

Cerrahi Destek Olmayan Bir Merkezin Primer Anjiyoplasti Sonuçları

PRIMARY ANGIOPLASTY IN A CENTER WITHOUT ON SITE SURGICAL BACK-UP

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Özet

Amaç: Bu çalışmanın amacı cerrahi destek olmayan bir merkezde yapılan primer anjiyoplasti işleminin güvenilirlik ve etkinliğini araştırmak ve sonuçları literatürle kıyaslamaktır.

Materyal ve Metod: Merkezimizde Ocak 2001 Şubat 2003 arası yapılan 78 primer anjiyoplasti vakasının demografik, klinik verileri ile erken ve geç sonuçları retrospektif olarak değerlendirildi. Anjiyoplasti güvenilirliğini değerlendirmek için hastane-İçi olaylar (ölüm, akut miyokard infarktüsü, inme) dikkate alındı. Rezidüel stenoz %50'nin altında ise ve TIMI III akım sağlanmış ise anjiyoplasti sonuçları başarılı kabul edildi.

Bulgular: Alet başarısı %92.3, anjiyografik başarı oranı %88.8, hastane İçi ölüm oranı %4.1 idi. Ölen üç hastanın hepsi kardiyojenik şok tablosunda hastaneye kabul edilmişti. Bu hastaların biri işlem sırasında, ikisi hastane yatışı sırasında kaybedildi. Altı aylık takip boyunca bir hastada ani ölüm, diğer bir hastada akut miyokard infarktüsü gözlemlendi. İnme geçiren veya cerrahiye gönderilen hasta olmadı. Takip sonunda dört hastaya tekrar anjiyoplasti uygulandı.

Sonuç: Merkezimizin sonuçları literatürde rapor edilen cerrahi desteğe sahip merkezlerin sonuçlarından farklı değildi. Cerrahi destek olmayan merkezlerde primer anjiyoplasti güvenle ve başarılı bir şekilde uygulanabilir.

Anahtar kelimeler: Anjiyografi, cerrahi destek, anjiyoplasti, koroner arter hastalığı

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Summary

Backgrounds: The aim of the present study is to assess the safety and efficacy of performing primary angioplasty in a center without on-site surgical back-up, and compare the data with the literature.

Methods: Seventyeight primary angioplasty procedures; performed in our center from January 2001 till February 2003 were analyzed retrospectively. Clinical and demographic characteristics of the patients, procedural success, early and late outcomes of the patients were taken into account. The safety of angioplasty was assessed by the analysis of in-hospital complications (death, urgent need for repeated revascularization, AMI with or without ST elevation and stroke). The angioplasty procedures were considered effective when the post-procedural residual stenosis did not exceed 50% with the distal Thrombolysis in Myocardial Infarction (TIMI) grade III flow.

Results: Device success rate was 92.3%. Angiographic success rate was 88.8%. In hospital mortality rate was 4.1%. These patients were admitted with cardiogenic shock, one of them was lost during the procedure and the other two died during hospital follow-up. One patient died suddenly and another developed acute MI during the 6-month follow-up period. No patients developed stroke or referred for urgent surgery. 4 patients (5.5%) underwent repeated angioplasty during follow-up.

Conclusions: Primary angioplasty can be safely performed in centers without on-site surgery. The efficacy and safety requirements of angioplasty, performed in a center without on-site surgical back-up facility using a mobile angiograph were similar with the data obtained from the literature.

Keywords: Angiography, on-site surgery, angioplasty, coronary artery disease

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Introduction

Multi-center randomized trials indicate that primary

angioplasty in acute myocardial infarction (AMI) lowers the rates of death, stroke, recurrent ischemia and re-infarction compared with fibrinolytic therapy [1]. For low risk patients

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with AMI, the mortality of primary angioplasty could be very low (< 0.5%), and hospital costs can be decreased [2]. Furthermore, most AMI patients are not candidates for fibrinolytic therapy, either because they have bleeding risks or shock, or do not have diagnostic electrocardiograms [3]. 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. The topic of debate is the safety issue on angioplasty performed in centers without surgical back-up. Although angioplasty is recommended for the management of AMI and refractory unstable angina, less than 10% of European hospitals are equipped with percutaneous coronary intervention (PCI) facilities, some of them equipped with mobile fluoroscopy machines and even less have on-site cardiac surgery back-up [4-5]. It becomes increasingly important for both clinical and economic reasons to address the question of whether interventional approaches to the treatment of AMI could be extended safely and effectively to a larger number of hospitals including the ones without on-site surgical back-up. This is especially important for underdeveloped countries, where cardiac surgery centers are rare and founded only in heavily populated cities therefore difficult to reach for patients living in remote areas. The present study analyses the safety and efficacy of therapeutic interventions performed in a center without surgical back-up.

