Cutting- and Drug Coated Balloon in Femoro-Popliteal Lesions - 6 months results of the DCB-Trak-Registry -

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Background:
Recent trials demonstrated favourable results with drug-coated balloons (DCB) in femoro-popliteal lesions. However, the effects of vessel preparation with cutting balloon angioplasty (CBA) prior to DCB-treatment are unknown. The DCB-Trak registry evaluated the concept of vessel preparation with CBA and subsequent DCB-angioplasty in femoro-popliteal lesions.

ClinicalTrials-Registration: NCT02198105

Methods:
In a single centre registry, 20 consecutive patients with femoro-popliteal lesions were treated with a cutting-balloon (VascuTrak®) and a DCB subsequently. The primary endpoint was the clinically driven target lesion revascularization (TLR). Secondary endpoints were clinically driven target vessel revascularization (TVR), binary restenosis (PSV>2.4), change in rutherford classification and ABI. Safety endpoints were major cardiovascular events (cardiovascular death, MI, stroke, death) and need for amputation.

Results:
The procedure was successful in 17 patients, 1 patient was lost of follow-up. Therefore 16 patients (4 female) were analyzed at the 6 months follow-up visit. Baseline and lesion characteristics were shown in table 1. There was no clinically driven TLR or TVR after 6 months (table 2). Rutherford classification improved from 3.5±0.97 to 0.88±0.72 (p<0.01) after 6 months (figure 1). ABI increased from 0.85±0.26 to 1.02±0.19 (p=0.01, figure 2) after the procedure with no further change after 6 months (1.01±0.15; p=0.83)

Conclusion:
Recent trials demonstrated promising results for the use of drug-coated balloons in femoro-popliteal lesions. Additional vessel preparation with a cutting-balloon might further increase clinical outcome of patients. Further trials with more patients were needed for validation of the results of our registry.

Table 1
Patient and Lesion Characteristics at Baseline

| Patient Characteristics | N (%)
|-------------------------|---------
| Male Gender            | 16 (80%)
| Age (yrs)              | 69 (52-81)
| HLP                    | 19 (95%)
| Diabetes               | 10 (50%)
| Hypertension           | 19 (95%)
| Smoking                | 14 (70%)
| Rutherford classification | 3.5±0.9 (3-6)
| Rutherford 4-6         | 5 (25%)
| ABI                    | 0.84±0.25 (0.4-1.3)
| Lesion length (mm)     | 62±59 (12-260)
| Grade of stenosis (%)  | 80±12 (55-100)
| Total occlusion        | 3 (15%)

Table 2
Primary and Secondary Endpoints (6 months FU)

| Primary Endpoint            | N (%)
|-----------------------------|---------
| Clinically driven TLR       | 0 (0%)  

| Secondary Endpoints         | N (%)
|-----------------------------|---------
| Clinically driven TVR       | 0 (0%)  
| Binary restenosis (PSV>2.4) | 1 (11%) 
| MACE                        | 0 (0%)  
| Any amputation              | 0 (0%)  

TLR: target lesion revascularization, TVR: target vessel revascularization, PSV: