

Benefits on coronary restenosis from elective paclitaxel-eluting stent implantation in patients aged 75 years and older

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Objective Elderly patients are increasingly referred for revascularisation yet have been underrepresented in some large clinical trials. Although the advent of drug-eluting stents has dramatically reduced clinical events related to restenosis, older age remains one of the most important correlates of adverse outcome, even after an elective percutaneous coronary intervention (PCI). We sought to evaluate the impact of paclitaxel-eluting stents on coronary restenosis in elderly patients undergoing elective PCI.

Methods Patients undergoing successful elective PCI with stenting of *de novo* coronary artery lesions were identified and screened for participation in this study. All patients included in our analysis were divided into two cohort groups: patients aged <75 years (younger cohort) and patients aged ≥75 years (elderly cohort). We evaluated the six-month incidence of target lesion revascularisation (TLR) and major adverse cardiac events, which included TLR, death and myocardial infarction.

Results A total of 171 (58 aged ≥75 years) consecutive patients were enrolled in the study. At six months, TLR rate was similar in both groups (1.77 vs. 1.72%, odds ratio [OR] 0.97, 95% confidence interval [CI] 0.08–10.9, $P=0.98$, in the younger and elderly group, respectively). Even the rate of

major adverse cardiac events was comparable between the two groups (7.96 vs. 8.62%, OR 1.09, 95% CI 0.34–3.41, $P=0.88$, in the younger and elderly group, respectively). Also the angiographic restenosis rates were comparable between patients <75 or ≥75 years (4.42 vs. 3.46%, $P=0.76$).

Conclusions After elective paclitaxel-eluting stent implantation, there is no difference in coronary restenosis in younger and elderly patients, suggesting an age-independent efficacy. *J Cardiovasc Med* 8:494–498 © 2007 Italian Federation of Cardiology.

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Introduction

The advent of drug-eluting stents (DESs) has dramatically reduced clinical events related to restenosis [1,2], a well known limitation of percutaneous coronary intervention (PCI). The polymer-regulated delivery of both paclitaxel and sirolimus at the site of arterial injury has been shown to reduce clinical and angiographic restenosis rates after stent implantation in some prospective, double-blind, clinical trials [3–5].

As PCI technology evolves and the worldwide population becomes proportionally older, assessment of PCI outcomes in older age groups is essential. Several studies have shown high procedural success not only in younger but in elderly patients as well [6–11]. The high procedural success rate has been associated with a low

procedural complication rate [12,13] owing to the use of coronary stenting and improved operator experience [14,15]. Despite this progress, older age remains one of the most important correlates of adverse outcomes, even after an elective PCI [16,17].

To date, no study was aimed at determining the incidence of restenosis after DES implantation in an elderly population. We sought to evaluate the impact of paclitaxel-eluting stents (PESs) on coronary restenosis in elderly patients undergoing elective PCI.

Methods

Study design

Between July 2004 and March 2005, patients undergoing successful elective PCI with stenting of *de novo* coronary

artery lesions were identified and screened for participation in this single-centre study. All patients included in our analysis were divided into two cohort groups: patients aged <75 years (younger cohort) and patients aged ≥ 75 years (elderly cohort).

Patients were excluded if requiring urgent procedures for an acute myocardial infarction (MI) or haemodynamic instability, undergoing interventions in previously instrumented vessels, having a chronic occlusion (present for longer than three months), target lesion with angiographically visible thrombus, trauma or major surgery in the preceding month or a stroke in the prior three months.

The protocol was performed in accordance with institutional guidelines and the Declaration of Helsinki. All patients gave written informed consent for PCI before entering the study.

Procedure

Elective PCI was performed via the femoral or radial artery, according to standard clinical practice, with DES implantation in all patients. The DES used in the study was the PES (Taxus, Boston Scientific Corporation, Natick, Massachusetts, USA), with paclitaxel incorporated into a slow-release copolymer carrier system that gives biphasic release.

Balloon predilation and postdilation were performed if necessary using conventional techniques. All patients were treated with aspirin before the procedure. Heparin was dosed to achieve an activated clotting time of ≥ 250 s. Before or immediately after stent implantation, all patients received clopidogrel (loading dose of 300 mg, followed by 75 mg/day for nine months). Other adjunctive pharmacotherapy was administered at the discretion of the operator.

