Three years of experience with a mobile angiograph in a center without on-site surgical back-up

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Background: The safety of percutaneous coronary interventions (PCI) performed in centers without surgical back-up is controversial, but data from several western countries indicates that this approach can be extended to a larger number of hospitals. We assessed the safety and efficacy of performing angiography and PCI with a mobile C-arm angiograph in a center without on-site surgical back-up, and compared our data with that reported in the literature.

Methods: We retrospectively analyzed 1485 coronary angiograms and 172 PCI procedures performed in our center from January 2001 to May 2003 using a mobile angiograph. Half of the patients that have undergone PCI had refractory unstable angina and one-third had acute myocardial infarction (AMI). The safety of PCI was assessed by the analysis of in-hospital complications (death, urgent need for repeated revascularization, AMI with or without ST elevation and stroke).The PCI procedures were considered effective when the post-PCI residual stenosis did not exceed 50% with distal Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow.

Results: In patients who underwent diagnostic coronary angiography there were no deaths, anaphylatic shock, acute renal failure or major ischemic complications. In patients who underwent PCI, the mortality rate was 1.1% (2 deaths), two patients (1.1%) developed acute MI with ST segment elevation, one patient (0.5%) underwent repeated PCI and three patients (1.7%) were referred for urgent by-pass surgery.

Conclusions: Diagnostic and PCI procedures can be safely performed using a mobile angiograph. The efficacy and safety requirements of PCI, performed in a center without an on-site surgical back-up facility using a mobile angiograph were similar to other data reported in the literature.

Key words: Percutaneous coronary interventions, mobile angiography, coronary artery disease, angioplasty, Turkey

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Coronary angiography is the gold standard in diagnosing coronary artery disease (CAD), but it is expensive. Technological innovations now allow mobile angiographs to compete with conventional stationary machines. Percutaneous coronary interventions (PCI) are an important part of diagnosis in cardiovascular disorders. The need for cheap but powerful angiographs will increase in the future. A topic of debate is the safety issue of PCI performed in centers without surgical back-up. Although PCI is recommended for the management of acute myocardial infarction (AMI) and refractory unstable angina, less than 10% of European hospitals are equipped with PCI facilities. Some are equipped with mobile fluoroscopy machines and even less have on-site cardiac surgery back-up.[1,2]

A meta-analysis of ten multicenter randomized trials indicated that primary angioplasty in AMI lowers the rates of death, stroke, recurrent ischemia and re-infarction compared with fibrinolytic therapy.[3] In addition, for low risk patients with AMI, the mortality of primary angioplasty can be very low (<0.5%), and hospital costs can be decreased.[4] Furthermore, most AMI patients are not candidates for fibrinolytic therapy, either because they have bleeding risks or shock, or do not have diagnostic electrocardiograms (ECGs).[5] These subgroups of patients may be at higher risk than those eligible to receive fibrinolytic therapy. The invasive approach can be applied to almost all of these patients at capable centers. Moreover, primary angioplasty may be more cost-effective than fibrinolytic therapy. Thus it becomes increasingly important, for both clinical and economic reasons, to address the question of whether interventional approaches to the treatment of AMI can be extended safely and effectively to a larger number of hospitals, including ones without on-site surgical back-up.

This is especially important for underdeveloped countries, where stationary angiographs and cardiac surgery centers are rare and are found only in heavily populated cities, and are therefore difficult to reach for patients living in remote areas. Can mobile angiographs in hospitals without surgical back-up facility solve the problem? The new generation of radiological mobile systems have the ability to obtain good quality images at low cost and will be used intensively in the future. However, guidelines on the use of mobile angiographs in centers without surgical back-up facilities have limitations. We analyzed the safety and efficacy of diagnostic and therapeutic interventions performed with the use of a C-arm mobile equipment in a center without surgical back-up.

Patients and methods

Between January 2001 and April 2003, 1485 coronary angiography and 172 PCI procedures were performed in our center with the use of the mobile angiograph (Table 1). Fifteen pacemakers and one ICD were also implanted. The indications for coronary angiography were consistent with American Heart Association/American College of Cardiology (AHA/ACC) guidelines for coronary indications published in 1987. Patients signed a written consent informing them about the status of the laboratory and possible complications.

The study population with AMI underwent primary angioplasty when there was more than 30 minutes of ischemic pain not controlled by conventional medications (aspirin, nitroglycerin, beta-adrenergic blocking agents and heparin, but not fibrinolytic agents) or an ECG demonstrating 2.0 mV of ST segment elevation in two or more contiguous leads. There was no time cutoff if the clinical impression suggested ongoing myocardial necrosis (ongoing chest pain and ST deviation with preserved R waves in two or more infarct leads). Patients who presented more than 12 hours after onset of pain were considered ineligible for PCI if they were symptom-free on emergency department arrival.

