Balloon Angioplasty versus Bypass Grafting in the Era of Coronary Stenting

Sivan Ekstein MD[1], Amir Elami MD[2], Gideon Merin MD[2], Mervyn S. Gotsman MD FACC[1] and Chaim Lotan MD FACC[1]

Departments of [1]Cardiology and [2]Cardiothoracic Surgery, Hadassah University Hospital, Jerusalem, Israel
Affiliated to Hebrew University Medical School, Jerusalem, Israel

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Abstract

Background: Patients with multivessel coronary artery disease are candidates for either angioplasty and stenting or coronary artery bypass grafting. A prospective randomized study designed to compare the both methods included only a minority of the eligible patients.

Objective: To compare coronary artery bypass grafting to angioplasty plus stenting in patients with multivessel disease who declined randomization to a multicenter study (the ARTS).

Methods: During 1997–98 we prospectively followed 96 consecutive patients who were eligible according to the ARTS criteria but refused randomization. Of these patients, 50 underwent angioplasty + stenting and 46 underwent coronary bypass surgery. We compared the incidence of major adverse cardiac and cerebral events, chest pain recurrence, quality of life and procedural cost during the first 6 months.

Results: All procedures were completed successfully without mortality or cerebral events. The rate of Q-wave myocardial infarction was 2% in the AS group vs. 0% in the CABG group (not significant). Minor complications occurred in 7 patients (14%) in the AS group and in 21 patients (45%) in the CABG group ($P < 0.01$). At 6 months follow-up the incidence of major cardiac and cerebral events was similar in both groups (11% and 4% in the AS and CABG groups respectively, P=NS). Seventeen patients (36%) in the AS group required repeat revascularization compared to only 3 (7%) in the CABG group (P=0.002). Nevertheless, quality of life was better, hospitalization was shorter and the cost was lower during the first 6 months after angioplasty.

Conclusion: Angioplasty with stenting compared to coronary bypass surgery in patients with multivessel disease resulted in similar short-term major complications. However, 36% of patients undergoing angioplasty may need further revascularization procedures during the first 6 months.

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Patients with multivessel coronary artery disease have traditionally been managed by coronary artery bypass grafting. During the last decade, a few randomized studies – EAST, ERACI and CABRI – compared balloon angioplasty with bypass grafting for such patients [1–5]. There were no differences in rate of death, myocardial infarction or cerebral vascular events between the groups, but repeat revascularization was more common after angioplasty during the 5 year follow-up.

Coronary stenting, which has significantly reduced the acute complications and improved the long-term restenosis rate [6,7], raised hope of a significantly better outcome in patients with multivessel coronary artery disease undergoing angioplasty. In view of these achievements, it became necessary to again compare coronary angioplasty with bypass grafting. Designed to answer this question, the multicenter randomized ARTS (Arterial Revascularization Therapy Study) was conducted in which 1,205 patients with multivessel disease were randomized to percutaneous transluminal coronary angioplasty plus stenting or to CABG [8]. However, a substantial portion of eligible patients in our hospital refused randomization, raising questions of selection bias and validity as well as generalization of the ARTS findings to the entire population. The purpose of this study was to assess the clinical outcome of ARTS-eligible patients who declined randomization and chose the method of revascularization. We compared the incidence of major adverse cardiac and cerebral events including death, MI and cerebrovascular accident. We also assessed chest pain recurrence, quality of life and financial costs during the first 6 months after angioplasty plus stenting, or bypass grafting.

Patients and Methods

Patients

During 1997–98 we prospectively followed a consecutive series of patients with multivessel disease referred to the Hadassah University Hospital for revascularization. All patients had angina pectoris or documented ischemia and were found suitable for either coronary angioplasty or bypass grafting. All patients were ARTS-eligible but refused randomization for a variety of reasons (personal or familial considerations, referring physician's opinion)

Inclusion criteria

General inclusion criteria:

- Patients with multivessel disease and stable (Canadian Cardio-

AS = angioplasty + stenting
CABG = coronary artery bypass graft

MI = myocardial infarction

vascular Society 1–4) or unstable angina pectoris (considered as having class IV angina), or silent ischemia
- Patients eligible for coronary revascularization (percutaneous transluminal coronary angioplasty or CABG) according to a surgical and cardiologic opinion
- At least two lesions (in different vessels and different territories) potentially suitable for stent implantation
- *De novo* lesions.