Angiographic analysis

All measurements were performed on cineangiograms recorded after intracoronary nitroglycerin administration. The same projections were used at baseline, after the procedure and at the time of follow-up angiography. The contrast-filled non-tapered catheter tip was used for calibration.

All patients enrolled in the study underwent an angiographic follow-up at six months in order to evaluate asymptomatic in-stent restenosis. Three coronary segments underwent quantitative angiography (Infinix CS-i, QCA software, Toshiba Medical Systems, New York City, New York, USA) in a double-blind manner: in-stent, proximal edge, and distal edge segment. The in-stent analysis encompassed the entire length of all stents used during the procedure. The proximal and distal edge segments included up to 5 mm on either side of the in-stent segment.

The reference vessel diameter, minimal lumen diameter, and percent diameter stenosis were measured before and after the procedure, and at follow-up. Angiographic restenosis was defined as a $>50\%$ diameter stenosis within the target lesion.

Follow-up

A clinical follow-up was performed at six months after the procedure, evaluating the incidence of target lesion revascularisation (TLR) and major adverse cardiac events (MACE), which included TLR, death and MI. MI was defined as Q-wave MI (development of new pathological Q waves in two or more electrocardiographic leads with creatine kinase-MB levels elevated above normal). An angiographic follow-up at six months was also planned.

Statistical analysis

The primary clinical analysis consisted of a comparison between the two cohorts that were divided by age. All continuous variables are expressed as mean \pm SD and are analysed by Student's *t*-test. Categorical variables are expressed as number of subjects and percentages, and are analysed by the χ^2 or Fisher's exact test, as appropriate. Differences were considered statistically significant at $P < 0.05$. Statistical analysis was performed with SPSS, version 11.0 (SPSS Inc., Chicago, Illinois, USA).

Results

Patient population

A total of 171 (58 older than 75 years) consecutive patients were enrolled in the study: 36 were asymptomatic and referred to out hospital for a positive stress test, and had unstable angina, 38 had unstable angina and 97 presented with stable angina (8 in Canadian Cardiovascular Society [CCS] class I, 52 in CCS class II, 28 in CCS class III and 9 in CCS class IV).

As shown in Table 1, patients <75 years were more likely to be normotensive (54.9 vs. 70.7%, $P = 0.049$), smokers (43.4 vs. 12.1%, $P = 0.0001$) and obese (25.7 vs. 3.4%, $P = 0.0002$). Other baseline clinical characteristics were well matched between the two groups. The angiographic and procedural findings were similar in the two groups in terms of angiographic measurements, lesion location and type (according to the American Heart Association/American College of Cardiology classification scheme [18]), postprocedural Thrombolysis In Myocardial Infarction flow grade and myocardial blush grade, except for a more severe minimal lumen diameter before intervention in the elderly group (0.8 vs. 0.9, $P = 0.04$) (Table 2). Importantly, a direct stenting was performed more frequently in younger patients (80.5 vs. 27.6%, $P = 0.0001$) (Table 2). Twenty-eight patients received a bare-metal stent and only one patient a tacrolimus-eluting stent in a coronary vessel or coronary segment other than the one where the PES has been implanted.

Table 1 Clinical characteristics of the study population

	Total (n = 171)	<75 years (n = 113)	≥75 years (n = 58)	P
Age (years)	64.3 ± 6.3	61.6 ± 5.3	78.7 ± 6.7	0.0001
Males	123 (71.9%)	77 (68.1%)	46 (79.3%)	0.15
Risk factors				
Hypertension	103 (60.2%)	62 (54.9%)	41 (70.7%)	0.049
Smoking	56 (32.7%)	49 (43.4%)	7 (12.1%)	0.0001
Obesity	31 (18.1%)	29 (25.7%)	2 (3.4%)	0.0002
Diabetes mellitus	61 (35.7%)	39 (34.5%)	22 (37.9%)	0.74
Family history of CAD	58 (33.9%)	35 (31%)	23 (39.6%)	0.31
Cholesterol (mg/dl)	168 ± 26	169 ± 35	167 ± 47	0.75
Triglycerides (mg/dl)	129 ± 27	130 ± 19	129 ± 16	0.73
Renal failure	34 (19.9%)	19 (16.8%)	15 (25.9%)	0.16
Ejection fraction <0.40	87 (50.9%)	63 (55.7%)	24 (41.4%)	0.08
Previous PCI	32 (18.7%)	24 (21.2%)	8 (13.8%)	0.3
Previous MI	40 (23.4%)	31 (27.4%)	9 (15.5%)	0.09
Previous CABG	16 (9.3%)	9 (7.9%)	7 (12.1%)	0.79

CAD, coronary artery disease; PCI, percutaneous coronary intervention; MI, myocardial infarction; CABG, coronary artery bypass graft.