PCI procedures. PCI procedures were performed in AMI patients treated by primary percutaneous transluminal coronary angioplasty (PTCA), in patients with refractory unstable angina and in patients with coronary artery disease (CAD) with type A lesions. Elective PCI for stable patients having B and C type lesions were referred to tertiary centers. PCI was not performed in patients having unstable angina if there was left main coronary artery (LMCA) disease (>50%), contraindications to anti-platelet therapy, or >3 stents needed for one target site.

In most cases we used Ephesus stents (Nemed Corporation, Turkey), a stainless-steel, laser-cut, tubular, slotted-tube multi-cellular device mounted on customized, non-compliant, polyethylene terephthalate, with a non-tapered short balloon overhang (0.5 mm). In the unexpended state, the crossing profile is 0.048". Clopidogrel 300 mg was administered orally before the intervention. Procedures were performed using standard angioplasty technique with an 8 French (Fr) guiding catheter via the femoral artery. A bolus of 100 IU/kg of heparin was administered intra-arterially after insertion of the vascular access sheath. Target lesions were initially treated with appropriate balloon dilatation. Intracoronary stenting was carried out after a sub-optimal result following conventional balloon angioplasty. The stent sizes were determined based on a stent-to-artery ratio of 1.1:1 to 1.2:1. The stents were deployed at 8-14 atmospheres and high-pressure balloon inflation to 14 atmospheres was then applied with a non-compliant short balloon to avoid distal dissection.

Post-procedure medication protocol and follow-up. After successful stent implantation, heparin was not routinely administered unless there was a clinical indication, such as a large residual dissection. The sheaths were removed the same day. After sheath removal, experienced technicians performed manual compression of the puncture site, and then applied a pressure bandage for 6 hours. Ambulation was allowed 6 hours after sheath removal. Clopidogrel 75 mg once daily was continued for 4 weeks and aspirin 100-300 mg once daily was continued indefinitely. Electrocardiograms (ECG) were recorded immediately after the procedure, then daily before discharge. If the patient had recurrent chest pain post-procedure, a creatine kinase-myocardial band (CK-MB) level was measured and an additional ECG was recorded. The majority of patients were discharged 2 days after the procedure. Follow-up coronary angiography was performed at 6 months, or earlier if clinically indicated.

Laboratory and operators. The fluoroscopy machine was a Siemens C-800 Powermobil (Erlangen, Germany) with an

Table 1. Number of diagnostic and therapeutic interventions performed in the study population.

Year	Coronary angiography	Percutaneous coronary intervention	Pacers implanted	Intracardiac defibrillators
2001	350	30	5	–
2002	740	69	9	1
2003	395	82	1	–
Total	1485	172	15	1

Table 2. Clinical and demographic characteristics of percutaneous coronary intervention patients.

	n (%)
Male/female	134/38 (77.9/22.1)
Hypertension	35 (20.3)
Diabetes mellitus	56 (32.5)
Hyperlipidemia	42 (24.4)
Stable angina	36 (20.9)
Unstable angina	80 (46.5)
Acute MI	56 (32.5)
Cardiogenic shock	11 (6)

Table 3. Angiographic characteristics of the PCI patients and overall procedural data.

Procedure	n (%)
Total number of PCI	172 (100)
Total number of dilated lesions	225 (100)
Single vessel disease	119 (69.1)
Two vessel disease	53 (30.8)
PTCA alone/stent implanted	24/201 (10.6/89.3)
IIb/IIIa receptor blocker usage	35 (20.3)

X-ray generator of maximum 20 kW output. The machine has a digital cine mode with a pulse rate up to 25 frame/sec at 60 Hz. The digital processor can eliminate motion-dependent noise. The C-arm can rotate 182o and angulate ±190o. An ambulance was available for urgent transport. A tertiary center (Kosuyolu Heart Center, approximately 200 kilometers away) with facilities for cardiovascular surgery for 24 hours a day was available for any urgent cases.

Two experienced operators performed diagnostic coronary angiography and PCI procedures. Both had performed more than 2000 coronary angiograms and 500 PCI procedures from January 1998 until December 2000 as the primary operator before working in the department where the study was performed. The nursing and technical catheterization laboratory staffs were experienced in handling acutely ill patients and comfortable with interventional equipment. They participated in PCI procedures on a 24-hour, 365-day call schedule. The catheterization laboratory was well equipped with resuscitative equipment and well stocked with a broad array of interventional equipment. The cardiac care unit nurses were trained for hemodynamic monitoring.There was an ongoing program for outcome analysis and formalized periodic case review.

