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Heart 2005;91:1176-1180; originally published online 9 May 2005;
doi:10.1136/heart.2005.064519

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INTERVENTIONAL CARDIOLOGY AND SURGERY

One year clinical follow up of paclitaxel eluting stents for acute myocardial infarction compared with sirolimus eluting stents

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Accepted 29 April 2005
Published Online First
9 May 2005

Objective: To compare clinical outcome of paclitaxel eluting stents (PES) versus sirolimus eluting stents (SES) for the treatment of acute ST elevation myocardial infarction.

Design and patients: The first 136 consecutive patients treated exclusively with PES in the setting of primary percutaneous coronary intervention for acute myocardial infarction in this single centre registry were prospectively clinically assessed at 30 days and one year. They were compared with 186 consecutive patients treated exclusively with SES in the preceding period.

Setting: Academic tertiary referral centre.

Results: At 30 days, the rate of all cause mortality and reinfarction was similar between groups (6.5% v 6.6% for SES and PES, respectively, $p = 1.0$). A significant difference in target vessel revascularisation (TVR) was seen in favour of SES (1.1% v 5.1% for PES, $p = 0.04$). This was driven by stent thrombosis ($n = 4$), especially in the bifurcation stenting ($n = 2$). At one year, no significant differences were seen between groups, with no late thrombosis and 1.5% in-stent restenosis (needing TVR) in PES versus no reinterventions in SES ($p = 0.2$). One year survival free of major adverse cardiac events (MACE) was 90.2% for SES and 85% for PES ($p = 0.16$).

Conclusions: No significant differences were seen in MACE-free survival at one year between SES and PES for the treatment of acute myocardial infarction with very low rates of reintervention for restenosis. Bifurcation stenting in acute myocardial infarction should, if possible, be avoided because of the increased risk of stent thrombosis.

The efficacy of drug eluting stents to treat coronary artery stenosis in stable patients has been proved in recent trials with single digit restenosis rates for non-complex lesions.¹⁻⁴

The potential risk of higher thrombogenicity, however, has led to prolonged antiplatelet treatment and cautious use of these stents for acute coronary syndromes. We have recently shown that the use of sirolimus eluting stents (SES) for acute myocardial infarction is safe and not associated with higher thrombogenicity.⁵ The safety and efficacy of paclitaxel eluting stents (PES) in this setting has not been reported yet.

A recent meta-analysis clearly showed the benefit of primary percutaneous coronary intervention (PCI) over administration of thrombolytics for the treatment of acute myocardial infarction.⁶ The superiority of (bare metal) stenting over balloon angioplasty has been well documented in the setting of acute myocardial infarction.⁷

We report the one year clinical outcome of a consecutive patient cohort treated solely with PES in the setting of primary PCI for acute ST elevation myocardial infarction. We compared their outcome with that of an earlier published patient population treated with SES.

METHODS

Patients

Since 16 February 2003, PES (Taxus; Boston Scientific, Galway, Ireland) has been implemented in our hospital as the default stent for all patients. Data were collected for the T-SEARCH (Taxus stent evaluated at Rotterdam Cardiology Hospital) registry.⁸ This is a prospective single centre registry

set up with the main purpose of evaluating the safety and efficacy of PES implantation for patients treated in daily practice. Until September 2003, 136 consecutive patients received exclusively PES in the setting of primary PCI for acute myocardial infarction. All patients were enrolled in the analysis including patients in cardiogenic shock (defined as persistent systolic blood pressure < 90 mm Hg or the need for vasopressors or intra-aortic balloon pumping required to maintain blood pressure > 90 mm Hg with evidence of end organ failure and increased left ventricular filling pressures). Patients who underwent rescue PCI after failed thrombolysis were not included in this study.

One year clinical outcome was compared with the one year data from the first 186 patients treated exclusively with SES in the setting of primary PCI for acute myocardial infarction between April 2002 and January 2003, when SES was the default stent in our centre.⁵

This study protocol was approved by the local ethics committee, and written informed consent was obtained from every patient.