Table 2 Angiographic data

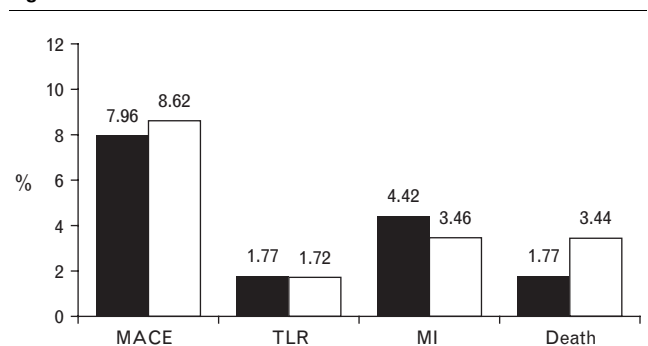
	Total (n = 171)	<75 years (n = 113)	≥75 years (n = 58)	P
Multivessel PCI	43 (25.1%)	29 (25.7%)	14 (24.4%)	0.85
Lesion location				
Left main	2 (1.2%)	2 (1.8%)	0	0.79
LAD/diagonal branch	98 (57.3%)	63 (55.7%)	35 (60.3%)	0.62
LCx/marginal branch	38 (22.2%)	22 (19.5%)	16 (27.6%)	0.25
Right coronary artery	76 (44.4%)	47 (41.6%)	29 (50%)	0.33
Complex (type B2/C) lesion	133 (77.7%)	86 (76.1%)	47 (81%)	0.56
Lesion length (mm)	15.1 ± 6.4	14.8 ± 5.7	15.3 ± 4.7	0.57
Vessel size (mm)	2.7 ± 0.1	2.7 ± 0.4	2.6 ± 0.9	0.32
MLD pre-intervention (mm)	0.8 ± 0.4	0.9 ± 0.3	0.8 ± 0.3	0.04
Diameter stenosis pre-intervention (%)	71.3 ± 9.6	69.5 ± 9.4	71.8 ± 11.1	0.16
Procedure				
Direct stenting	107 (62.6%)	91 (80.5%)	16 (27.6%)	0.0001
Post-dilatation	41 (24%)	28 (24.8%)	13 (22.4%)	0.85
MLD post-intervention (mm)	2.6 ± 0.6	2.7 ± 0.5	2.6 ± 0.4	0.79
Diameter stenosis post-intervention (%)	3.0 ± 4.4	3.2 ± 6.1	2.9 ± 4.8	0.74
TIMI flow grade 2–3 post-PCI	154 (90%)	102 (90.3%)	52 (89.6%)	0.9
Complications				
Coronary dissection	28 (16.4%)	16 (14.1%)	12 (20.7%)	0.28
Acute stent thrombosis	0	0	0	1.0
Major bleeding	5 (2.9%)	3 (2.6%)	2 (3.4%)	0.77

PCI, percutaneous coronary intervention; LAD, left centre anterior descending coronary artery; LCx, left centre circumflex coronary artery; MLD, minimal lumen diameter; TIMI, Thrombolysis In Myocardial Infarction.

Clinical and angiographic findings

Clinical and angiographic follow-up has been performed in all patients. At six months, TLR rate was similar in both groups [1.77 vs. 1.72%, odds ratio (OR) 0.97, 95% confidence interval (CI) 0.08–10.9, $P=0.98$, in the younger and elderly group, respectively]. One out of 113 patients in the younger group received a percutaneous revascularisation 87 days after PES implantation, for the onset of a new MI. Other TLRs have been performed at the time of angiographic follow-up. Even the rate of MACE was comparable between the two groups (7.96 vs. 8.62%, OR 1.09, 95% CI 0.34–3.41, $P=0.88$, in the younger and elderly group, respectively) (Fig. 1).

Also the angiographic restenosis rates were comparable between patients <75 and ≥75 years (4.42 vs. 3.46%,

Fig. 1

Six-month incidence of major adverse cardiac events (MACE), including target lesion revascularisation (TLR), death and myocardial infarction (MI) in patients aged <75 (closed bars) or ≥75 years (open bars).

