Infra-popliteal Interventions with Drug Eluting Balloons vs Regular Balloons in Critical Limb Ischaemia – Single Center Real World Experience

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Purpose
To date there is no consensus on the ideal treatment for infra-popliteal critical limb ischemia (CLI) and which patients are best suited for drug-eluting balloon (DEB) angioplasty revascularization. The project aims to determine what factors best predict success from DEB revascularization.

Method
We designed a single-center retrospective analysis of major amputation rates and mortality in groups of patients treated with DEB vs Plain Balloon Angioplasty (POBA) from 2012-2017 and 2009-2012 respectively.

Patient demographics like diabetes, hypertension, chronic kidney disease, and smoking status were recorded. We also documented lesion location, length, Rutherford Classification, and single- vs multi-level disease.

Primary outcomes are limb salvage rates at 6 and 12 months following intervention. Sub-group analysis was performed to determine if the above characteristics have an effect on outcomes.

Results
To date we have treated more than 130 CLI patients with DEB angioplasty and 74 patients with POBA for infra-popliteal disease. Eighty-eight patients treated with DEB and 60 patients treated with POBA have reached 12-month follow-up post-intervention.

At our center, we treat a population with high rates of comorbidities and risk factors. These patients also present with advanced disease (>2/3 present with tissue loss). Both cohorts of patients are similar in their demographic characteristics.

In patients treated with DEB, limb salvage was achieved in 85% and 82% at 6- and 12-month follow-up. In patients treated with POBA, limb salvage was achieved in 81% and 73% at 6 and 12 month follow-up.

We found no statistically significant difference in limb salvage or mortality between cohorts of patients treated with DEB vs POBA, although there was a trend towards benefit for limb salvage at 12 months from DEB.

Conclusions
In our real world experience, there is no statistically significant difference in limb salvage rates at 6 and 12 months in patients treated with DEB vs POBA for CLI. Our data and experience suggest that DEB patients with shorter, focal, stenotic lesions at pre-gangrenous stages may be the ideal candidates for DEB angioplasty.