RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

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UNIVERSITY CLINICAL HOSPITAL
SANTIAGO DE COMPOSTELA
Endovascular therapy works!

Results of iliac artery stenting and revascularization for iliac artery occlusions and occlusive disease: Endovascular therapy rivals open femoral grafting.

TASC C

ILIAC SECTOR

RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

Life is though!!!!
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

COVERED-STENTS

Outcomes of Covered Kissing Stent Placement Compared with Bare Metal Stent Placement in the Treatment of Atherosclerotic Occlusive Disease at the Aortic Bifurcation

Safer S. Sabri, MD, Asim Choudhri, MD, Gianluigi Orgera, MD, Bülent Arslan, MD, Ulku C. Turba, MD, Nancy L. Harthun, MD, Klaus D. Hagspiel, MD, Alan H. Matsumoto, MD, and John F. Angle, MD

Covered vs Uncovered Stents for Aortoiliac and Femoropopliteal Arterial Disease: A Systematic Review and Meta-analysis.

Haibandooh S1, Haibandooh S1, Antoniou SA1, Torella F1, Antoniou GA1.

1. Liverpool Vascular and Endovascular Service, Royal Liverpool University Hospital, Liverpool, UK.
2. Department of General Surgery, University Hospital of Heraklion, University of Crete, Heraklion, Greece.
3. Department of Vascular and Endovascular Surgery, The Royal Oldham Hospital, Pennine Acute Hospitals NHS Trust, Manchester, UK.

Durability of the balloon-expandable covered versus bare-metal stents in the Covered versus Balloon Expandable Stent Trial (COBEST) for the treatment of aortoiliac occlusive disease

Bhuvaneswar P. Murpattayil, MMed (Surg), FCS (SA), FRACS,1 Shashidhara Sharma, MBBS,1 Ali Dunsmuir, MD,1 Edmund D. Thomas, BMedSc, FRACS,1 Vikram Vyasam, MRCVS, FRCS,1 Niall Abbott, PhD, FRCS,1 Mark Garbowski, MB BS, FRACS,1 and Mark Jackson, MD, FRACS1 on behalf of the COBEST co-investigators,2 Perth, Sydney, and Queensland, Australia and Singapore.
Covered stents in iliac artery occlusive disease: what is the evidence?

B. Patrice MWIPATAYI 1, 2, *, Elizabeth SUTHERS 3, Shannon D. THOMAS 3, 4, 5, Nishath ALTAFA 1

1Department of Vascular Surgery, Royal Perth Hospital, Perth, Australia; 2School of Surgery, Faculty of Medicine, Dentistry and Health Sciences, University of Western Australia, Crawley, Australia; 3Department of Vascular Surgery, Prince of Wales Hospital, Sydney, Australia; 4Faculty of Medicine, University of New South Wales, Sydney, Australia; 5The Vascular Institute, Prince of Wales Hospital, Sydney, Australia

TABLE I.—Characteristics of all studies with covered balloon expandable stent.

