Role of Covered Stents in Treating Aorto-iliac Disease

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AOI disease

- Part of Atherosclerotic process affect 1/3 of Peripheral vascular disease
- 30-40% patients are young, often females
- Symptoms include, high thigh and buttock claudication, impotence in males and distal embolization
- Patients may present with toe ulcers
- Older Age group symptoms are often mistaken for OA disease
Surgical Therapy is offered as a last resort in ERA of Endovascular Therapy
Endovascular Therapy

Proven Technologies

Balloon Angioplasty
Balloon angioplasty with Stent placement
  Bx Stents
  Sx Stents
Covered Stents
  Bx/ Sx

On the horizon

Atherectomy
DES
DEB
TASC Classification

- Simple Form
  - Type A
  - Type B
- Complex form: C and D lesions
  - Bilateral severe ostial disease of iliac arteries with calcification
  - CTO
    - Unilateral/bilateral common iliac artery
    - Unilateral/bilateral ext iliac artery
    - Combination of the two
    - Aorto-iliac disease
    - Aortic stenosis or occlusion
Using Multiple Routes

- **Approach**
  - Femoral
    - Unilateral
    - Bilateral
    - SFA
  - Trans-brachial
  - All of above
- **Crossing**
  - Guide wires
  - Reentry devices
    - Front runner, outback, pioneer, Kitty Hawk, crosser etc
- **Angioplasty balloons**
- **Stent**
  - BM
  - CS
    - BA/SE

- Procedure should be individualized based on patient and anatomy
- Need to know when to stop
- Need to be aware of perforation or RUPTURE
  - FATAL
CTO tools

- Front Runner
- Crosser catheter
- Wildcat
- Ocelot
- True path
- Viance
Using reentry devices
Considerations

- Procedure should be individualized based on patient and anatomy
- Need to know when to stop
- Need to be aware of perforation or RUPTURE
  - FATAL

Remember
Some surgical procedure are also very simple
1. Fem-fem Cross over graft
2. Axillo- femoral bypass
Stents

- **Bare Metal**
  - Balloon Expandable
  - Self Expanding

- **Covered Stents**
  - Balloon expandable
    - Icast or Advanta V12
  - Self Expanding
    - Viabahn
AOI Reconstruction : Double Barrel

• Reconstruction is done with Two Stents placed from bilateral femoral approach

• SX or BX stents can be placed
• Aim is raise the aortic bifurcation
• Keep stent approximately 5-10 mm in Aorta

Double Barrel
Double Barrel

Advantage
- Simple
- Easy to position stents
- Good short term durability
- Questionable long term durability

Disadvantage
- Inability to perform over the horn intervention for lower extremity from Femoral approach
- * May be Radial approach can solve this issue
AOI reconstruction: V or Kissing Technique

- Similar to double Barrel
- Stents are placed at the origin of iliac arteries
- Can be done with Bx or Sx stent
- Bx preferred due to better Hoop Strength
Aortic disease progression in future may need further intervention
Aortic stent

Important to place iliac stent inside aortic stent, to prevent development of stenosis between stents

Iliac stents creating V
Top head and V: With Wall stents 1993

- Aortic stent
  - 20x50 Wallstent
- Two iliac stents
  - 8x40 Wallstent

7 Years later

Post BA
Long-term outcomes of endovascular therapy for aortoiliac bifurcation lesions in the real-AI registry.


Abstract

PURPOSE: To report long-term outcomes of endovascular therapy (EVT) for aortoiliac bifurcation lesions.

METHODS: Patients enrolled in the multicenter RETrospective AnaLysis of Aorto-IIiac stenting (REAL-AI) registry in Japan were pooled. Of 2096 patients who underwent EVT for de novo aortoiliac disease between January 2005 and December 2009, 190 patients (148 men; mean age 70±9 years) had aortoiliac bifurcation lesions that were treated with stents, whose configuration (single, V, or kissing) and type (balloon-expandable or self-expanding) were subjected to regression analysis to determine any impact on primary patency along with other demographic, clinical, and lesion characteristics, including Trans-Atlantic Inter-Society Consensus II C/D classification. The primary endpoints were restenosis and target lesion revascularization (TLR). Secondary endpoints were all-cause death, major cardiovascular events, and major cardiovascular + limb events.

