

Efficacy of Paclitaxel Balloon for Hemodialysis Stenosis Fistulae After One Year Compared to High-Pressure Balloons: A Controlled, Multicenter, Randomized Trial

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Abstract

Purpose A controlled, prospective, multicenter, randomized trial to compare primary patency after angioplasty with a drug-coated balloon versus plain angioplasty balloon in stenosis of dysfunctional fistulae and grafts for hemodialysis.

Materials and Methods A total of 136 patients (148 angioplasties) at four centers were randomized to receive a drug-coated balloon or plain angioplasty balloon after satisfactory angioplasty with a high-pressure balloon. The inclusion criteria were clinical signs of vascular dysfunction confirmed by Doppler Ultrasound and/or angiography. The primary endpoint was target lesion patency defined as time elapsed between the completion of effective and the appearance of restenosis at 6 and 12 months after angioplasty. Secondary endpoints included the relationship

between the location of the stenosis, previous angioplasty, demographic variables and survival.

Results Primary patency after angioplasty was higher in the group treated with the drug-coated balloon than the plain angioplasty balloon (153.01 to 141.69 days at 6 months; 265.78 to 237.83 days at 12 months). Drug-coated balloon angioplasty resulted in superior patency after 6 and 12 months, but this result was not statically significant ($P = 0.068$ at 6 months; $P = 0.369$ at 12 months). There was no relation between target lesion patency and the other variables studied. Overall mortality in the plain angioplasty balloon group was higher (9% vs. 5.7%) but not statistically significant.

Conclusions Drug-coated balloon angioplasty resulted in superior survival of dysfunctional peripheral vascular access at 6 and 12 months, but this result was not statistically significant. Both arms show equivalent complications and similar mortality.

Level of Evidence Level Ia, therapeutic study, RCT. EBM ratings will be based on a scale of 1-5.

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Keywords Paclitaxel · Drug-eluting balloon · Angioplasty · High-pressure balloon · Hemodialysis · Arteriovenous fistula · Primary patency

Introduction

Problems with vascular access are an important cause of morbidity and mortality in hemodialysis patients, and when stenosis or thrombosis occurs, a central venous catheter may be used, with an evident risk of infection [1, 2].

Stenosis could be treated with percutaneous transluminal angioplasty (PTA), with a high rate of technical success