Role of covered stents in Treating aorto-iliac Disease

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Aorto iliac Disease : 2017

Aorto iliac disease is treated with

1. Endovascular therapy
2. Surgical therapy is offered for failure of Endovascular

Endovascular therapy
 placement of stents in Stenosed or occluded segment of iliac arteries and Aorta

Bare Metal stents
   Balloon expandable
   Self expanding

Covered stents: Metal stents covered with Graft fabric on one or both surfaces
   Balloon Expandable: iCast
      : Viabahn VBX
      : Lifestream
      : BeGraft
   Self Expanding: Viaban stent graft
TASC II Classification

All forms of process can be treated with Endovascular therapy

TASC C and D Lesions may require additional CTO devices to achieve lumen
Balloon Expandable CS : iCast

- Stainless steel stent
- Covered on both surfaces with Thin Wall PTFE
- Available in Variety of sizes 5mm-10mm
- Pre-mounted on a balloon
- Delivered via 6F-7F Hemostatic sheath
- Precise stent placement
- Stent can be over expanded

**Stent**
- Continuous stent
- Stiff
- Allows no flexibility
- Requires pre-dilatation of lesion prior to placement
- It does foreshortens

**Additional uses**
- Vascular perforation or rupture
- Small Aneurysms
- Chimney procedures
Both wires went Subintimal in Aorta
Bilateral reentry was done with Outback catheter

54 yr old obese black female with DM, HTN
Bil thigh and hip pain
No foot pain
Treated for OA
Balloon Expandable CS: Viabahn VBX Stent

- Balloon expandable stent developed on SE platform
- Stainless steel
- Stent is not continuous: Flexibility
- Both surfaces are covered with Heparin coated PTFE graft
- Edges are scalloped: Perfect opposition of stent against vessel wall
- Available pre-mounted
  - 5mm-11mm diameter
  - 15mm-79 mm length
  - No foreshortening, except on over dilatation
  - Placed Via 7F-8F hemostatic sheath
  - Most cases require pre-dilatation of lesion
100% MAINTENANCE OF STENT LENGTH
Median Length Change = 0 mm
in the U.S. IDE Study
BeGraft

- Designed with Cobalt Chromium Stent, Bx
- Thin wall PTFE on External surface
- Flexible design
- Low profile
- 6F introducer Sheath for most
- 7F for larger diameter
- Available from 5mm-10mm diameter
- Length up to 57 mm

Not approved in USA
LifeStream Covered stent

• Stainless steel stent
• PTFE coating on both surfaces
• Sheath size 5-8F
• Delivered on balloon
• Over dilatation causes fore shortening
Self Expanding CS

- Viabahn Endoprosthesis
  - With or without Heparin Coating
  - 5mm- 13mm diameter
  - Length up to 25 cm
  - Unique pull cord delivery
  - Scalloped edges for better approximation and preventing in folding
  - Delivery via 6-12 F sheath
  - Nitinol
Stent Choice

- Personal Preference
- Ostial lesion : BA
- Non Ostial lesion : SE
Why CS

Bare metal stents allow Atheroma prolapse

Restenosis or occlusion

Excessive neo intimal growth

Lower long term patency
A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease.


Abstract

OBJECTIVE: This trial was conducted to determine if covered stents offer a patency advantage over bare-metal stents in the treatment of aortoiliac arterial occlusive disease.

METHODS: The Covered Versus Balloon Expandable Stent Trial (COBEST), a prospective, multicenter, randomized controlled trial, was performed involving 168 iliac arteries in 125 patients with severe aortoiliac occlusive disease who were randomly assigned to receive a covered balloon-expandable stent or bare-metal stent. Patient demographic data, clinical signs and symptoms, TransAtlantic Inter-Society Consensus (TASC) classification, and preprocedure and postprocedure ankle-brachial index measurements were recorded. The primary end points included freedom from binary restenosis and stent occlusion of the treated area, as determined by ultrasound imaging or quantitative visual angiography, or both. Postprocedural follow-up was at 1, 6, 12, and 18 months.

