RENAL ANGIOPLASTY AND STENTING UNDER PROTECTION. LIMITATIONS. FIRST HUMAN STUDY WITH A 3D FILTER: THE FIBERNET TM

ACC Poster Contributions
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Background: Atheroemboli are the rule in any intervention and the leading cause of complications during PCI, carotid angioplasty (CAS), but probably also after renal angioplasty stenting (RAS) which could explain the renal function deterioration after RAS in 20-30 % of the cases. Several series of RAS under protection were reported using current embolic protection devices (EPD), but these EPD have significant limitations which may be addressed by a new EPD, the FiberNetTM (Lumen Biomedical Inc, Plymouth MN).

Methods: Fibernet is a 3D expandable filter made of fibers, expanding radially to fill the lumen, mounted onto a 190 cm long 0.014 wire. No delivery sheath required. Low crossing profile (1.7-2.9F). Retrieval catheter with focal suction during device removal allowing meticulous cleaning of the vessel. The filter can fill vessels from 1.75 to 7 mm without requiring a long landing zone allowing protection in the majority of renal arteries. Fibernet can capture particles as small as 40 μ without compromising the flow.

Results: After a series of 139 protected renal angioplasties performed with current EPDs, we began the first human study with FiberNetTM. 12 ostial lesions (R:6, L: 6) treated in 12 hypertensive patients (Male: 10). Mean age 63 y., average stenosis 79 % 2 patients had moderate renal insufficiency. FiberNet crossed 11 lesions without predilatation (1 predilatation necessary for a suboccluive very calcified ostial lesion). Technical success 100 %. No complication. All samples visually contained significant amount of emboli. Mean debris surface area: 106mm² (aspirated debris: 82 mm², debris in the filter: 24 mm²). Mean number of particles 28-60μ : 2136 ± 776, >60μ: 5918±1362. At 6 month follow-up no deterioration of the renal function.

Conclusion: The first human use of this new novel EPD in RAS is encouraging. FiberNet was easy to use. It captures particles of 30/40μ without compromising the flow and seems an improvement in comparison with current EPD. The amount of debris removed is comparable during RAS and CAS. Additional patients will demonstrate the overall performance of this new EPD and its role to preserve the renal function and improve long term results of RAS.