Over the past 30 years, dramatic improvements have been achieved in the safety of percutaneous coronary intervention (PCI) procedures, despite the increasing complexity of clinical and anatomic conditions treated. The need for emergent bypass surgery has declined from 8% in 1990 to far less than 1% in the current era, and the rate of vascular complications has declined dramatically as techniques have improved and procedural experience has increased. Given the remarkable current periprocedural safety profile of elective coronary intervention, has the time come for us to consider whether outpatient PCI can be safely performed? In this issue of Circulation, investigators from the Academic Medical Center of the University of Amsterdam investigated this question as part of the Elective PCI in Outpatient Study (EPOS).1

The study by Heyde and colleagues randomly assigned 800 consecutive, elective, outpatient, planned PCI patients to a strategy of either same-day discharge or routine care that included an overnight observation in the hospital. 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-hospital for observation. The investigators found that 20% of patients in both disposition 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 3 patients suffered a vascular complication, with no differences observed in the 2 disposition groups. The patients assigned to same-day discharge reported significantly higher rates of overall satisfaction 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 2 disposition strategies, a finding that further supports the safety of the same-day discharge program.

Several previous investigators have explored the safety of same-day discharge after low-risk elective coronary intervention, and almost all have supported the safety of the practice.2–10 However, these analyses were predominantly non-randomized evaluations based on radial access procedures in which the time to ambulation was immediate. Because radial access procedures account for only a small minority of coronary interventions performed in the United States (US), these results had not been considered widely applicable in this country.

It is important to recognize that the routine practice of elective PCI in the Netherlands differs in many ways with the current standard practice in the US. First, although excluded from the study protocol, ad hoc PCI procedures that follow immediately from the diagnostic angiography procedure represent the majority of elective PCI procedures in the US. Ad hoc PCI has been shown to have equivalent short- and long-term safety in comparison to elective PCI procedures, and therefore inclusion of ad hoc PCI in same-day discharge programs would not likely change the results of the study.11,12 The use of drug-eluting stents was very low in the EPOS study relative to current practice in the US where a drug-eluting stent is used in >60% of PCI procedures. However, the use of drug-eluting stents is not associated with any increased risk of early vascular or ischemic complications in elective PCI13,14 and therefore would not be expected to affect the clinical outcomes of a same-day discharge program. Similarly, the widespread use of both glycoprotein 2b3a antagonists and the use of bivalirudin in elective PCI in the US differ from the protocol-mandated fixed-dose heparin anticoagulation used in EPOS. The use of these potent agents may make the risk of immediate sheath removal followed by manual compression, as per the protocol, less feasible. However, this effect may be modified by the use of vascular closure devices after PCI, which, though excluded from the study, are again popular in the US. Whereas vascular closure devices have not been shown to reduce overall vascular complications as compared with manual compression,15,16 these devices have been shown to enable the safe early removal of vascular sheaths in the setting of glycoprotein 2b3a use and bivalirudin use and therefore significantly reduce time to ambulation.17,18 It seems that use of vascular closure devices would likely offset the need for prolonged bedrest before access sheath removal if bivalirudin, higher-dose heparin, or glycoprotein 2b3a agents are used during the procedure, as would be likely in the US.
Despite the compelling results of the EPOS investigation and the reasonableness of the extension of these findings to US practice, 3 significant barriers exist that must be addressed before such programs can be implemented in the US. The first barrier is the likely hesitancy of patients to consider same-day discharge a safe and preferred strategy after PCI. The second challenge relates to the medicolegal risk that providers and hospitals adopting this strategy would experience from a change in the standard of care, despite evidence that overnight hospitalization is not required for selected patients. Finally, the current payment system for inpatient services provides a strong disincentive to hospitals to switch to an outpatient program without significant redesign of the payment structures for PCI.

Most patients who undergo PCI are anxious, whether from fear of a new diagnosis of coronary artery disease, concern about discomfort during or after the procedure, or about their long-term prognosis. The recent media frenzy related to the safety of drug-eluting stents has certainly increased the anxiety expressed by many patients who undergo PCI. From an admittedly unscientific survey of patients, colleagues, and staff, I have yet to find 1 person who, when faced with a hypothetical new diagnosis of coronary disease, would not prefer to stay in the hospital overnight after PCI, “just in case.” How can this perception be reconciled with the increased patient satisfaction reported by Heyde et al for the patients who were actually discharged on the day of the PCI? Perhaps asking a patient after their successful and uncomplicated procedure if they would rather be at home or be hospitalized, as done in the EPOS study, leads to a different answer than if one were to ask the patient before the procedure. Regardless, it is clear that patient education on the safety of same-day discharge for selected low-risk and uncomplicated conditions will be of paramount importance to the success of any such program.

