PrOspective multiCentEr study of cArotid artery steNting Using mer Stent

OCEANUS study

Przemysław Nowakowski
on behalf of all investigators

Department of Vascular Surgery AHoP Chrzanow

American Heart of Poland
Open cell
- Good flexibility
- Less plaque

Closed cell
- Good plaque
- Less flexibility
Differences in cell size by stent

Cell Sizes - Carotid Stents

- Precise prox.
- Precise mid.
- Precise dist.
- Acculink prox.
- Acculink mid.
- Acculink dist.
- Protégé prox.
- Protégé mid.
- Protégé dist.
- Xact prox.
- Xact mid.
- Xact dist.
- Wallstent prox.
- Wallstent mid.
- Wallstent dist.
- Cristallo prox.
- Cristallo mid.
- Cristallo dist.

MER
MER - cell area 6.2 mm²
PrOspective multicentEr study of cArotid artery steNting Using mer Stent– OCEANUS

- Self-expanding nitinol stent dedicated to carotid artery
- Open cells design
- Strut thickness: 0.19 mm
- Cell area: 6.2 mm²
- Atraumatic, flexible distal tip of the 5F delivery system
Enrollment and timelines

- First patient in the study: 10–Oct–2016
- Last patient enrollment to the study: 23–May–2017
- 1 month FU was completed for all subjects: Jun–2017
- 6 months FU was completed for all subjects: Nov–2017
- 12 months FU was completed for all subjects: June 2018

Enrollment by Sites

- Department of Vascular Surgery, John Paul II Hospital Cracow, Poland: 47
- The Department of Vascular Surgery, American Heart of Poland, Chrzanow, Poland: 23
- Department General and Vascular Surgery, University Katowice, Poland: 22
- Institute of Psychiatry and Neurology 2nd Department of Neurology, Warsaw, Poland: 8
OCEANUS endpoints

PRIMARY
• Stroke in 30 day follow-up

SECONDARY
• MAE (Major Adverse Events) death, stroke, MI in 30 days f–u
• MAE (Major Adverse Events) death, stroke, MI in 365 days and 2 years f–u
• Restenosis rate (%DS ≥50%) in 365 days and 2 years f–u
• Target Vessel Revascularization (TVR) in 365 days 2 years f–u
• Residual stenosis after CAS >30%
• SADE – Serious Adverse Device Event
### Demographics and baseline data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Measure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at enrollment, years</td>
<td>n 100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean (±SD) 68.55 (±8.24)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean 95% CI (66.87; 70.23)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Me (Q1; Q3) 68.00 (62.00; 75.00)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Min/Max 51.00 / 85.00</td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg</td>
<td>n 100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean (±SD) 152.39 (±23.68)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean 95% CI (147.51; 157.26)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Me (Q1; Q3) 152.00 (135.00; 170.00)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Min/Max 83.00 / 213.00</td>
<td></td>
</tr>
<tr>
<td>Diastolic blood pressure, mmHg</td>
<td>n 100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean (±SD) 78.41 (±11.48)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean 95% CI (76.04; 80.77)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Me (Q1; Q3) 80.00 (70.00; 85.00)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Min/Max 53.00 / 120.00</td>
<td></td>
</tr>
<tr>
<td>Diameter stenosis NASCET, %</td>
<td>n 100</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean (±SD) 76.42 (±9.79)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean 95% CI (74.40; 78.43)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Me (Q1; Q3) 76.00 (72.00; 83.00)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Min/Max 49.00 / 95.00</td>
<td></td>
</tr>
</tbody>
</table>

