Long-Term (3-5 Years) Clinical and Angiographic Follow-up Results of Coronary Stenting in Elderly Patients

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The early and late results of percutaneous transluminal coronary angioplasty in elderly patients are well known, but although stent implantation has become the most frequent percutaneous coronary intervention in many centers, little information exists about its long-term outcome in elderly patients. The aim of this study was to evaluate the long-term clinical and angiographic follow-up results of intracoronary stenting in a study cohort of 120 patients (92 male) over 65 years of age, who underwent successful coronary stenting between June 1995 and December 1997. The target coronary artery was 48% left anterior descending, 21% circumflex and 31% right coronary artery. Stent implantation was elective in 54%, suboptimal in 32% and bailout in 14% of the patients. Long-term (34 ± 14 months) clinical and angiographic follow-up was completed in 78% and 56% of the patients, respectively. The following end-points were considered: death, non-fatal myocardial infarction (MI), target and non-target lesion revascularization. Angiographic restenosis was detected in 31% of the patients. During the long-term follow-up period, 14% of the patients died and 11% developed a new MI. Target lesion revascularization was done in 19.4%, non-target lesion revascularization was done in 21%, and the survival rate was 86%. Although the restenosis rates did not deviate greatly from the expected long-term figures in younger populations, they do indicate that the potential for major cardiac events is still high among elderly subjects, in spite of developments in stent technology and medication. (*Circ J* 2002; 66: 1029–1033)

Key Words: Elderly patients; Long-term follow-up; Stents

In elderly patients, cardiovascular disease is the most common cause of morbidity and mortality.¹ Elderly subjects with coronary artery disease differ from younger patients in many ways; for example, a previous history of myocardial infarction (MI), unstable angina pectoris, multi-vessel disease and complex lesions are more frequent than in a younger population.^{2–5}

Several studies have demonstrated that stent implantation for the treatment of coronary lesions is superior to conventional balloon angioplasty during either a short- or long-term follow-up period.^{6–10} Parallel to the developments in procedural techniques and medication, stent deployment for coronary revascularization is being implemented widely in the general population as well as in elderly subjects.

The early and late results of percutaneous transluminal coronary angioplasty (PTCA) in the treatment of coronary lesions in elderly subjects are well documented^{2–5,11–13} but data on the long-term results with stent implantation in the elderly are limited. The objective of this study was to examine the long-term clinical and angiographic results in patients aged 65 or over who had undergone intracoronary stent implantation at a single center.

Methods

Patients

Between June 1995 and December 1997, 607 consecutive patients underwent 665 coronary stent placements at Kosuyolu Heart and Research Hospital, Istanbul. Of these, 120 patients were aged 65 or over (92 male, 28 female, mean age 72 ± 3.8) and underwent successful placement of 136 coronary stents; 487 patients were younger than 65 years of age (407 male, 80 female, mean age 53 ± 5.9) and underwent 529 coronary stent placements.

In the elderly patients, 24% of stents were MULTILINK, 21% were NIR stents, 19% were Wiktor stents, 17% were JO stents, and 19% were different types of stents with no difference when compared with younger patients. All stents were implanted in native vessel lesions, and in the elderly group, 13% had 2 stents. Patients with a contraindication to antiplatelet or anticoagulation therapy were excluded.

Stent Placement

Stenting was performed via the femoral approach using an 8Fr sheath and a guiding catheter. Pre-dilatation was performed on all lesions, which determined whether direct stenting would be feasible. Stent deployment was performed by inflation of balloon to a nominal pressure, after which cases that were considered inadequate upon visual angiographic evaluation (residual stenosis $>10\%$) underwent an additional inflation at a higher pressure to achieve a residual diameter stenosis $<10\%$. Inflation pressures higher than 16 atmospheres were discouraged. The ratio of final balloon size to arterial diameter was 1.1 ± 0.1 .

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Table 1 Baseline Clinical Characteristics of the Patients With Coronary Stents

	<65 years (n=487)	≥65 years (n=120)	p value
Mean age (years)	53±5.9	72±3.8	0.001
M/W	407/80	92/28	>0.05
Smoking (%)	63	51	0.01
Hypertension (%)	31	43	0.01
Hyperlipidemia (%)	54	41	0.01
DM (%)	13	14	NS
Stable AP (%)	47	36	0.03
Unstable AP (%)	41	56	0.004
Acute MI (%)	9	8	>0.05
Prior MI (%)	27	38	0.01

AP, angina pectoris; DM, diabetes mellitus; MI, myocardial infarction.

