Comparison of drug-eluting and bare metal stents for extracranial vertebral artery stenting

Prof. Piotr Pieniazek MD, PhD

Jagiellonian University Institute of Cardiology, John Paul II Hospital Krakow, Poland
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
A problem greater than the place in the recommendations

6.2 Vertebral artery disease

6.2.1 Definition and natural history

Up to 20% of ischaemic cerebrovascular events involving the posterior circulation are related to vertebral artery disease. For further details see Web addenda 6.2.1.
Vertebrobasilar ischemia (VBI)

Symptoms of Vertebral Ischemia

- Ataxia or clumsiness of both extremities
- Diplopia
- Dysarthria
- Dysphagia
- Bilateral homonymous hemianopia
- Vertigo
- Tinnitus
- Transient global amnesia
- Syncope

- Perioral numbness
- Drop attacks
- Nausea and vomiting
- TIA/Stroke
Why the true incidence of VASTenosis is difficult to estimate:

- Cerebral stroke is usually attributed to lesions in the cervical arteries.
- Patients after brain stem stroke – often “too ill for the diagnostics”.
- Minor symptoms – often underestimated.
- Symptoms from the “posterior cerebral circulation” are poorly defined.
- Symptoms are commonly attributed to degenerative lesions in the cervical spine.
Consequences of undiagnosed symptomatic VAStenosis... 
...can be fatal!

Patient AA, 69 years

- Several episodes of *sudden syncope* – cardiac reasons sought – admitted to the cardiology dept. for diagnostics.

- Treated at the neurology department for *recurrent syncope with retrograde amnesia*.

- Sudden LOC and *severe* head trauma requiring neurosurgical treatment - craniotomy in neurosurgery department - 3 months rehabilitation.

- Intracranial haematoma
This patient (AA) was admitted to our Department 9 months after first symptoms & after recovery from surgically-treated intracerebral and subdural haematoma with **continuing recurrent syncope and dizziness**

- Discharged on the 2\textsuperscript{nd} day after PTA
- Over 72 months follow-up - a **complete** resolution of the neurological symptoms

**Pressure gradient in LSA - 60 mmHg**
VAStenosis: era of POBA
...is definitively finished!

- often significant „recoil”
- often spasm after balloon angioplasty
- vertebral artery dissections
- unacceptable restenosis rate (10-90% in literature)

Angioplasty
ALWAYS with stent implantation!
Standard VAStenting in symptomatic pts. Tight stenosis.

Generally two wire technic.

V-18 in SA for Vertebral Artery-Ostium protection.

0.014” coronary guide wire for lesion crossing.

Direct stenting 70% of cases.

Small stent protrusion too SA is mandatory.

Rigorous follow-up.
Temporary brain protection in high risk VAStenting – temporary flow reversal by SA occlusion (Mo.Ma Cellio cath.)

Retrograde blood flow protected the brain from intracranial embolization (arrow!!!)
A systematic review of stenting and angioplasty of symptomatic extracranial vertebral artery stenosis.

Stayman AN¹, Nogueira RG, Gupta R.

Abstract

BACKGROUND AND PURPOSE: Extracranial vertebral artery stenosis (ECVAS) is common among patients with ischemic stroke. Despite the limited knowledge of the natural history of patients with symptomatic vertebral disease, endovascular revascularization techniques are now utilized in clinical practice. We sought to determine the risk of endovascular treatment for ECVAS with a systematic review of the literature.

METHODS: A search strategy was used using the terms "stenting," "vertebral," "ostium," "origin," and "extracranial" through Medline. All articles were reviewed along with their references to determine the risk and durability of endovascular treatment.

RESULTS: A total of 27 articles were identified that met inclusion criterion, with a total of 980 of 993 patients treated with stents. The majority of patients (56%) were noted to have contralateral vertebral artery stenosis or occlusion and 92% were symptomatic at the time of treatment. A total of 11 patients (1.1%) experienced a stroke and 8 (0.8%) experienced a transient ischemic attack within 30 days of the procedure. Drug-eluting stents were associated with lower restenosis rates (11%) compared to bare metal stents (30%) at a mean of 24 months of follow-up.