<table>
<thead>
<tr>
<th>Studies</th>
<th>N.</th>
<th>Type of study</th>
<th>Stent type</th>
<th>Iliac artery segment</th>
<th>TASC Classification</th>
<th>Technical success rate (%)</th>
<th>1-year primary patency (%)</th>
<th>3-year primary patency (%)</th>
<th>5-year primary patency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bosicrs et al.</td>
<td>91</td>
<td>Prospective non-randomized</td>
<td>CS</td>
<td>CIA/EIA</td>
<td>A-D</td>
<td>100%</td>
<td>91%</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>(2007)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sabri et al.</td>
<td>26 CS</td>
<td>Retrospective study</td>
<td>CS</td>
<td>Aorta/CIA</td>
<td>A-D</td>
<td>100%</td>
<td>CS 92%</td>
<td>CS 92%</td>
<td>n/a</td>
</tr>
<tr>
<td>(2010)</td>
<td>28 BMS</td>
<td></td>
<td>BMS</td>
<td></td>
<td></td>
<td></td>
<td>BMS 78%</td>
<td>BMS 62%</td>
<td>n/a</td>
</tr>
<tr>
<td>Grimme et al.</td>
<td>115</td>
<td>Retrospective study</td>
<td>CS</td>
<td>CIA/EIA</td>
<td>A-D</td>
<td>99%</td>
<td>83.6% [91.4%]</td>
<td>79.7% [85.9%]</td>
<td>63.4% [67.4%]</td>
</tr>
<tr>
<td>(2012)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Humphries et al.</td>
<td>64 CS</td>
<td>Retrospective study</td>
<td>CS</td>
<td>CIA/EIA</td>
<td>A-D</td>
<td>100%</td>
<td>CS 85% [96%]</td>
<td>CS 72% [92%]</td>
<td>n/a</td>
</tr>
<tr>
<td>(2014)</td>
<td>190 BMS</td>
<td></td>
<td>BMS</td>
<td></td>
<td></td>
<td></td>
<td>BMS 92% [99%]</td>
<td>BMS 89% [98%]</td>
<td>n/a</td>
</tr>
<tr>
<td>Tewksbury et al.</td>
<td>30</td>
<td>Retrospective study</td>
<td>CS</td>
<td>Aorta/CIA</td>
<td>D</td>
<td>100%</td>
<td>90%</td>
<td>79% at 2 years</td>
<td>n/a</td>
</tr>
<tr>
<td>(2015)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Piazza et al.</td>
<td>82 CS</td>
<td>Retrospective study</td>
<td>CS</td>
<td>CIA/EIA</td>
<td>C-D</td>
<td>99%</td>
<td>n/a</td>
<td>CS 93%</td>
<td>n/a</td>
</tr>
<tr>
<td>(2015)</td>
<td>85 BMS</td>
<td></td>
<td>BMS</td>
<td></td>
<td></td>
<td></td>
<td>BMS 80%</td>
<td>At 2 years</td>
<td>n/a</td>
</tr>
<tr>
<td>Mwipatayi et al.</td>
<td>83 CS</td>
<td>RCT</td>
<td>CS</td>
<td>Aorta/</td>
<td>B-D</td>
<td>100%</td>
<td>CS 88.5%</td>
<td>CS 79.9%*</td>
<td>CS 74.7%</td>
</tr>
<tr>
<td>(2011)</td>
<td>85 BMS</td>
<td></td>
<td>BMS</td>
<td>CIA/EIA</td>
<td></td>
<td></td>
<td>BMS 73.9%</td>
<td>BMS 84.7%</td>
<td>BMS 62.9%</td>
</tr>
</tbody>
</table>

CS: covered stent; BMS: bare metal stent; CIA: common iliac artery; EIA: external iliac artery; RCT: randomized controlled trial; n/a: not applicable.

Between square brackets are secondary patency percentages.
CONCLUSIONS: The 5-year results of the COBEST demonstrated acceptable patency.

Clinical benefit with uncovered stents.

- Covered stents work better than uncovered stents.

74.7% CS vs 62.5% BM

covered stents

results of VIABAHN in aorto-iliac occlusion
COVERED-STENTS

- INDEPENDENT OF THE LESION LENGTH

WHY FOR COMPLEX LESIONS???

- AVOID DIFUSE RE-STENOSIS

- PREVENT BLEEDING

- HIGH PRESSURE BALLOONS CAN BE USED
RESULTS OF VIABAHN IN AORTO
ILIAC OCCLUSION

ILIAC OCCLUSION

COVERED-STENTS

Creating a physical barrier

Prevents Ingrowth of proliferating SMCs
Try to obtain the **PATENCY** of open surgery

Endovascular advantage:

- Lower morbimortality
- Shorter hospital stay
- **PATIENT CONFORT**
## RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

### COVERED-STENTS

<table>
<thead>
<tr>
<th></th>
<th>6m</th>
<th>12m</th>
<th>18</th>
<th>24</th>
<th>36</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>V12CERAB</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prim patency</td>
<td>97.0%</td>
<td>89.55%</td>
<td>88.07%</td>
<td>85.07%</td>
<td>86.6%</td>
</tr>
<tr>
<td>Sec Patency</td>
<td>100%</td>
<td>95.5%</td>
<td>93.5%</td>
<td>93.5%</td>
<td>92.5%</td>
</tr>
<tr>
<td>Freedom from TLR</td>
<td>98.5%</td>
<td>91.5%</td>
<td>89.55%</td>
<td>86.5%</td>
<td>85.0%</td>
</tr>
</tbody>
</table>

P. Goverde. CERAB 3 years results @ LINC17
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

COVERED-STENTS

CONFORMABILITY MATTERS!!!
Nitinol Stent
- Inner layer of ePTFE
- Superb flexibility
- Low fractures reported
- Heparin-bonded luminal surface for thrombo-resistance
- Actually up to 25 cm length

