Original Article

Assessing Patient-Reported Outcomes and Preferences for Same-Day Discharge After Percutaneous Coronary Intervention
Results From a Pilot Randomized, Controlled Trial

Michael Kim, MD; Paul Muntner, PhD; Samin Sharma, MD; James W. Choi, MD; Robert C. Stoler MD; Mark Woodward, PhD; Devin M. Mann, MD; Michael E. Farkouh, MD, MSc

Background—Same-day discharge after percutaneous coronary intervention (PCI) may be safe for some patients. Few data are available on patient-reported outcomes and preferences for same-day discharge after PCI.

Methods and Results—Between March 2008 and March 2010, a total of 298 patients undergoing elective PCI via femoral access at 2 medical centers (Mount Sinai Hospital, New York, NY, and Baylor Medical Center, Dallas, TX) were randomized to same-day (n=150) or next-day (n=148) discharge. The primary outcome was high patient coping during the 7 days after discharge defined as scores <20 on the validated postdischarge coping difficulty scale. Safety outcomes, clopidogrel adherence, and patient preferences were secondary outcomes. Before discharge, patients randomized to same-day and next-day discharge were similar with respect to sociodemographic and clinical characteristics. High-coping ability, assessed 7 days after PCI, was present for 79% of patients randomized to same-day discharge and for 77% of patients randomized to next-day discharge. The difference in high coping ability, 2 (95% confidence interval, −7 to 11), did not cross the noninferiority threshold of −12% (P<0.001 that same-day discharge is not noninferior to next-day discharge). At 30 days after PCI, clopidogrel adherence, physician and emergency room visits, and hospitalization were similar in the 2 randomization groups. In addition, 80% and 68% of those randomized to same-day and next-day discharge, respectively, stated they would prefer same-day discharge if they were to have another PCI procedure.

Conclusions—Same-day discharge after PCI was associated with patient-reported and clinical outcomes similar to those of next-day discharge and was preferred by most patients.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov/show/NCT01230606. Unique identifier: NCT01230606.

Key Words: hospital discharge ● patient satisfaction ● percutaneous coronary interventions ● randomized trial

More than 600,000 percutaneous coronary interventions (PCIs) are performed each year in the United States.1 Typically, patients undergoing PCI stay in the hospital overnight for observation after their procedure. Several studies, including 3 randomized, controlled trials, have demonstrated same-day discharge to be as safe as an overnight hospital stay after PCI.2-4 In 2009, a consensus document from the Society for Cardiovascular Angiography and Interventions stated that same-day discharge can be considered for patients who are stable before their PCI procedure and have no obvious complications from PCI.5

One concern with discharging patients on the day of their PCI procedure is their ability to handle the stress and anxiety of not being monitored. Many patients may want an overnight hospital stay for monitoring after PCI, but there are few data assessing the ability of patients to cope or their preferences for discharge timing after PCI. The use of patient preferences is considered a central part of evidence-based medicine,5-8 and knowledge of patient-centered outcomes for same-day discharge after PCI may help inform treatment guidelines. Therefore, we conducted a randomized, controlled trial to compare patients coping after same-day discharge and next-day discharge after PCI. As secondary outcomes, we assessed patients’ readiness for discharge, anxiety before discharge, satisfaction, and preferences for same-day discharge compared with next-day discharge, as well as safety outcomes. Finally, because lack of counseling on medication adherence has been raised as an adverse effect of same-day discharge after PCI, we evaluated adherence to clopidogrel at 30 days after PCI.
WHAT IS KNOWN

• Same-day discharge after percutaneous coronary intervention (PCI) is safe for some patients.
• The majority of patients undergoing PCI in the United States stay overnight before being discharged from the hospital.

WHAT THE STUDY ADDS

• Patients discharged the same day as their PCI procedure report levels of coping during the 7 days after discharge similar to those of patients who stay overnight before being discharged.
• Medication adherence and safety outcomes are also similar for patients discharged on the same day and on the next day after PCI.
• Most patients prefer same-day discharge to next-day discharge after PCI.

