How BMS and POBA history?

J. Sobocinski, Lille
G. Goyault, Strasbourg
Approach by level

- Iliac
- Femoro-pop
- BTK

03/06/2016

i-MEET Nice
France, 2016

• Reimbursement only for DES in the SFA, and BTK

• No reimbursement yet for DEB
  application for reimbursement for IN.PACT, Medtronic

• Debate:
  – Any locations
  – Restenosis / de novo lesions
  – AVF
  – Young / old patients
  – Diabetes, Renal insufficiency
  – APA therapies management
Iliac level
Iliac arteries

- **Variations of Lesions that need to be treated**
  - Aorto-iliac bifurcation
  - Common, or external or both iliac
  - Occlusion / stenosis
  - Soft or highly calcified atherosclerotic plaque

- **Strategies**
  - Open surgery (aortobifem, aortofem, interfem bypass)
  - Endovascular treatment:
    - PTA
    - Stents: Self-expansible, balloon-expansible, Covered
  - Mixed repair
Iliac artery – Open>Endo?

- 101 patients TASC C & D
- Lower Primary Patency in stenting group **80% vs. 97% for complex lesions**
- **Similar in TASC B**

- Primary Patency : stenting 70% vs. Bypass 93% @ 48 mo
- But more complications in bypass group with younger patients
Iliac artery – Stent>PTA?

Angioplasty versus stenting for iliac artery lesions.
Bekken J¹, Jongsma H, Ayez N, Hoogewerf CJ, Van Weel V, Fioole B.

**SELECTION CRITERIA:** We included all randomised controlled trials (RCTs) comparing percutaneous transluminal angioplasty and primary stenting for iliac artery occlusive disease. We excluded quasi-randomised trials, case reports, case-control or cohort studies. We excluded no studies based on the language of publication.

**AUTHORS’ CONCLUSIONS:** There is insufficient evidence to assess the effects of PTA versus PS for stenotic and occlusive lesions of the iliac artery. From one study it appears that PS in iliac artery occlusions may result in lower distal embolisation rates. More studies are required to come to a firm conclusion.

No scientific evidence for the need of primary stenting...

Long-term outcomes and predictors of iliac angioplasty with selective stenting

Toshifumi Kudo, MD, PhD, Fiona A. Chandra, and Samuel S. Ahn, MD* Los Angeles, Calif.
Iliac artery – Which stents?

Table 1: Major studies of currently available iliac artery stents

<table>
<thead>
<tr>
<th>Study</th>
<th>Stent name</th>
<th>Stent type</th>
<th>Number of patients; number of lesions</th>
<th>Target lesion length</th>
<th>Primary patency</th>
<th>TLR, 1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melodie</td>
<td>Express LD</td>
<td>Balloon expandable</td>
<td>151 patients; 163 lesions</td>
<td>32.0±1.7 mm*</td>
<td>92.1% at 6 months; 87.8% at 2 years; 99.2% at 9 months</td>
<td></td>
</tr>
<tr>
<td>ACTIVE</td>
<td>Assurant</td>
<td>Balloon expandable</td>
<td>123 patients; 159 lesions</td>
<td>29.4±14.7 mm*</td>
<td>68% stent; 61% PTA; 14% stent; 18% PTA</td>
<td></td>
</tr>
<tr>
<td>Mobility</td>
<td>Omnilink</td>
<td>Balloon expandable</td>
<td>123 stent; 121 PTA</td>
<td>45 mm stent; 44 mm PTA</td>
<td>66% stent; 39% PTA; 13% stent; 21% PTA</td>
<td></td>
</tr>
<tr>
<td>Krol et al</td>
<td>Zilver</td>
<td>Self-expanding</td>
<td>34 stent; 39 PTA</td>
<td>82 mm stent; 65 mm PTA</td>
<td>94.7% at 12 months; 91.1% at 12 months with Wallstent</td>
<td></td>
</tr>
<tr>
<td>CRISP-US</td>
<td>SMART; Wallstent</td>
<td>Self-expanding</td>
<td>102/118 SMART stent; 101/114 Wallstent</td>
<td>24.7±15.6 mm (SMART stent); 24.5±19.1 mm (Wallstent)</td>
<td>NR</td>
<td></td>
</tr>
<tr>
<td>Mobility</td>
<td>Absolute Pro</td>
<td>Self-expanding</td>
<td>134 stent; 72 PTA</td>
<td>70 mm stent; 64 mm PTA</td>
<td>81% stent; 37% PTA; 13% stent; 55% PTA</td>
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</tr>
<tr>
<td>Luminexx</td>
<td>Lifestar</td>
<td>Self-expanding</td>
<td>134 patients; 156 lesions</td>
<td>25.7±18.2 mm*</td>
<td>94.0% stent; 3.73% (at 9 months)</td>
<td></td>
</tr>
<tr>
<td>Lammer et al</td>
<td>Viabahn</td>
<td>Covered self-expanding</td>
<td>61 lesions</td>
<td>69 mm</td>
<td>91% at 12 months</td>
<td>2.9% (at 9 months)</td>
</tr>
<tr>
<td>iCARUS</td>
<td>iCAST</td>
<td>Covered balloon expandable</td>
<td>165 patients</td>
<td>69 mm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Plenty of various results – either with balloon or self exp stents
Iliac artery – Which stents?

