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

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Declared competing interests of authors: Anthony Dorling was an Efficacy and Mechanism Evaluation (EME) Funding Committee member (2014–19) and an EME Funding Committee Sub-Group member – Remit and Compatibility Check (2018–19). Emily J Robinson received salary support from the National Institute for Health Research Biomedical Research Centre based at Guy's and St Thomas' NHS Foundation Trust (London, UK) and King's College London (London, UK).

Published September 2021
DOI: 10.3310/eme08130

Plain English summary

The PAVE RCT

Efficacy and Mechanism Evaluation 2021; Vol. 8: No. 13
DOI: 10.3310/eme08130

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Background

Reliable access to the blood circulation is essential for patients receiving haemodialysis. Surgical connection of an artery and vein in the arm (i.e. an arteriovenous fistula) is the preferred option, but the veins in these fistulas are prone to developing narrowed segments that affect their function. These narrowings are treated with a balloon inserted into the vein under X-ray guidance. However, the narrow segments often recur after this treatment. Paclitaxel is a drug used to treat cancer. Balloons coated with paclitaxel have been developed to allow deposition of the drug in the blood vessel at the time of treatment without significant absorption of the drug into other parts of the body. The PAVE (Paclitaxel-assisted balloon Angioplasty of Venous stenosis in haEmodialysis access) trial was conceived after a number of small studies suggested that recurrence of the narrowing may be reduced by these paclitaxel-coated balloons. We designed an investigator-led multicentre randomised controlled trial with a variable follow-up time, but with a minimum of 1 year, to assess the efficacy of paclitaxel-coated angioplasty balloons in prolonging the survival time of target lesion primary patency in arteriovenous fistulas.

Methods

We included 212 patients with an arteriovenous fistula that was not working properly and who were referred for a balloon treatment. We included patients with a single narrowed segment only; patients with complicating features, such as the presence of synthetic tubes that join the blood vessels or a narrowing in the larger veins towards the heart, were not included. Patients had the balloon treatment that they would have had even if they were not in the trial. After this, if they had a successful treatment and remained eligible, they were randomised. A web-based system was used to randomly allocate them to additional treatment with a paclitaxel-coated or a standard balloon. Patients were then followed up to see if there was a difference between the two groups to assess the effect of the paclitaxel-coated balloon.

Results

The main measure of success for the trial was the time taken until there was a need to re-treat the same narrow segment with another balloon or operation. If the fistula was abandoned or became blocked because of recurrence at the same segment, then this also meant that the treatment had failed. At the end of the study, there was no evidence of a difference between the groups for this main outcome measure. In addition, we looked at a number of other measures, including the time until treatment was needed in the fistula, even if this was in a different place from the initial treatment, and the time until the fistula was abandoned for any reason. Again, no evidence of any differences was seen. There was also no evidence of differences in adverse events.

Conclusion

There was no evidence of differences in any of the outcomes. The treatment of arteriovenous fistulas, used for haemodialysis, with paclitaxel-coated balloons does not provide a benefit.

Efficacy and Mechanism Evaluation

ISSN 2050-4365 (Print)

ISSN 2050-4373 (Online)

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Editorial contact: journals.library@nihr.ac.uk

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The EME programme is funded by the Medical Research Council (MRC) and the National Institute for Health Research (NIHR), with contributions from the Chief Scientist Office (CSO) in Scotland and National Institute for Social Care and Health Research (NISCHR) in Wales and the Health and Social Care Research and Development (HSC R&D), Public Health Agency in Northern Ireland.

This report

The research reported in this issue of the journal was funded by the EME programme as project number 13/94/10. The contractual start date was in May 2015. The final report began editorial review in December 2020 and was accepted for publication in July 2021. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The EME editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

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