Methods

The Ambulatory Closure Device Following PCI (ABCD-PCI) trial (NCT01230606) included patients undergoing elective PCI and was designed to determine patient satisfaction with and to confirm the safety of same-day hospital discharge compared with next-day hospital discharge after PCI. Patients were recruited from Mount Sinai Hospital in New York, NY, and Baylor Heart and Vascular Hospital at Baylor University Medical Center in Dallas, TX. The study was limited to patients <75 years of age with type A or B lesions who received a closure device after PCI. Patients with evidence of a recent acute coronary syndrome or who received 3 or more stents were not enrolled. A full list of inclusion and exclusion criteria is provided in the Appendix in the online-only Data Supplement. Between March 2008 and April 2010, a total of 298 patients completed a pretrial eligibility form and were consented and randomized (Figure 1). Consent and enrollment occurred ≥2 hours after their PCI procedure. Nurses were involved in the discharge process, and all patients and their family members were instructed on access-site care and the importance of medication adherence after discharge. The randomization was stratified by site (Mount Sinai or Baylor) through the use of random block sizes of 2, 4, or 8 patients. All aspects of the trial were approved by the Institutional Review boards of Mount Sinai School of Medicine and Baylor University Medical Center. Patient consent was obtained before enrollment in the trial.

Sample Size Justification

The present study was designed to test the noninferiority of same-day discharge compared with staying in the hospital for overnight observation (ie, next-day discharge) after PCI. Patient scores on the postdischarge coping difficulty scale (PDCDS) from the interview conducted 7 days after the PCI procedure were selected as the primary outcome. We considered using readmission to the hospital and mortality as the primary outcomes. However, given the very low rate of these events after PCI, the sample size required made this impractical. The study was originally designed to include 600 participants. No interim analyses to assess safety/benefits were planned or conducted. As a result of financial exigencies, in August 2009, the protocol was amended to halt recruitment at 300 patients. Investigators remained blinded to the randomization assignment throughout follow-up, including when the decision to halt recruitment at 300 patients was made.

For the primary outcome of high coping 7 days after PCI, on the basis of a sample size of 300 participants, we had 80% statistical power to conclude noninferiority if the lower bound of the 95% confidence interval (CI) for the difference in the prevalence of high coping for participants randomized to same-day discharge compared with next-day discharge was <12 percentage points. No clinical thresholds are available to guide differences in high coping using the PDCDS. The 12% threshold was chosen on the basis of what investigators determined to be a reasonable noninferiority margin. Figure 2 provides hypothetical examples of potential results and their interpretation on the basis of the originally proposed sample size of 600 participants and the final recruitment goal of 300 participants.

Data Collection

All baseline data were collected by trained staff using standardized questionnaires. Data were collected immediately before hospital discharge with a self-administered questionnaire. Additionally, computer-assisted telephone interviews were used for data collection at 1 day after PCI for participants randomized to same-day discharge and 7 and 30 days after PCI for all participants. At 7 and 30 days after PCI, the questionnaire data were collected by research staff members who were masked to participants’ randomization assignments.

Baseline Data Collection

The predischarge survey instrument included domains assessing sociodemographics, cigarette smoking, and several validated scales (described below). Predischarge scales were used to assess patient readiness for discharge, anxiety, postprocedure pain, and postdischarge care coordination. Sociodemographic information included age, sex, race, annual household income, educational level, and habitation status (alone or with others). The Readiness for Hospital Discharge scale assessed 4 attributes of discharge readiness: Personal Status (7 items), Knowledge (7 items), Coping Ability (4 items), and Expected Support (5 items). The instrument was designed to be used after the decision to discharge had been made and within 4 hours of the projected discharge time. Scores on this and other scales were dichotomized because of floor effects (ie, a clustering of scores at the low end of a scale). General patient anxiety was assessed with the validated 7-item general anxiety disorder scale, and low anxiety was defined as scores <14. Patient pain in the femoral access area was ascertained before hospital discharge with the Adverse Effects subscale of the coronary revascularization outcomes questionnaire. This 6-item scale assessed pain and soreness that patients may feel after their PCI procedure. Low adverse effects were defined as scores <26. The 5-item care coordination scale was used to assess the degree to which patients think they received guidance for self-care on their discharge, with scores <35 defining patients’ perception that they had high care coordination.