Table 2 Baseline Angiographic Characteristics of the Patients With Coronary Stents

	<65 years (n=487)	≥65 years (n=120)	p value
Stented vessel			
LAD	54%	48%	>0.05
CX	22%	21%	>0.05
RCA	24%	31%	>0.05
Restenotic lesion	14%	19%	>0.05
Patients with two stents	9%	13%	>0.05
Stent indication			
Elective	53%	54%	>0.05
Suboptimal	36%	32%	>0.05
Bailout	11%	14%	>0.05
Reference vessel diameter (mm)	3.2±0.3	3.2±0.4	>0.05
Stent length (mm)	16.5±4.4	16.8±4.7	>0.05
Pre-procedural diameter stenosis (%)	78±11	78±12	>0.05
Post-procedural diameter stenosis (%)	8±5	8±6	>0.05

LAD, Left anterior descending coronary artery; CX, Circumflex coronary artery; RCA, Right coronary artery.

Angiographic evaluations were performed by digital calipers and/or visual estimation by at least 2 experienced cardiologists. Pre and post procedural angiograms were obtained in a minimum of 2 orthogonal views and the lesion characteristics were based on the end-diastolic frame images at which the lesion could be observed at its narrowest. A contrast-media filled guiding catheter was used as the reference for calibration.

Bail-out stenting was defined as the placement of a stent as a consequence of acute complete occlusion or threatening occlusion following PTCA. Acute complete stent occlusion was considered as TIMI Grade 0 flow following PTCA, and a threatening occlusion considered as more than 50% stenosis and evidence of ischemia or dissection. A residual stenosis of more than 20% following PTCA was considered to be sub-optimal. Elective stent placement was performed in re-stenosed lesions and in de novo lesions that were considered eligible for this procedure by at least 2 experienced cardiologists.

Follow-up

Clinical follow up was obtained by examination of the patients by a cardiologist or by telephone interview. In all contacted patients, death, Q wave MI and any revascularization procedure were recorded. Survival and event-free survival were calculated from the date of the procedure to the date of adverse event.

In the elderly patients, 93 subjects (75 men, 18 women) whose long-term (>3 years) clinical follow-up was available, were included in the study. Within the context of the

study, patients' consent was obtained, and new coronary angiography was performed on 45 of them. The findings from the last angiography examination of the 15 subjects who had undergone coronary angiography within the previous year and who had had no cardiac complaints or signs of ischemia, were pooled together with the study results. Of the 93 patients, there were 7 who underwent coronary artery bypass grafting (CABG) during the earlier follow-up and who did not have any complaints at present, and for these patients, the results of their last angiography prior to CABG were included in the study.

Definitions

Angiographic Success Residual stenosis less than 20% of the target lesion in the post-procedural angiographic evaluation.

Procedural Success Angiographic success with no major cardiac events during the stenting procedure.

Major Cardiac Event (MCE) Death, new non-fatal MI and any new revascularization procedure. New Q-wave MI was defined as the presence of a new pathologic Q wave in at least 2 concomitant leads in the 12-lead control electrocardiogram (ECG).

Restenosis 50% or more stenosis at the stent site compared with the diameter of the reference vessel of the control coronary angiography image.

Medication

Heparin (15,000 IU) was administered to all patients prior to the procedure and additional boluses were given

Table 3 Baseline Clinical and Angiographic Characteristics of the Elderly Patients

	Angiographically followed	No angiographic follow-up	p value
M/W	51/16	41/12	>0.05
Mean age (years)	72±3.9	72±4.0	>0.05
Hypertension (%)	42	43	>0.05
DM (%)	13	14	>0.05
Hyperlipidemia (%)	41	40	>0.05
Stable AP (%)	35	36	>0.05
Unstable AP (%)	56	55	>0.05
Acute MI (%)	8	8	>0.05
Ejection fraction (%)	51±13	53±14	>0.05
Restenotic lesion (%)	18	19	>0.05
Patients with 2 stents (%)	13	13	>0.05
Reference vessel diameter (mm)	3.2±0.4	3.2±0.4	>0.05
Stent length (mm)	17.0±4.5	16.6±4.8	>0.05
Pre-procedural diameter stenosis (%)	81±11	76±13	>0.05
Post-procedural diameter stenosis (%)	8±6	7±6	>0.05

DM, diabetes mellitus; MI, myocardial infarction; AP, angina pectoris.

during the procedure to maintain an activated clotting time ≥ 300 s. Ticlopidine was started at a dose of 250mg/day b.i.d. the day before the procedure in some selected patients and on the day of the procedure for the remaining cases, and was continued at the same dose for 1 month thereafter. All patients were on 300 mg aspirin on the day of the procedure and aspirin treatment was continued without interruption. No oral anticoagulants were used after the procedure. Other antianginal, antihypertensive or lipid-lowering medications were determined on the basis of patients' needs.