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-Iliac 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, Y, 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±16 months, there were 38 (19.0%) restenoses, 22 (11.8%) 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 1.69 to 9.71, p=0.001] and residual diameter stenosis (AHR 1.04, 95% 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.

24-Month Data from the BRAVISSIMO: A Large-Scale Prospective Registry on Iliac Stenting for TASC A & B and TASC C & D Lesions

AVS 2015

No significant difference between Balloon & self exp stents
Iliac artery – Which stents?

- Covered vs balloon-exp stents (COBEST 2016)
  - At 7 years, 165 patients
  - TASC B, C, or D lesions
  - Similar results @ 5y for TASC B lesions
  - Benefit of CS for higher grade lesions
  - Similar limb salvage rate @ 5y
Iliac artery – place for DET?

• Pretty good results with bare stents
• Between 70 to 90% long-term PP

So... any place for DET in iliac location?
**Iliac artery – place for DET?**

- **DES**
  - No data; only in animal models up to date
  - Restenting: accepted policy, if reimbursed
  - In selected patient?

  - Young (<60yo)
  - Non-caucasian
  - EIA occlusion
Iliac artery – place for DET?

- DEB – no reimbursement, no routine use...

data with low quality evidence

The only data we have show that is
SAFE & EFFECTIVE
Iliac in 2016

- female 79 yo
- Conditions
  - MI
- CV risk factors:
  - HBP
  - Diabetes
  - Past smoker

CLI - RB 5 bilat
Bilat iliac occlusion

What do you do?
Iliac in 2016

- female 79 yo
- Conditions
  - MI
- CV risk factors:
  - HBP
  - Diabetes
  - Past smoker

CLI-RB 5 bilat
Roca & covered stents
Iliac in 2016

• Male 75 yo
• Conditions
  – MI
• CV risk factors:
  – HBP
  – Past smoker

CLI-RB 4 bilat
Bilat long iliac stenosis
Left SFA occlusion
Iliac in 2016

- Male 75 yo
- Conditions
  - MI
- CV risk factors:
  - HBP
  - Past smoker

Reca-Stenting SFA
Primary Kissing iliac with Sinus flex
Conservative management of EIA
Iliac in 2016

• Male 52yo
• Active smoker
• Vascular history
  – Previous kissing iliac stents in 2013
  – Left iliac occluded in 2014
  – Left transfem amputation

CLI - RB 6 left & RB 4 right
Intra-stent restenosis
Distal common iliac stenosis
Iliac in 2016