RESULTS: Aortoiliac lesions treated with a covered stent were significantly more likely to remain free from binary restenosis than those that were treated with a bare-metal stent (hazard ratio [HR], 0.35; 95% confidence interval (CI), 0.15-0.82; P = .02). Freedom from occlusion was also higher in lesions treated with covered stents than in those treated with a bare-metal stent (HR, 0.28; 95% CI, 0.07-1.09); however, this did not reach statistical significance (P = .07). Subgroup analyses demonstrated a significant difference in freedom from binary restenosis for covered stents in TASC C and D lesions compared with a bare stent (HR, 0.136; 95% CI, 0.042-0.442). This difference was not demonstrated for TASC B lesions (HR, 0.748; 95% CI, 0.235-2.386).

CONCLUSIONS: COBEST demonstrates covered and bare-metal stents produce similar and acceptable results for TASC B lesions. However, covered stents perform better for TASC C and D lesions than bare stents in longer-term patency and clinical outcome.
Only study shows better outcomes by BM stents

Short follow up
5 yr. follow up

COBEST trial

74.7% CS vs 62.3% BM
Covered vs Uncovered Stents for Aortoiliac and Femoropopliteal Arterial Disease: A Systematic Review and Meta-analysis.

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Abstract
PURPOSE: To evaluate outcomes of covered vs bare metal stents for the treatment of lower limb peripheral artery disease.

METHODS: A search of electronic databases was performed to identify all studies comparing outcomes of covered vs bare metal stents for treatment of aortoiliac and femoropopliteal arterial disease. The Cochrane tool and the Newcastle-Ottawa scale were used to assess the risk of bias in randomized controlled trials (RCTs) and observational studies, respectively. Fixed or random effects models were applied to analyze pooled outcome data. The results for dichotomous outcome variables are presented as the odds ratio (OR) and 95% confidence interval (CI); intergroup comparisons of continuous clinical variables are reported as the mean difference (MD) and 95% CI.

RESULTS: Two RCTs and 4 retrospective cohort studies, enrolling 744 patients (mean age 57 years: 477 men) and 918 diseased arteries, were identified. For aortoiliac disease, treatment with a covered stent showed no significant improvement in primary patency (OR 2.1, 95% CI 0.48 to 9.11, p=0.32), but it was associated with higher ankle-brachial index (ABI) (MD 0.08, 95% CI 0.07 to 0.09, p<0.001) and a lower reintervention rate (OR 0.19, 95% CI 0.09 to 0.42, p=0.001). For femoropopliteal disease, use of covered stents was associated with increased primary patency (OR 1.84, 95% CI 1.11 to 3.06, p=0.02), higher ABI (MD 0.08, 95% CI 0.00 to 0.16, p=0.04), and a lower reintervention rate (OR 0.51, 95% CI 0.30 to 0.87, p=0.01). No significant differences in technical success, complications, limb salvage, or survival were identified between the groups in either segment.

CONCLUSION: Theoretically, the use of covered stents may increase the patency rate due to decreased restenosis after stent placement. This analysis found that the primary patency was improved with the use of a covered stent in femoropopliteal lesions but not in aortoiliac disease. Improved outcomes were seen with covered stents compared with bare metal stents as indicated by a lower need for reintervention and an improved ABI. It remains to be investigated whether such beneficial effects can be translated into improved clinical outcomes, such as limb salvage and amputation-free survival. Long-term results of the comparative efficacy of covered stents over bare metal stents are not currently available.
Covered stents in iliac artery occlusive disease: what is the evidence?

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<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>
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<tr>
<td>Bosiers et al.</td>
<td>91</td>
<td>Prospective non-ran</td>
<td>CS</td>
<td>CIA/EIA</td>
<td>A-D</td>
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<td>(2007)</td>
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<td>omed randomized</td>
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<td>CS</td>
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<td>100%</td>
<td>CS 92%</td>
<td>CS 92% BMS 78%</td>
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<td>BMS</td>
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<td>115</td>
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<td>A-D</td>
<td>99%</td>
<td>83.6% [91.4%]</td>
<td>79.7% [85.9%] at 2 years</td>
<td>63.4% [67.4%] at 4 years</td>
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<td>CIA/EIA</td>
<td>A-D</td>
<td>100%</td>
<td>CS 85% [96%] BMS 92% [99%]</td>
<td>CS 72% [92%] BMS 89% [98%] at 2 years</td>
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<td>CS</td>
<td>Aorta/CIA</td>
<td>D</td>
<td>100%</td>
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<td>Piazza et al.</td>
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<td>CIA/EIA</td>
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<td>CS 79.9%*</td>
<td>CS 74.7%</td>
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<tr>
<td>(2015)</td>
<td>85</td>
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<td>BMS</td>
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<td></td>
<td>BMS 84.7%</td>
<td>BMS 62.9%</td>
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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.
Outcomes of Self Expanding PTFE Covered Stent Versus Bare Metal Stent for Chronic Iliac Artery Occlusion in Matched Cohorts Using Propensity Score Modelling.