The second challenge is the concern of liability if a patient discharged on the same day of the PCI procedure were to suffer a complication within the first day after the procedure, when the patient would have still been hospitalized under current standards. Therefore, a clear informed-consent procedure with meticulous documentation of the status of the patient during and after the PCI will be essential in order to encourage adoption of such programs.

The greatest potential barrier to the implementation of a successful same-day PCI program relates to the financial disincentive that hospitals will face in the conversion of PCI patients from overnight stays to same-day discharges. At my hospital, 41% of PCI patients would be eligible for inclusion in the protocol described by Heyde and colleagues. The average elective PCI admission in 2006 with 1 night of hospitalization resulted in charges of $33 600 and approximate reimbursements of $18 970. Average total costs for such patient admissions are estimated at $12 500 with a resultant net margin of over $6500. If the overnight stay were eliminated, the costs would decline only $1200, whereas expected reimbursements, on the basis of current average outpatient payor reimbursement rates for the institution, would decline more steeply to a conservative estimate of $12 000, which would result in a net margin of approximately $1000. This decline in hospital revenue could be partially offset by increased admissions for other conditions or by cost reductions enabled by lower usage of inpatient units. However, hospital costs tend to be inelastic, and increased admissions would only be financially beneficial to the hospital if they approximated the financial margin of the single overnight hospitalization for elective PCI. Perhaps the financial incentives for overnight hospitalization after PCI partly explains why so few investigations of same-day discharge have been conducted within the US.

If we extrapolate these costs and revenue impacts for the 800 000 PCI procedures performed annually in the US, $600 million to hospitals, which would simultaneously free up inpatient capacity by 250 000 patient bed days per year. However, this change in practice, without changes in the current payment and reimbursement rates, would lead to an annual decline in revenues to hospitals of $1.8 billion (which would be accrued as direct savings to third-party payors). Because profitable procedures such as elective PCI subsidize unprofitable admissions, it is predictable that many hospitals would be faced with serious fiscal challenges. Although this extrapolation from a single center is admittedly unscientific, the scale of the potential savings is worthy of serious consideration in an era of limited healthcare resources.

So how to proceed? In my opinion, it is essential that the results of the EPOS study be confirmed within the typical US practice before it is implemented as an alternative standard of care in this country. Given the financial disincentives for such a confirmatory study, it would seem that selected payors should partner with selected high-volume, high-quality provider hospitals to confirm the outcomes reported by Heyde et al in a true “pay for performance” alliance. These initial same-day elective PCI discharge programs must implement rigorous and consistent protocols for patient selection, evaluation, and triage that are at least as restrictive as the protocol implemented by the EPOS investigators. It would be reasonable to include both ad hoc PCI patients and patients who receive vascular closure devices in this evaluation. It will also be important to continue a minimum observation of 4 hours after PCI as per the EPOS protocol. As in the EPOS study, patients must live in close proximity (within 60 minutes travel time) to the treating center and must be universally contacted to assure their safety after the procedure. Finally, until a coordinated US experience confirms the safety of this approach, this type of program must be restricted to high-volume centers where clinical outcomes must be prospectively and continuously monitored, because only high-volume centers will have the volume of elective cases to adequately measure possible differences from historical benchmarks. Only when the safety of the same-day discharge program is confirmed through rigorous outcomes monitoring can the program, like PCI itself, be disseminated to routine practice in the interventional community.

The healthcare cost implications of the EPOS investigation, if confirmed through additional evaluations as outlined above, could conceivably save the healthcare system more
than $1 billion annually, without compromise of patient safety and with simultaneous improvement of patient satisfaction. Confirmation of these results through a carefully coordinated registry of high-volume, high-quality centers, as proposed above, would allow this practice to become the standard of care. However, only after careful consideration of adjustments to payments for PCI hospitalizations by the Centers for Medicare and Medicaid Services and other third-party payors would such a system become practical for the larger clinical community.

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Disclosures

None.

References


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