- Male 52yo
- Active smoker
- Vascular history
  - Previous kissing iliac stents in 2013
  - Left iliac occluded in 2014
  - Left transfem amputation

CLI - RB 6 left & RB 4 right
Intra-stent DEB
Distal common iliac stenting
Iliac arteries - Conclusion

• Excellent results of BMS
• Even better with covered stents
• DET only for selected patients?
Le ministre des finances et des comptes publics et la ministre des affaires sociales, de la santé et des droits des femmes,
Vu le code de la santé publique ;
Vu le code de sécurité sociale, notamment ses articles L. 165-1 à L. 165-5 et R. 165-1 à R. 165-30 ;
Vu l’avis de la Commission nationale d’évaluation des dispositifs médicaux et des technologies de santé,
Arrêtent :

Article 1

Au titre III de la liste des produits et prestations remboursables, chapitre 1er, section 1, sous-section 2, paragraphe 4, au D « Endoprothèses artérielles des lésions de l’artère poplitée, des artères sous-poplitées et émomo-poplitées », dans la rubrique Société ABBOTT France (Abbott), après le code 3163607, est ajouté le produit suivant :

**CODE**

| 3119210 |

**NOMENCLATURE**

Endoprothèse périphérique, stent lié évorolimus, Abbott, XIENCE PRIME BTK
Endoprothèse artérielle périphérique à libération d’évorolimus XIENCE PRIME BTK de la société Abbott France.
Indications de prise en charge :
- Traitement de l’artériopathie obstruante des membres inférieurs, au stade ischémie critique, imputable à des lésions ( 40 mm ) artériales sous-poplitées avec un diamètre de vaisseau de référence ≥ 2,25 mm et ≤ 4,25 mm, après échec de l’angioplastie par ballonnet.
Modalités de prescription :
- La décision d’implantation doit se faire dans le cadre d’une concertation multidisciplinaire.
- Références prises en charge :
  - diamètre 2,25 mm : 1012646-08, 1012646-12, 1012646-15, 1012646-18, 1012646-23, 1012646-28, 1012646-33, 1012646-38
  - diamètre 2,75 mm : 1012646-08, 1012646-12, 1012646-15, 1012646-18, 1012646-23, 1012646-28, 1012646-33, 1012646-38
  - diamètre 3 mm : 1012646-08, 1012646-12, 1012646-15, 1012646-18, 1012646-23, 1012646-28, 1012646-33, 1012646-38
  - diamètre 3,5 mm : 1012646-08, 1012646-12, 1012646-15, 1012646-18, 1012646-23, 1012646-28, 1012646-33, 1012646-38

Date de fin de prise en charge : 1er décembre 2019.

Article 2

Le présent arrêté prend effet à compter du treizième jour suivant la date de sa publication au Journal officiel.

Article 3

Le directeur général de la santé et le directeur de la sécurité sociale sont chargés, chacun en ce qui concerne, de l’exécution du présent arrêté, qui sera publié au Journal officiel de la République française.
BTK angioplasties

• Rutherford 4 to 6 - CLI

• Increasing pathology

• Goals of treatment :
  
  – Ulcer healing – relief of pain

  – Improving amputation free survival

• Major drawbacks : re-stenosis, -thrombosis and TLR

03/06/2016

i-MEET Nice
BTK angioplasties

• 10 years ago: angiograms stopped at the level of the knee.

• From short stenosis to long occlusion

• Now BTA

• Angiosome approach – debated

• Ever better devices - skills
Just angiosome?

• More is better!


PTA of infrapopliteal arteries: long-term clinical follow-up and analysis of factors influencing clinical outcome.


... One-year follow-up involved 1,069 limbs. Primary and secondary 1-year LS rates were 76.1 and 84.4%, respectively. The effect of clinical and morphological parameters on the 1-year LS was that the only associated disease with an adverse effect on LS rate was DM combined with dialysis. Regarding limb preprocedural status, gangrene was clearly a negative predictor. The most important factor affecting LS was the number of patent arteries post-PTA: patients with 0, 1, 2, and 3 patent arteries had 1-year primary LS rates of 56.4, 73.1, 80.4, and 83%, respectively.

