Vascular brachytherapy versus sirolimus eluting stents for the treatment of in-stent restenosis: a prospective registry

J J Goy, P Urban, C Seydoux, P Couke, E De Benedetti, J C Stauffer

Since they were first introduced 17 years ago,1 bare metallic stents have improved the outcome of angioplasty.2 However, in-stent restenosis (ISR) remains a major limitation with an incidence of additional revascularisation of 17–21%. Among the several approaches proposed to address this problem, vascular brachytherapy (VBT) has given the best results, with an incidence of major cardiac events at nine months from 18–28%.3 The preliminary results reported with the use of sirolimus eluting stents (SES) in de novo lesions were encouraging.4 We report our results with both techniques in patients with ISR.

METHODS

Between April 2001 and mid April 2002 all patients with ISR were treated with VBT, and from mid April to November 2002 they received one or several SES within the previous stent. The data from these patients were included in a prospective registry. All patients were pre-treated with aspirin 100 mg/day. Intravenous heparin was given initially and a 300 mg loading dose of clopidogrel was administered at the end. In the VBT group, we used the Beta-Cath with a 40 mm Sr-Y90 source train. The radiation dose was calculated after the diameter of the vessel was determined by computer based quantitative coronary angiography, in order to deliver 18–25 Gy at 2 mm from the source. Additional stent implantation was avoided. In the SES group direct stenting was applied whenever possible. A successful procedure was defined as a residual stenosis < 20% and no major cardiac event during the in-hospital stay.

After the procedure patients were monitored and discharged less than 24 hours after the intervention. Aspirin 100 mg/day was given long term and clopidogrel 75 mg/day was prescribed for 3–12 months. For patients with angiographic follow up, restenosis was defined as a 50% or more reduction of the luminal diameter.

Clinical follow up was obtained by a visit or by telephone contact. Control angiography was performed only when clinically required. Cardiac death, myocardial infarction, and additional revascularisation were considered as major adverse cardiac events (MACE). The mean (SD) follow up time was 11 (2) months.

RESULTS

A total of 76 patients were included in the registry. Thirty eight patients were treated with VBT and 38 patients received one or several SES. An additional stent was required in six patients in the VBT group. The demographic and angiographic baseline characteristics were similar in both groups, as well as the classification (Mehran classification) of the ISR. A platelet glycoprotein IIb/IIIa inhibitor was used in 12% of the patients. There was no in-hospital death, myocardial infarction, or need for emergency revascularisation, and no acute or subacute stent thromboses. Early procedure clinical success rate was 100% in both groups and no patient experienced an increased creatine kinase value. Follow up was obtained in 76 patients (100%). Twenty nine patients (38%) underwent control, clinically driven, angiography (VBT = 16, SES = 13). MACE occurred in nine patients (24%) in the VBT group and in two patients (5%) in the SES group, (p = 0.048) (table 1). One patient died suddenly seven days after VBT. However, at necropsy no stent thrombosis was found. The additional procedures in the VBT group were: two coronary artery bypass grafts (CABGs) and six percutaneous coronary interventions (PCIs); and in the SES group two PCIs. No patients in either group experienced myocardial infarction. Angina class was comparable although more patients were in class I in the SES group (74% vs 92%).

DISCUSSION

This registry, which compares VBT with drug eluting stents for the therapy of ISR, suggests that SES are associated with a significantly lower MACE rate at 11 months than VBT, primarily because of a lower requirement for further revascularisation procedures.

ISR leading to repeat revascularisation remains the major limitation following successful PCI. No single pharmacological regimen has been shown to be effective. Only VBT has been shown, in several randomised controlled trials, to have a

Table 1 Demography and incidence of MACE at 11 months

<table>
<thead>
<tr>
<th></th>
<th>Brachytherapy group</th>
<th>SES group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>38</td>
<td>38</td>
</tr>
<tr>
<td>Female</td>
<td>9 (24%)</td>
<td>5 (13%)</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>63 (10)</td>
<td>62 (11)</td>
</tr>
<tr>
<td>Previous myocardial infarction</td>
<td>9 (24%)</td>
<td>12 (32%)</td>
</tr>
<tr>
<td>Previous CABG</td>
<td>4 (11%)</td>
<td>6 (16%)</td>
</tr>
<tr>
<td>First restenosis of</td>
<td>32 (84%)</td>
<td>33 (87%)</td>
</tr>
<tr>
<td>Target lesion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrent restenosis</td>
<td>6 (16%)</td>
<td>5 (13%)</td>
</tr>
<tr>
<td>Prior VBT</td>
<td>0</td>
<td>3 (8%)</td>
</tr>
<tr>
<td>Adverse events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac death</td>
<td>1 (3%)</td>
<td>0</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PCI target lesion</td>
<td>6 (16%)</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>Revascularisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABG target lesion</td>
<td>2 (6%)</td>
<td>0</td>
</tr>
<tr>
<td>Revascularisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Late thrombosis</td>
<td>2 (6%)</td>
<td>0</td>
</tr>
<tr>
<td>MACE</td>
<td>9 (24%)</td>
<td>2 (5%)</td>
</tr>
</tbody>
</table>

Abbreviations: CABG, coronary artery bypass graft; ISR, in-stent restenosis; MACE, major adverse cardiac events; PCI, percutaneous coronary intervention; SES, sirolimus eluting stent; VBT, vascular brachytherapy
positive impact at 6–12 months. The residual incidence of MACE is still 19–28%; however, this is largely determined by a need for further target lesion revascularisation. Recently, preliminary data with the use of drug eluting stents were reported as encouraging in selected groups of patients and in patients with ISR. Our current data are not randomised, a limitation of the trial, and therefore cannot be considered as definite proof that SES is superior, or indeed equivalent, to VBT, but suggest a real benefit of SES over VBT for the treatment of ISR in an unselected patient population. Based on these positive results we have now changed our policy and use SES to treat all our patients with ISR. More definitive conclusions must await the results of ongoing randomised trials.

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REFERENCES

Anomalous origin of the right coronary artery from the left anterior descending coronary artery

A 88 year old woman with systemic hypertension presented with progressive hoarseness due to the presence of a thoracic aortic aneurysm (TAA). She had not experienced any chest pain. As part of her preoperative evaluation, coronary angiography was performed. During coronary angiography, the catheter for the right coronary artery (RCA; 4 French, Judkins RCA 4.0) could not engaged the ostium of the RCA and the injection of contrast medium in the right sinus of Valsalva (RCA 4.0) could not engage the ostium of the RCA and the injection of contrast medium in the right sinus of Valsalva. MDCT was performed. The MDCT revealed that the RCA originated from the proximal LAD, traversed in front of the pulmonary artery, and ran down along the atrioventricular groove between the right atrium and right ventricle. The patient underwent insertion of an endovascular stent graft to treat the TAA and the postoperative course was uneventful. Anomalous origin of the RCA from the LAD is quite rare but this type of anomalous coronary anatomy may not influence the coronary blood flow to the RCA and is associated with good prognosis.

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(Reference Image: Left coronary angiogram showing the right coronary artery originating from the proximal left anterior descending coronary artery, between the first and second diagonal branches. LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery; RCA, right coronary artery.)

(A) Multidetector computed tomography in the left anterior oblique view showing the right coronary artery originating from the left anterior descending coronary artery and traversing in front of the pulmonary artery. (B) Right anterior oblique view showing the right coronary artery traversing in front of the pulmonary artery and running along the atrioventricular groove between the right atrium and right ventricle. Ao, ascending aorta; LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery; PA, pulmonary artery; RA, right atrium; RCA, right coronary artery; RV, right ventricle.)
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