GORE VIABAHN® Endoprosthesis with Heparin Bioactive Surface

Control Endoprosthesis
...Restoring and improving the patency of the iliac arteries
Restoring and improving the patency of the iliac arteries
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

ILIAC OCCLUSION

VIABAHN

...Restoring and improving the patency of the iliac arteries
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

ILIAC OCCLUSION

VIABAHN

....Restoring and improving the patency of the iliac arteries
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

ILIAC OCCLUSION

VIABAHN
RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

VIABAHN

Hybrid Technique

Objective

- Healthy distal landing zone
- Improve the outflow

Patency is not affected

Go across inguinal ligament

24%–53% patients CFA LESIONS

RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION
RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

24%–53% patients CFA LESIONS

HYBRID TECHNIQUE

Go across inguinal ligament

• Retrospective study.
• Jan 2008 - Dec 2014. 43 patients. 22 EVR, 21 OSR.
• Primary patency at 2 years: 94% EVR vs 97% OSR.
• Secondary patency: 97% EVR vs 100% OSR.
• Complications rate: 4% EVR vs 18% OSR. (p .32)

Increasing efficacy of endovascular repair with covered stent graft for TransAortic Inter-Society Consensus II D and complex occlusion

Daniele Psacharopoulos, MD,a Emanuele Ferrero, MD,b Sandeep Singh Bahia, MBBS,c Andrea Trucco, c Tasso N. Vliakos, MD, a Andrea Viazzi, MD, a and Franco Nessi, MD, a Turin, Italy, and London, United Kingdom

RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

Femoral thromboendarterectomy 36% EVR
RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

VIABAHN

ILIAC OCCLUSION

6 Juxtarenal occlusion

5 Distal aortic occlusion

11 total iliac occlusion

Rutherford Class

<table>
<thead>
<tr>
<th>Class</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>III</td>
<td>13</td>
</tr>
<tr>
<td>IV</td>
<td>7</td>
</tr>
<tr>
<td>V and VI</td>
<td>2</td>
</tr>
</tbody>
</table>

TORINO EXPERIENCE
2014-2016: 22 cases

M. FERRI @ LINC2017
Torino Experience
2014-2016: 22 cases

Viabahn

Results of Viabahn in Aorto Iliac Occlusion

Technical success 100%
Renal/Visceral embolization 0%
Days hospital stay 3.9 +/- 2.2

Follow up (12 ± 9.1 m)

Primary patency 90.9%
Secondary patency 96.5%
RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

Outcomes of polytetrafluoroethylene-covered stent versus bare-metal stent in the primary treatment of severe iliac artery obstructive lesions.

Michele Piazza, MD, Francesco Squizzato, MD, Gaya Spolverato, MD, Luca Milan, Stefano Bonvini, MD, Mirko Menegolo, MD, Franco Grego, MD, and Michele

- Retrospective study.
- TASC C (51%) x TASC D (49%) 82 CS (49%) 85 BMS (51%)
- Primary patency for 2 years 93% CS vs 80% BMS (p=0.14)
- Permeability TASC D 88% CS vs 61% BMS (p=0.07)
- Permeability TASC D (CIA + EIA) 88% CS vs 57% BMS (p=0.03)

Conclusions: Overall, the use of CSs for severe iliac lesions has similar early and midterm outcomes compared with BMS. However, in a subcategory of TASC II D lesions with long-segment severe stenosis of both the common and external iliac arteries, CS should be considered as the primary line of treatment. (J Vasc Surg 2015;62:1210-8.)
RESULTS: Overall, iliac lesion length > 6 cm and occlusion length > 3.5 cm and calcification involving > 75% of the arterial wall circumference were predictors of primary patency in favour of CSs for IAOs > 3.5 cm in length (p = .04), total lesion length > 6 cm (p = .02), and TASC D lesions (p = .06). The use of self-expanding CS for IAOs has similar early and midterm outcomes compared with BMS. Even if further studies are needed, CSs seem to have higher midterm patency rates than BMSs for TASC D lesions, IAOs with a total lesion length > 3.5 cm, and calcification involving > 75% of the arterial wall circumference. These specific anatomical parameters may be useful to the operator when deciding between CS and BMS during endovascular planning.

CONCLUSIONS: Overall, the use of self-expanding CS for IAOs has similar early and midterm outcomes compared with BMS. Even if further studies are needed, CSs seem to have higher midterm patency rates than BMSs for TASC D lesions, IAOs with a total lesion length > 3.5 cm, and calcification involving > 75% of the arterial wall circumference. These specific anatomical parameters may be useful to the operator when deciding between CS and BMS during endovascular planning.

