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A Prospective Randomized Trial of Everolimus-Eluting Stents Versus Bare-Metal Stents in Octogenarians

The XIMA Trial (Xience or Vision Stents for the Management of Angina in the Elderly)

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Objectives The aim of this study was to determine whether drug-eluting stents (DES) are superior to bare-metal stents (BMS) in octogenarian patients with angina.

Background Patients ≥80 years of age frequently have complex coronary disease warranting DES but have a higher risk of bleeding from prolonged dual antiplatelet therapy.

Methods This multicenter randomized trial was conducted in 22 centers in the United Kingdom and Spain. Patients ≥80 years of age underwent stent placement for angina. The primary endpoint was a 1-year composite of death, myocardial infarction, cerebrovascular accident, target vessel revascularization, or major hemorrhage.

Results In total, 800 patients (83.5 ± 3.2 years of age) were randomized to BMS (n = 401) or DES (n = 399) for treatment of stable angina (32%) or acute coronary syndrome (68%). Procedural success did not differ between groups (97.7% for BMS vs. 95.4% for DES; p = 0.07). Thirty-eight percent of patients had ≥2-vessel percutaneous coronary intervention, and 66% underwent complete revascularization. Patients who received BMS had shorter stent implants (24.0 ± 13.4 mm vs. 26.6 ± 14.3 mm; p = 0.01). Rates of dual antiplatelet therapy at 1 year were 32.2% for patients in the BMS group and 94.0% for patients in the DES group. The primary endpoint occurred in 18.7% of patients in the BMS group versus 14.3% of patients in the DES group (p = 0.09). There was no difference in death (7.2% vs. 8.5%; p = 0.50), major hemorrhage (1.7% vs. 2.3%; p = 0.61), or cerebrovascular accident (1.2% vs. 1.5%; p = 0.77). Myocardial infarction (8.7% vs. 4.3%; p = 0.01) and target vessel revascularization (7.0% vs. 2.0%; p = 0.001) occurred more often in patients in the BMS group.

Conclusions BMS and DES offer good clinical outcomes in this age group. DES were associated with a lower incidence of myocardial infarction and target vessel revascularization without increased incidence of major hemorrhage. (Xience or Vision Stent–Management of Angina in the Elderly [XIMA]; ISRCTN92243650) (J Am Coll Cardiol 2014;63:1371–5) © 2014 by the American College of Cardiology Foundation

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Abbreviations and Acronyms

BMS = bare-metal stent(s)
CVA = cerebrovascular accident
DAPT = dual antiplatelet therapy
DES = drug-eluting stent(s)
MI = myocardial infarction
PCI = percutaneous coronary intervention
TVR = target vessel revascularization

Improved health care has led to an increase in the proportion of elderly patients in the population. As a consequence, patients are presenting with stable coronary disease and acute coronary syndromes at a much older age, and very elderly patients (age >80 years) are an increasing slice of day-to-day practice. Coronary stenting is feasible for and beneficial to elderly patients with anginal syndromes (1,2) but is associated with higher complication rates (3,4). Many trial protocols exclude elderly patients, and the data for longer-term outcomes with intervention are limited to retrospective analyses (5–9).

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Elderly patients often have complex coronary artery disease warranting use of drug-eluting stents (DES), but prolonged dual antiplatelet therapy (DAPT) puts them at higher risk for major bleeding complications (10). Noncompliance with DAPT may also be more likely in elderly patients, and this would put them at higher risk for stent thrombosis (11–14).

We designed a prospective randomized trial to examine the hypothesis that treatment of complex coronary disease with DES in patients ≥80 years of age with angina would prove superior to bare-metal stents (BMS) with respect to a combined endpoint of mortality, myocardial infarction (MI), target vessel revascularization (TVR), cerebrovascular accident (CVA), or severe hemorrhage.

Methods

Patients ≥80 years of age were considered for the trial at participating centers. Coronary disease warranting use of DES (≥15 mm long or <3 mm wide) was a requirement. Other subsets of disease that have a high risk of restenosis (chronic total occlusions, bifurcations, left main stem disease) were included. Second-generation everolimus-eluting stents (Xience, Abbott Vascular, Santa Clara, California) and bare-metal Vision stents (Abbott Vascular) were used.

