Ambulatory Outpatient Percutaneous Coronary Intervention

The time has come.

BY ISSAM D. MOUSSA, MD

Advances in clinical sciences and procedural technology have transformed percutaneous coronary intervention (PCI) from a risky procedure to one with an incredible safety profile. According to the NCDR CathPCI Registry, the rates of in-hospital mortality, stroke, and emergency coronary artery bypass grafting after elective PCI in all comers are 0.66%, 0.2%, and 0.3%, respectively.[1] The changes in health care priorities, providing quality, affordable, and patient-centered care, make the topic of same-day discharge after elective PCI more important than ever. Despite the cumulative clinical evidence and the shift in financial incentives for elective PCI, few programs across the United States have adjusted accordingly.

In this article, we address the following:

- Is there sufficient evidence to support the safety, efficacy, and cost-effectiveness of same-day discharge after elective PCI?
- Are the strategies for patient selection and triage for same-day discharge after PCI well defined?
- Does same-day discharge after PCI increase patient satisfaction?
- What is the current utilization of same-day discharge after PCI in the United States? How does it compare to noncardiac procedures?
- Why is there inertia in transforming practice? Why should hospitals embrace outpatient PCI?
- Is the acute care hospital setting the most cost-effective site of service for outpatient PCI? Should outpatient PCI be performed at freestanding facilities?

EVIDENCE OF SAFETY AND EFFICACY

The first randomized study to demonstrate that a strategy of same-day discharge after PCI (outpatient PCI) is as safe and effective as overnight observation after PCI (inpatient PCI) was published 16 years ago.[2] Although a detailed discussion of this topic is beyond the scope of this review, a brief overview of a few of the most important studies is worthwhile. The EPOS study randomly assigned 800 consecutive, elective, outpatient, planned transfemoral PCI patients to a strategy of either same-day discharge or routine care that included overnight observation in the hospital.[3] The patients and providers were blinded to the assignment until after evaluation according to predefined criteria for those patients who required additional observation or treatment. All patients eligible for same-day discharge, regardless of assignment, were then strictly observed for 4 hours and then underwent a rigorous triage evaluation to determine if same-day discharge would be appropriate. At that time, those patients who were randomized to the same-day discharge group were discharged, whereas the patients randomized to the overnight hospitalization group were kept in the hospital for observation. The investigators found that 20% of patients in both arms developed one of the predefined exclusions for same-day discharge. Of the 80% of patients suitable for same-day discharge, none suffered a cardiac event within 24 hours after PCI, and only three patients experienced a vascular complication, with no differences observed in the two groups. The patients assigned to same-day discharge reported significantly higher rates of overall sat-

Is there sufficient evidence to support the safety, efficacy, and cost-effectiveness of same-day discharge after elective PCI?

isfaction and incurred lower costs for the PCI procedure than the patients randomized to standard overnight hospitalization. At 1 year, no significant differences in outcomes were observed between the two strategies.

The largest 30-day outcome study was a retrospective registry of 107,000 elective low-risk older Medicare patients who were undergoing elective PCI procedures at 903 sites participating in the CathPCI Registry between November 2004 and December 2008 and were linked with Medicare Part A claims.[4] Patients were divided into two groups based on their length of stay after PCI: same-day discharge or overnight stay. The main outcome measures were death or rehospitalization within 2 days and by 30 days after PCI. The prevalence of same-day discharge was 1.25% with significant variation across facilities. Same-day discharge patients underwent shorter procedures with less multivessel intervention. There were no significant differences in the rates of death or rehospitalization at 2 days or at 30 days. Among patients with adverse outcomes, the median time to death or rehospitalization did not differ between the groups (same-day discharge, 13 days vs overnight stay, 14 days). After adjustment for patient and procedure characteristics, same-day discharge was not significantly associated with 30-day death or rehospitalization.

Numerous other registries and randomized clinical trials have replicated these findings across a broad spectrum of patients with stable coronary artery disease and coronary anatomy.[5-12] The evidence supporting the safety and efficacy of outpatient PCI in properly selected patients is indisputable.

