My journey with Roadsaver through the last four years!

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Disclosure

Speaker name: PIOTR PIENIAZEK.

I have the following potential conflicts of interest to report:

- [x] 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
The Krakow Program of Stroke Prevention by Carotid Artery Stenting (from Jan 2001)

- **comprehensive** patient evaluation including non-invasive imaging:
  - extra- and intracranial Doppler
  - extra- and intracranial CT angio
  - brain perfusion (MRI)
- **independent** neurological consultation (NIHSS, MMSE, Rankin Scale)

3710 CAS procedures in a single Krakow Center

- **coronary angiography** prior to CAS (except pts. after CABG or recent PCI)
- **rigorous** follow-up
Tailored CAS: Protocol for Patient- and Lesion-Specific Selection of the Neuroprotection System and Stent Type

General direct stenting strategy

Soft/thrombus-containing plaque or a severe string-sign lesion in a symptomatic patient (Fig. 1A1, 1B, 1E)

Predilate only if very tight or highly calcified lesion according to duplex ultrasound, CTA, and angiography.

1. Use a proximal NPD (flow reversal if (non-critical) ECA stenosis or severe angulation that precludes the use of a (one-piece) proximal flow blockade system); if no ECA stenosis/tortuosity, either of the 2 proximal systems can be used.

2. Use a closed-cell stent (cobalt-alloy braided in a straight segment; nitinol if tortuous).

Use an independent-wire filter with 1.25- to 1.5-mm balloon dilation prior to filter delivery or a 6-F–compatible distal occlusion system.

Use an open-cell stent.

Consider a hybrid (open-cell/closed-cell/open-cell) stent.

Consider cutting balloon predilation; avoid aggressive postdilation.

1. Use a distal NPD (Fig. 1A2).

2. Use open- or closed-cell stent (depending on the target segment tortuosity).

(1) Consider treating the less severe lesion with distal NPD first.

(2) If the contralateral lesion is tight/soft/symptomatic, treat it under proximal NPD (within a few days).

Consider using a tapered (nitinol) stent.

Use a proximal NPD; if not applicable (no femoral access, diffuse iliofemoral atherosclerotic disease, or severely angulated arch), use a distal occlusion system.

Use a transradial or brachial approach with a 6-F–compatible filter or distal occlusion system.

(1) Consider proximal NPD (document collateral supply via the basilar and posterior communicating artery(ies) on TCD).

(2) If proximal NPD excluded, use an independent-wire filter with 1.25 to 1.5-mm balloon predilation prior to filter delivery (Fig. 1C).

(3) Use a closed-cell stent.
From 2014 we started to treat high risk CAS procedures with ROADSAVER “Mesh” Stents.
Lesion specific stenting: for better protection from late embolization

- Main goal: sustained anti-embolic protection

What we have changed in practice from 2014

Lesion specific stenting: particular in symptomatic & high risk lesion!

High risk CAS

Roadsaver stent
RoadSaver Carotid Stent

- double layer micromesh scaffold
- enabling sustained embolic protection by very tight plaque coverage
- embolic protection starts with implantation of the stent into the lesion and continues throughout the process of neointimalization due to small free cell area (0.38mm²)
- Up to 50% deployment full re-sheathable and repositionable
- Extremely flexible – first option from radial access
- Preventing late embolization – close cell stent plus nitinol mesh
- All sizes of RsS are 5F and all CAS can be done with 5F sheath or 6F guiding cath.

The newest stent technology
Procedural data of 213 CAS procedures & stent selections from 2014 - 2018

**Baseline**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n=213)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (year)</td>
<td>70.36 (=8.64)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>146 (68.54%)</td>
</tr>
<tr>
<td>Symptomatic, n (%)</td>
<td>68 (31.92%)</td>
</tr>
<tr>
<td>CAD, n (%)</td>
<td>154 (72.30%)</td>
</tr>
<tr>
<td>Previous MI, n (%)</td>
<td>61 (28.64%)</td>
</tr>
<tr>
<td>Previous PCI, n (%)</td>
<td>78 (36.62%)</td>
</tr>
<tr>
<td>Previous CABG, n (%)</td>
<td>26 (12.21%)</td>
</tr>
<tr>
<td>HTN, n (%)</td>
<td>195 (91.55%)</td>
</tr>
<tr>
<td>DM, n (%)</td>
<td>69 (32.39%)</td>
</tr>
<tr>
<td>Active smoker, n (%)</td>
<td>106 (49.77%)</td>
</tr>
<tr>
<td>Contralateral occlusion, n (%)</td>
<td>18 (8.45%)</td>
</tr>
<tr>
<td>Ipsilateral amaurosis fugax, n (%)</td>
<td>10 (4.69%)</td>
</tr>
<tr>
<td>PSV at baseline (m/s)</td>
<td>3.81 (=1.22)</td>
</tr>
<tr>
<td>EDV at baseline (m/s)</td>
<td>1.36 (=0.59)</td>
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</table>