Definitions and angiographic analysis. Quantitative coronary angiographic analysis was performed using the quantitative coronary analysis system (AETMED S.P.a., Italy). Angiographic measurements were obtained during end-diastole using the image that showed the greatest narrowing, without overlap and with the least degree of foreshortening. Intra-coronary nitroglycerin was administered at baseline and final angiography. Measurements of the reference vessel diameter, minimal lumen diameter (MLD) and percent diameter stenosis were determined by an average of two orthogonal views. The index reference diameter was the average of the proximal and distal reference vessel diameters. Lesion length was measured on the baseline angiography using the "shoulder-to-shoulder" definition. The morphology of the coronary lesions was classified as A, B1, B2 and C according to Ellis' modification of the classification proposed by the American College of Cardiology and the American Heart Association Task Force.6 Changes in MLD were expressed as acute gain (post-procedural MLD minus pre-procedural MLD), late loss (post-procedural MLD minus 6-month follow-up MLD), and loss index (late loss/acute gain). Angiographic restenosis was defined as re-narrowing of the target lesion >50%. Q-wave myocardial infarction was defined as the development of new abnormal Q-waves not present at baseline in association with CK-MB enzyme elevation of three times the upper normal limit and non-q wave myocardial infarction was defined as CK and CK-MB elevation of three times the upper normal limit. Angiographic success was defined as (50% reduction in the diameter of the stenosis. Procedural success was defined as angiographic success without the occurrence of any major ischemic complications during hospitalization. A sub-optimal result was defined as a 30-50% residual stenosis after coronary angioplasty with a TIMI 3 flow. Restenosis was defined as the occurrence of >50% stenosis at the site of angioplasty, or clinical evidence of ischemia in the territory of the dilated vessel.

Complications. Vascular complications were defined as pseudoaneurysm formation, arteriovenous fistula, thrombotic occlusion requiring intervention and major bleeding from the puncture site necessitating blood transfusion. Major ischemic complications were defined as the occurrence of myocardial infarction, death or the need for emergency coronary artery bypass grafting.

Data collection and statistics. Demographic, clinical and technical data were gathered retrospectively. Follow-up coronary angiography was performed 6 months after the procedure. Statistical analysis was performed with SPSS 10.0 for Windows. Continuous variables are expressed as mean±SD.

Results

There were no deaths, anaphylactic shock, acute renal failure or major ischemic complications in the diagnostic coronary angiography group. Two patients had femoral artery pseudoaneurysms and were treated with surgery, and two patients had strokes. One, a 68-year-old male, had LMCA disease and a right occipital lobe infarction of the

Table 4. Pre- and post-procedural angiographic characteristics (n=110).

Characteristics	Pre-procedure	Post-procedure
Reference lumen diameter (mm)	2.74 ± 0.42	2.85 ± 0.28
Minimum lumen diameter (mm)	1.02 ± 0.46	2.42 ± 0.33
Percent diameter stenosis (%)	82 ± 16	16 ± 4
Lesion length (mm)	12.7 ± 4.7	–
Binary restenosis (>50%)	–	–
Acute gain (mm)	–	1.43 ± 0.48
Late loss (mm)	–	–
Loss index	–	–

Table 5. Outcome for all PCI procedures.

	In-hospital outcome (n=172)(%)
Total mortality	2 (1.1)
Death during PCI	1 (0.5)
Death during hospital follow-up	1 (0.5)
Acute MI with ST elevation	2 (1.0)
Acute MI without ST elevation	0
Need for repeat PCI	2 (1.1)
Need for urgent surgery	3 (1.7)
Stroke	0

brain. The other, a 72-year-old female had hemiplegia on the left side on the day after coronary angiography had been performed. Computerized tomography revealed a right parietal lobe infarction of the brain.

Baseline clinical and angiographic data for the patients who received PCIs are summarized in Tables 2, 3 and 4. The mean age of the 172 PCI patients was 58.1±11 years (mean±SD). There were a high proportion of patients with hypertension (40%) and diabetes mellitus (32%). Approximately half of the patients had refractory unstable angina and nearly one-third of the patients had received primary PTCA. Type B and C lesions were present in 36.9% of patients according to the ACC/AHA classification. The mean reference lumen diameter was 2.74±0.42 mm and 62% of the lesions were under 3 mm in diameter. In 7 cases in 172 patients the stent could not be deployed. The device success rate was 96%. The mean pressure used for stent deployment was 11.4±2.6 atm. The acute gain was 1.43±0.48 mm. Direct stenting was feasible in 52 patients with type A lesions and predilatation of lesions was performed in the majority of patients using undersized balloons with average pressures for 60 seconds. Events such as stent lost, stent dislocation or balloon burst before optimal deployment did not occur. No acute or subacute stent thrombosis occurred. Platelet glycoprotein IIb/IIIa receptor blockers were used in 35 (20%) patients (all tirofiban) in whom PTCA was performed in the acute phase of MI. In none of the elective procedures was the use of these agents necessary.