STRATEGIES FOR PATIENT SELECTION AND TRIAGE

Numerous studies have addressed the question of how to optimize patient selection, immediate outcome, and subsequent triage to same-day discharge after PCI.[8,10,13-16] The findings of these studies can be summarized as follows: patients with acute coronary syndromes, heart failure, renal insufficiency, frailty, and those who lack a social support structure would not be good candidates for same-day discharge after PCI. Although studies have not excluded patients based on angiographic criteria, it is clear that patients undergoing PCI for complex anatomy, such as chronic total occlusions, severely calcified lesions, and multivessel interventions, were not well represented in these studies. Patients with bifurcation and ostial lesions were studied and found not to be good candidates for same-day discharge. Of course, the incidence of any intraprocedural complication, such as acute closure, side branch occlusion, or suboptimal results, would preclude candidacy for same-day discharge.[13]

Elderly patients are no less safe after same-day discharge than younger patients,[8,10] but women are at an increased risk of postprocedure complications, primarily due to higher rates of comorbidities.[13]

Although it would seem intuitive that radial access would be preferable for patients being considered for same-day discharge due to the lower incidence of vascular complications and patient preference, femoral access remains an option. Actually, in the MEDICARE/NCDR CathPCI registry study, the overwhelming majority of patients were femoral access cases. When femoral access is used, the use of effective closure devices may reduce complications and would reduce the time to ambulation and facilitate early discharge.[14]

The optimal postprocedure observation period is 4 to 6 hours. Several studies have demonstrated that across all patient risk categories, procedural complications occur either within this "safety window" or after 24 hours.[13,15,16] Although a low incidence of complications did occur, none would have been affected by same-day discharge. Complications observed before 6 hours would have prevented early discharge, and those occurring after 24 hours would have been unaffected by routine next-day discharge.

SAME-DAY DISCHARGE AND PATIENT SATISFACTION

Patient satisfaction has always been an important objective of physicians and health care systems. In recent years, patient satisfaction has taken on an increasingly important dimension as a metric for quality and hospital/physician public rating. Numerous studies evaluating same-day discharge after PCI have documented increased patient satisfaction with this strategy.[6,9] In a dedicated randomized, controlled trial with a particular emphasis on patient preference, Kim et al[17] randomized 298 patients undergoing transfemoral elective PCI to same-day (n = 150) or next-day (n = 148) discharge. At 30 days after PCI, clopidogrel adherence, physician and emergency room visits, and hospitalization were similar in the two randomization groups. Furthermore, 79% of patients randomized to same-day discharge reported satisfaction with the timing of their discharge compared with 49% of those randomized to next-day discharge ($P < .001$). 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 earlier discharge ($P < .001$). 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 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.

The evidence supporting increased patient satisfaction after outpatient PCI is unequivocal, and it needs to be taken into strong consideration during the informed consent process.

CURRENT UTILIZATION OF SAME-DAY DISCHARGE

The majority of outpatient PCI procedures in the United States are performed in hospital-based facilities; fewer are performed at freestanding cardiac catheterization laboratories or ambulatory surgery centers. National utilization rates for hospital-based outpatient PCI procedures are tracked through the Healthcare Cost and Utilization Project (HCUP), while no reliable utilization data exist for freestanding cardiac catheterization laboratories. HCUP statistical briefs[18,19] demonstrate that in 2007, only 7% of PCIs were performed as outpatient procedures, whereas 99% of cataract surgeries, 18% of appendectomies, and 14% of hysterectomies were performed as outpatient procedures. In 2012, outpatient PCI increased to 12%, whereas outpatient appendectomy increased to 28%, and outpatient hysterectomy increased to 40%.

How can we explain the inertia in moving elective PCI in appropriate patients to the outpatient setting despite the proven safety and efficacy profile?

WHY SHOULD HOSPITALS EMBRACE OUTPATIENT PCI?

