TCT-178

Primary Endpoint Results from the TAXUS Element Post-Approval Surveillance Study (TE-PROVE): 1-Year Outcomes in Unselected Patients Treated With a Thin-Strut, Platinum-Chromium, Paclitaxel-Eluting Stent

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Background: The TE-PROVE post-market registry is evaluating clinical outcomes for patients receiving the third-generation, paclitaxel-eluting, platinum chromium TAXUS Element (TM) stent (Boston Scientific, Natick, MA) over 5 years in a real-world setting. This is the first report of results from this large multicenter registry.

Methods: This was a prospective, open-label, multicenter observational ‘all-comers’ study that included 1014 patients at 37 sites in Europe. Follow-up was at 30 days, 6 months, and 1 year, and will continue annually through 5 years. The primary endpoint was the overall and TAXUS Element stent-related target vessel failure rate (TVF) defined as cardiac death, and target vessel-related myocardial infarction (MI) and reintervention (TVR) at 1 year post-implantation. Secondary endpoints included the cumulative incidences of all-cause mortality, and ARC-definition/probable/stable thrombosis.

Results: Among 1014 enrolled patients, 1-year clinical follow-up or death occurred in 97.3% (987/1014) of patients. Patients were 75.0% male (760/1014), median age was 65.1±10.8 years, 25.5% had medically treated diabetes (259/1014), and 10.7% (109/1014) were treated for STEMI at baseline. Mean lesion length among 1299 treated patients was 19.8±10.1 mm and mean reference vessel diameter was 3.1±0.5 mm. At 1 year, the rate of TVF (primary endpoint) was 6.0% (59/987), of which 3.7% (37/987) was considered related to the study stent. Cardiac death was 0.7% (7/987), and TVR was 4.7% (46/987). All-cause death occurred in 1.2% (12/987) patients and ARC-definition/probable ST was 0.5% (5/987). Additional outcomes for subsets, including small vessels, long lesions, and diabetes, will be available at the meeting.

Conclusions: The primary endpoint results from the TE-PROVE registry demonstrate good performance and safety for the TAXUS Element paclitaxel-eluting stent at 1 year in everyday clinical practice.

TCT-179

Safety and Efficacy of Everolimus-Eluting Stents Versus Zotarolimus-Eluting Stents for 3-year of Follow-Up in Real-World Practice

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Background: There are limited data for comparing the safety and efficacy of everolimus-eluting stent (EES) versus zotarolimus-eluting stents (ZES-R) for long-term follow-up. This study evaluated the safety and efficacy of these two stents in real-world practice for 3-year of follow-up.

Methods: 926 patients who treated with EES (Xience V, Abbott Vascular, USA: n =459) and ZES-R (Endeavor Resolute, Medtronic Cardiovascular, USA; n = 467) were analyzed using single center registry from 2008 to 2010 except excluding the patients with cardiogenic shock at admission and the patients with in-hospital mortality for reducing the potential selection bias. Primary endpoint was a composite of any death, any myocardial infarction, and target vessel-revascularization at 3-year of follow-up.

Results: ZES-R group was younger (64.5±10.8 year vs. 66.0±10.2 year, p = 0.033) than EES group, but other baseline characteristics and laboratory findings were similar between two groups. EES was more used for left main lesion (9.8% vs. 3.9%, p < 0.001) but ZES-R was more used for right coronary artery (30.3% vs. 41.3%, p < 0.001). Although implanted number of stent was not different between two groups, EES was larger in diameter (3.11±0.42 mm vs. 3.00±0.40 mm, p = 0.026) and shorter in length (40.2±24.7 mm vs. 45.3±25.7 mm, p = 0.002) compared with ZES-R. Discharge medication was not different between two groups. During 3-year of follow-up (920±206 days in EES group vs. 900±216 days in ZES-R group, p = 0.152), primary endpoint was not different between two groups (14.4% in EES group vs. 16.3% in ZES-R group, p = 0.466). Stent thrombosis was similar between two groups (0.9% vs. 1.3%, p = 0.387).

Conclusions: In this real-world registry with unrestricted use of EES and ZES-R, two new generation drug-eluting stent showed comparable safety and efficacy during long-term follow-up.

TCT-180

One-Year “Real-World” Outcomes Following Implantation of the ICON™ Paclitaxel-Eluting Platinum Chromium Coronary Stent in Routine Clinical Practice: Primary Endpoint Results of the ICON U.S. Post-Approval Registry

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Background: The ICON Registry assessed clinical outcomes for the thin-strut, ICON™ (TAXUS Element) Paclitaxel-Eluting Platinum Chromium Coronary Stent System (Boston Scientific, Natick, MA) in unselected patients. This is the first report of results from this large multicenter registry.

Methods: This prospective, open-label registry enrolled the first 1121 consenting patients treated with the ICON stent for any indication at 40 clinical sites in the United States. Follow-up was at discharge, 30 and 180 days, and annually to 5 years. The primary endpoint was the 1-year rate of cardiac death or MI in PERSEUS-like patients (JACC 2010;56;264-71). Per protocol, the primary endpoint result from the ICON registry was also combined with the European post-approval registry (TE-PROVE), which enrolled 306 PERSEUS-like patients, and the PERSEUS WHSV populations (N=1166).

Results: 1111 patients received a study stent, 316 were PERSEUS-like, and 1-year follow-up was 92.1% (1023/1111). Most patients were male (70.3%, 781/1111) with a mean age 64.1±11.0 years. At 1 year, the primary endpoint of CD/MI occurred in 1.1% (62/592) of PERSEUS-like patients in ICON and 2.3% (40/1729) patients in the combined analysis. The upper 1-sided 95% CI for the combined analysis was 2.9%, which was significantly less than the prespecified performance goal of 7.6% (P<0.001). Secondary endpoints and subgroups are given in the Table.

Table. 1-Year Cardiac Events for the Overall Population and Subsets of the ICON U.S. Post-Approval Registry

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Overall (n=1111)</th>
<th>PERSEUS-like (n=316)</th>
<th>PERSEUS-like (n=316)</th>
<th>PERSEUS-like (n=316)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD/MI</td>
<td>9.4% (77/987)</td>
<td>0.7% (2/281)</td>
<td>1.2% (3/257)</td>
<td>4.0% (24/601)</td>
</tr>
<tr>
<td>MI</td>
<td>9.8% (76/987)</td>
<td>0.7% (2/281)</td>
<td>1.2% (3/257)</td>
<td>4.0% (24/601)</td>
</tr>
<tr>
<td>TVR</td>
<td>2.6% (25/1028)</td>
<td>0.7% (2/281)</td>
<td>1.2% (3/257)</td>
<td>4.0% (24/601)</td>
</tr>
<tr>
<td>ARC ST</td>
<td>11.0% (116/1028)</td>
<td>11.6% (20/172)</td>
<td>11.0% (20/172)</td>
<td>11.6% (20/172)</td>
</tr>
<tr>
<td>Total MACE</td>
<td>29.4% (309/1028)</td>
<td>27.2% (23/85)</td>
<td>27.2% (23/85)</td>
<td>27.2% (23/85)</td>
</tr>
</tbody>
</table>

Conclusions: The 1-year results of the ICON U.S. Post-Approval Study confirm the safety and effectiveness of the ICON stent for the treatment of coronary artery disease in everyday clinical practice.