The mobile angiograph in a center without on-site surgical back-up: the de facto standard?

Walid Hassan, MD, FCCP, FACP, FACC, FSCA&S; Suleiman Kharabsheh, MD

In 1976 Dr. Andreas Gruentzig started the era of percutaneous coronary intervention (PCI) with the first coronary artery balloon dilation. Since the introduction of percutaneous transluminal coronary angioplasty (PTCA) into clinical practice, authorities have recommended a surgical standby, i.e., prompt access to emergency surgery with cardiopulmonary bypass and a full operational team of anaesthesiologists, perfusionists and surgeons.¹ However, major advances in recent years in devices and pharmaceutical therapy have dramatically reduced the incidence of urgent coronary artery bypass graft (CABG) surgery performed due to PTCA complications from 10% to 25% at the time of technique introduction to 2% to 5% in the late '80s, and 1% to 2% today.^{2,3}

The main cause of death in patients undergoing PTCA is an abrupt arterial closure during or immediately after PTCA. This complication occurs in 3% to 8% of all procedures and may result from arterial wall dissection, clot formation blocking the blood flow in the vessel, arterial spasm and a sudden fall in blood pressure. Immediate restoration of blood flow is imperative for a patient's survival. Initially, abrupt arterial closure was treated with urgent CABG. However in the '80s, prolonged perfusion balloon inflation became a common practice. With the introduction of the intracoronary stents in the '90s, most cases of abrupt vessel closure due to dissection can be successfully treated with cover stents for perforation.² The optimization of anti-thrombotic treatment permits more effective prevention and treatment of platelet thrombi. The introduction of the high-pressure stent implantation technique and combined use of aspirin and Plavix (clopidogrel) or ticlopidine reduced the risk of acute and subacute thrombosis from 15% to less than 1%.⁴ The use of platelet glycoprotein IIb/IIIa receptor inhibitors permitted a further reduction in periprocedure complications and the need for urgent CABG.⁵ In patients with diminished left ventricular contractility or a large area of the myocardium supplied by the artery being dilated, acute vessel closure may lead to severe hemodynamic instability and cardiogenic shock. Intra-aortic balloon pump (IABP) support can stabilize the patient and improve myocardial blood supply, which increases angioplasty success or serves as a bridge to urgent surgical intervention.

Several randomized trials and meta-analyses have proved the superiority of PCI over thrombolytic therapy for acute myocardial infarction (AMI), and recent trials also favor an early initial invasive strategy for the treatment of high-risk acute coronary syndrome (ACS) patients. However, on average

*From the Department of Cardiovascular Diseases
King Faisal Specialist Hospital & Research Centre
Riyadh, Saudi Arabia*

Correspondence to:

Dr. Walid Hassan

Department of Cardiovascular Diseases - MBC 16

King Faisal Specialist Hospital & Research Centre

P.O. Box 3354

Riyadh 11211

Saudi Arabia

E-mail: hassan@kfshrc.edu.sa

Accepted for publication: May 2004

two-thirds of AMI and ACS patients present to community hospitals that have no cardiac catheterization laboratory or no on-site cardiothoracic surgery backup available, which precludes doing PCI in most parts of the world at the present time because of the fear of procedural complications that would require immediate surgical bail out.

The Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) trial,⁶ a prospective, randomized trial was conducted from July 1996 through December 1999 to determine whether treatment of acute MI with primary PCI is superior to thrombolytic therapy at hospitals without on-site cardiac surgery and, if so, whether superiority is durable. The study included 451 thrombolytic-eligible patients with an acute MI of less than 12 hours duration associated with ST-segment elevation on electrocardiogram. Patients were randomly assigned to receive primary PCI (n=225) or accelerated tissue plasminogen activator (bolus dose of 15 mg and an infusion of 0.75 mg/kg for 30 minutes followed by 0.5 mg/kg for 60 minutes; n=226). The primary end point was median hospital length of stay and the 6-month composite incidence of death, recurrent MI, and stroke. The incidence of the composite end point was reduced in the primary PCI group at 6 weeks (10.7% vs. 17.7%; $P=.03$) and 6 months (12.4% vs. 19.9%; $P=.03$) after index MI. Six-month rates for individual outcomes were 6.2% vs. 7.1% for death ($P=.72$), 5.3% vs. 10.6% for recurrent MI ($P=.04$), and 2.2% vs. 4.0% for stroke ($P=.28$) for primary PCI vs. thrombolytic therapy, respectively. Median length of stay was also reduced in the primary PCI group (4.5 vs. 6.0 days; $P=.02$).

No patient in the primary PCI group was sent for emergen-

Table 1. Rates of emergency bypass surgery and mortality for 54 379 patients undergoing percutaneous coronary intervention at hospitals with and without on-site cardiac surgery in France (62% of centers did not have cardiac surgery).⁷

	Centers with surgery	Centers without surgery
Emergency bypass surgery	0.44%	0.25%
Mortality	0.72%	0.41%

cy CABG surgery for a catheterization-related or PCI-related complication, including abrupt closure, dissection, or coronary perforation due to a complication at the index hospital. Sixty-nine percent of the thrombolytic therapy group was transferred to a tertiary hospital for additional care, whereas 31% of the primary PCI treatment group was transferred ($P=.002$). No patient was transferred to a tertiary facility because of a complication of primary PCI. The mean door-to-balloon time was 105.2 minutes, which represents a treatment time at least as good as the average of 120 minutes reported at the lowest-mortality (highest-volume) institutions in the NRM registry.