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<table>
<thead>
<tr>
<th>ENERO 2015- DIC 2016</th>
<th>138 ptes (178 iliacas)</th>
<th>Tech. Succes 98.3% (174/178)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutherford 3/4-5 ASA III/IV</td>
<td>69.2%/30.2% 50.8%</td>
<td></td>
</tr>
<tr>
<td>TASC C/TASC D</td>
<td>45.5%/40.3% 11.1%</td>
<td></td>
</tr>
<tr>
<td>• Aorto-iliac obstruction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Covered stents</td>
<td>364 (2.64) 78.7% 21.3%</td>
<td></td>
</tr>
<tr>
<td>- Viabahn® (7-8 mm)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Advanta®</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bare metal Stents</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Follow-up</td>
<td>3-24 months</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------</td>
<td>-------------</td>
</tr>
<tr>
<td><strong>Patency</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td></td>
<td>96.6% (172/178)</td>
</tr>
<tr>
<td>Secondary</td>
<td></td>
<td>100%</td>
</tr>
<tr>
<td><strong>TLR</strong> (100% EIA envolvement)</td>
<td>6 re-stenosis (distal edge Viabahn)</td>
<td>6.74% (12)</td>
</tr>
<tr>
<td></td>
<td>6 thrombosis (3 percutaneus access)</td>
<td>3 overlap/3 TEA / 6 thrombolysis/4 TEA</td>
</tr>
<tr>
<td><strong>TEA / Femoral Patch</strong></td>
<td>57%</td>
<td>74%</td>
</tr>
<tr>
<td>• EIA Occlusion</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Infrainguinal revascularization</strong></td>
<td>7% (9)</td>
<td></td>
</tr>
<tr>
<td><strong>Extra-anatomic by-pass</strong></td>
<td>1 FEM-FEM</td>
<td>0 AXILO-FEMORAL</td>
</tr>
</tbody>
</table>

Courtesy Dr. Zanabili/ Dr. Camblor
RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

CHUS experience

- More than 100 iliac treated with viabahn SE
- Adjuntive proximal or distal treatment
- Combined treatment devices
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

VIABAHN BX

- Balloon expandable stent developed on SE platform
- Stainless steel
- Semi-compliant covered balloon
- Stent is not continuous: Flexibility
- Both surfaces covered with Heparin coated PTFE
- Scalloped edges.

Available pre-mounted
- 5mm-11mm diameter
- 15mm-79 mm length
- No foreshortening, except on over dilatation
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

12 month follow-up results
96.6% primary patency (per-subject)

Interim 24 month analysis

- 28 patients ongoing in study at 24 months
  - 1 further edge stenosis > 50% diameter loss detected on 2 year US (day 723) – no TLR as yet
  - 0 TLR from 12 to 24 months

- Primary patency @ 2 years 93%
- Freedom from TLR @ 2 years 97%

- 1 patient with edge stenosis at 7 months, managed with angioplasty and stenting

First-in-Human Experience With the Gore Balloon-Expandable Covered Endoprosthesis in Iliac Artery Occlusive Disease.

Holden A1, Merrilees S1, Buckley B1, Connor B1, Colgan F1, Hill A2.
Clinical Trial results

• **Gore VBX FLEX IDE Clinical Study**
  - VBX FLEX IDE clinical study (n=134),
  - 32 percent presented with TASC II type C or D lesions,
  - 18 percent required contralateral access to the lesion,
  - and 42 percent involved kissing stents at the aortic bifurcation.

• 100 percent success rate in device delivery and coverage of target lesions in all study subjects

• 100 percent success rate in reducing the target lesion to less than or equal to 30 percent of the original stenosis

• Zero change in median length of the device upon deployment

• **96.9 percent primary patency at nine-months, including a 95.3 percent primary patency rate in those patients with TASC II C or D type lesions.**

• Further, there were no reported incidences of device dislodgement, failures in stent integrity, or device-related serious adverse events through the primary endpoint follow up.
RESULTS OF VIABAHN IN AORTOILIAC OCCLUSION

COMMENTS

- MARKS IN THE STENT
- DRUG IN THE EDGES
- CONICAL STENTS
- MORE STENT LENGTHS
- WHAT ELSE?
Viabahn Bx is a new tool that combine the best of the Bx and SE Covered Stents.
RESULTS OF VIABAHN IN AORTO ILIAC OCCLUSION

THANK YOU!!!