

NHS evidence update for the management of the foot in diabetes



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Those who work in the field of the diabetic foot are well aware of how difficult it is to achieve healing of chronic ulcers, the cost and suffering that results and the resultant desperate need for evidence to justify treatment choice. The evidence to date has not been good.

First the good news

The first piece of Good News is that our field seems to be attracting progressively more interest. Diabetes UK/NHS Diabetes together launched the *Putting Feet First* document in 2009 (Diabetes UK, 2009), and this triggered the publication of NICE clinical guidelines 119 on the in-patient management of the diabetic foot (NICE, 2011). And now, within two years, NICE has produced an update on the evidence base used to underpin clinical practice (NICE, 2013). Not only does it combine authority with brevity and clarity, but it is freely and easily available online, and also includes online access to key material on which it is based. Rather than try to summarise its wide-ranging content, I strongly recommend that readers take 10 minutes to look it through.

Good News part two is that this accessible document is only one of several that have appeared in the last 12 months or so. These include the Cochrane reviews by Dumville and colleagues on different groups of dressings (necessarily based only on randomised controlled trials [RCTs]), and the meta-analysis produced by the same group (Dumville et al, 2012). Brölmann et al (2012) also collated the results of all Cochrane reviews (i.e. all RCTs) on any aspect of wound care (including 14 on diabetic foot ulcers), while Brownrigg et al (2013) have very recently reviewed the evidence-based management of peripheral arterial disease (PAD) and the diabetic foot (but including aspects of foot ulceration unrelated to PAD). A working group established by the International Working Group on the Diabetic Foot reviewed all controlled

studies in all languages and examined the evidence to support a wide variety of interventions for established ulcers (NICE, 2011; Game et al, 2012). Greer et al (2012) have also recently reviewed the evidence for the use of so-called advanced wound care therapies for non-healing diabetic, venous and arterial ulcers and this gives an interesting view from the other side of the Atlantic.

Finally, we hear that NICE is planning new guidance on the management of the foot in diabetes, and that this will bring together the content of both clinical guidelines 10 and 119 and replace them. Presumably this will help reinforce the need for the foot care pathway to be considered as a whole, as emphasised by Diabetes UK (2010). The production of so many reviews is an indicator of the extent to which the world at large is starting to wake up to the size of the problem posed by disease of the foot in diabetes, and this is mighty encouraging.

And now the bad news

The first bit of Bad News is that none of these reviews deals with the acute Charcot foot, and although this is a completely separate condition, it is managed (or should be) by the same multidisciplinary teams (MDT) and there is a crying need for (a) harmonisation of the approaches to, and quality of, care of the Charcot foot and (b) more research to provide evidence to justify what we do. The best we have to date is the consensus statement from 2011 – which, although published by the American Diabetes Association and the American Podiatric Medical Association, is based on multinational input (Rogers et al, 2011). NICE should be urged to include the Charcot foot in its new guidance document.

The second bit of Bad News is the occasional disagreements that can be found between different observers assessing similar databases. Perhaps the most striking is the tendency for the authors of the Veterans Affairs Evidence-based Synthesis

Program review to draw more positive conclusions from the evidence to support certain interventions (specifically, Apligraf® [Organogenesis Inc, Canton, MA] and negative pressure wound therapy) than any other group (Greer et al, 2012).

Similarly, Brölmann et al (2012) drew different conclusions from other reviewers concerning the strength of the evidence to justify the use of sharp debridement and larvae for diabetic foot ulcers, as well as the role of granulocyte colony-stimulating factor (G-CSF) in limb-threatening infection. Many of these differences, but not all, can be attributed to the methods used for selecting and evaluating published papers. Having said that, none of these reviews reports any evidence to support that most over-used group of products – silver-impregnated dressings.

But the biggest bit of Bad News is that this latest review concludes that there is no new evidence to support the use of any intervention in clinical practice in any area of foot care in diabetes – whether in prevention, treatment and long-term care.

What do we do if the evidence base is so thin ?

What does it mean if there is no evidence? Of course, we have to acknowledge that there are different levels of evidence, and also have to acknowledge that it can be extremely difficult (and expensive) to get firm evidence to establish the effectiveness of either treatments or treatment strategies in such a complex group of disorders as those that affect the foot in diabetes. Our obligation as professionals is to do the best we can for the foot in front of us – or, to be more precise, for the person to whom the foot is attached. In the absence of robust evidence, our actions must be guided by three principles. These are:

1. Each person with active disease of the foot in diabetes should be managed by a closely integrated MDT. The need for prompt referral to a specialist MDT is clearly stated in NICE clinical guideline 119 (NICE, 2011), and the observational evidence to support this approach is strong – even though the current NICE Evidence Update states that “No *new* key evidence was found for this section” (NICE, 2013; *my italics*).

2. As far as possible, members of the MDT should use only treatments for which evidence is available. Not only should practice be evidence-based as much as possible, but in the absence of evidence, those who manage disease of the foot in diabetes should avoid the use of advanced wound care treatments if they are more expensive than simple treatments.

3. To promote the need for more evidence. Evidence can only be obtained from properly designed and conducted studies. Healthcare professionals should think hard about becoming actively involved in such research, because it is the only way in which our understanding will ever be improved. ■

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