Drive-Through Angioplasty
Is It Safe or Necessary?

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In this issue of *Circulation*, Bertrand et al report the results of the Early Discharge after Transradial Stenting of Coronary Arteries (EASY) Study. After receiving a standard bolus of abciximab and undergoing a successful and uncomplicated transradial stent placement, 1005 patients were randomized to a traditional strategy with overnight hospitalization or early discharge after 4 to 6 hours. All patients received aspirin, clopidogrel, and a bolus dose of abciximab before their procedure. Those in the traditional strategy group also received a 12-hour abciximab infusion, whereas those in the early discharge group did not. The goal of the EASY study was to show that stent implantation by the radial approach with only a bolus of abciximab and then early discharge was not inferior to the traditional strategy in terms of effectiveness and safety. The primary composite end point was the 30-day incidence of death, any myocardial infarction, unplanned revascularization, major bleeding, repeat hospitalization, access-site complications, or severe thrombocytopenia. On the basis of their data, the authors concluded that the abbreviated abciximab therapy with same-day discharge was clinically not inferior to the traditional strategy after uncomplicated stent placement.

With healthcare costs increasing, strategies to limit expenditures are popular and deserve careful examination. Accepted cardiology practice has moved toward dramatically shortened hospital stays for diagnostic coronary angiography and percutaneous coronary intervention (PCI) as well as many other procedures. The present study suggests that many patients who undergo PCI could be managed safely as outpatients. Substantial accomplishments in the practice of PCI have resulted in the excellent success and safety of the radial approach with only a bolus of abciximab and then early discharge was not inferior to the traditional strategy in terms of effectiveness and safety. The primary composite end point was the 30-day incidence of death, any myocardial infarction, unplanned revascularization, major bleeding, repeat hospitalization, access-site complications, or severe thrombocytopenia. On the basis of their data, the authors concluded that the abbreviated abciximab therapy with same-day discharge was clinically not inferior to the traditional strategy after uncomplicated stent placement.

The use of radial artery access has been well described in the literature. Despite studies demonstrating the feasibility, safety, and acceptance by patients of this method of access, it has not been adopted widely in the United States. For example, in the 2005 Report from the American College of Cardiology–National Cardiovascular Data Registry, only 1% of diagnostic procedures and 1.2% of PCIs at participating facilities were performed by the radial approach. The concept of outpatient PCI is also not new. One of the first reports of outpatient PCI was by Laarman et al in 1994 using brachial artery puncture. Even in the era when Plamaz–Schatz stents were being hand crimped on balloons and coumadin was required, Kiemeneij and colleagues reported outpatient stent implantation by the radial artery approach. As PCI techniques have evolved, outpatient PCI has been described in different scenarios including radial access with only balloon angioplasty and no glycoprotein IIb/IIIa inhibitors; femoral access with or without stent placement and with or without glycoprotein IIb/IIIa inhibitors; radial access with stent placement and with or without only an abciximab bolus; and radial access with stenting and abbreviated infusion of eptifibatide. These studies used well-defined clinical criteria to carefully select patients for same-day PCI before the procedure, and patients who had any predictors of adverse outcomes after PCI, such as the presence of a dissection or thrombus, were excluded.

To place the present study in perspective, 3 issues need to be examined. First, it is important to establish the potential benefit to patients from the proposed treatment. Access-site bleeding and other vascular complications remain an important concern, and they persist despite the use of smaller-caliber guiding catheters and vascular-closure devices. Bleeding and vascular complications add to length of stay and total procedure costs. A contemporary benchmark for the current incidence of bleeding complications exists in the control arm of the Randomized Evaluation in PCI Linking Angiomax to Reduced Clinical Events (REPLACE-2) trial, in which heparin and a glycoprotein IIb/IIIa inhibitor were administered. Major bleeding occurred in 4.1% of control patients, bleeding at the site of vascular access occurred in 2.5%, and retroperitoneal hematoma in 0.5%. In contrast, major bleeding identified by the same set of criteria occurred in only 0.5% of the patients in the present report. Although there are limitations to simply comparing the incidence of major bleeding between these 2 studies, a randomized comparison of radial, brachial, and femoral access confirmed the low incidence of access-site complications from the radial approach compared with the other techniques. Unfortunately, radial artery access has its own set of limitations. These including a steeper learning curve; a limited variety of generally smaller-caliber guiding catheters, which may not provide adequate backup support in all situations or allow all interventional devices to be used; the need for an adequate ulnar pulse; radial artery spasm; loss of the radial pulse by Doppler examination in 5% to 9% of patients; and an increasing inability to use radial access after repeated procedures.

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Therefore, the present study simply adds to the existing body of literature highlighting the potential for a lower incidence of bleeding and vascular complications with radial arterial access.

