

Combined use of directional atherectomy and drug coated balloon for the Endovascular Treatment of Common Femoral Artery Disease: one year outcomes of 30 consecutive patients.

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Background

Atherosclerotic Common Femoral Artery (CFA) obstruction is a known cause of symptomatic peripheral arterial disease. Although surgical endarterectomy is considered the therapy of choice for this condition, recently some large single center series have shown encouraging results for percutaneous treatment of this arterial segment.

Endoarteriectomy
Proven acute and long-term Results
Plaque excition
No additional matherials

Endovascular
Less invasive
Re-doing
Safety
Patient compliance

- ✓ Invasive
- ✓ Complications
- ✓ Patient discomfort

- ✓ No advantage vs CEA
- ✓ Stent implantation
- ✓ Compromise further treatment options.

Ideal -Technique
Good acute and long-term results
No additional matherials (stent)
Less invasive
Safety
Good patient's compliance

Aims of the Study

The purpose of this study was to evaluate safety and feasibility, safety, acute and 1-year efficacy of the endovascular treatment of atherosclerotic common femoral artery (CFA) obstructions with combined use of Directional Atherectomy (DA) and Paclitaxel Coated Balloon (DCB).

Methods

30 consecutive patients were treated in our center for severely symptomatic CFA stenoses or occlusions

- DCA was performed with TurboHawk System.



- DEB used was Lutonix Paclitaxel-Eluting System. Sizing was 1:1 to Ref. Vessel Diam. and 10 mm longer than stenosis. Inflation time was at least 180 sec.



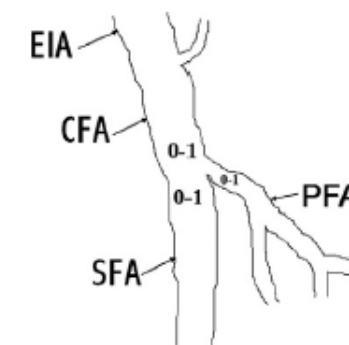
- Drug: Paclitaxel ($\mu\text{g}/\text{mm}^2$ surface)
- Paclitaxel + carrier polysorbate + sorbitole

Patient's Characteristics

	# patients (%)
Male gender	25(84%)
Age (years)	71 ± 10
Hypertension	18 (60%)
Dyslipidemia	21 (70%)
Smoking status:	
Previous smoker	21(70%)
Current smoker	3 (10%)
Diabetes mellitus : non-insulin-dependent insulin-dependent	12(40%) 6 (20%)
Renal failure:	
eGFR < 30 ml/min	5 (15%)
ESRD in dialysis	3 (10%)
Rutherford class at admission	% of patients ABI Index
1	0 -
2	0 -
3	2 (6%) 0.65 ± 0.11
4	15 (50%) 0.48 ± 0.12
5	6 (20%) 0.31 ± 0.06
6	7 (24%) 0.26 ± 0.20

Angiographic and procedural characteristics

	# patients (%)
Medina Classification:	
Class 1/0/0	5(15%)
Class 1/1/0	15 (50%)
Class 1/0/1	7(25%)
Class 1/1/1	3 (10%)
Concomitant treatment of in /out flow	7 (23%)
Total occlusion	6 (20%)
Mean lesion length (mm)	50 ± 35
Minimal Lumen Diameter	1,2 ± 0,9
Calcium Score >3	26(88 %)



Acute Results

Procedural success meaning ability to cross lesion with filter-wire and to treat the lesion with DCA without predilatation was achieved in all the patients (100%).

Large amount of debris was collected in the reservoir in all cases.

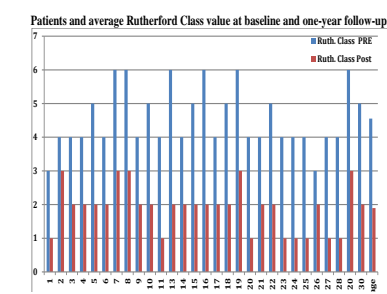
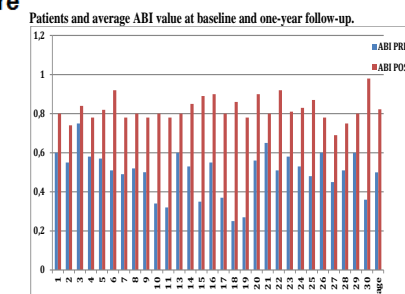
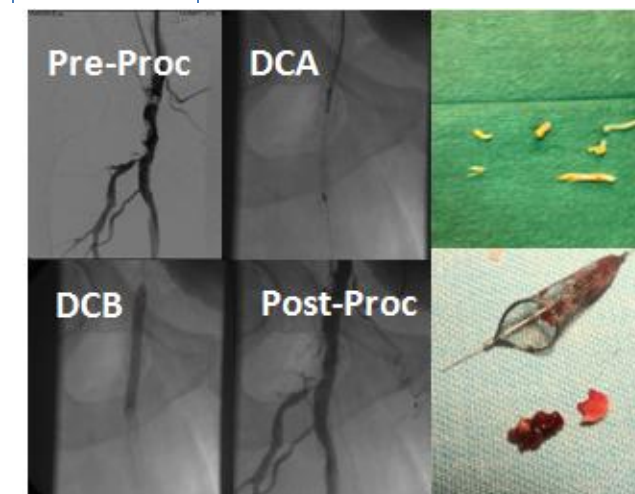
No distal embolization occurred. In two cases a significant amount of debris was collected distal protection system.

Acute angiographic success was achieved in all cases. At the end of procedure residual stenosis was 10,2 ± 5,8%.

Bailout stentina was in 3 (10%) cases.

Clinical results at one-year follow-up

	# patients (%)
Follow-up completion	30 (100 %)
Clinical follow-up duration (days)	350±51
Major amputations (above the ankle) in CLI patients	0
Minor amputations (below the ankle) in CLI patients	0
Limb salvage rate (CLI patients)	5/5 (100%)
Re-hospitalizations (any cause)	9 (30 %)
Restenosis Rate (>50%)	3(10%)
Repeat percutaneous transluminal angioplasty	2 (6%)
Medical Therapy	1 (3%)
Target Limb Revascularization	6 (20%)
Secondary patency at 1 year	30 (100%)



CONCLUSIONS

These data suggest that combined use of DCA and DEB may represent a potential alternative therapeutic strategy for the treatment of CFA lesions.

Further randomised trials are needed to confirm this hypothesis.