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Prospective randomized trial comparing heparin-bonded versus non-heparin bonded PTFE grafts in femoro-popliteal bypass.

F. Vermassen, B. Jacobs, All contributors to the study
Ghent University Hospital, Gent, Belgium

Introduction: Increased thrombogenicity contributes to the lesser results with prosthetic grafts compared to venous grafts in femoro-popliteal reconstructions. Heparin-bonding to the graft material might improve the results by reducing the thrombogenicity but its efficacy has never been proven yet.

Material and methods: We performed a prospective randomized multicentre trial comparing a heparinbonded PTFE (HB) graft (Jotec[®]) to the same graft without heparin bonding (NHB) in above and below knee femoro-popliteal bypass. Primary endpoint was primary patency after 2 years.

Results: A total of 537 patients (73% male, mean age 69y) were enrolled in 23 centres (269 HB; 261 NHB). Risk factors were evenly distributed in both groups. 385 were above-knee bypasses (AK), 145 were belowknee (BK). As expected overall patency in the AK-group was significantly better than in the BK group (70% vs 56% at 2yrs; $p=0,001$, HR:1,76). Significant risk factors for patency were: smoking status, lower age, no statin use, higher Fontaine stage and bad outflow. In the total group better results were obtained with HB grafts than with NHB grafts (72% vs 62% at 2 yrs; $p=0,12$, HR:1,29). This difference was statistically significant in the AK group (80% vs 63% at 2yrs; $p=0,01$, HR:1,70), but was not present in the BK-group (55% vs 59% at 2yrs; $p=0,76$, HR:0,91).

Conclusion: In a large prospective RCT the results with heparin-bonded PTFE grafts (Jotec[®]) in femoropopliteal bypasses were excellent and better than with the same non heparin-bonded grafts. This difference was statistically significant in above-knee bypasses but not present in the below-knee group. Based on these results heparin-bonded grafts should preferentially be used in AK FP-bypasses.