Patients with non–ST-segment elevation myocardial infarction, unstable angina, and stable angina were eligible to participate in this study. Patients with acute ST-segment elevation myocardial infarction, cardiogenic shock, thrombocytopenia ($<50 \times 10^9/mm^3$), poor life expectancy, gastrointestinal hemorrhage ≤3 months, or previous intracerebral bleeding were excluded.

Patients were randomized on a 1:1 basis using web-based methodology. Before revascularization, all patients underwent an assessment of angina status, angina medication, physical examination, and measurement of creatine kinase/troponin levels. Techniques for stent deployment were left to the discretion of the operator. Lesion preparation before stent deployment was encouraged.

Before percutaneous coronary intervention (PCI), loading doses of aspirin 300 mg and clopidogrel 600 mg were given unless the patients were established on these drugs. Long-term treatment with warfarin was not a contraindication, but caution was emphasized. The use of glycoprotein IIb/IIIa inhibitors was at the discretion of the operator, but caution was urged.

Creatine kinase and troponin levels were measured 16 to 22 h after PCI. For patients receiving BMS, 1 month of DAPT was mandatory. For patients receiving DES, DAPT was prescribed for 1 year.

After discharge from the hospital, patients were followed up at 6 months and 1 year to determine progress, drug compliance, and clinical events. All clinical events were adjudicated by an independent adjudication committee in Spain and the United Kingdom (see the Online Appendix).

Definitions. Death was determined to be cardiac or noncardiac. For patients with undetermined cause, the full circumstances of demise were considered by the endpoints committee before adjudication. MI was defined using the European Society of Cardiology/American College of Cardiology Foundation/American Heart Association/World Heart Federation 2007 definition (15). Bleeding endpoints were defined by the Thrombolysis In Myocardial Infarction classification (16) as none, minor, or major. TVR was defined as any stented vessel requiring revascularization with balloon angioplasty, stenting, or coronary artery bypass grafting within 1 year of the original procedure. CVA was defined as a new neurological deficit lasting >24 h confirmed with appropriate imaging abnormality. Stent thrombosis was defined using the Academic Research Consortium criteria (17).

Statistics and data management. The expected composite primary endpoint rate for this group of patients treated with BMS was estimated to be 20% at 1 year based on ARTS (Arterial Revascularization Therapies Study) I and II (18,19). We estimated the composite primary endpoint for the DES group would be 12%. Using this estimate, a sample size of 658 patients would achieve 80% power to a 5% significance level. We were concerned about loss to follow-up in this age group and therefore proposed to recruit 800 patients. Data were collected on a dedicated web-based secure site, entered by the host institution, and validated by the trial organization (Sussex Cardiac Centre, Brighton, England, and RPS Research Ibérica, Barcelona, Spain). All clinical events were adjudicated by an independent committee using pre-defined endpoints. The Data and Safety Monitoring Committee was responsible for the analysis of the data. All analyses were based on an intention-to-treat principle.

Categorical variables are reported as frequencies and percentages and compared using the chi-square test or, in the case of low frequencies, the Fisher exact test. Continuous variables are reported as mean ± SD and compared using the Student *t* test. Event-free survival was estimated using

Table 1 Demographic Data Comparing the Patients Randomized to BMS or DES

	BMS (n = 401)	DES (n = 399)	p Value
Age (yrs)	83.4 ± 3.1 (80–99)	83.6 ± 3.2 (80–101)	0.35
Female	40.9	38.9	0.64
Diabetes	24.2	25.6	0.65
Hypertension	77.6	75.1	0.42
Hypercholesterolemia	52.9	57.6	0.17
Current smoker	4.0	5.0	0.49
Previous CVA/TIA	10.7	7.8	0.15
Peripheral vascular disease	12.5	10.3	0.33
Creatinine >200 μmol/l	7.0	6.0	0.57
Previous MI	21.5	29.8	0.007
Previous PCI	10.2	12.8	0.25
Previous CABG	4.2	7.0	0.088
Left ventricular function <40%	10.1	13.5	0.21
On warfarin pre-PCI	1.3	2.8	0.12

Values are mean ± SD (range) or %. Patients randomized to the DES group were more likely to have had a previous MI and previous CABG.

