Regular drug eluting stent versus dedicated bifurcation paclitaxel-eluting stent in coronary bifurcation treatment (POLBOS study) – interim analysis

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Background

The provisional T-stenting (PTS) is the recommended strategy for the coronary bifurcation treatment. However, results obtained with use of regular drug eluting stents (DES) are not optimal and relatively often associated with a side branch compromise and restenosis. Dedicated bifurcation stents are claimed to be a solution for these complications. The POLBOS study was to compare two strategies for the bifurcation treatment – PTS with any regular DES or with a dedicated bifurcation paclitaxel-eluting stent BiOSS® Expert (Balton, Poland).

Methods

Patients with stable IHD, UA or NSTEMI were enrolled. A single stent implantation in the main vessel-main branch (MV-MB) across a side branch (SB) was the default strategy. A stent in SB was implanted only in case of the significant flow impairment. Sequential envelope system located in each center was used for blinded randomization (1:1). The primary endpoints were MACEs (in-hospital and after 1, 3, 6, 12 months). An angiographic control was planned at 9 months in all patients.

Target lesion revascularization

<table>
<thead>
<tr>
<th>Group</th>
<th>Whole DES group</th>
<th>p</th>
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<tbody>
<tr>
<td>BiOSS group</td>
<td>10.99%</td>
<td>8.9%</td>
</tr>
<tr>
<td>paclitaxel DES subgroup</td>
<td>10.99%</td>
<td>12.8%</td>
</tr>
<tr>
<td>BiOSS group</td>
<td>5.7%</td>
<td>&lt; 0.05</td>
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</tbody>
</table>
Disclosure

RJG – Balton medical consultant, DV, JB, AK, RF, SD, IU – no disclosure

Results

BiOSS Expert was implanted in 119 patients (49.4%) and regular DES was implanted in 122 patients (50.6%). In BiOSS group there were significantly more patients with NSTE-ACS (9.6% vs 3.5%), diabetes (32.2% vs 16.8%), prior MI (45.2% vs 32.7%), prior CABG (8.7% vs 3.5%) and with chronic kidney disease (15.7% vs 7.1%). In DES group there were more patients addicted to smoking (13% vs 22.1%).

The dominant vessel was LAD (BiOSS vs DES: 52.1% vs 70.5%) followed by LMS (22.7% vs 13.9%, respectively). According to Medina classification true bifurcations were present in 70%. In DES group 33% of stents eluted paclitaxel. There were 16% and 11.2% cases with second stent implanted within the side branch, respectively in BiOSS group and DES group. There was also trend to shorter radiation time and smaller contrast media volume in BiOSS group.

At one and three months all patients were unevengul (out-of hospital MACE rate 0%). Up to now control angiography was performed in 76.4% of patients in BiOSS group and in 73.8% of patients in DES group. TLR in BiOSS group was 10.99%, whereas in regular paclitaxel-eluting stents subgroup – 12.8%.

Conclusions

Interim analysis has shown that dedicated paclitaxel eluting bifurcation stent provides satisfactory results which seem to be inferior to those obtained by means of –limus eluting stents, but comparable with those of paclitaxel-eluting stents.