Follow-up Data Collection

The 7- and 30-day follow-up questionnaires included the 10-item PDCDS and items about satisfaction with hospital discharge. The PDCDS measures attributes of postdischarge satisfaction, including difficulties with stress, recovery, self-care, and self-management of

Figure 1. Flowchart of participants in the Ambulatory Closure Device Following Percutaneous Coronary Intervention (ABCD-PCI) study.
medical needs; family difficulty; help and emotional support needed; confidence in self-care and medical management abilities; and adjustment. The items are measured on an 11-point rating scale (0–10), resulting in an overall range of 0 to 100, with higher scores indicating greater coping difficulty and less satisfaction. Previous analysis of the PDCDS indicates a single dominating factor and high reliability. Because of floor effects of this scale, participants were grouped as having high coping (scores ≥20) or not (scores <20). This cut point was chosen on the basis of the distribution of PDCDS scores in the overall study population and represents the 80th percentile. Adherence to clopidogrel at 30 days after PCI was assessed with an adapted version of the 8-item Morisky Medication Adherence Scale. The Morisky Medication Adherence Scale-8 contains 7 “yes” or “no” responses and 1 item scored on a 5-point Likert-type. Scores on the Morisky Medication Adherence Scale-8 can range from 0 to 8. On the basis of published cut points, low adherence to clopidogrel was defined as Morisky Medication Adherence Scale scores ≤6 or the self-report of clopidogrel discontinuation. Finally, patients were asked whether they were satisfied with the timing of their discharge, would have preferred to stay longer, or go home earlier, and if they had another procedure, whether they would prefer to go home on the same day as their procedure or stay in the hospital overnight.

Adverse Events

Adverse events were determined through patient report during the 7- and 30-day follow-up interviews and included chest pain, myocardial infarction, bleeding, emergency department visits, and hospitalization. When patients were unable to be reached to complete their follow-up interviews, proxies were contacted to ascertain mortality.

Statistical Methods

Data were analyzed with the use of an intention-to-treat approach. Given that randomization occurred within 2 hours before discharge for patients in the same-day discharge arm, no crossover occurred. Therefore, an on-treatment analysis was not necessary. Characteristics of patients were calculated by randomization assignment with differences assessed by t tests or \( \chi^2 \) tests as appropriate. Readiness for discharge, anxiety, and care coordination immediately before hospital discharge were compared across randomization assignment with \( \chi^2 \) tests. The prevalence of high coping, based on the PDCDS, indicates a single dominating factor and high reliability.9 Because of floor effects of this scale, participants were grouped as having high coping (scores ≥20) or not (scores <20). This cut point was chosen on the basis of the distribution of PDCDS scores in the overall study population and represents the 80th percentile. Adherence to clopidogrel at 30 days after PCI was assessed with an adapted version of the 8-item Morisky Medication Adherence Scale. The Morisky Medication Adherence Scale-8 contains 7 “yes” or “no” responses and 1 item scored on a 5-point Likert-type. Scores on the Morisky Medication Adherence Scale-8 can range from 0 to 8. On the basis of published cut points, low adherence to clopidogrel was defined as Morisky Medication Adherence Scale scores ≤6 or the self-report of clopidogrel discontinuation. Finally, patients were asked whether they were satisfied with the timing of their discharge, would have preferred to stay longer, or go home earlier, and if they had another procedure, whether they would prefer to go home on the same day as their procedure or stay in the hospital overnight.

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Results

The mean age of patients in this study was 55.9±7.9 years; 26% were women, and 33%, 15%, 25%, and 22% were white, black, Hispanic/Latino, and Asian, respectively. No significant differences across randomization assignment were present in patient demographics, socioeconomic, or other characteristics evaluated at baseline (Table 1).

Regardless of randomization assignment, >96% of patients reported being ready to go home before their hospital discharge (Table 2). However, the percentage of patients with high readiness for hospital discharge scale scores was lower for those randomized to same-day discharge compared with those randomized to next-day discharge. In addition, although not statistically significant, a lower percentage of patients in the same-day discharge group had high scores on the readiness for hospital discharge scale.