**Procedure**

<table>
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<tr>
<th>Variable</th>
<th>Total (n=213)</th>
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<tbody>
<tr>
<td>%DS (QCA)</td>
<td>84.87 (=9.69)</td>
</tr>
<tr>
<td>High risk lesion (%DS ≥80%), n (%)</td>
<td>162 (76.06%)</td>
</tr>
<tr>
<td>Distal protection, n (%)</td>
<td>213 (61.03%)</td>
</tr>
<tr>
<td>Proximal protection, n (%)</td>
<td>83 (38.96%)</td>
</tr>
<tr>
<td>Proximal protection time (min:sec)</td>
<td>6:04 (=1:22)</td>
</tr>
<tr>
<td>Direct stenting, n (%)</td>
<td>99 (46.48%)</td>
</tr>
</tbody>
</table>

**Stents**

<table>
<thead>
<tr>
<th>Stent</th>
<th>Total (n=213)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5x20</td>
<td>1 (0.47%)</td>
</tr>
<tr>
<td>6x25</td>
<td>1 (0.47%)</td>
</tr>
<tr>
<td>7x18</td>
<td>12 (5.63%)</td>
</tr>
<tr>
<td>7x25</td>
<td>27 (12.68%)</td>
</tr>
<tr>
<td>7x30</td>
<td>6 (2.82%)</td>
</tr>
<tr>
<td>8x20</td>
<td>23 (10.80%)</td>
</tr>
<tr>
<td>8x25</td>
<td>47 (22.07%)</td>
</tr>
<tr>
<td>8x30</td>
<td>30 (14.08%)</td>
</tr>
<tr>
<td>8x40</td>
<td>3 (1.41%)</td>
</tr>
<tr>
<td>9x20</td>
<td>42 (19.72%)</td>
</tr>
<tr>
<td>9x30</td>
<td>20 (9.39%)</td>
</tr>
<tr>
<td>10x30</td>
<td>1 (0.47%)</td>
</tr>
</tbody>
</table>
Complications during hospitalization & 30d follow-up after CAS procedures with Roadsaver implantation.

1.4% (!!) (symptomatic & high risk lesions)

- Stroke at day 5 (acute stent occlusion)
- Minor stroke 8 h after CAS procedure
- Death – hyperperfusion syndrom at day 2 & death at day 9!
- MI - 0%
All-caused and Cardiovascular Death

**All cause death-free Survival**

- Days: 0, 183, 365, 548, 730, 913, 1095, 1278, 1460
- Survival Probability:
  - 0.957
  - 0.914
  - 0.882
  - 0.840

**Cardiovascular death-free Survival**

- Days: 0, 183, 365, 548, 730, 913, 1095, 1278, 1460
- Survival Probability:
  - 0.972
  - 0.949
  - 0.949
  - 0.904

**At Risk**

- Days: 0, 183, 365, 548, 730, 913, 1095, 1278, 1460
- # at risk: 213, 159, 121, 75, 49, 29, 22, 9, 0
Asymptomatic and symptomatic patients (9 deaths including 5 non cardiovascular reasons)
Long ASYMPTOMATIC: LICA stenosis with huge burden of soft plaque! 60 y-old patient not accepted for CEA! Too risky for CAS with old generation of STENTS

Always asymptomatic carotid stenosis of high risk for complication is a huge challenge for operators.
Sometimes, supposedly simple CAS procedure can turn out to be breakneck: Patient after bilateral CEA with RICA occlusion and symptomatic 80% LICA restenosis.
CAS procedure with right radial access with strategy, distal protection and Open Cell stent implantation (Bovine arch our main indication for radial access!!)

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**Image Description:**
- The image shows an angiogram of a patient's vasculature, likely after a cerebrovascular intervention. The angiogram displays the carotid arteries, with a focus on the bifurcation region. The images capture the contrast dye flow, indicating the luminal morphology and the presence of anomalies such as stenosis or occlusions. The diagnostic nature of the procedure is evident from the detailed visualization of the arterial structures, crucial for assessing the need for interventional therapies or further diagnostic workup.