Due to recent improvements in the safety of PTCA procedures, the indications for the procedure have been extended. At present PCI is performed in complex type C lesions, multivessel disease, LV dysfunction, and ACS. Despite the increased frequency of PTCA, the need for emergency CABG has been reduced to less than 1% at experienced centers with a high volume of procedures.² For this reason, the number of centers worldwide that perform the PTCA without on-site surgical cover is increasing (in the USA alone, the range is 200-300 centers). The same applies to the Middle East, where the rising demand for interventional cardiac procedures has also caused an increase in the number of laboratories that perform PTCA without on-site surgical cover.

Germany, France, and Italy have a long history of not requiring bypass surgery at centers that perform PCI. A large registry of over 50,000 patients undergoing intervention in France recently reported no differences in outcomes at centers with and without cardiac surgery, with less than 0.4% of patients

requiring emergency surgery; 0.44% of patients at surgical hospitals and 0.25% of patients at non-surgical hospitals were sent for emergency bypass.⁷ Two-thirds of the hospitals in this registry had no on-site surgical facilities. The mortality at surgical hospitals was 0.7%; at non-surgical hospitals it was only 0.4%. Thus the non-surgical hospitals in this very large registry sent fewer patients to emergency surgery and had fewer deaths! (Table 1). There are at least eight other registries of PCI without on-site surgery, located in Canada, the United Kingdom, Germany, and Italy.⁸⁻¹⁴ These report outcomes of an aggregate of over 70,000 patients undergoing non-emergent angioplasty at hospitals without in-house surgery. The overall mortality, pooling data from all of these series, was 0.48%.

The article by Akdemir and colleagues in this issue of the *Annals* (page 265) provides some important insights and validation of the abovementioned approach. There were no major adverse cardiac events (MACE) during their diagnostic cardiac procedures. They performed advanced PCI using a mobile angiograph without on-site surgical cover in patients with a different spectrum of CAD, ranging from stable angina (20.9%), unstable angina (46.5%), acute MI (32.5%) to cardiogenic shock (6%), and despite their relatively small volume, they achieved a 96% success rate (using predilation technique) with no acute or subacute thrombosis and comparable MACE (mortality 1.2%, urgent CABG 1.8%, MI 1.2%). Six months of follow-up revealed a comparable binary restenosis and target vessel revascularization (18.1%). Dr. Akdemir and colleagues must be congratulated for their effort to validate this approach in our region. I hope it will be studied further in future large-scale trials with longer follow-up. Important prerequisites for successful implementation of this approach include proper training with appropriate patient and lesion risk characterization, a high volume of procedures, prompt access to equipment including different types of coronary stents, IABP, and a close liaison with the nearest cardiac surgical center, with effective transfer that would enable patients to be on cardiopulmonary bypass within 90 minutes.

References

1. Angelini P. Guidelines for surgical standby for coronary angioplasty: should they be changed? *J Am Coll Cardiol*. 1999; 33:1266-1268.
2. Seclwer J, Butte A, Harrell L, et al. Acute occlusion during coronary interventions: the changing pattern in era of stents. *J Invas Cardiol*. 1998; 10:208-212.
3. Topol EJ, Serruys PW. Frontiers in interventional cardiology. *Circulation*. 1998; 98: 1802-1820.
4. Schmig A, Neumann FJ, Kastrati A, et al. A randomized comparison of antiplatelet and anticoagulant therapy after the placement of coronary-artery stents. *N Engl J Med*. 1996; 334:1084-1089.
5. EPISTENT Investigators. Randomized placebo-controlled and balloon angioplasty-controlled trial to assess safety of coronary stenting with use of platelet glycoprotein-IIb/IIIa blockade. *Lancet*. 352: 87-92.
6. Aversano T, Aversano LT, Passamani E, et al. Thrombolytic Therapy vs. Primary Percutaneous Coronary Intervention for Myocardial Infarction in Patients Presenting to Hospitals Without On-site Cardiac Surgery: A Randomized Controlled Trial. *JAMA*. 2002;287:1943-1951.
7. Loubeyre C, Morice MC, Berzin B, et al. Emergency coronary artery bypass surgery following coronary angioplasty and stenting: results of a French multicenter registry. *Cathet Cardiovasc Intervent*. 1999; 48:441-448.
8. Klinker WP, Hui W. Percutaneous transluminal coronary angioplasty without on-site surgical facilities. *Am J Cardiol*. 1992; 77:1520-1525.
9. Reifart W, Schwarz F, Preusler W, Stoerger H, Hofmann M. Results of PTCA in more than 5,000 patients without surgical standby in the same center [abstract]. *J Am Coll Cardiol*. 1992; 19:229A.
10. Ribichini F, Uslenghi E, Picco L, et al. Elective coronary angioplasty in total absence of heart surgery. *G Ital Cardiol*. 1994;24:949-956.
11. Baduini G, Belli KR, de Benedicdis M, et al. Coronary angioplasty in an Italian hospital without on-site cardiac surgery: the results and outlook [in Italian]. *G Ital Cardiol*. 1994;24:1529-1536.
12. Reifart N, Preusler W, Schwarz F, et al. A large center experience of coronary angioplasty without on-site surgical standby. In: Topol EJ, Serruys PW, eds. *Current Review of Interventional Cardiology*. 2nd ed. Philadelphia: Current Medicine;1995:296-303.
13. Dellavalle A, Steffenino G, Ribichini F, et al. Elective coronary angioplasty with and without surgical standby: clinical and angiography for the selection of patients. *Coronary Artery Disease* 1995;6: 513-520.
14. Vogt A, Bonzel T, Harmjan D. PTCA registry of German community hospitals. *Eur Ht J* 1997; 18: 1110-1114.