BMS = bare-metal stent(s); CABG = coronary artery bypass graft; CVA = cerebrovascular accident; DES = drug-eluting stent(s); MI = myocardial infarction; PCI = percutaneous coronary intervention; TIA = transient ischemic attack.

the Kaplan-Meier method and differences assessed using the log-rank test. A value of $p < 0.05$ was used for statistical significance.

Results

Between 2009 and 2011, 800 octogenarian patients (400 in the United Kingdom and 400 in Spain) were recruited from 22 centers and randomized to BMS (n = 401) or DES (n = 399). The clinical presentation was stable angina (32.0%), troponin-negative acute coronary syndrome (18.0%), and troponin-positive acute coronary syndrome (50.0%).

Demographics are shown in Table 1 and demonstrate that the groups were well matched. Procedural characteristics are shown in Table 2. The only significant difference between the 2 groups was the slightly longer stent length in the DES group. At 1 year, the rates of DAPT for the 2 groups were 32.2% for BMS and 94.0%

Table 2 Procedural Details Comparing the 2 Groups

	BMS (n = 401)	DES (n = 399)	p Value
Left main stem PCI	8.3	7.6	0.72
Left anterior descending PCI	63.0	60.7	0.50
Circumflex PCI	30.0	31.7	0.61
Right coronary artery PCI	35.3	38.1	0.41
Bypass graft PCI	1.5	3.6	0.067
Number of PCI vessels			0.71*
1	60.5	62.7	
2	31.5	27.2	
>2	8.0	10.2	
Radial approach	58.2	52.4	0.12
Rotational atherectomy	12.0	9.5	0.26
Complete revascularization planned	66.3	66.5	0.96
Staged procedure	7.3	8.3	0.28
Length of stent (mm)	24.0 ± 13.4	26.6 ± 14.3	0.011†
Number of stents deployed	2.0 (1–3)	2.0 (1–3)	0.32*
Correct stent deployed	95.0	93.9	0.73
Procedural success	97.7	95.4	0.075
Use of glycoprotein IIb/IIIa inhibitors	1.7	1.5	0.79
Number of days in hospital	4 (1–8)	4 (1–8)	0.77*

Values are %, mean ± SD, or median (interquartile range). The stent length was significantly greater in the DES group. Chi-square test was used for significance unless otherwise stated. *Mann-Whitney test. †Two-sample Student *t* test.

Abbreviations as in Table 1.

Table 3 The Primary Endpoint Was More Likely to Occur in the BMS Group

Cause	Period (months)	Vision BMS (n = 401)	Xience DES (n = 399)	p Value
All-cause death	0–12	7.2% (29)	8.5% (34)	0.51
	<1	1.2% (5)	1.5% (6)	0.77
	1–6	2.7% (11)	3.3% (13)	0.68
	6–12	3.2% (13)	3.8% (15)	0.71
Cardiac	0–12	4.7% (19)	3.3% (13)	0.37
	<1	0.7% (3)	0.5% (2)	1.00
	1–6	2.5% (10)	1.8% (7)	0.63
	6–12	1.5% (6)	1.0% (4)	0.75
Noncardiac	0–12	2.5% (10)	5.3% (21)	0.045
	<1	0.5% (2)	1.0% (4)	0.45
	1–6	0.2% (1)	1.5% (6)	0.069
	6–12	1.7% (7)	2.8%	0.48
Major hemorrhage	0–12	1.7% (7)	2.3% (9)	0.61
	<1	0.7% (3)	0.5% (2)	1.00
	1–6	0.7% (3)	0.8% (3)	1.00
	6–12	0.2% (1)	1.0% (4)	0.22
MI	0–12	8.7% (35)	4.3% (17)	0.014
	<1	3.5% (14)	2.5% (10)	0.53
	1–6	4.2% (17)	1.0% (4)	0.006
	6–12	1.0% (4)	0.8% (3)	1.00
TVR	0–12	7.0% (28)	2.0% (8)	0.0009
	<1	0.5% (2)	0.5% (2)	1.00
	1–6	4.2% (17)	1.0% (4)	0.007
	6–12	2.2% (9)	0.5% (2)	0.064
CVA	0–12	1.2% (5)	1.5% (6)	0.77
	<1	0.7% (3)	0.0% (0)	0.25
	1–6	0.0% (0)	1.0% (4)	0.061
	6–12	0.5% (2)	0.5% (2)	1.00
Hemorrhagic	0–12	0.2% (1)	0.8% (3)	0.37
	<1	0.0% (0)	0.0% (0)	1.00
	1–6	0.0% (0)	0.3% (1)	0.50
	6–12	0.2% (1)	0.55% (2)	0.62
Ischemic	0–12	1.0% (4)	0.8% (3)	1.00
	<1	0.7% (3)	0.0% (0)	0.25
	1–6	0.0% (0)	0.8% (3)	0.25
	6–12	0.2% (1)	0.0% (0)	1.00
Primary endpoint	0–12	18.7% (75)	14.3% (57)	0.09
	<1	5.5% (22)	4.5% (18)	0.63
	1–6	7.5% (30)	5.35% (21)	0.25
	6–12	5.7% (23)	4.5% (18)	0.52