Angiographic inclusion criteria
- Multivessel disease with one or more significant stenoses in at least two major epicardial coronary arteries
- One totally occluded major epicardial vessel or side branch, provided that another major vessel had a significant stenosis amenable to angioplasty and that the age of occlusion was less than 1 month
- Significant stenosis, defined as a reduction of at least 50% of luminal diameter (in at least one view on visual interpretation or quantitative coronary angiography)
- Minimal luminal diameter adjacent to the lesion amenable to stenting of at least 2.75 mm
- Conventional balloon angioplasty without stent implantation as a complementary treatment of vessels smaller than 2.75 mm, provided that at least two of the other targeted lesions were amenable to stenting
- The indication for stenting in lesions with bifurcation, fresh thrombus, calcification, very long obstruction (> 20 mm), complex anatomy or stenting of side branches was left to the operator's discretion
- The number of stents to be implanted per patient was not restricted
- Left ventricular ejection fraction of at least 30%.

Exclusion criteria

General exclusion criteria:
- CABG or PTCA in past history
- Concomitant non-cardiac disease likely to limit long-term prognosis (e.g., cancer)
- Overt congestive heart failure
- Need for concomitant major surgery (e.g., valve surgery or resection of aortic or left ventricular aneurysm, carotid endarterectomy, abdominal aortic aneurysm surgery, etc.)
- Congenital heart disease
- Transmural MI within the past week
- Acute or chronic renal failure (serum creatinine > 150 mol/L or creatinine clearance < 50 ml/min).
- History of stroke.

Angiographic exclusion criteria:
- Left main stenosis > 50%
- Intention to treat more than one totally occluded major epicardial vessel.

PTCA = percutaneous transluminal coronary angioplasty

Catheterization

Diagnostic catheterization was performed in either a referring hospital or in our institution. After catheterization, an experienced interventional cardiologist and a surgeon considered the patient's suitability for either multivessel PTCA or CABG. The patient was presented with the two options, information was given on the different procedures and risks, and the patient was asked to participate in the ARTS trial. Patients included in our study were those who refused consent for the ARTS trial. Two experienced interventional cardiologists reviewed the cine-angiography in the PTCA group to assess angiographic findings and PTCA results.

Revascularization techniques

Coronary angioplasty was performed using standard techniques. There was no restriction on the number or kind of stents used in the procedures. Successful angioplasty was defined as reducing arterial stenosis by > 50% and achieving good distal coronary flow (TIMI III). Successful stenting was defined as a final residual stenosis < 20% and good distal flow. CABG was performed with standard surgical techniques, using internal mammary and radial arteries and saphenous veins as conduits.

Follow-up

Follow-up at 1 month and 6 months was conducted by phone calls and questionnaires. Medical information was summarized from hospital and clinic records. In cases where patients were lost to follow-up we addressed the Ministry of the Interior to determine mortality.

The combined endpoint of major adverse cardiac and cerebral events included death, MI and stroke. Definition of Q-wave MI was based on the appearance of new Q-waves on electrocardiogram and peak creatine kinase-myocardial band >10% of peak total CK or plasma level of CK-MB 5 times or more than the upper limit for normal.

Quality of life assessment

To measure changes in quality of life, we employed a similar questionnaire used in the ARTS study [8], which consisted of two parts. The first part included six questions on different aspects of the healing process: difficulty in walking, ability to independently perform basic tasks, return to usual daily activity, pain, discomfort, and anxiety. The patient was asked to choose an answer between 1 (the best) and 3 (the worst).

The second part of the questionnaire presented the patient with a "ruler" describing general health, with 0 signifying the worst option and 100 the best. The patient had to choose a number depicting his/her health condition at that time. Results are given as the average grades that patients assigned for their health condition.

Procedural costs

Calculation of expenses was based on diagnosis-related grouping according to the Ministry of Health publication for June 1999 as

CK = creatine kinase
MB = myocardial band

follows: diagnostic catheterization US$2,193, balloon angioplasty (with or without stenting) $5,397, and bypass grafting $11,339. In addition, the hospitalization duration for the primary revascularization procedure was recorded for each patient.

Statistical analysis

All values of continuous variables are expressed as mean ± standard deviation. Differences in proportions were analyzed by the Fisher's exact test. The Student *t*-test was used to detect significant differences ($P < 0.05$) between continuous variables.