Long-term follow-up of LS rates demonstrated secondary LS rates of 84.4, 78.8, and 73.3% at 1, 5, and 10 years. Every effort should be made to perform PTA for as many arteries as possible, even if TASC D type, to improve clinical outcome. Our study shows that repeat PTA is capable of keeping the long-term LS rate close to 75%.
M. W., 62 yo
DM
Hemodialysis
Diabetic foot ulcer

i-MEET Nice
Angiographic restenosis and its clinical impact after infrapopliteal angioplasty.

RESULTS: 95% of cases had 3-month angiography; restenosis rate was 73%; 40% restenosis and 33% re-occlusion. Twelve-month follow-up angiography was conducted for the patients without 3-month angiographic restenosis, and restenosis rate at 12 months was 82%. Non-administration of cilostazol and statin, and chronic total occlusion were 3-month angiographic restenosis predictors. Three- and 12-month mortality was 5% and 12%, respectively. Despite no patients having undergone amputation, 15% had persistent ischemic symptoms, and 48% of limbs underwent reintervention within 12 months. During the same study period, ambulatory status and limbs with complete healing were more frequently observed in the non-restenosis group than in the restenosis group. In the tissue loss group, time to wound healing in the restenosis group was longer than in the non-restenosis group (127 days vs. 66 days, p = 0.02).
Drug-eluting balloon in peripheral intervention for below the knee angioplasty evaluation (DEBATE-BTK): a randomized trial in diabetic patients with critical limb ischemia.


1y restenosis rate: 27%

Single-Center Experience With Lutonix Drug-Coated Balloons in Infrapopliteal Arteries.

Steiner S¹, Schmidt A², Bausback Y², Bräunlich S², Ulrich M², Banning-Eichenseer U², Scheinert D².

TLR of 16% at 8m
**RESULTS:** Eighteen nonrandomized studies were retrieved comprising 640 patients. After a median follow-up of 12 months, binary in-stent restenosis occurred in 25.7% (95% CI 11.6% to 40.0%), primary patency in 78.9% (95% CI 71.8% to 86.0%), improvement in Rutherford class in 91.3% (95% CI 85.5% to 97.1%), target vessel revascularization in 10.1% (95% CI 6.2% to 13.9%), and limb salvage in 96.4% (95% CI 94.7% to 98.1%). Head-to-head comparisons showed that sirolimus-eluting stents were superior to balloon-expandable bare metal stents in preventing restenosis and increasing primary patency (both p<0.001); sirolimus-eluting stents were also better than paclitaxel-eluting stents in terms of primary patency (p<0.001) and repeat revascularizations (p = 0.014).
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>DES</th>
<th>Limbs</th>
<th>Design</th>
<th>No. of Stents</th>
<th>Primary Stent Versus Bailout Stent</th>
<th>Primary Patency or Comments</th>
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</thead>
<tbody>
<tr>
<td>Balzer</td>
<td>2010</td>
<td>Sirolimus</td>
<td>128</td>
<td>Registry</td>
<td>341</td>
<td>Primary</td>
<td>83% at 18 mo</td>
</tr>
<tr>
<td>Bosiers</td>
<td>2006</td>
<td>Sirolimus</td>
<td>18</td>
<td>Registry</td>
<td>24</td>
<td>Primary</td>
<td>100% at 6 mo</td>
</tr>
<tr>
<td>Commeau</td>
<td>2006</td>
<td>Sirolimus</td>
<td>30</td>
<td>Registry</td>
<td>106</td>
<td>Bailout</td>
<td>97% at 7 mo</td>
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<tr>
<td>Feiring</td>
<td>2010</td>
<td>Sirolimus/primary</td>
<td>118</td>
<td>Registry</td>
<td>228</td>
<td>Primary</td>
<td>12% TLR at 36 mo</td>
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<td>Sirolimus</td>
<td>5</td>
<td>Registry</td>
<td>11</td>
<td>Primary</td>
<td>100% at 18 mo</td>
</tr>
<tr>
<td>Grant</td>
<td>2008</td>
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<td>81</td>
<td>Everolimus vs BMS</td>
<td>332</td>
<td>Bailout</td>
<td>81% vs 68% TLR at 36 mo</td>
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<td>Fischman</td>
<td>2010</td>
<td>Sirolimus</td>
<td>56</td>
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<td>101</td>
<td>Bailout</td>
<td>82% at 16 mo</td>
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<td>Rastan</td>
<td>2010</td>
<td>Sirolimus</td>
<td>104</td>
<td>Registry</td>
<td>256</td>
<td>Primary</td>
<td>84% at 12 mo</td>
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<td>Rosales</td>
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<td>Registry</td>
<td>62</td>
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<td>30% at 1 y</td>
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<td>Siablis</td>
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<td>Bailout</td>
<td>63% vs 35% at 2.5 y</td>
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<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>765</strong></td>
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<td><strong>1,854</strong></td>
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</tbody>
</table>

