

Bringing the evidence to heel: Heel cups and the diabetic foot

Trial Management Group of the Health Technology Assessment Heels Study

In 2008, Louise Stuart and colleagues in north Manchester described the use of a lightweight fibreglass heel cup in the management of ulcers of the heel in diabetes, and she presented the results of an uncontrolled observational series to the annual meeting of the Diabetic Foot Study Group of Europe, held that year in Lucca, Italy (Stuart et al, 2008). In this series, she demonstrated that the use of a heel cup appeared to hasten healing, as well as induce rapid relief from any local pain or discomfort in some people. The median time to healing of a heel ulcer in diabetes is 200 days (Chipchase et al, 2005), half as long again as ulcers of the foot in general (Ince et al, 2007).

It was on the basis of this study that the Foot Ulcer Trials Unit (Nottingham) successfully applied for funding from the NHS National Institute for Health Research (Health Technology Assessment; HTA) to undertake a definitive trial, with participants being randomised to be managed either with usual care plus a heel cup, or to usual care alone. The trial was started in the spring of 2011 and aims to confirm the effectiveness and safety of these new devices, as well as their cost-effectiveness. As in all studies of foot ulcers, the improvement in healing is unlikely to be as great as first suggested and the trial is powered to detect an improvement in healing by 24 weeks from 40% to 55%.

The trial is going well. Twenty-nine centres in sites across the UK are currently recruiting and keeping pace with the target: 179 participants have been randomised to date, out of the planned total of 529. Studies like this are massive undertakings, requiring dedicated managers and armies of co-investigators and other staff – and patients – at numerous clinical sites. These studies are also massively expensive, and it is possibly because of the work and investment involved that the evidence base for the management of chronic wounds is so thin. Repeated systematic reviews have shown that there is virtually no evidence on which to base the selection of any wound care product in the management of diabetic foot ulcers (Game et al, 2012; Durnville et al, 2012).

Participation in a study like this can pose ethical problems for some of the centres involved, especially those that have already had experience of using heel cups and felt that they were effective. Two of our previous collaborating centres actually declined to participate because they did not have “ equipoise ” – meaning that they did not feel comfortable randomising someone if it meant that they might end up in the usual care group.

At Nottingham University Hospital we had been using heel cups for several years, but made the decision that as this intervention had not yet been proved to work, we would

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not use them at all as part of usual care after the trial started – not even for patients who were ineligible for the study. We felt this was necessary to avoid potential bias in the selection of participants, and that it was also justified on the basis of our continuing need to conform to evidence-based practice.

Work like this is essential if we are to establish the effectiveness of new treatments, and thereby improve the evidence base of the work we do. Nearly all clinicians select dressings on the basis of certain wound characteristics, but without evidence that this practice is justified. In a previous HTA-funded multicentre trial of dressings for foot ulcers, we found no difference in healing by 24 weeks whether people’s ulcers were dressed with Inadine® (Johnson & Johnson Medical, Berkshire, UK) N-A® (Johnson & Johnson Medical) or Aquacel® (ConvaTec, Middlesex, UK) – irrespective of wound type (Jeffcoate et al, 2009). In this study, we found incidentally that the incidence of secondary infection was no lower in the group treated with the antiseptic containing dressing (Inadine) than it was with the other products. It is regrettable that the dressings industry rarely conducts its own trials.

One of the manufacturers of fibreglass casting material is currently running free training courses for healthcare professionals on the production of heel casts. This is welcome because it will help ensure more widespread availability of the necessary skills to be used – if and when these casts have been shown to be both effective and cost-effective. ■

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