Treatment strategy and definitions

The interventional strategy and use of glycoprotein IIb/IIIa inhibitors was left entirely to the discretion of the operator. Clopidogrel was recommended for six months, in addition to

Abbreviations: ASA, acetylsalicylic acid; MACE, major adverse cardiac events; PCI, percutaneous coronary intervention; PES, paclitaxel eluting stents; SES, sirolimus eluting stents; T-SEARCH, Taxus stent evaluated at Rotterdam Cardiology Hospital; TIMI, thrombolysis in myocardial infarction; TVR, target vessel revascularisation

lifelong acetylsalicylic acid (ASA) 80 mg. The loading dose of 300 mg clopidogrel was given before the intervention. If the patient was not taking ASA, 250 mg of intravenous ASA was given at the start of the procedure.

The occurrence of major adverse cardiac events (MACE) was evaluated at one year. MACE were all cause mortality, non-fatal myocardial infarction, and target lesion revascularisation or target vessel revascularisation (TVR).

Reinfarction was defined as new symptoms or new ECG changes in association with an increase in creatine kinase MB fraction concentrations of 1.5 times the previous value if measured within 48 hours or > 3 times the upper normal limit if measured > 48 hours after the index infarction. Target lesion revascularisation was defined as a repeat intervention (surgical or percutaneous) to treat a luminal stenosis within the stent or in the 5 mm distal or proximal segments adjacent to the stent. TVR was defined as a repeat intervention driven by any lesion located in the same epicardial vessel treated at the index procedure. Thrombotic stent occlusion was angiographically documented as a complete occlusion (TIMI (thrombolysis in myocardial infarction) flow grade 0 or 1) or a flow limiting thrombus (with TIMI flow 1 or 2) of a previously successfully treated artery.

Follow up

All patients were clinically followed up. Repeat angiography was clinically driven by symptoms or signs of ischaemia. Information about in-hospital outcomes was obtained from

Table 2 Major adverse cardiac events at 30 days and one year

	SES (n = 186)	PES (n = 136)	p Value*
0–1 month			
Death	5.9%	5.9%	1.0
Death or re-MI	6.5%	6.6%	1.0
TLR	1.1%	4.4%	0.07
TVR	1.1%	5.1%	0.04
Death, re-MI, or TVR	7.5%	10.3%	0.4
Stent thrombosis	0%	2.9%	0.03
0–12 months			
Death	8.1%	8.1%	1.0
Death or re-MI	9.2%	10.3%	0.7
TLR	1.1%	5.9%	0.02
TVR	1.1%	6.6%	0.01
Death, re-MI, or TVR	9.7%	14.7%	0.22
Stent thrombosis	0%	2.9%	0.03

*By Fisher's exact test.

re-MI, reinfarction; TLR, target lesion revascularisation; TVR, target vessel revascularisation.

our institutional electronic clinical database and by review of the hospital records for patients discharged to referring hospitals (patients were referred from 14 local hospitals). Postdischarge survival status was obtained from the municipal civil registries at one, six, and 12 months. Data on all repeat interventions (surgical and percutaneous) and repeat