Historically, hospital administrations' reluctance toward adopting same-day discharge for PCI was predicated upon reimbursement policies when a significant number of PCIs received reimbursement as inpatients when hospital stay exceeded 24 hours. For example, in 2007, hospitals charged $34,920 for outpatient PCI and $46,769 for inpatient PCI.[18]

The introduction of the Center for Medicare & Medicaid Services' (CMS) two-midnight rule, which specifies that admission is only appropriate when a physician expects the patient's hospital stay to span two midnights, will shrink the percentage of elective PCI cases that receive inpatient reimbursement rates. The recently released 2016 proposed changes to the two-midnight rule will allow some flexibility in determining the appropriate length of inpatient stay on a case-per-case basis. If the vast majority of elective PCI cases will receive outpatient—rather than inpatient—reimbursement rates, the traditional financial disincentive for hospitals to adopt same-day discharge strategies no longer exists. With reimbursement set at outpatient rates, the best financial strategy would be to limit overhead and direct costs associated with unnecessary overnight observation. Eliminating the overnight stay associated with elective PCI significantly lowers the total cost of the care episode. Hospital-based procedures constitute a significant and nonsustainable financial burden on society. Consider the following highlights for a 2011 HCUP report:

- Hospitalizations that involved operating room (OR) procedures constituted 29% of the total 38.6 million hospital stays and 48% of the total $387 billion in hospital costs.[20]
- Compared with hospital stays that did not include an OR procedure, stays involving an OR procedure resulted in a longer length of stay, were more likely to be elective admissions, and were less likely to involve major or extreme severity of illness. Hospital stays involving OR procedures were approximately half as likely to result in patient death as were stays without an OR procedure.
- PCI was the fourth most commonly hospital-based procedure, accounting for 3.5% of the total number of hospital-based procedures after Cesarean section, circumcision, and knee arthroplasty.
- PCI was the third most costly hospital-based procedure, accounting for 5.4% of all costs of stays involving OR procedures after spinal fusion and knee arthroplasty.

Hospitals should embrace outpatient PCI in appropriate patients because this strategy is aligned with the triple aim of high-quality, patient-centered, and affordable care.

OUTPATIENT PCI AND FREESTANDING FACILITIES

If we accept the fact that selected patients can be safely discharged 4 hours after elective PCI, why perform these procedures in a hospital setting? Although hospital-based outpatient PCI is more cost-effective than inpatient PCI, the fixed and direct costs of operating within an acute care hospital setting are significantly higher than the operating costs at a freestanding outpatient facility. Accordingly, freestanding facilities can deliver care at lower reimbursement rates. Let us assume that out of the 800,000 PCIs performed annually in the United States, approximately 250,000 elective PCI procedures would

be eligible for same-day discharge. The current Medicare reimbursement rate for hospital-based outpatient PCI is ~$18,000. If outpatient PCI at freestanding facilities is reimbursed at a discounted rate of $14,000 ($4,000 cost savings per procedure), the potential cost savings of performing outpatient PCI at freestanding facilities would amount to more than $1 billion annually, without compromise of patient safety and with simultaneous improvement of patient satisfaction.

Employers and patients are demanding more transparency in reporting and comparing health care costs among different hospitals and providers. The lack of enthusiasm by health care systems and providers regarding sharing health care cost data will not stop this trend. Already, there are independent not-for-profit organizations that have begun to report on the costs of medical procedures, making this information accessible to the public. These efforts are supported by patient advocacy groups, select health care systems, and payors. The Health Care Cost Institute is one of these organizations, and it reports medical procedure costs on www.guroo.com.

Given the financial disincentives for hospitals to encourage migration of PCI from hospital to ambulatory settings, perhaps the impetus for this migration should be shouldered by medical societies, physicians, patients, and payers in a pay-for-performance alliance. It is critically important, however, to adopt a national platform to monitor quality and utilization metrics at the freestanding facilities. Existing national cardiovascular registries, such as the NCDR CathPCI registry, can serve as a platform for prospective evaluation of the quality, utilization, and cost-effectiveness of same-day discharge after elective PCI at freestanding facilities and acute care hospitals. The registry can partner with payers to link reimbursement for same-day discharge after PCI to participation in the registry and meeting prespecified quality and utilization metrics. ■

Issam D. Moussa, MD, is Professor of Medicine, UCF College of Medicine, and Chief Medical Officer, First Coast Cardiovascular Institute, in Jacksonville, Florida. He has stated that he has no financial interest related to this article. Dr. Moussa may be reached at imoussa@firstcoastcardio.com.

