Value Of Debs (Paclitaxel) Vs. Uncoated Balloons After SFA Nitinol Stenting – The Freeway Multicenter RCT: What Are The Cost Implications?
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Introduction:
The restenosis rate of self-expanding stents in the femoro-popliteal artery segment is still a major limitation in terms of restenosis and patency. The Freeway Stent Study is the first trial, which investigates the inhibition of restenosis by Paclitaxel-eluting balloon angioplasty after Nitinol stent placement versus Nitinol stenting followed by uncoated balloon angioplasty for treatment of SFA lesions. By this, the Freeway Stent Study follows a new approach to potentially overcome the problem of restenosis.

Methods:
The Freeway Stent Study is a randomized, controlled multicenter trial which is conducted in 15 centers in Germany and Austria. This study intends to enroll 200 patients being randomized in a 1:1 relation to either Nitinol stenting followed by drug-eluting balloon (DEB) Freeway™ (Eurocor GmbH, Bonn, Germany) post-dilatation or stenting followed by PTA using an uncoated balloon. Primary endpoint is clinically driven target lesion revascularization at 6 months. Further, secondary safety and efficacy endpoints such as late lumen loss at 6 months, patency rate and major adverse events are investigated.

Results:
130 patients have already been enrolled. More than 100 have completed the 6 months follow up. The results show a favorable outcome for the DEB arm in relation to the TLR rate in this patient population which presented predominately with occlusions. The results are supported by the clinical outcome of patency rate, ABI index and presentation according to Rutherford.

Conclusions:
In this trial, the Freeway Paclitaxel-coated balloon is investigated in a new approach to decrease the restenosis rate of stents in patients after Nitinol stenting in the SFA. Interim results will be provided to show that DEB after SFA Nitinol stenting might provide an advantage also in these patients to overcome the existing limitations of peripheral artery disease treatment. With respect to procedural costs implication, the situation in Germany is as follows: additional DEBs are reimbursed up to four (!) balloons, resulting in positive mutually satisfactory result.

Similar trails comparing the value Value of DEBs (Paclitaxel) vs. uncoated balloons after SFA Nitinol stenting are on the way (1).

References: