Evaluation of the effectiveness and cost-effectiveness of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes: a randomised controlled trial

William Jeffcoate,[1]* Frances Game,[1,2] Vivienne Turtle-Savage,[1] Alison Musgrove,[1] Patricia Price,[3] Wei Tan,[4] Lucy Bradshaw,[4] Alan Montgomery,[4] Deborah Fitzsimmons,[5] Angela Farr,[5] Thomas Winfield[5] and Ceri Phillips[5]

[1]Foot Ulcer Trials Unit, Nottingham University Hospitals Trust, Nottingham, UK
[2]Diabetes and Endocrinology, Derby Teaching Hospitals NHS Foundation Trust, Derby, UK
[3]Vice-Chancellor's Office, Cardiff University, Cardiff, UK
[4]Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK
[5]Swansea Centre for Health Economics, College of Human and Health Science, Swansea University, Swansea, UK

*Corresponding author william.jeffcoate@gmail.com

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Scientific summary

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Background

Chronic ulceration of the foot represents a major problem in people with diabetes mellitus, and ulcers of the heel present particular difficulties, with only around 40% healing within 6 months. However, a recent study suggested that the use of lightweight fibreglass heel casts was associated with a marked improvement in healing time. The aim of the present study was to use a definitive, multicentre, randomised controlled trial to compare the effectiveness of such casts in addition to usual care with usual care alone in the management of heel ulcers of National Pressure Ulcer Advisory Panel/European Pressure Ulcer Advisory Panel (NPUAP/EPUAP) grades 2–4 in people with type 1 or type 2 diabetes mellitus, and to explore the cost-effectiveness of such casts.

Methods

The participants were randomised to receive either usual clinical care in a specialist centre or a fibreglass heel cast in addition to usual care in a parallel, group design clinical trial. Randomisation was stratified by NPUAP/EPUAP grade (depth) and ulcer cross-sectional area (< 100 mm^2 or ≥ 100 mm^2) using blocks of variable size. The primary outcome was healing (confirmed by a blinded observer and maintained for at least 4 weeks) at or before 24 weeks. The target sample size was 496, and based on a difference in primary outcome of 55% (intervention) and 40% (control), allowing for 30% attrition. Secondary outcomes included the time taken for the ulcer to heal, secondary infection, new ulceration, hospital admission, minor and major amputation and health status. The primary analysis estimated the absolute and relative effectiveness on ulcer healing at or before 24 weeks, comparing the intervention group with usual care. A within-trial health economic analysis was undertaken to estimate the incremental cost per quality-adjusted life-year (QALY) and incremental cost per percentage of healed ulcers at 24 weeks.

Results

A total of 509 participants with ulceration of the heel complicating diabetes mellitus [68% male, 15% type 1 and 85% type 2 diabetes, mean age 67.5 years (standard deviation 12.4 years)] and attending one of 35 specialist centres in the UK were randomised 1 : 1 to either the intervention arm ($n = 256$) or the control arm ($n = 253$) of the study. Primary outcome data were available for 212 participants in the intervention arm and for 213 participants in the control arm. The median (25th–75th centile) ulcer area at baseline was 275 mm^2 (104–683 mm^2) in the intervention group and 206 mm^2 (77–649 mm^2) in the control group, and the ulcer grades in the two groups were identical (grade 2, 32%; grade 3, 62%; and grade 4, 6%). When analysed by intention to treat, 44% ($n = 94$) of the intervention group's ulcers had healed at or before 24 weeks, compared with 37% ($n = 80$) of the control group's [odds ratio 1.42, 95% confidence interval (CI) 0.95 to 2.14; $p = 0.088$; risk difference 8%, 95% CI –1% to 17%; $p = 0.087$]. There were no differences between the two groups for any of the secondary outcome measures, including the reduction of local pain at 2 and 4 weeks. There was no clear excess of adverse events in either group.

The results of the cost–utility analysis showed that usual care dominated the intervention, that is, usual care had lower costs and more QALY gains under the base case (the incremental cost-effectiveness ratio was –£35,478.95), and a one-way sensitivity analysis indicated that the intervention would be cost-effective (£9057.89 per QALY gain) only when the lower-bound 95% CI cost estimate was used. The probability of the intervention being cost-effective at a societal willingness-to-pay threshold of £20,000 was estimated at 5%.

The adjusted analysis estimated that the incremental cost of a 1% likelihood of achieving a healed ulcer was £9.63 (£963 per additional healed heel ulcer).

Discussion

The data suggest that there may be a small increase in healing with the use of a heel cast, but the estimate was not sufficiently precise to provide strong evidence of an effect. There was no evidence of any subgroup in which the intervention appeared to be particularly effective. There was also no evidence of any benefit in terms of reduced local pain. The results of the health economic analysis suggest that it is unlikely that the intervention represents good value for money. The provision of a lightweight heel cast may be of benefit to some individuals, but we found no evidence to justify the routine adoption of the use of this treatment in clinical practice. It is unlikely that further study of this intervention will have an impact on usual clinical care, and so future efforts should be directed towards other interventions designed to improve the healing of ulcers in this population.

Trial registration

This trial is registered as ISRCTN62524796.

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