Table 1 Baseline characteristics

	SES (n = 186)	PES (n = 136)	p Value
Men	74.7%	83.8%	0.06
Age (years)	59.7 (11.7)	59.2 (12.1)	0.7
Diabetes	10.8%	3.7%	0.02
Current smoking	45.7%	44.9%	0.9
Hypercholesterolaemia	33.9%	30.1%	0.5
Hypertension	24.2%	20.6%	0.5
Previous myocardial infarction	14.4%	10.6%	0.4
Previous PCI	6.5%	5.9%	1.0
Previous CABG	1.6%	2.2%	0.7
Coronary artery disease			0.9
1 vessel	54.8%	52.2%	
2 vessel	27.4%	28.7%	
3 vessel	17.7%	19.1%	
Cardiogenic shock	13.4%	11.8%	0.7
Time from symptom onset to PCI (hours)	3.2 (1.9)	3.1 (2.4)	0.7
Infarct related vessel			0.6
LAD	52.7%	51.5%	
LCx	8.2%	8.8%	
RCA	37.4%	36.0%	
Left main stem	1.6%	2.2%	
Saphenous vein graft	0%	1.5%	
Bifurcation lesion	8.6%	9.6%	0.8
Number of vessels treated			1.0
1	84.9%	86.0%	
>1	15.1%	14.0%	
TIMI flow baseline grade			0.4
0–1	73.1%	78.7%	
2	16.5%	11.0%	
3	10.4%	10.3%	
TIMI flow final grade			0.7
0–1	2.1%	2.2%	
2	14.8%	11.8%	
3	83.0%	86.0%	
Number of stents	1.9 (1.2)	1.8 (1.1)	0.4
Total stented length (mm)	34.7 (23.5)	35.9 (22.9)	0.6
Mean nominal stent diameter (mm)	2.89 (0.16)	3.11 (0.33)	<0.001
Glycoprotein IIb/IIIa inhibitor	36.6%	55.1%	0.001
Peak CK (IU)	3126 (3126)	3234 (2567)	0.8
Peak CK-MB (IU)	296 (255)	359 (330)	0.2

Data are mean (SD) or percentage.

CABG, coronary artery bypass graft; CK, creatine kinase; LAD, left anterior descending coronary artery; LCx, left circumflex artery; PCI, percutaneous coronary intervention; PES, paclitaxel eluting stents; RCA, right coronary artery; SES, sirolimus eluting stents; TIMI, thrombolysis in myocardial infarction.

hospitalisations were prospectively collected during follow up. Questionnaires regarding anginal status and medication use were sent to all living patients at six and 12 months. Referring physicians and institutions were contacted for additional information if required.

Statistical analysis

Continuous variables are presented as mean (SD) and were compared by Student's unpaired *t* test. Categorical variables are presented as counts and percentages and compared by Fisher's exact test. All statistical tests were two tailed. The cumulative incidence of adverse events was estimated according to the Kaplan-Meier method and compared by the log rank test. Cox proportional hazards survival models were used to assess risk reduction. Multivariate analyses were performed to identify independent predictors of long term MACE. Significant baseline and procedural characteristics at univariate analysis (tested variables: age, diabetes, cardiogenic shock, multivessel disease, left main stem as the infarct related artery, postprocedural TIMI flow, bifurcation treatment, multivessel treatment, and duration of pain), sex, and stent type were tested for their multivariate predictive value. The first model was built by backwards stepwise variable selection with the exit criteria set at the *p* = 0.1 level; the final model was built by forcing stent type together with all significant predictors.

RESULTS

In total 136 patients were treated with PES only in the setting of primary PCI for acute myocardial infarction in the study period. These patients were compared with 186 patients treated with SES for the same indication in the period before our centre switched to PES as the default strategy. Follow up of the 186 patients with SES from our earlier report⁵ was extended from 300 days to one year for the comparison. At one year after the procedure, follow up was available for 98.4% of patients.

Table 1 lists baseline characteristics. Fewer PES patients had diabetes (3.7% v 10.8%, *p* = 0.02). PES patients had a larger nominal stent size (3.11 v 2.89 mm, *p* < 0.001) and a higher percentage of periprocedural glycoprotein IIb/IIIa inhibitor use (55.1% v 36.6%, *p* = 0.001). Despite inclusion of consecutive patients in both SES and PES groups, the prevalence of diabetes differed significantly. This does not reflect selection bias. The smaller nominal stent size in the SES group reflects the unavailability of SES > 3.0 mm at the time of the study.