RESULTS: The overall complication rate was 6.3%, and 1- and 5-year primary patency rates were 87% and 73%, respectively. Over a mean follow-up of 31±15 months, there were 36 (19.0%) restenoses, 22 (11.6%) TLRs, and 4 (2.1%) reocclusions; stent fracture (2.1.1%) and major amputation (2.1.1%) were rare. Only female gender [adjusted hazard ratio (AHR) 4.26, 95% CI 1.89 to 9.71, p<0.001] and residual diameter stenosis (AHR 1.04, 96% CI 1.01 to 1.06, p=0.01) were independent predictors of primary patency.

CONCLUSION: Stenting for aortoiliac bifurcation lesions was found to be safe and effective. Neither stent configuration nor type appeared to affect vessel patency in true bifurcation lesions.
Clinical Outcomes of SMART Versus Luminexx Nitinol Stent Implantation for Aortoiliac Artery Disease: A Propensity Score-Matched Multicenter Study.

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Abstract

BACKGROUND: Endovascular therapy for aortoiliac (AI) lesions using stents is widely accepted. However, the long-term outcome of 2 different types of nitinol stents for AI lesions is unknown. The aim of this study was to examine the long-term outcome of the SMART and Luminexx nitinol stents for the treatment of de novo AI lesions.

METHODS: This study was a multicenter retrospective analysis of a prospectively maintained database. The study enrolled consecutive patients undergoing primary stenting for de novo AI artery stenosis between January 2005 and December 2009. A total of 1503 lesions in 1229 patients treated with SMART or Luminexx primary stenting were enrolled. The primary end point was primary patency, secondary end points were the primary assisted patency, secondary patency, and major adverse limb events (MALEs), which included major amputation and major reintervention. To minimize the differences between the groups, a propensity score matching analysis was performed, and 284 lesions per group were analyzed to identify outcomes.

RESULTS: After the propensity score matching analysis, the lesion length was 60 ± 37 and 57 ± 31 mm (P = .275), and the reference vessel diameter was 8.2 ± 1.5 and 8.3 ± 1.5 mm (P = .482) in the SMART and Luminexx groups, respectively. The primary patency at 3 years was not significantly different between the groups (83.5% vs 82.2%, P = .842, respectively). The assisted primary patency and secondary patency rates were also not significantly different (91.7% vs 93.2%, P = .340, 99.2% vs 98.8%, P = .922). In addition, the MALE rate was not significantly different between the groups (98.3% vs 97.3%, P = .821).

CONCLUSION: The current data suggest that the use of nitinol stents for the AI artery provided good long-term patency and freedom from MALE for 3 years of follow-up, regardless of whether SMART or Luminexx stents were used.

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**Covered Stents**

- Useful in avoidance of complications
  - Better coverage of lesion in calcified and lesions with thrombus
  - Prevent Rupture in thin wall and small vessels
  - Protect after Subintimal entry

- Complications
  - Urgent sealing after perforation or Rupture of the Artery
  - Provide better long term patency in TASC C and D lesions

*Used in Precise situations*
A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease

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.
Challenges of AI intervention

- Severe calcified lesions
  - Specially females with small calcified vessels
- Complications: embolization, perforation, Thrombosis
- Difficulty regaining access to the true lumen in TASC C and D

- Restenosis
- re-occlusion
Covered Stent to the rescue
54 yr old obese black female with DM, HTN
Bil thigh and hip pain
No foot pain
Treated for OA

Both wires went Subintimal in Aorta
Bilateral reentry was done with Outback catheter
Two outback devices placed simultaneously

[Image of medical procedure]
The 5-year results of the COBEST showed that
1. CS had a significantly higher patency rate than the BMS
   18, 24, 48, and 60 months (95.1%, 82.1%,
   79.9%, 74.7% for CS
   73.9%, 70.9%, 63% and 62.5% for BMS);
2. Fewer patients received target limb
   revascularization in the CS group than in the BMS
   group (odds ratio, 2.32; 95% CI, 1.47-3.36; P = .02);
   however, there was no statistically significant
   difference in the rate of amputations between the
groups.
Conclusion

- Aorto iliac Occlusive disease is ideally suited for endovascular therapy.
- May be treated with Variety of techniques including, double Barrel, V and High top and V
- Chronic occlusions are prone to multiple complications and therapeutic issues
- It is important to individualize the procedure to prevent interventional nightmares
- Use of PTFE covered stents enhance the patency in TASC C and D lesions
- Covered stents are beneficial in Preventing as well as treating Arterial rupture
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