Initial treatment results of Eluvia paclitaxel-eluting stent for treatment of femoropopliteal lesions in Japanese population

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Disclosure

Speaker name: Katsutoshi Takayama, MD.

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest
Background

The MAJESTIC clinical study in European population using the Eluvia Drug-Eluting Stent (Boston Scientific, Marlborough, MA) showed a high patency rate at one year and up to 3 years after treatment for femoropopliteal artery lesions.

On the other hand, February 2019, Eluvia stent became available in Japan. There is no published studies was treated with Eluvia Drug-Eluting Stent in Japanese population.
Purpose

Our aim was to assess safety and effectiveness of Eluvia paclitaxel-eluting stent for treating femoropopliteal lesions in Japanese population.
Material and Methods

The prospective, two centers study enrolled 103 patients, 125 limbs (mean age 75.6 years [range 53-90]; 47 men) with intermitted claudication and chronic lower limb ischemia referable to de novo or restenotic lesions after stent placement in the superficial femoral and/or proximal popliteal arteries between January 2019 and December 2019.
Major inclusion/exclusion criteria

Major inclusion criteria
1) Age > 40 years
2) Symptomatic ISR (Rutherford-Becker category 2 to 5), in the SFA and P1 segment of the popliteal artery, and a distal runoff of at least 1 artery

Major Exclusion criteria
1) Inability to give written informed consent;
2) Known allergy, hypersensitivity, or intolerance to radiologic contrast media, aspirin, clopidogrel and Paclitaxel
3) Creatinine >2.5 mg/dl (except hemodialysis patients)
Interventional Radiology Procedure

- Pre and post dilation were performed at the interventionalist discretion.
- Unfractionated heparin was administered during the procedure to maintain an activated clotting time over 250 second.
- Dual antiplatelet agent (Aspirin 81 to 100 mg and Clopidogrel 75 mg) was administered at least 24 h before the procedure. Following treatment, Dual antiplatelet therapy was continued for at least 90 days and mono antiplatelet therapy was continued for life.
Demographics and Baseline Characteristics
n: 103, 125 limbs

- Male, n (%) 78 (75.7%)
- Mean age ± SD 76.3 ± 8.7
- Hypertension, n (%) 86 (96.0%)
- Diabetes, n (%) 63 (67.6%)
- Hyperlipidemia, n (%) 43 (67.6%)
- Previous smoking, n (%) 60 (61.9%)
- Active smoking, n (%) 28 (27.1%)
- Coronary artery disease, n (%) 22 (21.3%)
- Cerebrovascular disease, n (%) 67 (53.6%)
- Rutherford stage II-III n (%) 71 (56.8%)
- Rutherford stage VI, n (%) 23 (18.4%)
- Rutherford stage V, n (%) 20 (16.0%)
- CLI 43 (34.4%)
<table>
<thead>
<tr>
<th>Lesion</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>de novo stenosis</td>
<td>51 (40.8%)</td>
</tr>
<tr>
<td>de novo occlusion</td>
<td>32 (25.6%)</td>
</tr>
<tr>
<td>in-stent stenosis</td>
<td>28 (22.4%)</td>
</tr>
<tr>
<td>in-stent occlusion</td>
<td>14 (11.2%)</td>
</tr>
<tr>
<td>occlusions</td>
<td>46 (36.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Length of the treated lesion</th>
<th>Mean ± SD (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20.2 ± 8.7</td>
</tr>
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<table>
<thead>
<tr>
<th>The number of distal run off</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>76 (60.8%)</td>
</tr>
<tr>
<td>2</td>
<td>33 (26.4%)</td>
</tr>
<tr>
<td>3</td>
<td>8 (6.4%)</td>
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</tbody>
</table>
Study Endpoints

Primary endpoint
Primary patency at 6-month, 12-months follow-up
< A peak systolic velocity ratio 2.4

Secondary endpoint
Technical success rate (residual stenosis <30%)

Major adverse event
Stent thrombosis and device related adverse event
Target limb major amputation through 12 months
Target lesion revascularization (TLR) through 12 months
Primary patency at 6 months

The average of postoperative monitoring (months): 5.5 ± 2.14
Number at risk: 72

KAPLAN-MEIER PRIMARY PATENCY RATE

92.5%
Secondary Endpoint

6.73 ± 2.67 (months)

Technical success 100% (125/125)
the MAEs rate 8/103 (5.8%)
Death within 30 days 1/103 (2.9%)
due to brain hemorrhage
Stent thrombosis within 30 days 2/125 (1.6%)
due to poor responder for clopidogrel
Psudoaneurysm of proximal SFA 1/125 (0.8%)
Pts underwent surgical repair after stent was removed.
Target Limb Major Amputation 2/125 (1.6%)
Target Lesion Revascularization 3/125 (2.4%)
n:57 (Mean lesion length: 70.8 ± 28.1 mm)

Primary patency at 24 months: 83.5%
TLR at 36 months: 85.3%
No major target limb amputations occurred

1-Year All-Comers Analysis of the Eluvia Drug-Eluting Stent for Long Femoropopliteal Lesions After Suboptimal Angioplasty

Theodosios Bisdas, MD, Efthymios Beropoulis, MD, Angeliki Argyriou, MD, Giovanni Torsello, MD, Konstantinos Stavroulakis, MD

n:62 long femoropopliteal lesions
(Mean lesion length: 20 ± 12 cm)

Primary patency at 12 months 87%
Amputation-free survival in CLI patients 87%
Aneurysm formations 8%
to be attributable to paclitaxel

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In conclusion

The Eluvia drug-eluting stent showed promising high patency and low MAE rates through at least 6 months in real-world femoropopliteal lesions in Japanese population.
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