The vascular surgeon’s perspective: Italian comparative experience of Roadsaver vs. other stents

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Disclosure

Speaker name:
Andrea Kahlberg

I have the following potential conflicts of interest to report:

☒ Consulting (Alvimedica, Boston Sc., Medtronic, Gore, Terumo, Abbott)
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
A brief foreword...
Current ESVS Guidelines

CAS never an indication, always an alternative
When vascular surgeons choose CAS?

Post-CEA restenosis
Post-irradiation stenosis
Hostile neck
"High" stenosis

Systemic high-risk conditions
(i.e. cardiac comorbidities)
SO a lot of SELECTED, HIGH-RISK patients....
...already considered UNFIT for surgery!
What do I need?
Optimal material (carotid stents)

- Double-layer (scaffold)
- Flexible (follow tortuositises)
- Adapt to different diameters
- Covering long lesions
- Low profile (5F)
- High deliverability (navigation)
New generation stent design

Double layer, braided mesh: Roadsaver (Terumo)

All sizes 5-Fr compatible
When CAS was considered impossible...

• M, 84 yrs
• Symptomatic RICA 80%
  post-irradiation stenosis
• Two failed CAS attempts
  @ other Centers
  (both with femoral access)
New strategy: radial access

Access from right radial artery

Inability to advance any catheter
Facing tight angulation

ECA “anchoring technique”
(5 x 30mm-balloon + Flexor 6F)
Distal EPD

Filter positioning (Spider FX + ECA buddy-wire)
NO WAY to cross angulation with old stents!

Standard open-cell stent attempt
Solution is the new technology

Advancing a Roadsaver stent
Stent must adapt to tortuosity

Stenting (Roadsaver 9 x 30 mm)
“Unexpected” procedural success

Final result
San Raffaele comparative experience

April 2015 – December 2018
Study design

• Single-center, retrospective, non-randomized study

• **Comparison of procedural data and outcomes for patients treated with Roadsaver vs. first generation carotid stents**

• **Primary endpoint:**
  - Major adverse cerebrovascular events (MACE) including death, ipsilateral stroke, and TIA

• **Secondary endpoints:**
  - Procedural time
  - Type of access
  - Adverse cardiovascular events
  - Primary patency* through 5 years

*Freedom from reintervention, stent occlusion, or in-stent restenosis (PSV < 250 cm/s)

1438 carotid stenosis patient referrals for revascularization

Vascular Surgery Team

CAS in n=199 patients (bilateral in 6)*

(14.26%)

(85.74%)

CEA in n=1233 patients

205 CAS (pts. @ high-risk for CEA)

100 Roadsaver

15 CGuard*

VS

90 other stents (single-layer)

*Excluded from statistical analysis
Cases included in the analysis (2015 – 2018)

190 CAS

100 Roadsaver vs 90 other stents

- 39 Precise Pro Rx
- 37 Xact
- 9 Carotid Wallstent
- 5 Cristallo Ideale
Preoperative differences between the two groups

«Roadsaver» group vs «Other stents» group
Carotid disease characteristics

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<td>75.6±8.0</td>
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<td>Peak systolic velocity (cm/s)</td>
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<td>&quot;High-risk&quot; plaque type</td>
<td>63 (63%)</td>
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<td>3 (3%)</td>
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<td>5 (5%)</td>
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<td>28 (28%)</td>
<td>10 (11%)</td>
<td>0.003</td>
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Patients treated with Roadsaver presented more «high-risk»* plaques

*Defined as SVS grade 2 (moderate risk) and 3 (severe risk), i.e. multi-fibrous plaque, ulcerated, thin capsule, multiple calcifying stenosis or lipid / necrotic core
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Roadsaver patients were more symptomatic and had more previous brain lesions as detected by preop CT scan.
Procedural data

«Roadsaver» group VS «Other stents» group
Intraoperative details

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<td>23 (23%)</td>
<td>4 (5%)</td>
<td>&lt; 0.001</td>
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<tr>
<td>Cervical surgical access</td>
<td>1 (1%)</td>
<td>14 (16%)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Use of embolic protection devices</td>
<td>98 (98%)</td>
<td>84 (93%)</td>
<td>0.152</td>
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CAS with Roadsaver was performed more frequently through radial access (> 4x) and required less cervical cut-down.
Radial access (LICA)

Right radial artery access for left carotid catheterization
Advancement of 5 Fr hydrophilic sheath on 0.018” Advantage Track guidewire
Radial access (LICA)

Stenting (Roadsaver 8 x 30 mm)
# Intraoperative details

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<td>Use of embolic protection devices</td>
<td>98 (98%)</td>
<td>84 (93%)</td>
<td>0.152</td>
</tr>
<tr>
<td>Need of predilatation</td>
<td>2 (2%)</td>
<td>3 (3%)</td>
<td>0.669</td>
</tr>
<tr>
<td>Number of implanted stents</td>
<td>1.1±0.3</td>
<td>1.1±0.3</td>
<td>1.0</td>
</tr>
<tr>
<td>Stent length (mm)</td>
<td>31.0±5.5</td>
<td>36.8±5.5</td>
<td>&lt; 0.01</td>
</tr>
<tr>
<td>Stent post-dilatation</td>
<td>92 (92%)</td>
<td>70 (78%)</td>
<td>0.007</td>
</tr>
<tr>
<td>Atropine administration</td>
<td>16 (16%)</td>
<td>12 (13%)</td>
<td>0.684</td>
</tr>
<tr>
<td><strong>Duration of procedure (min)</strong></td>
<td><strong>40.7±16.9</strong></td>
<td><strong>49.4±27.3</strong></td>
<td><strong>0.008</strong></td>
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CAS procedures with Roadsaver were significantly shorter.
CAS outcomes

«Roadsaver» group VS «Other stents» group
30-day results

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<td>Length of stay (mean ± SD)</td>
<td>2.25 ± 1.22</td>
<td>2.27 ± 1.03</td>
<td>0.903</td>
</tr>
<tr>
<td>Access complications</td>
<td>0 (0%)</td>
<td>2 (2%)</td>
<td>0.223</td>
</tr>
<tr>
<td>Cerebral hemorrhage</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Inotropic support</td>
<td>3 (3%)</td>
<td>3 (3%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Arrhythmias</td>
<td>1 (1%)</td>
<td>1 (1%)</td>
<td>1.0</td>
</tr>
<tr>
<td>TIA</td>
<td>3 (3%)</td>
<td>1 (1%)</td>
<td>0.623</td>
</tr>
<tr>
<td>Stroke</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>MI</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Death</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Any complications</td>
<td>6 (6%)</td>
<td>6 (7%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Stroke/TIA/Death</td>
<td>3 (3%)</td>
<td>1 (1%)</td>
<td>0.623</td>
</tr>
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No significant differences in primary endpoint (stroke/TIA/death)
Follow-up (22.3 + 13.9 months)

No significant differences in primary patency

**Roadsaver group**
- 5 in-stent restenosis
- no stent occlusion

**Other stents group**
- 5 in-stent restenosis
- 1 stent occlusion
Conclusions
Roadsaver vs other stents in vascular surgery practice

• Due to its technical features, operators tend to select Roadsaver for use in high-risk cases (symptomatic pts, vulnerable plaques, difficult access etc)

• Despite expected higher rate of complications in these patients, CAS with Roadsaver resulted in comparable outcomes (early and late)
Roadsaver vs other stents in vascular surgery practice

- Roadsaver low-profile and high deliverability allow to increase the use of radial access, avoid cervical surgical cut-down, reduce arch manipulation, and decrease procedural time