Postdischarge Coping

A floor effect was present for the PDCDS, with 21% and 20% of those randomized to same-day and next-day discharge (P>0.80), respectively, having a score of 0 (indicating no coping difficulties). High coping ability was present for 79% (95% CI, 73–86) of patients randomized to same-day and 77% (95% CI, 70–84) of patients randomized to next-day discharge. The difference in the prevalence of high coping in the same-day discharge minus next-day discharge group was 2% (95% CI, −7 to 11). The 95% CI for this difference did not cross the tolerability threshold of −12%, suggesting that same-day discharge is noninferior to next-day discharge with respect to patient coping (P<0.001 for the probability that same-day discharge is not noninferior to next-day discharge).

Clopidogrel Adherence

Overall, 39 patients (13%) had low adherence by 30 days after PCI; 26 patients had a Morisky Medication Adherence Scale score <6, and 13 patients had discontinued clopidogrel. Among patients randomized to same-day and next-day discharge, 15% and 11% of patients, respectively, had low adherence (P=0.38). Among those receiving a drug-eluting stent, the rate of clopidogrel discontinuation was similar among those randomized to same-day discharge and those randomized to next-day discharge (12% and 13%, respectively).
Adverse Effects
No patients randomized to same-day discharge reported chest pain or a myocardial infarction within the first day after PCI. However, within the first day after PCI, 3 patients (2%) randomized to the same-day discharge reported visiting their doctor, and 1 patient (<1%) reported having an emergency room visit. Although data were not available on the reasons for follow-up medical care, each of these patients completed the 24-hour telephone follow-up from home, and none of them experienced a rehospitalization or died by 30 days.

Patient Satisfaction With Discharge Timing
At 30 days after PCI, 79% of patients randomized to same-day discharge reported being satisfied with the timing of their discharge compared with 49% of those randomized to next-day discharge (P<0.001; Figure 3). At 30 days, only 9% of patients randomized to same-day discharge reported wanting to have stayed in the hospital longer, whereas 37% of those randomized to next-day discharge reported that they would have preferred to have been discharged earlier (P<0.001). When asked their preferences for discharge timing if they had another PCI procedure, 80% of those randomized to same-day discharge and 68% of those randomized to next-day discharge reported being satisfied with the timing of their discharge.

Table 1. Baseline Characteristics of the ABCD-PCI Study Population by(175,467),(866,538)(236,742),(867,812)

Table 2. Readiness for Discharge Anxiety, and Care Coordination Evaluated Before Discharge After Percutaneous Coronary Interventions

Table 3. Adverse Events Reported at 7 and 30 Days After Percutaneous Coronary Intervention

ER indicates emergency room; and PCI, percutaneous coronary intervention.
discharge stated they would prefer going home the day of the procedure. Only 9% and 20% of patients in the same-day and next-day discharge groups, respectively, reported they would want to stay in the hospital overnight if they had another PCI procedure, whereas between 10% and 15% of each group reported no timing preference.

Discussion

In the present randomized, controlled trial, same-day discharge compared with next-day discharge after PCI did not affect patient-centered and clinical outcomes. Although patients randomized to same-day discharge reported being less ready to go home after PCI, levels of anxiety before discharge and coping and adherence to clopidogrel after discharge were not different across randomization arms. Adverse outcomes, including rehospitalization, myocardial infarction, or death, were rare and did not differ across randomization arms. Importantly, when asked 30 days after discharge, <10% of patients randomized to same-day discharge stated that they would prefer staying in the hospital longer if they had another PCI.

A consensus document from the Society for Cardiovascular Angiography and Interventions provides recommendations on discharge timing after PCI. In this report, the authors present a decision matrix for guiding discharge timing. The inclusion and exclusion criteria for same-day discharge after PCI are based primarily on identifying low-risk patients (no significant comorbidities, normal renal function, etc). The willingness of patients and family members for a same-day discharge was also noted as a consideration in making a decision on the appropriateness of a same-day discharge. In the present study, the level of coordination of care at the time of discharge was similar for patients in the same-day and next-day randomization arms. Furthermore, 30 days after PCI, most patients expressed a preference for same-day discharge if they were to have another PCI.