Abbreviations: TVR, target vessel revascularization.
<table>
<thead>
<tr>
<th>Author</th>
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</table>

Abbreviations: TVR, target vessel revascularization.
# First RCT

## TABLE 2. RANDOMIZED CONTROLLED TRIALS OF BTK DES

<table>
<thead>
<tr>
<th>Trials</th>
<th>Stent/Drug</th>
<th>Finish</th>
<th>No. of Patients</th>
<th>Lesion Length</th>
<th>Endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACHILLES(^{15})</td>
<td>Cypher vs PTA (sirolimus)</td>
<td>2010</td>
<td>200</td>
<td>≤ 120 mm</td>
<td>Binary restenosis 19% vs 49% at 1 y</td>
</tr>
<tr>
<td>DESTINY(^{16})</td>
<td>Xience (everolimus) vs MultiLink Vision</td>
<td>2010</td>
<td>140</td>
<td>≤ 40 mm</td>
<td>Primary patency 85% vs 54% at 1 y; TLR 34% vs 9% at 1 y</td>
</tr>
<tr>
<td>YUKON-BTK(^{17})</td>
<td>Yukon DES (sirolimus) vs Yukon BMS</td>
<td>2010</td>
<td>177</td>
<td>≤ 45 mm</td>
<td>Primary patency 81% vs 56% at 1 y</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>517</strong></td>
<td></td>
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</tr>
</tbody>
</table>

From EVT

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**CONCLUSION:** Based on low- to moderate-quality evidence, PTA with optional bailout stenting using BS should remain the preferred strategy in treating CLI patients with BTK arterial lesions. Before other strategies can be implemented, larger and high-quality RCTs assessing clinically relevant outcomes are needed.

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Randomized trials for endovascular treatment of infrainguinal arterial disease: systematic review and meta-analysis (Part 2: Below the knee).

Jens S\(^1\), Conijn AP\(^2\), Koelemay MJ\(^2\), Bipat S\(^3\), Reekers JA\(^3\).
Our experience...

...and first impressions
Case 1

• Ms G. Nicole, 77 yo, DM

• Chronic hyperalgic leg ulcer (6 months of local treatment without improvement)

• DUS: BTK involvement

• DSA and angioplasty
03/06/2016
i-MEET Nice
One week later
Increasing pain
03/06/2016

i-MEET Nice
2 months later
Pain recurrence
Delayed healing
Came back 6 months later for left side
Right side healed
Case 2

• Mr S. Armand, 63 yo
• Severe DM
• Chronic ulcer 4th toe
• DUS: BTK involvement
• DSA and angioplasty
July 2013
September 2013
Delayed healing
January 2014
4th toe necrosis
pTA recanalization
February 2014
Diabetic phlegmon
4th toe amputation
Case 3