Material and Methods

Laboratory and operators: The fluoroscopy machine is Siemens C-800 Powermobil (Erlangen, Germany) with an X-ray generator of maximum 20 kW output. An ambulance was maintained for urgent transport reasons. A tertiary center (Kosuyolu Heart center, approximately 200 kilometers-160 miles away) with facilities for cardiovascular surgery for 24 hours a day was informed for any urgent cases. The catheterization laboratory is well equipped with resuscitative equipment and well stocked with a broad array of interventional equipment.

Primary angioplasty procedures were performed by two experienced operators. The nursing and technical catheterization laboratory staff is experienced in handling acutely ill patients and comfortable with interventional equipment. They have participated PCI procedures in a 24-h 365-day call schedule. The cardiac care unit nurses were trained for hemodynamic monitoring.

Patients: Between January 2001 and February 2003, 78 primary angioplasty procedures were performed in our center. A written consent informing the patient about the status of the laboratory and possible complications was signed by every patient.

Primary angioplasty procedure: The study population with AMI had been underwent primary angioplasty if ischemic pain taken under control in 30 minutes 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 cut-off 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 h after onset of pain if they were symptom-free on emergency department arrival were considered not suitable for PCI.

Three hundred mg clopidogrel was administered orally before the interventions. Procedures were performed using standard angioplasty technique with a 8 French (Fr) guiding catheter via the femoral artery approach. 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 in 41 (57%) patients. Intracoronary stenting was carried out for a sub-optimal result following conventional balloon angioplasty. The Ephesos stents (Nemed Corporation, Turkey) were used for stenting in majority of cases. Ephesos is a stainless-steel, laser-cut, tubular, slotted-tube multicellular device mounted on a customized, non-compliant, polyethylene terephthalate, non-tapered balloon with a short balloon overhang (0.5mm). In the unexpanded state, the crossing profile is 0.048". The stent size 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 (atm.) and high-pressure balloon inflation (to 14 atm.) 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, following which a pressure bandage was applied for 6 h. Ambulation was allowed 6 h after the sheath was removed. Clopidogrel 75 mg once daily were 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 creatine kinase-myocardial band (CK-MB) level was measured and additional ECG was recorded. The majority of patients were discharged 2 days after the procedure. Follow-up coronary angiography was performed at 6 months in selected patients, or earlier if clinically indicated.

Definitions and Angiographic analysis: Quantitative coronary angiographic analysis was performed using the quantitative coronary analysis system (AET-med 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 average of 2 orthogonal views. The index reference diameter was the average of proximal and distal reference vessel diameters. Lesion length was measured on the baseline angiography using the "shoulder-to-shoulder" definition. 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 target lesion > 50%. Q-wave myocardial infarction was defined as the development of new abnormal Q-waves not present at the 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.

Device success rate was defined as advancing the guide-wire through the culprit lesion and dilating the lesion by balloon or stent. Angiographic success was defined as $\geq 50\%$ reduction in the diameter of the stenosis with distal TIMI III flow. 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: Major ischemic complications were defined as the occurrence of myocardial infarction, death or the need for emergency coronary artery bypass grafting. The patients were screened for major ischemic complications and stroke during follow-up.

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 (Statistical Package for Social Sciences). Continuous variables are expressed as mean \pm SD.

Results

Baseline clinical and angiographic data of the patients who were performed primary angioplasty are summarized in Table 1. There were a high proportion of patients with hypertension

(21%) and diabetes mellitus (33%). In six out of 78 patients the guide-wire could not be passed distal to the lesion; therefore device success rate was 92, 3%. In 31 out of 72 patients direct stenting was feasible (43%). The mean pressure used for stent deployment was 11.4 ± 2.6 atm. No events such as stent lost, stent dislocation, balloon burst before optimal deployment, acute or sub acute stent thrombosis occurred. Platelet glycoprotein IIb/IIIa receptor blockers were used in 35 patients (all tirofiban).

Clinical and angiographic follow-up is still going-on as a part of another study. Control angiography at the six-month was performed in 30 patients (at an average of 180 ± 23 days). The binary restenosis rate (50% stenosis at six months follow-up) was 13.3 %. Data demonstrated a 1.84 ± 0.46 mm maximum lumen diameter at the end of the study.

The acute gain was 1.43 ± 0.48 mm. Mean reference lumen diameter was 2.74 ± 0.42 mm and overall 62% of the lesions were under 3 mm in diameter (Table 2).