Patients in the present study discharged on the same day after PCI had significantly lower scores on the Readiness for Hospital Discharge Scale, suggesting that they were not ready to go home. This may have resulted from the inclusion of patients who were not ready for discharge, which may, in turn, have biased the results against same-day discharge. However, despite this difference, patients randomized to same-day discharge had a similar prevalence of high coping at 7 days after PCI. Additionally, rates of clopidogrel adherence were similar in each randomization arm at 30 days after PCI, suggesting that patients received adequate counseling before discharge. It is unclear why patients randomized to same-day discharge reported less readiness for discharge yet there were no differences in postdischarge outcomes compared with their counterparts randomized to a next-day discharge. Future work is needed to understand why patients who are discharged on the same day as their PCI report not being as ready for discharge as those who stay in the hospital overnight. Increasing patients’ readiness will be important if same-day discharge is to become a more widely accepted practice.

Three previous randomized, controlled trials provide evidence of the safety of same-day discharge after PCI. In the largest of these trials, 800 consecutive patients undergoing elective PCI were randomized to same-day discharge compared with an overnight stay after PCI. The primary end point of death, myocardial infarction, coronary artery bypass graft surgery, repeat PCI, or puncture-related complications occurring within 24 hours of PCI occurred in 2.2% of patients randomized to same-day discharge and in 4.2% of patients randomized to next-day discharge. Observational studies have also demonstrated the safety of same-day discharge in real-world clinical practice. For example, using data on 107,108 patients 65 years and older from the CathPCI registry, Rao et al found no significant differences in death or rehospitalization at 2 or 30 days after same-day discharge or discharge after an overnight stay. Among those discharged on the same day as their procedure and those discharged on the next day, 0.30% and 0.22%, respectively, died and 9.56% and 9.60%, respectively, were rehospitalized within 30 days of their discharge. The present study confirms these previous findings in a US population using a randomized, controlled design. The rates of rehospitalization after PCI in the present study were similar to those reported by Curtis et al using a national sample of Medicare patients, and no deaths occurred within 30 days of rehospitalization. All patients in the present study had femoral access for their PCI. A large randomized trial has demonstrated that the rate of bleeding events may be reduced with radial versus femoral-access PCI. Although femoral-access PCI is well tolerated and positions many patients for same-day discharge, radial-access PCI may provide even broader acceptance of same-day discharge after PCI.

At least 3 studies have reported on patient satisfaction with same-day discharge after PCI. For example, in an observational study of 811 patients undergoing radial access PCI with same-day discharge, 88.6% were satisfied with a same-day discharge. In addition, in a small trial of 39 patients randomized to discharge 2 hours after procedure (n=19) or next-day discharge (n=20), patient satisfaction was high in both groups. Additionally, 30 days after PCI, 69% of the patients randomized to early discharge said they preferred a same-day discharge or had no preference on the timing of their discharge. These previous studies are consistent with the present data and suggest that many patients prefer same-day discharge after PCI.
Patients encounter new stressors after hospitalizations. A study by the American Hospital Association and the Picker Institute found that 29% of patients were not satisfied with the preparation they received for hospital discharge. Difficulty coping has been reported after discharge for myocardial infarction, and many patients were not informed about signs of adverse events, medication side effects, wound care, and when they would be able to resume regular activity. In a previous study including >2000 patients with a history of myocardial infarction, those who reported being socially isolated and having a high degree of life stress had >4 times the risk of death compared with their peers with low levels of stress and isolation. Similar associations between difficulty coping and stress after myocardial infarction and increased mortality have been reported in other studies. From these previous findings, ensuring that patients are empowered to cope with the stress they encounter after discharge is crucial. Therefore, it is reassuring that in the present study we found that same-day discharge did not reduce patients’ ability to cope after PCI.

Selecting the appropriate time for post-PCI discharge should follow an evidence-based approach. Patient safety is central when considering an appropriate discharge timing after PCI. Consideration of patient preferences is becoming a central part of evidence-based medicine, and it is recommended that guidelines should incorporate patients’ values and preferences. Although many have criticized guidelines for not incorporating patient preferences, others have pointed out that this evidence is often of low quality. In the present study, we used a randomized study design and standardized questionnaires to assess patient preferences for same-day discharge compared with longer observation after PCI. The vast majority of patients stated that if they were to have another PCI, they would prefer a same-day discharge.

