

Making diabetic foot care evidence-based: what is missing?

Part 2: Treatment



Dr Peter Cavanagh

In a guest editorial for the Summer 2004 issue of *The Diabetic Foot* (Vol 7, No 2, pages 60–64) I identified a number of areas in the screening and prevention of foot complications of diabetes where an evidence base seemed to be lacking. In this issue, I turn my attention towards treatments for which there is a similar lack of evidence.

Debridement

For the most part, wound care is a fairly barren terrain from an evidence-based perspective. This starts with debridement. A Cochrane review (Smith, 2004) concluded that surgical debridement – and, incidentally, the currently popular larval therapy – showed ‘no significant benefit’. Yet, in common with many of the aspects of treatments discussed below, despite the lack of evidence, there is strong clinical belief that debridement is an essential component of wound healing.

Wound dressings

Given the great variety, and widespread use, of wound dressings on diabetic foot ulcers, it is remarkable that comparative data on the efficacy of different dressings are not readily available. For example, two recent Cochrane reviews (Briggs and Nelson, 2004; Nelson and Bradley, 2004) of dressings and topical agents for leg ulcers found only one eligible trial for arterial leg ulcers and none for venous ulcers.

It is interesting to note that in one UK survey (Mitchell et al, 1999) 80% of physicians delegate the responsibility for the choice of dressing to a nurse. This may perhaps reflect the frustration felt about the lack of available data. The migration from dry gauze dressings to ‘modern’ dressings that provide a moist wound-healing environment has taken place slowly over the past 15 years, but the evidence base for this shift is thought by some to be relatively poor (Falanga, 2001).

In Europe and the USA, wound dressings are not regulated in the same manner as prescription medicines; therefore, as long as no claims are made regarding efficacy, no burden of proof is required from the manufacturers. There is thus little motivation for manufacturers to fund comparative trials of their own product against that of a competitor. In contrast, in the past year the UK Department of Health’s Health

Technology Assessment Programme (<http://www.hta.nhsweb.nhs.uk/>) has funded a two-year multicentre study to compare three different wound treatments.

Third-generation wound-healing agents

Discussion of dressings leads logically to what might be called the third-generation wound-healing products, i.e. active wound-healing agents, including bioengineered skin substitutes and growth factors. The scientific appeal of these products is tremendous, and many people believe that regenerative medicine holds the key for wound healing in the future.

However, the published results to date have been rather dismal compared with treatments such as the total contact cast. As has frequently been pointed out (Caputo et al, 1997; Boulton and Armstrong, 2003), the lack of standardised unloading protocols in most clinical trials of these products makes it very difficult to discern the biological action of the various treatments. One has to wonder how many of these newer products were dislodged from their location on the wound in the first few hours by uncontrolled weight bearing.

Hyperbaric oxygen

The use of hyperbaric oxygen (HBO) treatments for wound healing continues to be a contentious issue. This is particularly true in the USA, where Medicare (the Government healthcare reimbursement system for patients over 65 years of age) has recently agreed to pay for up to 30 treatments per patient for any ‘non-healing foot ulcer’. Many observers think the high cost of these treatments could be better spent on more conventional approaches.

A recent Cochrane review (Kranke et al, 2004) reported very mixed results in five trials, but nevertheless concluded that, despite ‘modest numbers of patients, methodological shortcomings, and poor reporting’, HBO may improve the chance of healing. It is unfortunate that some physicians at several US centres see this as a *carte blanche* to refer all foot ulcer patients to this expensive treatment, which is most often administered by a ‘for-profit’ organisation.

Peter R Cavanagh PhD, DSc (Med) is Academic Director of the Diabetic Foot Care Program at the Cleveland Clinic Foundation, USA

Topical negative-pressure

Topical negative-pressure therapy has recently sprinted to the forefront as the method of choice for wound healing. This meteoric rise is remarkable, given that at present there is no evidence for efficacy of this approach. A Cochrane review (Evans and Land, 2004) reported a grand total of 34 patients in the entire literature, and indicated that these trials provided only 'weak' evidence of superiority of this method over gauze dressings.

Perhaps the success of this approach represents a thirst for technology in wound healing, and dissatisfaction with 'passive' approaches. Or perhaps clinical experience is the driving force, and the evidence will eventually catch up.

Therapeutic footwear

I am fond of saying that 'patients with healed ulcers become footwear patients for life'. However, as I mentioned in a recent article (Cavanagh, 2004), I must agree with Maciejewski et al (2004) that the evidence base showing that footwear can prevent ulcer recurrence is slim. Part of the problem is that therapeutic footwear means different things to different people. What this field needs is studies showing how prescription footwear can best be matched to individual foot structures and individual pathologies. Equally important is that the dual factors of footwear efficacy and patient compliance be addressed, because even the very best shoes will not help if they are not worn!

Final comment

It is worth acknowledging an interesting observation by Falanga (2001) on what he calls the 'dark side of evidence-based

management'. His point is that, because of economic imperatives, some treatments that are clearly effective in a clinician's hands are never likely to be subjected to the kind of randomised controlled trials that will make it into a Cochrane review. There are clear precedents to support this view, but it should not be taken as an excuse for the dominance of opinion over evidence. ■

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Coming soon!

Over the next few issues there will be a series of articles written by Neil Baker, Chief Podiatrist at Ipswich Hospital, that will give a practical common sense approach to examining the diabetic foot. These articles will give pointers to help you identify the 'wheat from the chaff', i.e. those feet at risk and in need of being closely monitored, and those that are not.

Topics will include:

- General foot assessment
- Tips on vascular assessment
- Neurological assessment made simple
- Joint and gait assessment