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**Clinical Relevance:**
- The patient's condition, marked by bilateral carotid artery disease, highlights the complexities in managing symptomatic or asymptomatic stenosis and restenosis. The use of radial access, combined with distal protection and Open Cell stent implantation, demonstrates an advanced approach to minimally invasive therapy, aiming to achieve optimal procedural outcomes with reduced risk.

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**Technical Note:**
- The technical aspects of the procedure are not detailed in the text but are implied through the clinical context and the use of advanced imaging techniques. The mention of Bovine arch as the main indication for radial access underscores the preference for radial access in certain cases due to its benefits over femoral access, such as reduced mechanical complications and faster recovery.

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**Conclusion:**
- The case underscores the importance of tailored, evidence-based treatments in cerebrovascular interventions, emphasizing the need for comprehensive diagnostic strategies and innovative procedural techniques to manage complex vascular lesions.
After MER stent implantation and postdilatation – neurological symptoms occurred with slow flow in left hemisphere. **MASSIVE PLAQUE BURDEN THRU THE STENT**
You never and never can remove the filter and than leave the patient with such angiography without additional treatment. Are there many options????
The best one was to implant asap Roadsaver mesh-stent - 5F easy too cross the first stent and no problem with filter retrieval
Normal angiography after Roadsaver stent in stent implantation. Example why we need NPD in all CAS procedures !!!!!!!! Resolution of neurological symptoms & normal intracranial angiography.
90% of coronary angioplasty was done via radial access in 2018. I think that time for CAS from radial artery access is coming. Probably none of 9mm diameter stents could pass through such a sharp bend. Don’t start CAS program from radial access without ROADSAVER stent in your lab !!
In some Institution only distal protection is available!! So triple protection in high risk patients can be safe option. Distal protection with filter, mesh Roadsaver stent & Paladin system for postdilatation. Very easy access & retrieval of Paladin within Roadsaver.
Patient of high risk for hyperperfusion syndrome!!!
Recent major stroke with large cerebral scare.
Tight ICA stenosis with slow flow.

How to prevent hyperperfusion syndrome - Achile's heel of CAS procedures
Patient of high risk for hyperperfusion syndrome!!!
Recent major stroke with large cerebral scare.
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How to prevent hyperperfusion syndrome - Achile's heel of CAS procedures
Patient of high risk for hyperperfusion syndrome!!!
Recent major stroke with large cerebral scare. Tight ICA stenosis with slow flow.

2.5 -3.0/20mm balloon for predilatation plus Roadsaver implantation !!!!
Temporary ICA flow restoration for 10 min for intracranial artery precondition before massive inflow after postdilatation. Roadsaver is a very safe stent in this CAS strategy.
Patient of high risk for hyperperfusion syndrome!!!
Recent major stroke with large cerebral scare.
Tight ICA stenosis with slow flow.

After aggressive postdilatation – normalization of intracranial circulation.
Small aneurysm on left ACA represents additional risk of intracranial bleeding after CAS.
Now we have a more dense sieve device - the ROADSAVER stent used in the prevention of strokes. During 17 years CAS technology has been dramatically improved and operators experience make milestone progress!!!
Comparison with CEA recommendation

Ad Hoc Committee, American Heart Association

Maximally allowed 30-day stroke/death-rate (after CEA)

- 6-7% for symptomatic
- 3% for asymptomatic

Restenosis Surgery

- 5-11%

During 24 years CAS technology have changed a lot. However, guidelines for acceptable complication rates are still from previous century.

In asymptomatic patients with a carotid stenosis who present with adverse anatomical features or medical comorbidities that are considered to make them ‘high risk for CEA’, CAS should be considered, provided the documented procedural death/stroke rate is < 6%.

When revascularization is indicated in ‘average surgical risk’ patients with symptomatic carotid disease, CAS may be considered as an alternative to surgery, provided the documented procedural death/stroke rate is < 6%.
Personal home message

• The Roadsaver Dual layer micro mesh stent due to its unique design has a long term embolic protection.

• If you still have complication around 3% in asymptomatic and 6% in symptomatic patients stop your carotid CAS program immediately.

• Training for this stent implantation is required.

• But BEST TREATMENT STRATEGY FOR CAROTID STENTING IN 2019 !!!

Mo.Ma EPD + Roadsaver Stent
Thank you

John Paul II Hospital Krakow PL
My journey with Roadsaver through the last four years!

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