Table 3 Angiographic parameters of restenosis at six months

	Total (n = 171)	<75 years (n = 113)	≥75 years (n = 58)	P
Minimal lumen diameter (mm)	2.4 ± 0.73	2.3 ± 0.88	2.4 ± 0.56	0.43
Diameter stenosis (%)	22.5 ± 13.1	24.7 ± 15.1	22.4 ± 11.5	0.31
Angiographic restenosis	7 (4.1%)	5 (4.4%)	2 (3.4%)	0.76
Proximal edge	5 (2.9%)	4 (3.5%)	1 (1.7%)	0.85
In-stent	1 (0.6%)	0	1 (1.7%)	0.73
Distal edge	1 (0.6%)	1 (0.9%)	0	0.47

$P=0.76$). Both continuous measures of restenosis, namely minimal lumen diameter and diameter stenosis, indicated an equally low luminal re-narrowing in PES-treated patients, regardless of age (Table 3).

Discussion

The findings of this study do not support a significant difference in coronary restenosis rate in elderly patients undergoing an elective PES implantation compared with younger patients. Elderly patients are increasingly referred for revascularisation yet have been under-represented in some large PCI clinical trials [11,19]. Our knowledge concerning the magnitude of age-associated risks of revascularisation therapies has also been limited.

Regarding PCI in the elderly population, the literature has predominantly been composed of retrospective single-institution case series. These studies showed that, compared to the general population, elderly patients undergoing coronary revascularisation have traditionally been more likely to present with more co-morbid diseases, complex lesions, unstable angina, co-morbidities and lower ejection fractions [20–29]. As a consequence, elderly patients have traditionally had higher rates of procedure-related death, MI, bleeding complications and stroke than younger patients undergoing elective PCI [30–35].

Although there is an extensive amount of published information regarding PCI and coronary artery bypass grafting (CABG) in the elderly, there are limited data available regarding stenting in this population. De Gregorio *et al.* [36] compared the short and long-term outcomes of elderly patients undergoing bare-metal stenting with those of younger patients in order to determine the long-term clinical outcome and survival of elderly patients after stent implantation. Older patients had higher rates of procedure-related complications including procedural MI, emergency CABG, and death. The six-month angiographic follow-up, obtained in both groups, demonstrated significantly higher restenosis rates in the elderly than in younger patients [36]. Compared to our data, the significant differences found in this study that help to explain their inferior outcomes, include the fact that they presented with lower ejection fractions, more frequent three-vessel disease, calcified and complex lesions. Importantly, they used only bare-

metal stents, which could influence the restenosis-related clinical outcomes.

Recently, a report from the e-CYPHER Registry [37], a worldwide post-marketing surveillance registry dedicated to follow prospectively sirolimus-eluting stent implantation in real-world PCI activity outside the United States, analysed the incidence of MACE in 504 patients aged ≥ 80 years, compared with a younger cohort. At six-month follow-up, advanced age was strongly associated with an increase in mortality (5.2 vs. 1.2%), MI (1.9 vs. 0.8%) and overall MACE (6.8 vs. 2.8%, in elderly and younger patients, respectively). In contrast, TLR (0.5 vs 1%) and target vessel revascularisation (0.5 vs. 0.3%) after sirolimus-eluting stent implantation were not different in the younger and elderly population [37]. Accordingly, Vijayakumar *et al.* [38] demonstrated that sirolimus-eluting stent implantation in octogenarians was feasible and associated with very small subsequent need for repeat target vessel revascularisation at one year. Compared to our study population, patients enrolled in these studies were older (≥ 80 vs. ≥ 75 years), with more multivessel disease and calcified lesions. In our study population, even if there is no statistical difference in B2 or C angiographic lesions, we used more frequently a predilatation in the elderly group, suggesting the presence of highly calcified stenoses, not clearly visible at coronary angiography. However, as in our prospective study, the benefits of DESs on coronary restenosis appear to exist equally in the younger and elderly population.

Study limitations

This is part of a larger ongoing study that we are conducting in order to evaluate the angiographic coronary restenosis rate of PESs in an unselected population. Because in this single-centre experience we did not observe any statistical difference in long-term clinical findings, our small sample size may underestimate the true incidence of MACE. Therefore, the real-world impact of PESs on coronary restenosis in the elderly population needs further evaluation with a larger number of patients.

Conclusions

In conclusion, after an elective PES implantation, there is no difference in coronary restenosis in younger and elderly patients, suggesting an age-independent efficacy of DESs.

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