Second, it is important to determine whether the patients in the present study are similar to those one would likely encounter and whether early discharge is appropriate in a given practice. Although this was a randomized study, certain patients were excluded before the point of randomization. Patients were excluded for clinical reasons if they had a recent (<72 hours) ST-segment elevation myocardial infarction, a left ventricular ejection fraction £30%, transient vessel closure or hemodynamic collapse during PCI, a femoral artery sheath, or any other outside consideration precluding same-day home discharge, allergy or intolerance to aspirin or thienopyridines, International Normalized Ratio >2.0, or contraindication to abciximab. Most of these exclusions are not related to radial access per se but, rather, to the testing of same-day discharge in the present study. Regardless of the vascular access site, there are certain patients whom most would consider inappropriate for early discharge after PCI (very recent myocardial infarction, important left ventricular dysfunction or associated cardiac abnormalities, severe comorbidities, history of or increased risk for bleeding complications). At the opposite end of the spectrum, some patients could reasonably be considered for early discharge after PCI, such as patients with stable angina without important comorbidities undergoing a simple, straightforward PCI and in whom preloading with clopidogrel is complete. There is a substantial group in the middle, however, where a divergence of opinion would exist about the wisdom of early discharge after PCI. These include patients presenting with unstable angina, those undergoing multivessel or more complex PCI, those with moderate cardiac or systemic comorbidities, and the elderly. Procedure risk can be assessed using many different variables, including clinical presentation, angiographic characteristics, comorbidities, and other factors. Patients with an increasing number of unfavorable characteristics are frequently referred to as high-risk patients. Like beauty, however, risk is in the eye of the beholder. Although the investigators characterize their study cohort as moderate to high risk, comparison with other interventional trials suggests that this study population may have been somewhat lower in risk. In the first Intracoronary Stenting and Anti-thrombotic Regimen: Rapid Early Action for Coronary Treatment (ISAR-REACT) study, patients were characterized as low to medium risk. Although these are not statistical comparisons, the low- to medium-risk patients in the ISAR-REACT trial seemed to be older (mean age 65 years versus 60 years) and had a higher incidence of multivessel disease (74% versus 36%) and type B2/C lesions treated (56% versus 46%) compared with the EASY study population. To be fair, some indicators of higher risk were more frequent in the EASY study population, such as an elevated troponin-T (18.5% versus 0%), but the definition of an elevated troponin-T differed between the 2 studies. Using a similar study design, the ISAR-REACT 2 trial examined patients at higher risk; specifically, all had a non-ST-segment elevation acute coronary syndrome defined by an elevated troponin-T, ischemic electrocardiographic changes, or both. Compared with the patients in the EASY trial, patients in the ISAR-REACT-2 trial were older (mean age 66 years versus 60 years) and had a higher incidence of diabetes (26% versus 16%), a higher incidence of multivessel disease (74% versus 36%), and a higher incidence of type B2/C lesions treated (81% versus 46%). Descriptions of the risk level of the patient population treated in any study will always be somewhat subjective because many variables are used to determine risk. The patients studied in the EASY trial fit best within that large group in the middle, with a lower risk profile than the ISAR-REACT-2 population, yet a higher risk profile that the ISAR-REACT trial. The occurrence of early ischemic events and the possibility of arrhythmias or other early complications have been a strong influence in support of overnight hospitalization for monitoring. Although the incidence of these complications has surely declined with improved drug therapies and stenting, these uncommon complications have dire consequences, including the potential for irreversible myocardial damage or death. Although it is true that controlled scientific studies have not demonstrated whether overnight hospital observation lowers or prevents these events, this would seem to be a case of res ipsa loquitur, with any adverse outcome being optimally managed if promptly recognized and rapidly treated.

Finally, the proposed bolus-only abciximab therapy deserves further scrutiny. The low- to moderate-risk patients of the ISAR-REACT trial were preloaded with clopidogrel before randomization to the bolus and infusion of abciximab versus placebo. In ISAR-REACT, the addition of abciximab provided no additional benefit in lowering the primary end point, 30-day composite of death, myocardial infarction, or urgent target vessel revascularization. Thus, in truly low-risk patients loaded with clopidogrel, even a bolus of abciximab would seem unnecessary. The same end point was evaluated in the ISAR-REACT-2 trial, but in patients with a non-ST-elevation acute coronary syndrome. Despite clopidogrel loading before PCI, the bolus and infusion of abciximab further reduced adverse events. This benefit was confined only to those with an elevated troponin-T level, however. Therefore, is a bolus of abciximab alone enough to provide this benefit for 18.5% of patients in the EASY trial with an elevated troponin at baseline? In the Evaluation of 7E3 for the Prevention of Ischemic Complications (EPIC) trial, it was clearly shown that the best outcome was obtained with a bolus and infusion of abciximab. Because of this initial observation, a bolus and infusion of abciximab has been the standard practice. However, balloon angioplasty alone was used for more than 90% of the patients in the EPIC trial, and many of the immediate complications of PCI, such as acute vessel closure, are reduced by stenting. Nevertheless, when this was retested in the era of stenting, a bolus and infusion of abciximab was confirmed to provide benefit compared with stenting alone. The question remains, however, whether a bolus of abciximab alone would be enough. A recent reanalysis of the EPIC data examined outcomes at 6-hour intervals during the first 24 hours after balloon angioplasty to identify any benefit in the group receiving only the abciximab bolus. At 6 hours, the primary composite end point (death, myocardial infarction, or urgent intervention)
was reduced by 46% with an abciximab bolus only compared with placebo (2.9% versus 5.3%), mainly because of a reduced rate of urgent intervention. Such a post hoc analysis can only be considered thought provoking and hypothesis generating at this point, however.

In the final analysis, 2 pivotal questions remain about the treatment proposed in the EASY trial: Is it safe? Is it necessary? Outpatient PCI is feasible and seems to be safe in low-risk patients. The keys to success are wise selection of patients and lesions, coupled with well-planned drug therapies and excellent interventional technique. How far this can be extended into higher-risk groups remains unclear. Proponents argue that outpatient PCI is necessary to save healthcare dollars and open hospital beds. This argument hinges on the characteristics of the healthcare delivery system and reimbursement while realizing only a mild cost savings. For outpatient PCI to become a standard and sustainable practice, a reassessment of procedure reimbursement is warranted.

In the United States, hospitals could predict a considerable reduction in reimbursement while realizing only a mild cost savings. For outpatient PCI to become a standard and sustainable practice, a reassessment of procedure reimbursement would be required. Whether a broad group of patients truly prefer drive-through angioplasty and whether outcomes differ based on these short stays also requires clarification.

Disclosures
None.

References

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