- Ms F. Bernadette, 78 yo
- DM
- Subacute right foot ischemia with heel ulcer
- DUS: popliteal occlusion and BTK involvement
- DSA and angioplasty
July 2015

i-MEET Nice
DES 2.25 x 28mm

FOV: 30 cm
LAI: 3.1 deg
CAU: 0.6 deg
L: 94.8 deg
Tilt: 0 deg
Mag: 1.00
FL: ROT:
WW: 4096 WL: 2048
XA: 750x750
Follow up

• Pain relief
• Heel ulcer healing...
Follow up

• Pain relief
• Heel ulcer healing....
• ...until october 2015
• Ulcer of lateral aspect of the foot
• DUS: BTK occlusion
6 weeks follow up: ulcer healing
Conclusions
BTK angioplasties

• Clinically challenging
  – CLI
  – Limb salvage

• Technically challenging
  – Long occlusions
  – Heavy calcium lesions (HD, DM)
  – High EV expertise (CART, retrograde, double balloon, etc...)

• DUS and DSA

• High rate of restenosis - thrombosis

• TLR if clinically driven!!
DES in BTK

- Promising results in short or intermediate lesions
- Very helpful in P3 segment and proximal BTK

However...
DES in BTK

• Promising results in short or intermediate lesions
• Very helpful in P3 segment and proximal BTK

However...

• Few EBM
• Need 6 months double anti-platelet therapy
DES in BTK

- Promising results in short or intermediate lesions
- Very helpful in P3 segment and proximal BTK

However...
- Few EBM
- Need 6 months double anti-platelet therapy

Bail out spot stenting after POBA

2\textsuperscript{nd} intention after early restenosis ou rethrombosis

1\textsuperscript{st} intention on short P3 or proximal BTK stenosis
Femoropopliteal level
If you look at statistics...
Long lesions: PP 63% HBG vs 41% BMS
Drug-eluting balloons for femoropopliteal lesions show better performance in de novo stenosis or occlusion than in restenosis.

Herten M¹, Torsello GB², Schönefeld E², Imm B³, Osada N³, Stahlhoff S³.

Abstract

OBJECTIVE: Although drug-eluting balloons (DEBs) have shown promising results treating de novo (DN) atherosclerotic lesions and appear to have been widely adopted in Europe, their long-term efficacy in the broad spectrum of femoropopliteal restenosis (RE) remains to be proven. The purpose of the study was to assess the efficacy of paclitaxel-DEBs in restenotic (stented and nonstented) vs DN stenotic femoropopliteal arteries.

METHODS: The study prospectively enrolled 100 patients undergoing femoropopliteal endovascular intervention by DEB for RE or DN stenosis. Patients who received additive atherectomy were excluded. The primary end point was the primary patency (PP) rate at 12 months. Secondary end points were sustained clinical improvement and clinically driven target lesion revascularization.

RESULTS: DEBs were used to treat 105 limbs for intermittent claudication (82 [78%]) or critical limb ischemia (23 [22%]) in 100 patients. Of these, 111 lesions were DN stenosis (46 [41%]) or RE (65 [59%]). The overall PP was 86% at 6 months and 74% at 12 months. PP of DN stenosis was higher at 6 months (93% vs 81%) and was significantly (P = .021) better than RE at 12 months (85% vs 68%). Sustained clinical improvement based on Rutherford classification was significant in both groups (P < .001). Target lesion revascularization was significantly lower in DN stenosis compared with RE at 12 months (15% vs 32%; P = .021).

CONCLUSIONS: DEB angioplasty is an effective therapy for DN femoropopliteal lesions. The results of DEB angioplasty for RE are inferior compared with DN stenosis after 12 months. Nevertheless, results of DEB angioplasty for RE seem comparable with technically more demanding literature-derived strategies.
German Center Subanalysis of the LEVANT 2 Global Randomized Study of the Lutonix Drug-Coated Balloon in the Treatment of Femoropopliteal Occlusive Disease.