Statistical Analysis

SPSS for Windows 7.0 software was used for the statistical analysis. Data are expressed as mean value $\pm$ SD. Differences between the groups were evaluated using the chi-square test or Fisher's exact chi-square test for categorical values. Continuous variables were compared using Student t test. Survival and event-free survival were estimated by Kaplan-Meier curves. A $p < 0.05$ was considered to be statistically significant.

Results

Baseline clinical characteristics of the elderly and younger subjects are given in Table 1, and baseline angiographic characteristics are presented in Table 2.

Hypertension, unstable angina pectoris and prior MI were more prevalent in the elderly group (Table 1) in whom 8% of the lesions were Type A, 77% were Type B, and 15% were Type C, according to the AHA/ACC classification.¹⁴

Angiographic findings were available for 67 of the elderly patients after a mean follow-up period of 34 ± 14 months. Thus, assessed overall, long-term clinical follow-up was available in 78% (93/120), and long-term angiographic follow-up was available in 56% (67/120) of the subjects. Of these 67 patients, 7 had had 2 stents. Consequently stents with angiographic follow-up data made up 54% (74/136) of all stents. There was no difference in the baseline clinical and angiographic characteristics of patients who could or could not be followed clinically. Furthermore, there was no statistically significant difference between the baseline clinical and angiographic features of the elderly cases who did or did not have follow-up angiographic data (Table 3).

The in-hospital mortality rate was 0.4% in patients less

Table 4 Long-Term Clinical and Angiographic Results of the Elderly Patients

Event	Results
All cause of death	14% (13/93)
MI	11% (10/93)
Restenosis	31% (23/74)
Revascularization	40% (27/67)
Target lesion revascularization	
PTCA	4% (3/67)
CABG	15% (10/67)
Total	19.4% (13/67)
Non-target lesion revascularization	
PTCA	9% (6/67)
CABG	12% (8/67)
Total	21% (14/67)

CABG, coronary artery bypass graft; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty.

than 65 years of age and 2.5% in those aged 65 years or more ($p = 0.055$). The difference was close to the statistically significant level.

Outcomes in the Elderly Patients (Table 4)

Angiographic restenosis or total occlusion were observed in 31% (23/74) of the stents for which long-term follow-up angiography was performed.

Of the 7 subjects with 2 stents implanted, 2 had restenosis in both stents and all stents were patent in the remaining 5 subjects. Of the total 21 cases with stent restenosis, PTCA was performed on 3 subjects, CABG was proposed for 10 and the remaining 8 subjects were managed medically. Thus the target lesion revascularization rate was 19.4% (13/67) in the angiographically followed patients. Of the patients with stent restenosis, 62% underwent revascularization with PTCA or CABG.

New lesions had developed in 24% (16/67) of the patients at the long-term follow-up coronary angiography, and of these 16 cases, CABG was proposed for 6, and 8 underwent PTCA/stenting; the remaining 2 subjects had medical treatment only. Consequently the non-target lesion revascularization rate (NTLR) was 21% (14/67) in angiographically followed elderly patients and the total rate of revascularization during follow-up was 40% in angiographically followed patients (27/67). If the clinically and angiographically followed patients were considered

Fig 1. Kaplan-Meier curves of survival and event-free survival in patients ≥ 65 years of age.

together, the rate of revascularization was 29% (27/93).

Comparison of the new ECG data with the ECG recorded during the stenting procedure revealed a new Q-wave MI in 11% (10/93) of the cases.

Of the 93 subjects that we followed clinically, 13 died, which gave a long-term (>3 years) follow-up mortality rate of 14%, reflecting both cardiac and non-cardiac deaths. From the Kaplan-Meier estimates, the cumulative survival rate was, respectively, 93%, 90%, 86% and 82% at 1, 2, 3 and 4 years follow-up after stent implantation, and the cumulative event-free survival was 78%, 69%, 56% and 49%, respectively (Fig 1). In the younger patients (<65 years of age) the long-term follow-up mortality rate was 9%. Although long-term mortality rate in the elderly patients was higher than in the younger cases, the difference was not statistically significant ($p>0.05$).