Values are % (n). There was no significant difference in mortality, major hemorrhage, and permanent stroke between the 2 groups. There was an increased likelihood of MI and TVR in the BMS group.

Abbreviations as in Table 1.

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for DES. Of the 6% not on DAPT in the DES group, 6 patients did not have a stent deployed for technical reasons, 1 patient was noncompliant with all medication, and the remaining 9 patients had DAPT withdrawn because of clinical concerns (e.g., falls, easy bruising, dyspeptic symptoms).

The primary endpoint and its components are shown in Table 3. The cumulative primary endpoint of death/MI/TVR/CVA/major hemorrhage was 18.7% in the BMS group and 14.3% in the DES group ($p = 0.09$). Death rates were 7.2% for the BMS group (4.7% cardiac, 2.5% noncardiac) and 8.5% for the DES group (3.3% cardiac, 5.3% noncardiac). Noncardiac deaths were chiefly attributable to cancer (35%), infection (26%), or respiratory failure (14%). Time to first event is shown in the Kaplan-Meier analysis in Figure 1.

Thrombolysis In Myocardial Infarction minor hemorrhage occurred in 2.0% of the BMS and 3.5% of the DES group ($p = 0.20$). There were 2 definite stent thromboses in the DES group (one at 6 days and one at 115 days) and 2 probable stent thromboses (sudden cardiac death 2 days after BMS implantation and 28 days after DES implantation). A forest plot analysis is shown in Figure 2. A table of estimates of the odds ratio (with 95% confidence intervals) of the primary endpoint for all patients and various subgroups is shown.

Discussion

This prospective randomized trial of octogenarian patients undergoing stent placement for symptomatic coronary disease showed that DES, when compared with BMS, reduce the incidence of MI and TVR in the subsequent year.

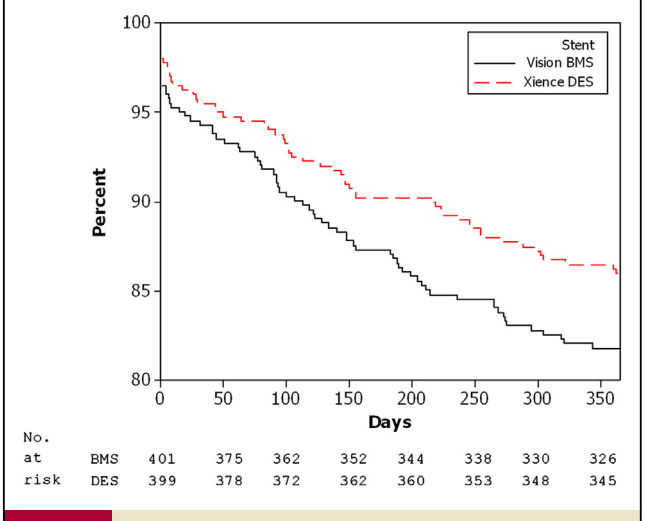

Figure 1 Kaplan-Meier Survival Plot

Kaplan-Meier survival plot for time to first primary endpoint event for the DES and BMS groups. BMS = bare-metal stent(s); DES = drug-eluting stent(s).

There was no significant difference in the incidence of death from all causes, major hemorrhage, or CVA.