Scheinert D1, Schmidt A2, Zeller T3, Müller-Hulsbeck S4, Sixt S5, Schröder H6, Weiss N7, Kestelsen D8, Ricke J9, Steiner S2, Rosenfield K10

+ Author information

Abstract

PURPOSE: To report a subanalysis of the German centers enrolling patients in the prospective, global, multicenter, randomized LEVANT 2 pivotal trial (ClinicalTrials.gov identifier NCT01412541) of the Lutonix drug-coated balloon (DCB) for the treatment of femoropopliteal occlusive disease.

METHODS: Among the 476 patients in LEVANT 2, 126 patients (mean age 67.1±9.6 years; 79 men) were enrolled at the 8 participating German sites between August 2011 and July 2012 and were randomized 2:1 to treatment with the Lutonix DCB (n=84) vs an uncoated balloon during percutaneous transluminal angioplasty (PTA, n=42). Average lesion length was 56 lesions, and 23% were total occlusions. The freedom from a composite of perioperative and revascularization. Secondary endpoints included:

RESULTS: Demographic, clinical, and lesion percent diameter stenosis (19%) and procedural variables vs 58% (p=0.015) and the composite safety were in DCBs (96%) vs PTA (82%, p=0.002). Major adverse events were observed in 0.0% in men and women. Complication rates per treatment (21.8 vs 39.5 vs PTA 7.7 atm, p<0.001) but for a shorter period of time, a higher baseline stenosis, final postprocedural

CONCLUSION: Superiority of DCB over PTA safety, and freedom from TLR. The benefit of procedural variables may account for differences in outcomes.

Durability of Treatment Effect Using a Drug-Coated Balloon for Femoropopliteal Lesions: 24-Month Results of IN.PACT SFA.

Laird JR1, Schneider PA2, Tepe G3, Brodmann M4, Zeller T5, Metzger C6, Krishnan P7, Scheinert D8, Micari A9, Cohen DJ10, Wang H11, Hasenberg MS11, Jaff MR12, IN.PACT SFA Trial Investigators.

+ Author information

Abstract

BACKGROUND: Evidence from large, randomized, controlled peripheral artery disease trials reporting long-term outcomes using drug-coated balloons (DCBs) is limited. Previously, the DCB showed favorable 1-year outcomes compared with conventional percutaneous transluminal angioplasty (PTA), yet durability of the treatment effect with DCBs remains unknown.

OBJECTIVES: This study sought to investigate the longer-term outcomes of a paclitaxel-eluting DCB compared to PTA for femoropopliteal lesions.

METHODS: We enrolled 331 patients with symptomatic (Rutherford 2 to 4) femoropopliteal lesions up to 18 cm in length. Patients were randomly assigned in a 2:1 ratio to treatment with DCB or PTA. The 24-month assessments included primary patency, freedom from clinically driven target lesion revascularization (CD-TLR), major adverse events, and quality of life and functional outcomes as assessed by the EuroQOL-5D quality-of-life questionnaire, walking impairment questionnaire, and 6-min walk test.

RESULTS: At 24 months, patients treated with DCB showed significantly higher primary patency when compared with PTA (78.9% vs. 50.1%, p < 0.001). The rates of CD-TLR were 9.1% and 28.3% (p < 0.001) for the DCB and PTA groups, respectively. The overall mortality rate in the DCB group was 8.1% versus 0.9% in the PTA group (p = 0.008). There were no device- or procedure-related death or major amputations in either group through 24-month follow-up. The rate of vessel thrombosis was low (1.5% DCB vs. 3.8% PTA; p = 0.243), with no new events reported between 1 and 2 years. Both groups showed similar functional improvement at 2 years, although DCB patients achieved this level of function with 58% fewer reinterventions.