1. Masoudi FA, Ponirakis A, Yeh RW, et al. Cardiovascular care facts: a report from the national cardiovascular data registry: 2011. J Am Coll Cardiol. 2013;62:1931-1947.
2. Knopf WD, Cohen-Bernstein C, Ryan J, et al. Outpatient PTCA with same day discharge is safe and produces high patient satisfaction level. J Invasive Cardiol. 1999;11:290-295.
3. Heyde GS, Koch KT, de Winter RJ, et al. Randomized trial comparing same-day discharge with overnight hospital stay after percutaneous coronary intervention: results of the Elective PCI in Outpatient Study (EPOS). Circulation. 2007;115:2299-2306.
4. Rao SV, Kaltenbach LA, Weintraub WS, et al. Prevalence and outcomes of same-day discharge after elective percutaneous coronary intervention among older patients. JAMA. 2011;306:1461-1467.
5. Bertrand OF, De Larochelliere R, Rodes-Cabau J, et al. 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. Circulation. 2006;114:2636-2643.
6. Ziakas A, Klinke P, Fretz DE, et al. Same-day discharge is preferred by the majority of the patients undergoing radial PCI. J Invasive Cardiol. 2004;16:562-565.
7. Slagboom T, Kiemeneij F, Laarman GJ, et al. Outpatient coronary angioplasty: feasible and safe. Catheter Cardiovasc Interv. 2005;64:421-427.
8. Ziakas A, Klinke P, Mildenberger R, et al. Safety of same day discharge radial PCI in patients under and over 75 years of age. Int Heart J. 2007;48:569-578.
9. Glaser R, Gertz Z, Matthai WH, et al. Patient satisfaction is comparable to early discharge versus overnight observation after elective percutaneous coronary intervention. J Invasive Cardiol. 2009;21:464-467.
10. Ranchord AM, Prasad S, Seneviratne SK, et al. Same-day discharge is feasible and safe in the majority of elderly patients undergoing elective percutaneous coronary intervention. J Invasive Cardiol. 2010;22:301-305.
11. Gilchrist IC, Rhodes DA, Zimmerman HE. A single center experience with same-day transradial PCI patients: a contrast with published guidelines. Catheter Cardiovasc Interv. 2011;79:583-587.
12. Muthusamy P, Busman DK, Davis AT, et al. Assessment of clinical outcomes related to early discharge after elective percutaneous coronary intervention. Catheter Cardiovasc Interv. 2013;81:6-13.
13. Koch KT, Piek JJ, Prins MH, et al. Triage of patients for short-term observation after elective coronary angioplasty. Heart. 2000;83:557-563.
14. Allen DS, Marso SP, Lindsey JB, et al. Comparison of bleeding complications using arterial closure device versus manual compression by propensity matching in patients undergoing percutaneous coronary intervention. Am J Cardiol. 2011;107:1619-1623.
15. Small A, Klinke P, Della Siega A, et al. Day procedure intervention is safe and complication free in higher risk patients undergoing transradial angioplasty and stenting. The discharge study. Catheter Cardiovasc Interv. 2007;70:907-912.
16. Jabara R, Gadesam R, Pendyala L, et al. Ambulatory discharge after transradial coronary intervention: preliminary US single center experience (Same-Day Transradial Intervention and Discharge Evaluation, the STRIDE Study). Am Heart J. 2008;156:1141-1146.
17. Kim M, Muntner P, Sharma S, et al. Assessing patient-reported outcomes and preferences for same-day discharge after percutaneous coronary intervention: results from a pilot randomized, controlled trial. Circ Cardiovasc Qual Outcomes. 2013;6:186-192.
18. Russo A, Elixhauser A, Steiner C, and Wier L. Hospital-Based Ambulatory Surgery, 2007. Health Care Cost and Utilization Project. Statistical Brief #86.
19. Wier L, Steiner C, Owens PL. Surgeries in Hospital-Owned Outpatient Facilities, 2012. Health Care Cost and Utilization Project. Statistical Brief #188.
20. Weiss AJ, Elixhauser A, Andrews RM. Characteristics of Operating Room Procedures in U.S. Hospitals, 2011. Health Care Cost and Utilization Project. Statistical Brief #170.