Elderly patients have more complex coronary disease. The burden of disease is greater, and the nature of the coronary disease (calcification and tortuosity in particular) is likely to present more of a challenge to successful treatment. These patients should therefore benefit from DES technology, but longer duration of DAPT puts these patients at higher risk for bleeding (14). BMS have the advantage of reduced DAPT and the limited functional significance of vessel restenosis in this more sedentary age group.

A potential confounder in this trial was the unpredictable nature of mortality in this age group. Indeed, the DES group had a significantly higher rate of noncardiac mortality than the BMS group, a finding that might have had an important bearing on the primary endpoint.

A common clinical dilemma for elderly patients is whether the risk of significant hemorrhage with anticoagulant or antiplatelet drugs is less than the risk of restenotic or thrombotic events after stenting. For example, the Rockall scoring system for the risk of rebleeding or death after admission to hospital for acute gastrointestinal bleeding gives 2 points for ≥80 years of age, 2 points for ischemic heart disease, 2 points for blood seen on endoscopy, and 2 points if blood pressure is <100 mm Hg. A Rockall score of 8 translates to a very high risk of mortality (20). Our study is reassuring in that despite this anxiety, overall rates of major hemorrhage have been remarkably low.

The risk of stroke was low and was not different between the 2 groups. There was a prior concern that the risk of intracerebral bleeding, either spontaneous or induced by falls, would be greater in the DES group, but this did not translate into an important clinical finding. Indeed, the rate of stroke seen in this trial was no different than expected for this age group.

Rates of MI and TVR were similar to those predicted from the ARTS trials. The nature of the coronary disease in this age group meant that there would be significant in-stent restenosis, but whether or not this would translate into relevant clinical events was a doubt. Many of these patients had significant mobility limitations, but despite this, there was a marked increase in clinical MI and TVR in the BMS group.

The forest plot analysis determined whether specific pre-defined subgroups had different results for the incidence of primary outcomes. None of the groups analyzed showed a benefit for the BMS strategy. Of particular interest was the reduction in primary endpoint events with the DES strategy when using the radial artery for access or performing multivessel procedures.

Study limitations. The inclusion of all-cause mortality as a primary endpoint was a potential confounder in the design of the trial. We included it because the 2 groups of patients had different antiplatelet regimens and there was a potential for increased hemorrhagic deaths in the DES group. The higher rate of noncardiac death in the DES group influenced the final result.

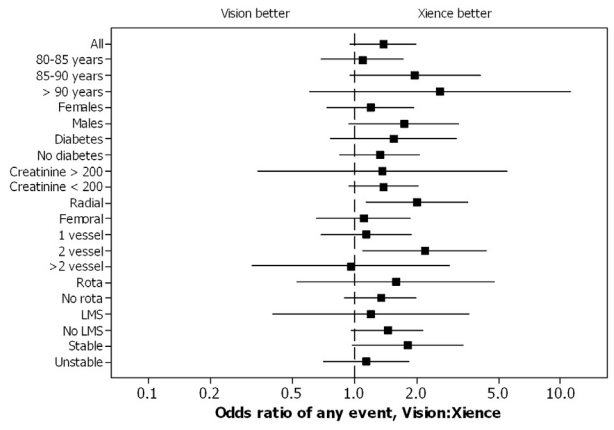

Figure 2 **Forest Plot Determining the Odds Ratio of the Primary Endpoint for Different Subgroups**

There were no subgroups that had better outcomes with the BMS strategy. LMS = left main stem disease; Rota = rotational atherectomy; other abbreviations as in Figure 1.

A significant proportion of patients undergoing implantation of BMS were being treated for an acute coronary syndrome. The protocol encouraged 1 month of DAPT, but some investigators continued the use of DAPT for 1 year, in line with guidelines for the treatment of acute coronary syndromes. Our analysis of this cohort of patients showed no significant increase in bleeding for those treated for 1 month or 1 year.

Conclusions

In patients ≥80 years of age undergoing stent placement for symptomatic coronary disease, DES, when compared with BMS, had no impact on all-cause death, CVA, and major hemorrhage but reduced the incidence of MI and TVR.

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Key Words: bare-metal stent(s) ▪ drug-eluting stent(s) ▪ octogenarians.

APPENDIX

For a list of contributing centers to the XIMA trial and members of the Clinical Events Committee, please see the online version of this article.