In addition to patient preference, same-day discharge after PCI affects the healthcare system. A previous study from Canada estimated cost savings exceeding $1000 per patient associated with same-day compared with next-day discharge after PCI. At the population level, this could translate into well over $60 million dollars per year in cost savings even if only 10% of patients of the 600,000 in the United States undergoing PCIs were discharged without an overnight stay. Additionally, same-day discharge will have the added benefit of freeing up hospital beds.

The present study should be interpreted in the context of known and potential limitations. Most important, for financial reasons, we had to limit our study to 300 participants rather than the 600 participants in the original study protocol. Although this may have limited statistical power for some of the analyses we conducted, the 95% CI for differences in coping after discharge did not cross the noninferiority limit. Nonetheless, a definitive trial that includes the assessment of patient-centered outcomes (eg, readiness, coping) and compares same-day discharge with next-day discharge after PCI is needed. The occurrence of adverse outcomes was limited to self-report, and reasons for rehospitalization were not captured. Floor effects were present for multiple scales (eg, 20% of patients had a score of 0 on the PDCDS), resulting in the need to dichotomize scores with a potential loss of important information. Evaluation and refinement of postdischarge coping scales may be warranted. As with most randomized trials, we had strict inclusion criteria. Therefore, caution should be taken in generalizing these findings. Finally, patients randomized to same-day discharge received a telephone call 1 day after discharge. This was conducted by a nonclinical research staff member and was used to collect data on outcomes that were available for patients randomized to next-day discharge. However, we cannot exclude the possibility that the 1-day follow-up call may have served as a cointervention. Despite these limitations, the present study has many strengths. They include the use of a randomized, controlled study design, assessment of multiple patient-centered outcomes and clopidogrel adherence, and collection of data using structured questionnaires by trained staff members who were masked to patients’ randomization assignment.

In conclusion, data from the present study confirm the safety of same-day discharge after PCI for select patients. Additionally, there were no differences in patient-reported outcomes and medication adherence between patients randomized to same-day and next-day discharge after PCI. An important point is that the vast majority of patients in this study reported preferring same-day discharge if they were to have another PCI procedure. These data further support the strong consideration of same-day discharge for patients undergoing elective PCI without complications.

Sources of Funding
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Disclosures
None.

References
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SUPPLEMENTAL MATERIAL
# Appendix. Inclusion and exclusion Criteria for the ABCD-PCI trial.

## INCLUSION CRITERIA

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<th>Criteria</th>
<th>Details</th>
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<tr>
<td>&lt;65 years of age</td>
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<td>Patient has a type A or B lesion(s)</td>
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<td>Femoral access site is amenable to closure with a vascular closure device.</td>
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<td>Patient provides informed consent and agrees to the follow-up schedule prior to PCI procedure.</td>
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## EXCLUSION CRITERIA

<table>
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<td>Patient has a life expectancy less than 12 months.</td>
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<td>Patient has recent evidence of an acute coronary syndrome</td>
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<td>Femoral access is difficult or site has been utilized more than 2 times in the past</td>
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<td>Anticoagulants other than unfractionated heparin or bivalirudin were used during the procedure (i.e. enoxaparin).</td>
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<td>Patient has sub optimal angiographic outcome or clinical complication(s) during PCI</td>
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<td>The PCI occurred in something other than a native coronary artery</td>
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<td>Angiographic evidence of thrombus</td>
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<td>Patient has more than 3 stents implanted during this PCI</td>
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<td>Patient has an INR &gt;2, Platelet count &lt;100,000 or Hematocrit &lt;25</td>
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<td>Occlusion of major side branch during PCI of &gt;1.5mm</td>
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<td>Patient has ejection fraction ≤30%</td>
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<td>Known allergy to PCI procedural medications</td>
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<td>Patient unable to ambulate with supervision at 4 hours post-procedure but before they are randomized into the study.</td>
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<td>Evidence of vascular complication(s) (e.g. dissection, hematoma, bleeding) peri-procedure</td>
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<td>Evidence of vascular complication(s) (e.g. dissection, hematoma, bleeding) peri-procedure</td>
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<td>Patient is pregnant</td>
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<td>Evidence of infection (e.g. fever, pus, swelling) peri-procedure</td>
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<tr>
<td>Patients in chronic renal insufficiency (e.g, serum creatinine ≥1.5 mg/dL)</td>
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