance from our institution to the patient's home was similar in the two arms (42.3 miles and 43 miles, respectively), so proximity to the hospital did not play a role in influencing patients' answers on the questionnaire.

The limitation for this particular data set is its small sample size and the restriction to a single medical center. The results of the larger multicenter trial will be analyzed and presented in the near future.

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