MACE were analysed at one month and one year. Table 2 shows the results. No significant difference was seen in death and death or reinfarction between the two groups either in the first month or at late follow up. However, a significant

Table 4 Bifurcation lesions: treatment strategy

	SES (n = 16)	PES (n = 13)	p Value
Main branch stent only	3 (18.8%)	3 (23.1%)	0.4*
Crush	2 (12.5%)	4 (30.8%)	
Culotte	0	1 (7.7%)	
T stent	9 (56.3%)	3 (23.1%)	
V stent	2 (12.5%)	2 (15.4%)	
Final kissing balloon	6 (42.9%)	8 (61.5%)	0.3

*Across all strategies by χ^2 test.

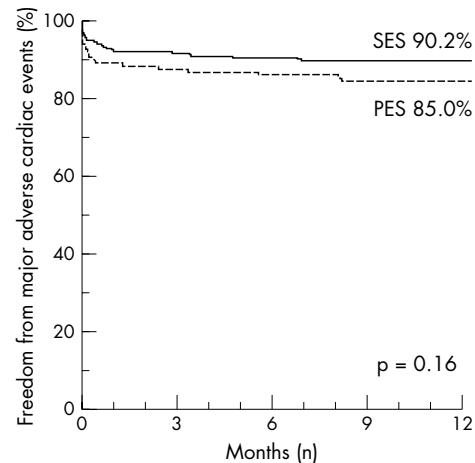


Figure 1 Survival free of death, reinfarction, or target vessel revascularisation of patients who received a sirolimus eluting stent (SES) versus a paclitaxel eluting stent (PES) by Kaplan-Meier estimate.

difference in TVR was seen in favour of SES, which was already apparent at 30 days driven by stent thrombosis.

Six of seven patients with TVR within 30 days in the PES group received target lesion reintervention. Of these, four interventions were necessary because of subacute stent thrombosis (table 3). Only one of these patients had been treated with periprocedural glycoprotein IIb/IIIa inhibitor during the index procedure.

Two of four stent thromboses were in patients treated with bifurcation lesions (one patient with crush bifurcation stenting without kissing balloon postdilatation but with periprocedural glycoprotein IIb/IIIa inhibitor and one patient with T stent bifurcation stenting without kissing balloon postdilatation and without glycoprotein IIb/IIIa inhibitor). The two remaining cases were caused by stent under-expansion, diagnosed at reintervention.

Table 3 Characteristics of individual cases of PES stent thrombosis

	Patient number			
	1	2	3	4
Patient age (years)	59	50	52	47
Sex	Male	Male	Female	Female
Time to thrombosis	1 hour	4 days	4 days	6 days
Lesion type (AHA classification)	B2	B2	C	C
Number of stents	1	1	2	2
Total stent length (mm)	28	24	44	36
Smallest stent diameter (mm)	3.0	3.5	2.25	2.5
Treated vessel	RCA	LAD	LCx, OMcx	LAD, 1st diagonal
Bifurcation stenting	No	No	T stent	Crush
Kissing balloon postdilatation	NA	NA	No	No
Abciximab during index procedure	No	No	No	Yes

AHA, American Heart Association; NA, not applicable; OMcx, obtuse marginal branch of the left circumflex artery.

Table 5 Final Cox regression model of independent predictors of major adverse cardiac events at one year with stent type forced in

Independent predictor	HR	95% CI	p Value
TIMI flow grade 3 (reference)	1.00	NA	NA
2	2.90	0.86 to 9.77	0.09
0 or 1	10.24	2.61 to 40.13	0.001
Cardiogenic shock	4.38	1.63 to 11.8	0.003
Diabetes mellitus	4.77	1.61 to 14.1	0.005
Duration of pain (per hour increment)	1.17	0.98 to 1.39	0.08
Multivessel disease	2.13	0.79 to 5.78	0.14
Use of PES	2.07	0.78 to 5.48	0.14

CI, confidence interval; HR, hazard ratio.

The bifurcation stenting percentage was not significantly different between groups (8.6% v 9.6% for SES and PES, respectively, $p = 0.8$). Although across all strategies no significant difference was found in bifurcation lesion treatment between SES and PES patients, a trend was seen towards more crush stenting and less T stenting in PES patients (table 4).