CONCLUSIONS: The 24-month outcomes from the trial demonstrate a durable and superior treatment effect of DCB versus PTA with significantly higher primary patency, lower CD-TLR, and similar functional status improvement with fewer repeat interventions. (Randomized Trial of IN.PACT Admiral Drug Eluting Balloon vs Standard PTA for the Treatment of SFA and Proximal Popliteal Arterial Disease [IN.PACT SFA I]: NCT01175850; and IN.PACT Admiral Drug-Coated Balloon vs. Standard Balloon Angioplasty for the Treatment of Superficial Femoral Artery [SFA] and Proximal Popliteal Artery [PPA] [IN.PACT SFA II]: NCT01566461).
Economic analysis of endovascular interventions for femoropopliteal arterial disease: a systematic review and budget impact model for the United States and Germany.

Pietzsch JB, Geisler BP, Garner AM, Zeller T, Jaff MR.

Abstract

OBJECTIVES: To study the economic impact on payers and providers of the four main endovascular strategies for the treatment of infrainguinal peripheral artery disease.

BACKGROUND: Bare metal stents (BMS), drug-eluting stents (DES), and drug-coated balloons (DCB) are associated with lower target lesion revascularization (TLR) probabilities than percutaneous transluminal angioplasty (PTA), but the economic impact is unknown.

METHODS: In December 2012, PubMed and Embase were systematically searched for studies with TLR as an endpoint. The 24-month probability of TLR for each treatment was weighted by sample size. A decision-analytic Markov model was used to assess the budget impact from payers’ and facility-providers’ perspectives of the four index procedure strategies (BMS, DES, DCB, and PTA). Base cases were developed for U.S. Medicare and the German statutory sickness fund perspectives using current 2013 reimbursement rates.

RESULTS: Thirteen studies with 2,406 subjects were included. The reported probability of TLR in the identified studies varied widely, particularly following treatment with PTA or BMS. The pooled 24-month probabilities were 14.3%, 19.3%, 28.1%, and 40.3% for DCB, DES, BMS, and PTA, respectively. The drug-eluting strategies had a lower projected budget impact over 24 months compared to BMS and PTA in both the U.S. Medicare (DCB: $10,214; DES: $12,904; uncoated balloons $13,114; BMS $13,802) and German public health care systems (DCB €3,619; DES €3,632; BMS €4,026; PTA €4,290).

CONCLUSIONS: DCB and DES, compared to BMS and PTA, are associated with lower probabilities of target lesion revascularization and cost savings for U.S. and German payers.
DES

Twelve-Month Results From the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Treatment of Obstructive Femoropopliteal Disease.

Müller-Hülsbeck S¹, Keirse K², Zeller T³, Schröe H⁴, Diaz-Cartelle J⁵.

TASC A/B lesions TLR 3,8%
Durable Clinical Effectiveness With Paclitaxel-Eluting Stents in the Femoropopliteal Artery: 5-Year Results of the Zilver PTX Randomized Trial.

Case 1

• Ms K. Danielle, 71 yo

• Left calf claudication

• DUS : long femoropopliteal stenosis

• DSA and angioplasty
What would you do?

• POBA?

• DEB – spot stenting?

• Directional atherectomy – DEB?

• Long stents?

• Fem-pop bypass?

03/06/2016

i-MEET Nice
Case 2

- Ms B. Huguette, 81yo
- CLI with rest pain
- DM, dyslipemia, history of smoking
- DUS: long fem-pop occlusion
- DSA and angioplasty
What would you do?

• Sympathectomy
• Fem-pop bypass?
• Sub-intimal recanalization?
• Long stent?
• DEB and spot stenting?
• Long DES?
Conclusion

• DET: valuable tools
• Selected patients
• Low-quality evidence in literature
• Economic issues
How BMS and POBA history?

J. Sobocinski, Lille
G. Goyault, Strasbourg