DEBATE -
Why We Should Stay Away From DEBs For BTK Interventions

Erich Minar
Medical University Vienna

SESSION 26: MORE LOWER EXTREMITY NEW DEVELOPMENTS AND HOT TOPICS - NEW DEVELOPMENTS IN DEBS

Disclosure
Speaker name: Erich Minar
I do not have any potential conflict of interest

VEITH Symposium
November 2015; New York

European Heart Journal Advance Access published May 24, 2015

Drug-coated balloon treatment for lower extremity vascular disease intervention: an international positioning document

Bernardo Cortese1, Juan F. Grazado1, Bruno Scheler2, Peter A. Schneider3, Gunmar Toge1, Dirk Scherzer1, Lawrence Garcia4, Eugenio Stefano1, Fernando Allimo1, Gary Ansel5, and Thomas Zeller6

Drug-coated balloon for below-the-knee artery disease

PREVENTION OF AMPUTATION
Revascularization
Wound management

Patency

European Heart Journal Advance Access published May 24, 2015

Longer term patency is desirable in these patients, but ultimately wound healing and limb salvage are the desired outcome and it is not yet clear that DCB will positively influence these endpoints.
Drug-Eluting Balloon Versus Standard Balloon Angioplasty for Infrapopliteal Arterial Revascularization in Critical Limb Ischemia

12-Month Results From the IN.PACT DEEP Randomized Trial

J Am Coll Cardiol 2014;64:1568–76

- No difference in treatment effect confirmed on all imaging endpoints: LLL, binary restenosis, occlusion rates
- No evidence of beneficial sub-groups
- No predictors of failure identified

The recent results of the IN.PACT DEEP study that alarmed in terms of safety and lack of efficacy suggest that an abundance of caution is reasonable.

Paclitaxel-coated balloon in infrapopliteal arteries


Prospective, international, multicentre, 1:1 RCT DEB vs. POBA, for the treatment of stenosis and occlusion of the infrapopliteal arteries BIOLUX P-II N=72

Idea - Concept
Ideal - Proof of concept - SFA
Pilot studies BTK (promising)
Larger randomized clinical study/studies negative
Widespread routine clinical use

Conclusion:
The DCB is safe but not superior to standard PTA balloon alone, with high patency loss seen over time in both groups.
Many issues must be resolved before DCB can significantly impact the care of BTK disease.

Problems with coating technology
Tapered artery: drug application may not be uniform.
Multiple lesions in different arteries: opportunity for geographic miss
Much of the drug may be lost from the balloon surface during the advancement in the BTK arteries (friction between vessel wall and balloon surface)

Drug-coated balloon treatment for lower extremity vascular disease intervention: an international positioning document

There exists vital need for further investigation of DCB in a variety of BTK lesion subsets and clinical conditions.

Studies in patients with CLI and BTK-treatment remain the most challenging in the cardiovascular field

* Heterogeneity of (high-risk) patient population
* Heterogeneity of vascular anatomy including the below the ankle run-off/plantar arch status
* Heterogeneity of wound types and locations
* Wound related artery revascularization
* Optimal wound care

Why we should stay away from DCB for BTK?

Conclusions:

* Largest and most rigorous BTK-CLI trials completed to date failed to demonstrate superior treatment effect of a DEB vs. PTA
* Complete lack of Level I-Evidence of its efficacy
* The increased costs of DCB are not justified based on the current data.

Further research -- using DEB with alternative coating technologies - is necessary in combination with standardized wound care.