Discussion

PTCA and CABG, currently the common coronary reperfusion methods carried out in the elderly patient population, have been extensively studied and the findings indicate that early phase morbidity and mortality rates after both procedures are higher in elderly subjects than in younger patients.^{3-5,11-13,15-18} As a consequence, advanced age is considered a risk factor for both interventions and the other factors leading to the high morbidity and mortality seen with CABG and PTCA in elderly patients have also been established: coronary artery disease is the most common, together with a high rate of left main coronary artery involvement, a higher incidence of peripheral artery disease and cerebrovascular disease, more advanced stage of left ventricular dysfunction and the presence of congestive impairment.^{3-5,11-13,15-18}

Stent deployment for the treatment of coronary artery disease has become the most commonly practiced therapeutic percutaneous coronary intervention today,^{19,20} but data on the long-term follow-up results in the elderly population are limited for such a widely practiced procedure. Initially, vascular complications because of the anticoagulant therapy used with coronary stenting were frequent in the general patient population, and even more so in the elderly.^{21,22} With modification of the anticoagulant and antiplatelet therapies, the vascular complications were sub-

stantially reduced and stenting has become the main percutaneous coronary intervention procedure in elderly subjects. Early studies examining coronary stenting in elderly subjects suggested that procedural success was high, with good results in the mid- and long-term follow-up; however, the data were conflicting in subsequent studies. In a study comparing the early and 6-month results of intracoronary stent implantation in 3 different age groups (<65 years, 65–75 years and >75 years), MCE did not differ among the age groups either during the in-hospital period or at 6 months.²³ A later study reported that both procedural complications and 6-month results were more unfavorable in patients aged 75 years and over compared with younger subjects.²⁴ Similarly, Alfonso et al found both in-hospital and long-term results to be more unfavorable in elderly cases, but a difference in the restenosis rates was not found to be associated with age.²⁵ In our present study, the in-hospital mortality rate was higher in the elderly patients.

Restenosis rates vary considerably between studies examining the intermediate and long-term results in elderly subjects: between 22% and 47%.²⁴⁻²⁸ In the 6-month follow-up period in the study of Trabattioni et al, the restenosis rate was 33.3%,²⁸ whereas for the same length of follow-up it was 47% in the study of De Gregorio et al.²⁴ Munoz et al, with a mean of 3.0 ± 1.5 years of follow-up, reported a restenosis rate of 22%.²⁷ Although most of these studies could not find a difference between the elderly and younger groups, De Gregorio et al observed stent restenosis to be higher in elderly subjects.²⁴

The long-term angiographic restenosis rate in the present elderly subjects was 31%, which when compared with the other reported restenosis rates is lower than that of De Gregorio et al.²⁴ However, it is close to the restenosis rates detected in other studies with either a follow-up period of 6 months or a follow-up period similar to the present study.²⁵⁻²⁸

In the present subjects, the target lesion revascularization rate as a whole was 14%, and 19.4% in patients with angiographic follow-up, compared with 11.2% and 28%, respectively, in elderly subjects in studies with a follow-up period of 6–12 months.^{23,24,28}

A new coronary lesion developed in 24% of the patients undergoing long-term angiographic follow-up, so the non-target lesion revascularization was especially high (21%). This is an important finding and indicates that progression of atherosclerosis and development of new coronary lesions are the major problems for elderly patients in the long-term follow-up period.

In elderly patients with coronary stents, death rates vary between 9% and 15% during a 6–12-month follow-up period.^{24,27} As with the in-hospital mortality rate, the long-term mortality rate was higher among the elderly patients (≥ 65 years) than the younger patients in the present study. The death rate reflects both cardiac and non-cardiac deaths because it was not possible to discriminate cardiac deaths in the follow-up period. In elderly patients, the new Q-wave MI rate was 11%.

In the long-term follow-up period the rate of cardiac events such as revascularization, MI and death seems to be high in patients older than 65 years who have coronary stents. This results could be explained by the presence of higher incidences of multi-vessel disease, complex lesions, main stem coronary lesions, unstable angina pectoris and other comorbid factors in the elderly population.

Although restenosis rates in our study do not deviate

greatly from the expected long-term figures in younger populations, our results indicate that the potential for major cardiac events is still high among elderly subjects, despite developments in stent technology and medication. The high rate of non-target lesion revascularization in the long term underlines the importance of therapies targeted at the progression of atherosclerosis and prevention of new lesions.

Study Limitations

One of the major limitations was the absence of an angiographically followed control group, so we could not compare the end-points other than death between the elderly and younger patients.

Another major limitation was the low angiographical follow-up rate of the patients. Because of the limited size of the study population who had undergone follow up coronary angiography, this study did not include a multivariable analysis of the factors that are considered to affect the outcome.

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