Paclitaxel-assisted balloon angioplasty of venous stenosis in haemodialysis access: PAVE RCT

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Scientific summary

The PAVE RCT

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Scientific summary

Background

Reliable vascular access is essential for patients receiving haemodialysis. An arteriovenous fistula (AVF) is the preferred option; however, these are prone to developing stenotic segments. These lesions are treated with angioplasty, but there is a high rate of recurrence. When the PAVE (Paclitaxel-assisted balloon Angioplasty of Venous stenosis in haEmodialysis access) trial was conceived, a number of small studies suggested that restenosis may be reduced by paclitaxel-coated balloons.

Methods

The PAVE trial is multicentre randomised controlled trial and included 212 patients with a dysfunctional AVF undergoing an angioplasty. Twenty UK centres participated in the trial. Exclusion criteria included the presence of one or more lesions outside the treatment segment, a central stenosis, thrombosis at the time of intervention, the presence of a stent or synthetic material in the access circuit and the presence of a significant residual stenosis after a plain balloon angioplasty. Following treatment with a high-pressure plain balloon, inclusion and exclusion criteria were again assessed by the radiologist. If patients remained eligible, then they were randomised to treatment with a paclitaxel-coated or standard balloon. Radiologists were aware of the treatment allocation because of the appearance of the paclitaxel-coated balloon. However, the patients, clinical staff and research team were not aware.

The primary end point was time to loss of target lesion primary patency (TLPP). This occurred when there was a radiological or surgical intervention for a clinical reason that included the index segment, or if the fistula was thrombosed or abandoned because of restenosis at the index segment. Referral for radiology or surgery would be made by a member of the clinical team who was blinded to treatment allocation. Secondary outcomes included time to loss of access circuit primary patency and time to loss of access circuit cumulative patency. Access circuit primary patency ended when there was access circuit thrombosis, an intervention (either radiological or surgical) anywhere in the access circuit, or the access circuit is abandoned because of an inability to treat any lesion. Access circuit cumulative patency ends when the AVF was abandoned, regardless of radiological or surgical intervention, with or without a thrombosis event. At 6 months, patients were invited for a protocol fistulogram. Prespecified secondary end points were angiographically determined late lumen loss (mm) and binary angiographic restenosis based on this fistulogram. Other secondary end points were procedural success, the number of thrombosis events, fistula interventions, adverse events during follow-up and patient quality-of-life assessments.

Primary end-point data were analysed using Cox proportional hazards regression adjusted for two binary minimisation factors (previous radiological intervention and patient on haemodialysis at study entry). Time-to-event secondary outcomes were analysed in the same way. A secondary analysis of the primary outcome assessed the impact of prespecified baseline covariates. The minimum follow-up was 1 year.

Results

Primary analysis showed no evidence for a difference in time to end of TLPP between groups [hazard ratio (HR) 1.18, 95% confidence interval (CI) 0.78 to 1.79; $p = 0.440$]. An adjusted secondary analysis with prespecified clinical covariates gave similar results (HR 1.11, 95% CI 0.69 to 1.78; $p = 0.664$).

Prespecified secondary outcomes included the time to intervention anywhere in the access circuit or the time until the fistula was abandoned. There was no evidence of differences in these patency-related secondary outcomes or in any other secondary outcomes, such as adverse events.

Conclusion

There was no evidence of differences in primary or secondary outcomes. Following a plain balloon angioplasty, additional treatment with a paclitaxel-coated balloon does not provide benefit.

Trial registration

This trial is registered as ISRCTN14284759.

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This report

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