On average 36 patients per one publication
<table>
<thead>
<tr>
<th>Author</th>
<th>Journal</th>
<th>Year</th>
<th>Nb patients</th>
<th>Symptomatic O6</th>
<th>Procedure</th>
<th>Tech. success (%)</th>
<th>Early neur. comp. (%)</th>
<th>Mean FU (month)</th>
<th>% asympt.</th>
<th>ISR (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higashida</td>
<td>J Neurosurg</td>
<td>1993</td>
<td>41/42 vessels</td>
<td>NA</td>
<td>VA</td>
<td>100</td>
<td>14.3</td>
<td>12</td>
<td>100</td>
<td>7.1</td>
</tr>
<tr>
<td>Higashida</td>
<td>Stroke</td>
<td>1999</td>
<td>21</td>
<td>NA</td>
<td>VAS</td>
<td>100</td>
<td>9.6</td>
<td>20.7</td>
<td>57.1</td>
<td>NA</td>
</tr>
<tr>
<td>Chastain</td>
<td>J Neurosurg</td>
<td>1999</td>
<td>50/55 vessels</td>
<td>NA</td>
<td>VS</td>
<td>98</td>
<td>2</td>
<td>25</td>
<td>96</td>
<td>10</td>
</tr>
<tr>
<td>Jenkins</td>
<td>Catheter Cardiovasc Interv</td>
<td>2001</td>
<td>32/38 vessels</td>
<td>96.9</td>
<td>VS</td>
<td>100</td>
<td>2.6</td>
<td>10.6</td>
<td>97</td>
<td>3</td>
</tr>
<tr>
<td>Albuquerque</td>
<td>Neurosurgery</td>
<td>2003</td>
<td>33</td>
<td>90.9</td>
<td>VAS</td>
<td>97</td>
<td>NA</td>
<td>16.2</td>
<td>96.7</td>
<td>43.3</td>
</tr>
<tr>
<td>Mathias</td>
<td>Cardiovasc Interv Radiol</td>
<td>2004</td>
<td>16</td>
<td>87.5</td>
<td>VAS</td>
<td>87</td>
<td>12.5 (V4)</td>
<td>0</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Janssens</td>
<td>Neuroradiology</td>
<td>2004</td>
<td>16</td>
<td>NA</td>
<td>VA</td>
<td>100</td>
<td>NA</td>
<td>30</td>
<td>93.75</td>
<td>25</td>
</tr>
<tr>
<td>Ko</td>
<td>Yonsei Med J</td>
<td>2004</td>
<td>25</td>
<td>44</td>
<td>VS</td>
<td>100</td>
<td>0</td>
<td>25</td>
<td>100</td>
<td>16</td>
</tr>
<tr>
<td>Lugmayr</td>
<td>Rofo</td>
<td>2004</td>
<td>7/8 vessels</td>
<td>100</td>
<td>V-DES</td>
<td>100</td>
<td>0</td>
<td>6</td>
<td>71.5</td>
<td>62.5</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td>171/178 vessels</td>
<td>85.8</td>
<td></td>
<td>98.2</td>
<td>2.34</td>
<td>16.1</td>
<td>95.3</td>
<td>16.9</td>
</tr>
<tr>
<td>Barrow</td>
<td>Stroke</td>
<td>2006</td>
<td>31</td>
<td>100</td>
<td>V-DES</td>
<td>97</td>
<td>3</td>
<td>4 ± 2</td>
<td>NA</td>
<td>7</td>
</tr>
</tbody>
</table>
## STenting for Ostial Vertebral Artery Stenosis (STOVAST Trial): Results from a prospective randomized study comparing bare-metal with drug-eluting stents.

**Results:**

<table>
<thead>
<tr>
<th></th>
<th>RVA/LVA</th>
<th>Baseline VAS severity</th>
<th>Residual stenosis after stenting</th>
<th>Deaths at one year</th>
<th>Consent for f/u angio withdrawn</th>
<th>Angiographic follow-up</th>
<th>Restenosis rate (&gt;50% ISR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DES (n=49)</td>
<td>26 / 23</td>
<td>84.1±9.7%</td>
<td>2.2 ± 4.7%</td>
<td>4</td>
<td>4</td>
<td>41 (84%)</td>
<td>10 (24.3%)</td>
</tr>
<tr>
<td>p</td>
<td></td>
<td>0.19</td>
<td>0.36</td>
<td>0.38</td>
<td>0.23</td>
<td>0.63</td>
<td>0.95</td>
</tr>
<tr>
<td>BMS (n=50)</td>
<td>23 / 27</td>
<td>81.3±9.1%</td>
<td>3.5 ± 6.1%</td>
<td>2</td>
<td>8</td>
<td>40 (80%)</td>
<td>10 (25%)</td>
</tr>
</tbody>
</table>

12 patients withdrew follow-up angiography consent, 81 patients were thus available for one-year angiographic follow-up.

P.Pieniazek / EuroPCR: 2012
Comparison of drug-eluting and bare metal stents for extracranial vertebral artery stenting

Damian R. Maciejewski, Piotr Pieniazek, Lukasz Tekieli, Piotr Paluszek, Tadeusz Przewlocki, Tomasz Tomaszewski, Roman Machnik, Mariusz Trystula, Jacek Legutko, Anna Kablak-Ziembicka

Adv Interv Cardiol 2019; 15, 3 (57): 328–337
DOI: https://doi.org/10.5114/aic.2019.87887
Online publish date: 2019/09/18

Material and methods

The registry is a consecutive series of patients with signs and symptoms of HI seen at our institution, in whom stent-supported angioplasty was performed during a 13-year period (between the years 2003 and 2016). Written informed consent was obtained from all patients and the study was approved by the local ethics committee, and the study was conducted in compliance with the Declaration of Helsinki.