Results

Of 96 consecutive patients with multivessel disease who refused randomization to the ARTS trial at the Hadassah University Hospital, 50 elected to have angioplasty plus stenting (AS group) and 46 preferred to have a bypass operation (CABG group). During that period, 10 other patients agreed to randomization and 315 patients were unsuitable for randomization according to the ARTS criteria. The demographic characteristics and risk factors for coronary artery disease of the study patients are summarized in Table 1. Both groups were similar with regard to age, gender, and risk factors for heart disease. It should be noted that close to 50% of the patients in each group had diabetes mellitus.

The choice of revascularization procedure was based on the patient's own preference or after consulting the referring physician.

Functional capacity

According to the Canadian Cardiovascular Society criteria, 21 patients (42%) in the AS group and 25 (54%) in the CABG group were assessed as functional capacity class IV (*P*=NS). Class III included 18 patients (36%) in the AS group and 9 (20%) in the CABG group ($P = 0.018$). Thus, the majority of patients in both groups reported poor functional capacity at the time of hospitalization .

Medications

At the time of hospitalization the average number of cardiac medications per patient was 3.2 ± 1.3 in the AS group and 2.8 ± 1.1 in the CABG group (*P*=NS).

Table 1. Baseline characteristics and reasons for non-randomization

	PTCA + stenting (n=50)	CABG (n=46)	*P*
Male	40 (80%)	37 (80.4%)	NS
Female	10 (20%)	9 (19.6%)	NS
Age (yr)	61.54±8.6	61.6±8.7	NS
Previous MI	18 (36%)	13 (28%)	NS
Hypertension	26 (52%)	26 (57%)	NS
Diabetes mellitus	24 (48%)	22 (48%)	NS
Smoking	28 (56%)	22 (48%)	NS
Hyperlipidemia	29 (58%)	31 (67%)	NS
Family history	24 (48%)	13 (28%)	NS
Body mass index ⩾ 27	6 (12%)	11 (24%)	NS
Patient/family preference	12 (24%)	2 (4%)	<0.0001
Referring physician preference	38 (76%)	44 (96%)	0.0015

Angiography

Triple vessel disease was more common in both groups (56% in the AS group vs. 63% in the CABG group, *P*=NS) than double vessel disease (44% vs. 37% respectively, *P*=NS). The average number of lesions per patient was 7.3 ± 1.1 and 7.6 ± 0.8 respectively (*P*=NS).

Revascularization

The average number of lesions dilated by balloon angioplasty was 5.7 ± 0.8 per patient, and the average number of stents was 1.3 ± 0.5. Of these patients nine (18%) received IIb/IIIa inhibitors following the procedure. The average number of grafts performed during bypass surgery was 3.15 ± 0.7 per patient (arterial grafts 2.0 ± 0.8, vein grafts 1.15 ± 0.9). Each patient received at least one arterial graft. Complete revascularization was accomplished in 45 (90%) of the angioplasty procedures and in 44 (96%) of CABG patients.

Complications during hospitalization

Major and minor complications during hospitalization are listed in Table 2. All revascularization procedures were considered successful with no incidents of death or stroke. The rate of periprocedural myocardial infarction was 14% in the AS group (Q-wave MI 2%) vs. 11% in the CABG group (no Q-wave MI), *P*=NS. The incidence of minor complications was higher among patients after bypass grafting (14% in the AS group compared to 46% in the CABG group, $P < 0.01$). This difference was attributed to the higher rate of pericarditis and pulmonary complications after surgery.

Major adverse cardiac and cerebral events at 6 months

Survival follow-up at 6 months was completed. During this period one death occurred in the CABG group: a 78 year old woman died from a hemorrhagic stroke 6 months after surgery. Detailed follow-

Table 2. Complications during hospitalization

Complication	PTCA + stenting (n=50)	CABG (n=46)	*P*
Death	0	0	NS
MI	7 (14%)	5 (11%)	NS
Q-wave	1 (2%)	0	NS
Non Q-wave	6 (12%)	5 (11%)	NS
Stroke	0	0	NS
Acute renal failure	3 (6%)	2 (4.3%)	NS
Infection	1 (2%)	3 (6.5%)	NS
Pericarditis	0	5 (11%)	0.053
Arrhythmia	1 (2%)	10 (21%)	0.007
Atrial fibrillation	0	8 (17.4%)	0.007
Other	1 (2%)	2 (4.3%)	NS
Pulmonary	0	7 (15.2%)	0.013
Pneumothorax	0	1 (2.2%)	NS
Pleural effusion	0	6 (13%)	0.027
Psychoneurologic	0	2 (4.3%)	NS
Delirium	0	1 (2.2%)	NS
Vocal cord paralysis	0	1 (2.2%)	NS
Intra-aortic balloon counterpulsation	2 (4%)	0	NS