MACE-free survival at 12 months was 90.2% for SES and 85% for PES patients ($p = 0.16$, by Kaplan-Meier estimate) (fig 1).

On multivariate analysis, stent type was not an independent predictor of MACE at one year and, when forced into the model of significant predictors, remained non-significant ($p = 0.14$) (table 5). However, independent predictors were TIMI flow 0 or 1 (hazard ratio (HR) 10.2), cardiogenic shock (HR 4.4), and diabetes mellitus (HR 4.8).

DISCUSSION

The main finding of this sequential registry report is that patients treated with drug eluting stents for acute myocardial infarction have a very low rate of repeat revascularisation for restenosis at one year's follow up.

Although no significant difference in MACE at one year was found between the two drug eluting stents, a trend to worse outcome was seen in the patients treated with PES, despite more favourable baseline characteristics such as less diabetes, higher use of glycoprotein IIb/IIIa inhibitors, and larger nominal stent diameter.

Short term follow up

The largest difference between the groups was TVR in the first 30 days. These were mainly driven by stent thrombosis.

With respect to these observations of two of 13 stent thromboses in bifurcation lesions and two of 123 in non-bifurcation lesions, it seems prudent to try to avoid using two stents for bifurcation treatment in acute myocardial infarction. If this is unavoidable, the risk for stent thrombosis may be reduced by kissing balloon postdilatation and periprocedural glycoprotein IIb/IIIa inhibitor. In a separate study of 2500 patients we confirmed that bifurcation stenting in acute myocardial infarction was a significant predictor of stent thrombosis and conferred a 13-fold increase in risk.⁹ It may be advisable to keep procedures short and simple for patients undergoing angioplasty for acute myocardial infarction.

The overall rate of stent thrombosis was 1.2% (four of 322) for drug eluting stent use in acute myocardial infarction. This is comparable with the stent thrombosis rate with bare stents^{9,10} and drug eluting stents⁹ used in the treatment of patients for stable coronary lesions.

Long term follow up

Between 30 days and one year two patients treated with PES were referred for TVR, both for in-stent restenosis (1.5%),

compared with no additional interventions for the SES patients.

No late stent thrombosis was diagnosed in either group. In this study, the risk for late stent thrombosis after stopping clopidogrel, which was prescribed for six months for the PES and 3–6 months for the SES group, does not seem to be increased for treatment of patients with acute coronary syndromes with drug eluting stents. It is important that, to address this potential problem conclusively, larger studies specifically looking at this end point be performed. Furthermore, until more is known, complete cessation of antiplatelets should be avoided if possible to avoid the risk of late thrombosis, as McFadden *et al*¹¹ recently pointed out.

Early and one year mortality was identical in both groups (5.9% at 30 days and 8.1% at one year for SES and PES). This is very comparable with earlier studies⁶ despite the presence of cardiogenic shock in 12% of patients and multivessel disease in almost half. As shown before, mortality is not changed by the use of drug eluting stents.⁵ Their benefit is reduction of reintervention as in elective PCI.

The recommendations in the most recent National Institute for Health and Clinical Excellence guidelines explicitly exclude acute myocardial infarction and lesions with visible thrombus as indications for use of drug eluting stents.¹² Our results are reassuring and do not indicate that patients with acute myocardial infarction should be denied the benefit of the very low reintervention rates with drug eluting stents.

Conclusions

The use of PES for the treatment of acute myocardial infarction seems safe. No significant differences were seen with the results of SES at one year's follow up with a very low rate of reintervention for restenosis. However, a trend towards more early reinterventions was evident, mainly due to stent thrombosis. Bifurcation stenting should be avoided in the setting of primary PCI, if possible.

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Study supported by the Erasmus MC, Rotterdam, and by unrestricted institutional grants from Boston Scientific Corporation and Cordis, a Johnson and Johnson company.

