Same-day discharge after elective percutaneous coronary intervention was noninferior for safety to staying overnight in hospital

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;115:2299-306.

Clinical impact ratings: Cardiology ★★★★★★☆ Hospitalists ★★★★★☆☆

QUESTION

In patients having elective percutaneous coronary intervention (PCI), is same-day discharge as safe as staying overnight in the hospital?

METHODS

Design: Randomized, controlled, noninferiority trial.
Allocation: Concealed.*
Blinding: Blinded (clinicians).*
Follow-up period: 1 year.
Setting: University hospital in Amsterdam, the Netherlands.
Patients: 800 patients 30 to 88 years of age (mean age 62 y, 81% men) who were scheduled for elective PCI (not just a diagnostic procedure with possible PCI) and remained at home without the acute coronary syndrome the week before PCI. Exclusion criteria included living > 60 minutes away from the hospital and use of guiding catheters > 6 French in diameter, glycoprotein IIb/IIIa-receptor blockers, or long-term anticoagulation.
Intervention: Discharge 4 hours after PCI, unless extended clinical observation was deemed necessary (assessed by an operator blinded to treatment group) (n = 403) or overnight stay with discharge the next day (n = 397). All patients received appropriate anticoagulation and antiplatelet medications.
Outcomes: Composite endpoint (major adverse cardiac or cerebral event [MACCE] [cardiac death, myocardial infarction, stroke, coronary artery bypass grafting, or repeat PCI], severe complication of the arterial puncture with blood transfusion, or repeated compression) at 24 hours and 30 days after PCI, MACCE at 1 year, and cost.
Patient follow-up: 100% (intention-to-treat analysis).

MAIN RESULTS

19% of patients in the same-day discharge group and 21% in the overnight-stay group were identified as requiring extended hospital stay. 77% and 4% of patients, respectively, were discharged 4 hours after PCI. Groups did not differ for incidence of the composite endpoint at 24 hours or 30 days (Table). Risk for MACCE in the first 24 hours was lower in the same-day discharge group than in the overnight-stay group but was similar at 30 days (Table) and 1 year. In the patients deemed suitable for same-day discharge, the only adverse events at 24 hours were false aneurysms in 1 patient in the same-day discharge group and 2 patients in the overnight-stay group. Mean costs were €4675 and €4933, respectively, a savings of €258 (95% CI −93 to 598) with same-day discharge.

CONCLUSION

In patients having elective percutaneous coronary intervention, same-day discharge was noninferior for safety to staying overnight in hospital.

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*See Glossary.

Same-day discharge vs overnight hospital stay after percutaneous coronary intervention†

Outcomes	Follow-up	Same-day discharge	Overnight stay	Difference (95% CI)
Composite endpoint	24 h	2.2%	4.3%	−2.0% (−4.8 to 0.4)‡
				RRR (CI)
	30 d	3.7%	5.3%	30% (−33 to 63)
MACCE	24 h	1.5%	4.0%	63% (10 to 85)
	30 d	3.0%	4.8%	38% (−25 to 69)

†Composite endpoint = major adverse cardiac or cerebral event (MACCE) (cardiac death, myocardial infarction, stroke, coronary artery bypass grafting, or repeat percutaneous coronary intervention) (1.5% vs 4.0% at 24 h), severe complication of the arterial puncture with blood transfusion (0.7% vs 0.8%), or repeated compression. Other abbreviations defined in Glossary.
‡Criterion for noninferiority was met because the upper limit of the CI was < 6%.

COMMENTARY

Overnight observation after a major procedure allows early detection and treatment of complications but is costly and may be inconvenient for patients compared with same-day discharge. The EPOS tested whether 4-hour observation after PCI was "noninferior" to a standard overnight observation period.

Although the trial was randomized, this advantage was negated by several major design problems. First, patients were randomized before PCI, and the 20% of randomized patients who were not eligible for early discharge had almost all (88%) of the adverse events within 24 hours of PCI. Second, the authors made little effort to identify late PCI complications, especially in the early-discharge group—they used phone interviews at 24 hours and 3 days instead of bringing all patients back for a clinic visit to detect any adverse events by checking troponin levels, an electrocardiogram, and the puncture site. This design introduced a very strong bias in favor of the early-discharge group since adverse events that developed between 4 and 24 hours after PCI could be documented in patients who were kept in hospital for observation but not in those who were sent home. The reported lower rate of complications in the early-discharge group is unconvincing in light of this haphazard follow-up. Finally, the overall complication rate in the study was much lower than expected (3% instead of 10%), so the "noninferiority margin" of 6% was far too generous.

The bias in the trial design, low event rate, small sample size, and poor follow-up make the authors' conclusion of "noninferiority" not credible. A larger and better study is necessary to prove the safety of same-day discharge after PCI, especially for patients who have a PCI ad hoc after a diagnostic cardiac catheterization, an approach that is typical of PCI practice in the United States.

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