Table 3. Major and minor events during first 6 months

Complication	1 month			6 months*		
	PTCA + stent (n=47)	CABG (n=44)	*P*	PTCA + stent (n=47)	CABG (n=44)	*P*
Death	0	0	NS	0	1(2%)	NS
MI	1 (2%)	0	NS	5 (11%)	0	NS
Q-wave	0			1 (2%)	0	NS
Non Q-wave	1 (2%)			4 (9%)	0	NS
Stroke	0	0	NS	0	1 (2%)	NS
Chest pain	4 (9%)	4 (9%)	NS	17 (36%)	9 (21%)	NS
Congestive heart failure	1 (2%)	0	NS	7 (15%)	1 (2%)	NS
Infection	0	4 (9%)	NS	1 (2%)	5 (11%)	NS
Pleural effusion	0	1 (2%)	NS	0	2 (5%)	NS
Pericarditis	0	1 (2%)	NS	0	0	NS
Arrhythmia	0	5 (11%)	0.06	0	0	NS
Rehospitalization	7 (15%)	10 (23%)	NS	21 (45%)	20 (46%)	NS
Recatheterization	3 (7%)	1 (2%)	NS	19 (40%)	4 (9%)	0.001
Revascularization	2 (4%)	1 (2%)	NS	17 (36%)	3 (7%)	0.002
(re)PTCA	2 (4%)	1 (2%)		11 (23%)	3 (7%)	0.057
(re)CABG	0	0		6 (13%)	0	<0.0001

* 1 month included

up was obtained for 94% and 96% of patients from the AS and CABG groups, respectively [Table 3]. Five patients (11%) from the AS group suffered myocardial infarction compared to none in the CABG group (*P*=NS): one patient (2%) had Q-wave MI and four patients (9%) had non-Q-wave MI. The rate of rehospitalization was similar in both groups (45% in the AS vs 46% in the CABG group, *P*=NS). Nineteen patients (40%) in the AS group and 4 (9%) in the CABG group required recatheterization ($P = 0.001$). Seventeen patients (36%) in the AS group and 3 (7%) in the CABG group underwent repeat revascularization ($P = 0.002$). In the AS group 11 patients (23%) had rePTCA and 6 (13%) had CABG. In the CABG group three patients had PTCA. Restenosis of previously treated lesions occurred in 11 of the 17 patients (23%) undergoing re-intervention in the AS group. The other six patients (13%) had balloon angioplasty for new lesions. Graft stenosis or occlusion was found in two of the three patients (5%) undergoing repeat revascularization in the CABG group. In the third patient a new lesion was found in an untreated vessel.

Minor complications

During the first month 11 patients in the CABG group (25%) reported minor complications compared to only 1 in the AS group (2%) ($P < 0.05$). These included infections, pericarditis, arrhythmia and pulmonary complications [Table 3]. During the 6 month follow-up, eight patients in each group (17% AS and 18% CABG) reported minor events (*P*=NS).

Functional capacity

After 1 month the average functional capacity was 1.7 ± 0.8 in the AS group compared to 1.9 ± 0.9 in the CABG group (*P*=NS). At 6 months the score was 1.7 ± 0.9 compared to 1.6 ± 0.7 respectively (*P*=NS). The majority of patients in both groups were in functional capacity I or II – 37 AS patients (86%), 37 CABG patients (86%), *P*=NS.

Chest pain and medications

Four patients in the AS group (9%) and four in the CABG group (9%) reported chest pain during the first month (*P*=NS). During the 6 month follow-up, 17 patients in the AS group (36%) had chest pain compared to 9 in the CABG group (21%) (*P*=NS). After 1 month, the average number of medications per patient was 3.7 ± 1 compared to 2.8 ± 0.7 respectively ($P < 0.05$), and after 6 months the number was 3.5 ± 0.9 compared to 2.8 ± 0.8 ($P < 0.05$).