Piazza M, Squizzato F, Dell'Antonia A, Lapidis S, Menegolo MF, Greco F, Antonello MP.

Abstract

OBJECTIVES: The aim was to compare outcomes of self expanding PTFE covered stents (CSs) with bare metal stents (BMSs) in the treatment of iliac artery occlusions (IAOs).

METHODS: Between January 2009 and December 2015, 128 iliac arteries were stented for IAO. A CS was implanted in 78 iliac arteries (61%) and a BMS in 50 (49%). After propensity score matching, 94 limbs were selected and underwent stenting (47 for each group). Thirty day outcomes and midterm patency were compared; follow-up results were analysed with Kaplan-Meier curves.

RESULTS: Overall, iliac lesions were classified by limb as TASC B (15%), C (21%), and D (60%). Technical success was 98%. Comparing CS versus BMS, the early cumulative surgical complication rate (12% vs. 12%, p = 1.0) and 30 day mortality rate (2% vs. 2%, p = 1.0) were equivalent. At 36 months (average 23 ± 17), overall primary patency was similar between CS and BMS (87% vs. 66%, p = .06), and this finding was maintained after stratification by TASC B (p = .29) and C (p = .27), but for TASC D, CSs demonstrated a higher patency rate (CS, 88% vs. BMS, 54%, p = .03). In particular, patency was in favour of CSs for IAOs > 3.5 cm in length (p = .04), total lesion length > 6 cm (p = .04), and IAO with calcification > 75% of the arterial wall circumference (p = .01).

CONCLUSIONS: Overall, the use of self expanding CS for IAOs has similar early and midterm outcomes compared with BMS. Even if further confirmatory studies are needed, CSs seem to have higher midterm patency rates than BMSs for TASC D lesions, IAOs with a total lesion length > 6 cm, occlusion 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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First-in-Human Experience With the Gore Balloon-Expandable Covered Endoprosthesis in Iliac Artery Occlusive Disease.

Holden A, Merilees S, Buckley B, Connor B, Coogan F, Hill A.

Abstract

PURPOSE: To report the first-in-human iliac artery experience of a new balloon-expandable covered endoprosthesis.

METHODS: A prospective, single-center pilot study recruited 30 symptomatic patients (mean age 64 years; 18 men) to evaluate the safety and early efficacy of the new Gore balloon-expandable covered endoprosthesis for the treatment of de novo or restenotic common and/or external iliac artery lesions. According to protocol, up to 2 discrete lesions could be treated with a maximum total treated length ≤110 mm. Follow-up included clinical evaluation with duplex ultrasound at 1, 6, and 12 months. Data are presented through 12-month follow-up. The primary safety endpoint was a composite of device- or procedure-related death, myocardial infarction, or amputation in the treated leg within 30 days of the index procedure. Multiple performance outcomes were also evaluated.

RESULTS: The primary 30-day safety endpoint was 0%. Per-subject estimates of primary patency, freedom from target lesion revascularization, and freedom from target vessel revascularization were 100% at 1 and 6 months and 96.6% at 12 months. Estimates of assisted primary and secondary patency were both 100% at 12 months. Freedom from major adverse events at 12 months was 100%. Most patients experienced improvements in Rutherford category, ankle-brachial index, and functional status that were sustained to 12 months.

CONCLUSION: This positive first-in-human experience with the Gore balloon-expandable covered endoprosthesis suggests this device will have an important role in the management of aortoiliac occlusive disease.

12 month data
Patients 30 (18 males)
All TASC lesions and restenosis
Success 100%
6 m = 100%
12 m=96.6% PP
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.

- Clinical data from the Gore VBX FLEX IDE clinical study conducted for FDA approval reflected that the design components of the VBX Stent Graft were resilient both during stenting procedures and over time:
  - 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; and
  - 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.
Conclusion

• Covered stents prevent atheroma prolapse and future restenosis and occlusion

• Short term patency for all TASC lesion is comparable to BMS, except in TASC C and D lesions, where CS performed better

• Long term patency is superior to BMS with lower TLR

• Use of CS recommended for CTOs, and complex TASC lesions
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