Drug Eluting Balloon Versus Bare-Metal Stent in Treating Chronic Total Occlusion of Femoro-Popliteal Arterial Segment

A review of TASC C and D lesion.

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Purpose: To evaluate the results of drug eluting balloon versus bare metal stenting in treating long chronic total occlusion (CTO) of superficial femoral and proximal popliteal artery in patients with disabling claudication and critical limb ischemia regarding technical success, primary patency, target lesion revascularization (TLR), limb salvage rate, Associated comorbidities and complications.

Stent scaffolding of superficial femoral artery occlusive lesions have been associated with high rates of late clinical failure; the concept of leave nothing behind has evolved and percutaneous balloon angioplasty becomes preferred option for endovascular treatment. Drug eluting balloons (DEBs) have shown promise in improving the outcomes and decreasing incidence of restenosis for patients with de novo superficial femoral occlusive disease.

Patients and methods: This prospective randomized multicenter study was conducted on 90 patients (110 limbs) complaining of lower limb disabling claudication and critical limb ischemia due to femoropopliteal atherosclerotic occlusive lesions, with Age over 50 years; Patients were randomly allocated into two groups according to the intervention method performed. Group (A): 48 patients (57 limbs) were submitted for treatment with paclitaxel DEB and Group (B): 42 patients (53 limbs) submitted for treatment with Bare Metal Stents (BMS). Follow-up period was for 1, 6 and 12 months.

Results and conclusion: BMS had lower patency and limb salvage rates compared to patients treated with Paclitaxel DEB. 12 months primary patency rates were 92% with TLR 8% in DEB group, Vs 77.1% for primary patency with TLR 22.9% in group BMS, however not statistically significant P value > 0.999. Regarding device success, BMS associated with higher success in TASC D 92.5% vs 89% for DEB (P value 0.041) with no difference in 12 months clinical improvement. Conclusions: Paclitaxel Drug Coated Balloons (DCB) seems to have promising very impressive results in prevention of restenosis with low TLR rate in comparison to BMS for TASC D lesions, however long term follow up is required.