Diabetic patients

Of the 96 patients 46 were diabetic (48%). Twenty-four patients (52%) chose angioplasty and 22 (48%) CABG. At angiography, the number of involved segments per patient was higher in the diabetic (7.4 ± 1.3) than in the non-diabetic (6.8 ± 0.9) patients ($P < 0.05$). During hospitalization, the incidence of total major adverse cardiac and cerebral events among patients after angioplasty was 4% in diabetic compared to 0% in non-diabetic patients, and the rate of secondary complications was 16% in the diabetic compared to 4% in the non-diabetic (*P*=NS). The incidence of total major adverse cardiac and cerebral events after CABG was 0% in diabetic and non-diabetic patients, and the rate of minor complications was 38% in diabetic compared to 50% in non-diabetic patients (*P*=NS). During the 6 month follow-up, the incidence of major adverse cardiac and cerebral events after angioplasty was 5% in the diabetic compared to none in the non-diabetic (*P*=NS), and the incidence of repeat revascularization was also higher, although not significantly, in diabetic (46%) compared with non-diabetic patients (32%, *P*=NS). In patients after CABG, the incidence of major adverse cardiac and cerebral events was 10% in diabetic compared to 0% in non-diabetic patients (*P*=NS) and the rate of repeat revascularization was 5% in diabetic and 9% in non-diabetic patients (*P*=NS).

Quality of life

One month after revascularization, the patients in the AS group reported less pain and discomfort, returned earlier to their usual activity, and felt that their general health was better compared to patients in the CABG group [Table 4]. At 6 months these differences persisted but did not reach statistical significance. Using the quality of life ruler, on which patients marked their heath status between 0 and 100, patients in the AS group considered their health better than did patients in the CABG group. These differences became statistically significant after 6 months.

Financial costs and hospitalization time

The average cost per patient was calculated according to DRG. During the first 6 months the average cost was $8,390 for a patient

DRG = diagnosis-related grouping

Table 4. Quality of life assessment at 1 month and at 6 months*

	1 month			6 months		
	PTCA + stenting (n=47)	CABG (n=44)	*P*	PTCA + stenting (n=47)	CABG (n=44)	*P*
Mobility	1.6 ±0.7	1.5 ±0.7	NS	1.5 ±0.6	1.5 ±0.7	NS
Self-care	1.6 ±0.3	1.3 ±0.42	<0.001	1.1 ±0.2	1.1 ±0.2	NS
Usual activity	1.6 ±0.7	2.1 ±0.7	0.001	1.4 ±0.6	1.5 ±0.6	NS
Pain/discomfort	1.6 ±0.6	1.9 ±0.6	0.04	1.4 ±0.6	1.5 ±0.6	NS
Anxiety/depression	1.8 ±0.6	2.0 ±0.6	NS	1.5 ±0.7	1.8 ±0.7	NS
General health	1.2 ±0.4	1.6 ±0.7	<0.001	1.3 ±0.45	1.5 ±0.6	NS
Ruler	72 ±17	67 ±17	NS	80 ±14	71 ±18	0.008

* See text for grading definitions.

in the AS group and $14,242 for a patient in the CABG group. Average hospitalization time for a patient in the AS group was 5.9 ± 2.1 days and 8.6 ± 1.2 days for a patient in the CABG group ($P < 0.001$).

Discussion

New developments in interventional cardiology have widened the revascularization options for patients with multivessel coronary artery disease. According to randomized trials such as the EAST [1,2], ERACI [3,4], CABRI [5], RITA [9], BARI [10,11] and GABI [12,13], coronary angioplasty was found to be equal to bypass grafting in terms of major adverse events during 5 years of follow-up, although repeat revascularization procedures were much more common following angioplasty. However, these trials were conducted in the late 1980s and early 1990s and did not include coronary stenting. The effectiveness of coronary stenting was established later in the STRESS and BENESTENT trials [6,7], where restenosis rates were reduced by 10%, thus lowering the need for repeat revascularization. Hence, it has become necessary to again compare angioplasty versus CABG. Comparison of angioplasty plus stenting with bypass grafting was carried out in the ARTS trial where patients with multivessel disease were randomized to PTCA + stenting or to CABG. However, a substantial number of eligible patients in our institution refused randomization, making extrapolation of results questionable. The purpose of this study was to compare PTCA plus stenting with CABG for patients with multivessel disease who refused randomization.