### Bar Chart

- **Previous stroke**
  - Hypertension: 90%
  - Hypercholesterolemia: 69%
  - Male: 64%
  - Current or previous smoking: 57%
  - Symptomatic subject: 45%
  - Previous stroke: 41%
  - Diabetes mellitus: 38%
  - Previous PCI: 33%
  - Previous MI: 26%
  - Previous TIA: 20%
  - Previous CABG: 14%
  - Family history of stroke: 12%
Baseline lesions characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Measure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter stenosis QCA</td>
<td>n</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Mean(±SD)</td>
<td>82.10 (±9.23)</td>
</tr>
<tr>
<td></td>
<td>Mean 95% CI</td>
<td>(80.17; 84.03)</td>
</tr>
<tr>
<td></td>
<td>Me(Q1:Q3)</td>
<td>80.00 (77.00; 90.00)</td>
</tr>
<tr>
<td></td>
<td>Min/Max</td>
<td>56.00 / 99.00</td>
</tr>
<tr>
<td>Reference vessel diameter, mm</td>
<td>n</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Mean(±SD)</td>
<td>5.69 (±0.94)</td>
</tr>
<tr>
<td></td>
<td>Mean 95% CI</td>
<td>(5.49; 5.89)</td>
</tr>
<tr>
<td></td>
<td>Me(Q1:Q3)</td>
<td>5.80 (5.00; 6.00)</td>
</tr>
<tr>
<td></td>
<td>Min/Max</td>
<td>2.60 / 8.00</td>
</tr>
<tr>
<td>Lesion length, mm</td>
<td>n</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Mean(±SD)</td>
<td>17.04 (±8.34)</td>
</tr>
<tr>
<td></td>
<td>Mean 95% CI</td>
<td>(15.28; 18.79)</td>
</tr>
<tr>
<td></td>
<td>Me(Q1:Q3)</td>
<td>15.00 (10.00; 21.65)</td>
</tr>
<tr>
<td></td>
<td>Min/Max</td>
<td>2.80 / 46.50</td>
</tr>
</tbody>
</table>

Lesion characteristics

- **CCA**: 6%
- **ICA**: 94%

Calcification
- **Calcification**: 51%
- **Mild calcification**: 23%
- **Moderate calcification**: 21%
- **Moderate-severe calcification**: 7%

### Procedural data

#### Neuroprotection systems used

- **SpiderFX**: 31%
- **FilterWire**: 27%
- **Mo.MA**: 18%
- **Emboshield**: 9%
- **WIRION**: 8%
- **Robin**: 7%

#### Variable | Measure | Total
--- | --- | ---
Occlusion time for proximal protection, min:sec | n | 18
| Mean (±SD) | 6:19 (±2:55)
| Mean 95% CI | (4:46; 7:52)
| Me(Q1;Q3) | 4:45; 7:08
| Min/Max | 3:30 / 16:00
MER® stents used during procedure

Data reported for 100 subjects

Two subjects required 2\textsuperscript{nd} stent implantation (102 stents used)
Do we still need open-cell carotid stents ????

Unique vessel flexibility and adaptability with carotid MER stems.
High grade angulation LICA. Excellent MER flexibility.
Ruptured plaque in LICA. Excellent MER laying and plaque covering.
Symptomatic patient with bovine arch LICA symptimatic stenosis.
Right radial artery access.
Diagnostic angiogram.
Inserted EPD – Robin by Balton.
Implanted MER stent.
Control angiogram. Good MER plaque covering.
Final angiogram.
Complication during hospitalization & 30d follow-up

- TIA 0%
- Stroke minor (ischemic) at day 4 – 1pts 1% !!!
- Death 0%
- MI 0%
- Edge dissection required additional MER stent implantation 1pts – 1%
- Hematoma or bleeding complication 0%
- Renal insufficiency 0%
- Hypotonia required inotropic agents – 1pts 1%
7 MAE during 12 months follow-up !!! (6 patients)

Stroke (ischemic) at day 4 – 1 pt (30 days observation)

Death: 3 pts
- 1 pt cardio–pulmonary insufficiency
- 1 pt complication during treatment of acute leg ischemia
- 1 pt died due to suicide !!

MI – 3 pts – 2 pts successfully treated with PCI
1 pt died due to post MI complications.

ADDITIONAL IMPORTANT EVENT
1 pt developed instant restenosis required re CAS
Excellent 6 months follow-up with MER stents
Excellent 12 months follow-up with MER stent.
Conclusions

- CAS is a fast developing interventional treatment of carotid artery stenosis.

- Great technological progress is observed in the field of devices used for CAS, for example a new MER carotid stent.

- The 30-day, 6-month and 1 year clinical outcomes of 100 patients treated with a MER stent show very good results.

- Our study suggests that the MER stent is safe and effective device for endovascular treatment in both symptomatic and asymptomatic patients.
lucky men in korea

thank you