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IMAGES IN CARDIOLOGY

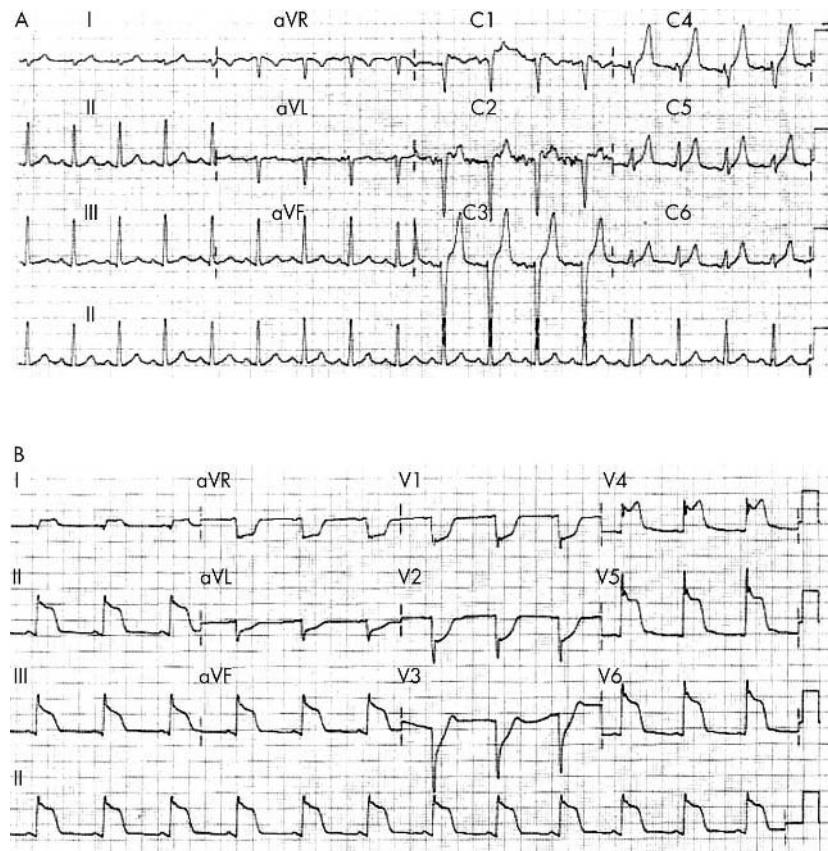
doi: 10.1136/heart.2004.056663

Diabetic keto-acidosis and hyperkalaemia induced pseudo-myocardial infarction

ST segment elevation on ECG has other causes apart from myocardial infarction (MI) and in the thrombolytic treatment era, this may expose the patient to unnecessary drug treatment or invasive procedures that have the potential risk of complications.

A 30 year old insulin dependent diabetic man was treated for severe diabetic keto-acidosis. He was a smoker with a 15 year history of diabetes mellitus. His potassium on admission was 6.5 mmol/l and his ECG showed tall, peaked T wave (panel A). Eight hours following admission, ST segment elevation was noted on the monitor and an inferolateral acute MI pattern (panel B) was confirmed by ECG. The patient had no chest pain but was thrombolyzed with tenecteplase with no resolution of his ST segment elevation; his potassium at the time of the ST elevation was 6.9 mmol/l. He was referred to our centre for coronary angiography, which surprisingly was entirely normal but with poor left ventricular function. Cardiac troponin T was raised at 2.54 µg/l and the ST segment elevation was improving gradually. He was treated medically and made a good recovery and was discharged home seven days later.

Hyperkalaemia may produce multiple ECG abnormalities, including ST segment elevation and pseudoinfarct pattern with resolution of these abnormalities on correcting the hyperkalaemia. When faced with a patient with hyperkalaemia, ST segment elevation may pose a diagnostic and management dilemma regarding the use of thrombolysis. We suggest that while measures are undertaken to correct the metabolic derangement, an immediate referral for coronary angiography should be the first approach. Alternatively, bedside echocardiography, to demonstrate any regional wall motion abnormalities, and cardiac troponin measurement can be used where angiography is not available.



In case of doubts, thrombolysis should not be withheld, as it remains largely safe with life saving effects.

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