Major adverse cardial and cerebral events and repeat revascularization

Six months after self-assignment, combined major adverse cardial and cerebral events (death, MI and stroke) was 5% in the AS group compared to 2% in the CABG group (*P*=NS). However, 36% of patients in the AS group needed repeat revascularization during the first 6 months, compared to only 7% in the CABG group ($P = 0.002$). These findings concur with the conclusions of the randomized trials – such as EAST, EARCI and CABRI – in which angioplasty (without stenting) was compared to CABG [1–5]. These studies showed no difference in rates of death, MI or stroke, but after 1 year follow-up the incidence of repeat revascularization following angioplasty was 32–44% compared to 3–15% after bypass grafting. Interestingly, the use of stenting in our study did not reduce the rate of repeat revascularization, as expected. This can be explained by the worse clinical and angiographic baseline characteristics in our population; namely, the prevalence of diabetes mellitus, a risk factor for restenosis, was significantly higher compared to the other studies (48% vs 11–25%), and triple vessel involvement was also much more common in our study (60% vs.12–45% in other studies). In addition, treatment of high risk lesions with a high tendency for restenosis, such as totally occluded vessels and calcified lesions which were included in our study, was not possible in other trials. Thus, the restenosis rate remained high despite stenting.

Minor complications

During hospitalization, the incidence of minor complications was much higher among patients after surgery (46% in CABG compared to 14% in AS patients, $P < 0.01$). During the first month after revascularization it was still higher among these patients (25% compared to 2% respectively, $P<0.05$). During the 6 month follow-up the incidence of minor events was similar for the two groups (17% in the AS group vs. 18% in the CABG group, *P*=NS). However, one should notice the increasing incidence of minor events among patients after angioplasty during that period.

Hospitalization time was shorter after angioplasty (5.9 ± 2.1 vs. 8.6 ± 1.2 days after surgery, $P < 0.001$) and the cost to the health system (based on DRG) was lower during the first 6 months after angioplasty ($8,390 for a patient in the AS group and $14,242 for a patient in the CABG group).

The ARTS trial

The results of the ARTS trial at 1 year were recently reported [14]. In this trial 1,205 patients with multivessel disease were randomized to angioplasty plus stenting (600 patients) versus bypass grafting (605 patients). After 1 year, there was no difference in the rates of death, MI or stroke between patients undergoing angioplasty or bypass grafting (combined major adverse cardial and cerebral events: 10.4% in the stenting group compared to 9.6% in the surgery group, *P*=NS), which was similar to the 6 month outcomes in our study. In the ARTS, repeat revascularization was more common after angioplasty plus stenting (21% in the stenting group compared with 3.8% in the surgery group, $P < 0.00001$). The rate of repeat revascularization after angioplasty was significantly higher in our study (36%) than in the ARTS, probably due to our higher proportion of diabetic patients (48% compared to only 16–19% in the ARTS) and the higher proportion of patients with unstable angina pectoris and triple vessel disease compared to the ARTS.

Diabetic patients

Angioplasty carries a higher incidence of complications, re-interventions and mortality in diabetic patients than in non-diabetic patients. A probable explanation for the inferior outcomes

in these patients is the higher rate of restenosis after angioplasty. The BARI study investigators [15] found that diabetic patients undergoing angioplasty had a higher rate of cardiac mortality than after CABG during 5 years follow-up (21% mortality after PTCA compared to 6% after surgery, $P = 0.0003$). Rozenman et al. [16] explained the BARI results by showing that the combination of diabetes mellitus and the performance of angioplasty had an additive risk for development of new narrowing. Weintraub et al. [17] followed 2,639 diabetic patients for 10 years after intervention and found that during hospitalization the mortality was significantly higher after surgery (5% after CABG compared to 0.36% after angioplasty, $P < 0.0001$). There was no difference in survival between the groups during 10 years follow-up (45% survival after angioplasty vs. 48% after surgery, *P*=NS), but repeat revascularizations were more common after angioplasty.