Early clinical outcomes of the patients are shown in Table 5. In-hospital and procedural total mortality was 1.1% (2 patients). Both patients had acute MI complicated with cardiogenic shock on admission. One died during PCI from refractory ventricular fibrillation and the other died during hospital follow-up due to advanced low cardiac output upon intraaortic balloon pumping. Three patients had been sent for urgent cardiac surgery because of cardiogenic shock untreatable by PCI alone. One had acute mitral regurgitation; the second had ventricular septal rupture and the third had acute papillary muscle rupture associated with acute MI.

Discussion

Although the number of invasive procedures performed in Turkey in patients with ischemic heart disease constantly increases, it is still lower than the expected number because of limited access to catheterization laboratories. A possible solution to this problem-use of mobile angiographs in hospitals without on-site cardiac surgery-has some drawbacks. ACC/AHA guidelines do not recommend elective PCI and primary PCI without on-site cardiac surgery except when there is a proven plan for rapid access to a cardiac surgery room within 1 hour. However, the guidelines stress that that

complication rates will be subject to future revision as newer data emerge.[7]

The rationale behind PCI without on-site surgery is the decrease in need for emergency coronary artery bypass, which ranges between 0.4% and 2%,[8] with the advent of intracoronary stenting. Not surprisingly, emergency coronary artery bypass for a patient with an occluded or dissected coronary artery is associated with a higher mortality than elective surgery.[9] Emergency procedures are also associated with high rates of per operative infarction and less frequent use of arterial conduits. Complex CAD intervention, hemodynamic instability, and prolonged time to reperfusion are contributing factors to the increased risk of emergency bypass surgery. These data encouraged the authors to perform PCI in hospitals without on-site surgery. Many studies report successful angioplasty series without on-site surgical backup and with little need for off-site surgery in failed angioplasty. Nevertheless, the appropriateness of elective angioplasty in centers without on-site surgical coverage is a concern.[10] PCI were performed in AMI patients by Wharton et al. and in refractory unstable angina by Michalis et al., in hospitals without on-site surgery with excellent results.[11,12] Hayat et al. performed PCI in 117 consecutive patients without applying any exclusion criteria. Patients had stable angina, unstable angina and silent ischemia. Angiographic success was 91% with major complications in only four patients (1 death, 2 AMI and 1 tamponade) with no need for emergency surgery.[13] The ACC/AHA guidelines recommend timely management of ischemic complications, adequate specialized post-interventional care, logistics for managing cardiac surgical or vascular complications and operator/laboratory volumes.[7] Interventional cardiology procedures are associated with complications that in general are inversely related to operator and institutional volume.[14]

All of the procedures in our study were performed with a mobile angiograph. While the usefulness of this type of angiograph for coronary angiography has been well documented, the safety and efficacy of PTCA performed with the use of mobile angiograph has been a matter of debate in the interventional cardiologist community, mainly because of certain drawbacks with this type of equipment. The main disadvantages include a less effective cooling system, which leads to the x-ray tube overheating during the longer duration of fluoroscopy, particularly during projections with the voltage close to the maximal values. There is also an increased risk of an automatic temporary switch-off due to overheating with the machine turning back on after as long as several minutes, and the inferior quality of the images in some projections and in obese patients. The advantages include low cost, feasibility of installation, ease of use, a modern digital recording system on CD ROM in the DICOM system and the mobility of the apparatus.

In recent years, portable fluoroscopic imaging systems have been developed to reduce costs and bring coronary angiography services closer to patients. Vergara demonstrated the reliability of the new generation mobile systems with respect to the quality of coronary angiograms and the routine use in a multipurpose cardiac catheterization laboratory.[15] Carosio et al compared a portable system with a stationary system, and found complete concordance between the systems for lesion location, stenosis quantification, morphologic characterization, TIMI flow and collateral demonstration, concluding that a portable imaging system can produce high-quality images.[16] Aliabadi et al. found similar results.[17] Reczuch et al. reported a mortality rate of 0.4% and a major adverse cardiac event rate of 0.9% in 687 PCI patients, including AMI patients. There was no need for urgent cardiac surgery.

The major cardiac event rate in our study was 4.5% and the in-hospital mortality rate was 1.2% after PCI. Urgent cardiac surgery was need in 1.7% of patients.[18] These data are compatible with a recent study published by Anderson et al. which was based on PCI data collected and analyzed by the American College of Cardiology-National Cardiovascular Data Registry from January 1, 1998, through September 30, 2000 from 100 292 PCI procedures. Anderson et al reported 77% stent utility and an overall mortality rate of 1.4%.[19]

We think that because of achievements in stent technology and newly available drugs, diagnostic coronary angiography can be safely performed with mobile angiographs in all patients and electively to selected patients without the need for surgical standby. However, large, prospective, randomized trials are needed to increase the evidence level for this approach.

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