Drug Eluting Devices Are The New Standard For Fem-Pop Endovascular Treatments For IC: The Timing of Development of Restenosis is a Guide To Why Extended Drug Release Is Important With DESs: Which DES Has It

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Disclosure
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Potential conflicts of interest to report:
Enter patients in studies sponsored by: Gore, Cordis, Medtronic, Silk Road, Bard, NIH, Limflow
Modest royalty: Cook
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Dispersion of Coronary DES Technology in the US

Probability of Restenosis
Restenosis after SFA stenting peaks at 12 months

- Timing of SFA restenosis is longer compared to coronary stenting, which predominantly occurs within 6 months after stenting.
- Factors for restenosis in the SFA include the number of runoff vessels, severity of lower limb ischemia, and length of diseased segments.

Femoral-popliteal Technology
Work in Progress

PTA
Stent

Lesion length (cm)

12-month Primary Patency

RCT Data: PTA vs Stent

FACT
4EVER
Astron
Vienna
Vienna-3

Drug Eluting Technology
Big Picture

DCB
DES

Fem-pop
Paclitaxel: Levant, IN.PACT, Iluminate pivotal trial data
Ranger pivotal enrolling Multiple with CE mark and varying excipients, all with paclitaxel

Zilver: 5 year data
Eluvia: polymer-based, 1y data
Pivotal trial enrolled Bioabsorbable Vascular Scaffold?

BTK
Levant BTK enrolling At least 3 others in various stages of development

Everolimus, sirolimus: balloon expandable coronary stents, focal lesions
Solid phase paclitaxel is embedded in the vessel wall, creating "reservoirs" that provide sustained release of drug over time.

To show the effect of the medication, the lesion complexity and the injury of angioplasty had to be minimized.

From R Vermani, Charing Cross 2016

Stellarex Illumenate Trial
Primary Patency at 12 Months
ITT Data Set

Femoral-popliteal Technology
Drug Eluting Devices

IN.PACT SFA Trial
Primary Patency at 3 Years

Primary Patency-DCB for Long Lesions

PACLITAXEL RESERVOIR
PACLITAXEL RESERVOIR
PACLITAXEL RESERVOIR
Zilver: DES vs BMS
5-year Primary Patency (PSVR < 2.0)

5-year Primary Patency

BMS: 53.3%  
Zilver PTX: 72.4%

Zilver PTX vs BMS: 72.4% vs 53.3%

p = 0.03

Primary Patency
DCB vs DES for Long Lesions

Lesions >10cm
Mean lesion length 19cm
53% occlusions
Primary patency at 1 year:
DCB=78.1%
DES=69.6%

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Drug Eluting Devices for Claudication

Conclusion

• Both DCB and DES show promise for improving patency, including for long lesions.
• Appears safe in claudication.
• Paclitaxel only available drug so far.
• Not yet clear how best deliver drug.
• Multiple studies underway to compare devices.