Regarding stenting in diabetics, Joseph and colleagues [18] followed 272 diabetic patients undergoing stenting and compared their results with those in non-diabetic patients. After 1 year, mortality was higher in diabetic patients (9.3%) than in non-diabetics (2.4%, $P < 0.05$), but the rate of repeat revascularization was similar between the groups (8.2% vs. 10.5% respectively, *P*=NS). Higher mortality among diabetics after stenting was also demonstrated by Elezi and associates [9]: 1 year after the procedure the mortality rate was 8.3% in diabetic vs. 3.8% in non-diabetics ($P < 0.001$). The use of IIb-IIIa inhibitors during PTCA might change these results: the diabetic sub-study of EPISTENT (Evaluation of Platelet IIb-IIIa Inhibitor for Stenting Trial) [20] showed that the combination of stenting and abciximab therapy in diabetics resulted in a significant reduction in 6 month rates of death, MI and target vessel revascularization compared with stent-placebo or balloon-abciximab.

In our study, diabetic patients had a higher incidence of major adverse cardiac and cerebral events and re-intervention and suffered more secondary complications (especially infections) than non-diabetic patients, but these differences did not reach statistical significance probably because of the relatively small sample size. However, based on the trend reflected by these differences, we can assume that the high rate of repeat revascularization in this study was due to the high prevalence of diabetes mellitus, a well-documented risk factor for restenosis. These patients may benefit from the use of IIb-IIIa inhibitors during coronary angioplasty, as noted earlier.

Quality of life

Quality of life in this study was found to be better after angioplasty during the first 6 months. Similar results were obtained in the RITA trial [21], where 1 month following revascularization patients after surgery complained more about dyspnea and lower exercise ability and tended to stay home instead of returning to work. After 2 years, however, these differences were not apparent. In the CABRI trial [22] no difference was found in quality of life 1 year after revascularization, and in the ARTS trial there was even a slight difference in favor of surgery after 12 months [14]. Thus, differences in quality of life in favor of angioplasty tended to persist only for short periods after intervention.

Randomization vs. non-randomization

Comparing results of randomized patients and patients who declined randomization enabled us to examine the assumption that randomized patients represent the entire population. A similar approach was taken in the ERACI trial [3,4], where 175 patients who fulfilled criteria for the study but refused randomization were followed. Ninety-nine patients were treated with angioplasty (without stenting) and 76 patients with bypass grafting. After 1 year there were no significant differences in survival between the groups, but patients treated with angioplasty had a higher incidence of angina and 32% of them needed repeat revascularization compared to only 3.2% of patients treated surgically ($P < 0.001$). These results were essentially the same as those in the randomized patients. In the WEST study [23], conducted by the EAST investigators [1,2], 450 patients who were EAST-eligible but refused randomization were followed for 3 years. Incidence of death was significantly higher among randomized (6.6%) than non-randomized patients (3.6%, $P = 0.044$), with no difference between the two treatment modalities in the latter group (4.9% in the PTCA group vs. 3% in the CABG group, *P*=NS). Although this finding was attributed to the higher rate of unstable angina and proximal left anterior descending artery involvement in randomized patients, it raised the possibility that the patient or his referring physician may know better what is good for the patient. In our study, we could not detect a linkage between the patient's decision and the rate of major adverse cardial or cerebral events, which was similar to that among the randomized patients in the ARTS trial. We did observe that when patients were asked to elect the revascularization approach they tended to rely mostly on experts' opinion.

Study limitations

This study was a prospective trial focusing on the outcomes in non-randomized patients. A single tertiary hospital was involved in the study, thus its population can be considered representative of patients with multivessel disease. The relatively short follow-up period might pose a problem when evaluating the study results. However, since the majority of major adverse cardiac or cerebral events and repeat revascularizations are known to occur during the early period after intervention, the likelihood of reaching different conclusions after a longer follow-up is low. In addition, detailed subgroup analysis is limited by the relatively small sample size.

Conclusions

Our study shows that PTCA plus stenting compared to CABG has similar short-term major complications for patients with multivessel disease. However, 36% of patients with multivessel disease undergoing angioplasty may need repeat revascularization during the first 6 months, compared to only 7% of patients after CABG. During this early phase the quality of life was better, hospitalization duration was shorter, and the cost to the health system was lower following angioplasty. Our findings should be reassessed in the future in view of the increasing use of multiple arterial conduits in bypass grafting on the one hand, and recent advances in interventional cardiology such as IIB-IIIA antagonists, new covered stents and brachytherapy, on the other.

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Correspondence: Dr. A. Elami, Dept. Of Cardiothoracic Surgery, Hadassah University Hospital, P.O. Box 12000, Jerusalem 91120, Israel.
Phone: (972-2) 677-6960
Fax: (972-2) 643-8005
email: eamir@md2.huji.ac.il