Of the 392 consecutive patients in the registry, 428 endovascular procedures with stent implantation were performed for V0-V1 segment lesions.

Group I comprised 280 lesions covered with BMS in 270 patients (195; 72.2% male), with the mean age of 67.5 ±8.6 years.

Group II comprised 148 lesions covered with DES in 144 patients (98; 68.1% male), with the mean age of 66.6 ±8.5 years. Group II was additionally subdivided into subgroups of patients who had DES I (21 lesions) and DES II implantation (127 lesions).
### Procedural data and stent type

<table>
<thead>
<tr>
<th>Parameter</th>
<th>DES (n = 148)</th>
<th>BMS (n = 280)</th>
<th>(P)-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right VA, (n (%))</td>
<td>79 (53.4)</td>
<td>118 (42.1)</td>
<td>0.037</td>
</tr>
<tr>
<td>Left VA, (n (%))</td>
<td>71 (48)</td>
<td>162 (57.9)</td>
<td></td>
</tr>
<tr>
<td>Transradial approach, (n (%))</td>
<td>10 (6.8)</td>
<td>16 (5.9)</td>
<td>0.668</td>
</tr>
<tr>
<td>Contralateral VA occlusion, (n (%))</td>
<td>13/140 (9.3)</td>
<td>23/260 (8.9)</td>
<td>0.884</td>
</tr>
<tr>
<td>V0/V1 segment, (n)</td>
<td>148</td>
<td>275</td>
<td>0.041</td>
</tr>
</tbody>
</table>

#### Old generation DES, \(n (\%) \text{ of DES}\):

- Sirolimus-eluting stent: 14 (9.4)
- Paclitaxel-eluting stent: 8 (5.3)

#### Second generation DES, \(n (\%) \text{ of DES}\):

- Everolimus-eluting stent: 57 (38)
- Biolimus-eluting stent: 35 (23.3)
- Zotarolimus-eluting stent: 36 (24)

#### Stenosis severity – angio (\%):

- Pre-treatment, mean ± SD: 86.0 ± 9.7
- Post-treatment, mean ± SD: 2.7 ± 5
- Stent diameter, mean ± SD [mm]: 3.4 ± 0.5
- Stent length, mean ± SD [mm]: 12 ± 3.9
- Direct stenting, \(n (\%)\): 110 (73.3)
- Maximum inflation pressure, mean ± SD [atm]: 11.6 ± 2.4
- Maximum post-dilatation balloon pressure, mean ± SD [atm]: 16.7 ± 3.2
- Simultaneous VAS + SAS, \(n (\%)\): 6 (4)

---

\[1\] Two stents implanted to cover one lesion. Continuous data are presented as the mean ± standard deviation; categorical data are given as the count and percentage. VAS + SAS – vertebral and subclavian artery stenting.
Comparison of drug-eluting and bare metal stents for extracranial vertebral artery stenting.

**Results:** The technical success rates for DES and BMS groups were 96.7% and 94.6% (p=0.103), with similar periprocedural complication rates (1.4% vs 2.2%; p=0.565). VAS degree was reduced from 86±9.7 to 2.7±5.0% in DES (p<0.001) and from 84.1±9.4 to 4.3±6.9% in BMS (p<0.001). Angiography confirmed in-stent restenosis/occlusion (ISR/ISO) 50-99% in 53 (14.2%) and 21 (5.6%) out of 373 patients (409 arteries) with at least 6 month follow-up. ISR/ISO rates were similar in DES vs BMS (22.8% vs 19.4%; p=0.635), as well as in DES I vs DES II (6/19; 31.6% vs 25/92; 27.2%, p=0.325). Stainless steel (24/135; 17.8%) and cobalt-chromium (23/121; 19%) BMSs had significantly lower incidence of ISR/ISO, as compared to platinum-chromium (7/18; 38.9%), p=0.034. ISR/ISO was associated with age (p=0.01) and CRP level>5mg/l (p=0.043), while higher stent length was associated with ISR only in DES group (p=0.024).

**Conclusion:** Our results do not support significant differences in ISR/ISO rates between DES and BMS, although differences between particular stent types and ISR rates require further investigation.
Patient age 55 with severe vertigo and balance disorders

IVUS verification after LVA – stenting: complete symptoms restoration.
Conclusions

- Symptomatic vertebral artery stenosis is associated with a risk of death / cerebral stroke
- The use of BMS or DES in VA-PTA is safe & feasible
- The angiographic restenosis rate of approx. 20% - confirmed in a larger sample and is acceptable
- Our initial findings form a large cohort of patients indicate that new generation of DES versus BMS had similar incidents of in-stent restenosis however new large stents DES for LM should be tested in VA area!!
Thank you

John Paul II Hospital Krakow PL
Comparison of drug-eluting and bare metal stents for extracranial vertebral artery stenting

Prof. Piotr Pieniazek MD, PhD

Jagiellonian University Institute of Cardiology, John Paul II Hospital Krakow, Poland