Early and late outcome of all PCI procedures were summarized in Table 3. Angiographic and procedural success rate was 88.8%. In hospital mortality rate was 4.1%. These patients were admitted with cardiogenic shock, one of them was died during the procedure and the other two died in the second day of admission during hospital follow-up.

One patient died suddenly and another developed acute MI during the 6-month follow-up period. No patients developed stroke or referred for urgent surgery. Four patients (5.5%) underwent repeated angioplasty during follow-up. All other patients were major cardiac event-free during the overall follow-up time

Table 1. Clinical angiographic characteristics and overall procedural data of patients.

	Number of patients (n)	%
Age (years: mean \pm SD)	58.1 \pm 11	
Sex: Male/Female	56/16	77.9/22.09
Hypertension	15	20.8
Diabetes Mellitus	24	33.3
Hyperlipidemia	18	25
Cardiogenic shock	5	7
PTCA alone/Stent Implanted	7/65	9.6/90.3
IIb/IIIa receptor blockers usage	35	48.6

Table 2. Peri-procedural and 6-month angiographic characteristics.

Characteristics	Pre-procedure (n = 72)	Post-procedure (n = 72)	6-month (n = 30)
Reference lumen diameter (mm)	2.74 \pm 0.42	2.85 \pm 0.28	2.70 \pm 0.34
Minimum lumen diameter (mm)	1.02 \pm 0.46	2.42 \pm 0.33	1.84 \pm 0.46
Percent diameter stenosis (%)	82 \pm 16	16 \pm 4	34 \pm 14
Lesion length (mm)	12.7 \pm 4.7	-	-
Binary restenosis (> 50%)	-	-	4(%13.3)
Acute gain (mm)	-	1.43 \pm 0.48	-
Late loss (mm)	-	-	0.72 \pm 0.44
Loss index	-	-	0.46 \pm 0.34

Table 3. Early and late outcome of all PCI procedures.

	In-hospital outcome		6-months follow up		Total	
	(n:72)	(%)	(n:72)	(%)	(N:72)	(%)
Total Mortality	3	(4.1)	1	(1.1)	4	(5.5)
Death During PCI	1	(1.1)	-	-	-	-
Death During Hospital follow-up	2	(2.2)	-	-	-	-
Acute MI with ST elevation	0	(0)	1	(1.1)	1	(1.1)
Acute MI without ST elevation	0	(0)	0	(0)	0	(0)
Need for repeat PCI	0	(0)	4	(5.5)	4	(5.5)
Need for urgent surgery	0	(0)	0	(0)	0	(0)
Stroke	0	(0)	0	(0)	0	(0)

Discussion

The rationale behind PCI without on-site surgery is the decrease in the need for emergency coronary artery bypass with the advent of intracoronary stenting, ranging between 0.4 and 2% [6]. 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 [7]. Emergency procedures are also associated with high rates of per operative infarction and less frequent use of arterial conduits. Complex intervention, hemodynamic instability, and prolonged time to reperfusion are contributing factors to the increased risk of emergency bypass surgery. This data encourage the authors to perform PCI in hospitals without on-site surgery and many studies reported successful angioplasty series without on-site surgical backup and a very low percentage need for off-site surgery in failed angioplasty. Even; the appropriateness of elective angioplasty in centers without on-site surgical coverage was concerned [8]. 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 and found excellent results [9-10]. Hayat et al. performed PCI in 117 consecutive patients without any exclusion criteria. Patients were having 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 [11]. Smit et al. recommend timely management of ischemic complications, adequately of specialized post-interventional care, logistics for managing cardiac surgical or vascular complications and operator/laboratory volumes, and accreditation in spite of an unrestricted policy [12]. Interventional cardiology procedures are associated with complications that in general are inversely related to operator and institutional volume [13].

Another issue that should be discussed in our study is that all of the procedures 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 have been a matter of debate in the interventional cardiologists' community, mainly because of some drawbacks of this type of equipment. The main disadvantages include a less effective cooling system which leads to the x-ray tube overheating during longer duration of fluoroscopy, particularly during

projections with the voltage close to the maximal values, an increased risk of temporary switch-off by the machine due to overheating with a subsequent turning on after as long as several minutes, inferior quality of the images in some projections and in obese patients. The advantages include low cost, feasibility of installation, easiness of use, a modern digital recording system on CD ROM in the DICOM system and the mobility of the apparatus.

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 [14]. The urgent cardiac surgery need was 0%.

The major cardiac event rate in the present study is 4.1% and in-hospital mortality rate is the same. These data are compatible with a recent study published by Anderson et al. which is 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; reporting 77% stent utility and an overall mortality rate of 1.4% [15]. The authors of the present study suggest that regarding the achievements of the stent technology and new drugs in use; coronary angioplasty can be safely performed primarily in all patients with MI.

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