

Things we think we know but actually do not



Matthew Young

Many of the techniques used in diabetic foot care are employed because we know they are correct, despite a lack of any evidence base. This is not because what we do is wrong, but because the trials do not exist. Hopefully, we base our knowledge on personal experience and regular audit, rejecting practices that we find ineffective and continuing with those we find useful. However, if we compare practice between units there will be variations in care and outcomes. If we write protocols and integrated care pathways for foot care, how much will be opinion rather than fact?

Why the trials have not been done

The paucity of evidence underpinning diabetic foot care is partly due to a lack of adequately sized, high-quality clinical studies. This is understandable for a number of reasons.

- Research governance regulations are making research harder to complete.
- The variability influencing the origin and progress of diabetic foot ulcers, such as site, depth and patient factors, is so great that any standard trial effect – even a 20% improvement in outcome – will require hundreds of patients to detect.
- The funding for clinical trials is difficult.
- Drug and dressings companies cannot justify the cost of trials with little prospect of positive outcomes or significant increases in sales.

Therefore, we are often left to form our own opinions, not always correctly.

Education

Education improves outcomes in patients with diabetes at risk of ulceration. Is this a statement so obvious that it needs no proof? Actually, there is no evidence base clarifying the most effective education method; nor is there a base for education programmes alone reducing ulceration rates. In a recent review (Valk et al, 2005), only one study had positive results. Multi-

disciplinary clinics are effective in reducing amputations, but not ulceration. With neuropathic self-denial, with patients reporting no knowledge of how the ulcer developed, and with delays in presenting once an ulcer develops, is this surprising? Would education on earlier ulcer reporting by patients, and healthcare professionals, be more effective in reducing chronic ulcers and their consequences?

Metabolic control

Wound healing reviews frequently cite the need for micro-nutrient supplementation or tight glucose control in healing ulcers. There are a number of theoretical reasons why keeping blood sugars below 10 mmol/l at all times should improve healing. White cell function is impaired above this level and capillary blood flow is impaired due to increased viscosity and coagulopathy. However, two large studies show no association between healing rate and initial HbA_{1c} or change in HbA_{1c} (Apelqvist and Agardh, 1992; Margolis et al, 2000). In addition, the problems with obtaining adherence to off-loading, antibiotics and dressings, and the high HbA_{1c} levels documented in foot ulcer patients, make it difficult to meaningfully improve control. It may well be impossible to confirm the effects of good control in clinical settings as many foot clinics do not have diabetes specialist nurses.

In our practice we encourage improved control when it is very poor, and impose strict control in septic patients once admitted, but do not routinely examine control in most patients. Despite this, we have very good outcomes, with an overall healing rate of over 85% (Young and Heinrichs, 2003). Would we do better if we did routinely examine control?

Dressings

We are often asked to try new dressings, with persuasive arguments as to their effectiveness. However, when the Cochrane reviews examined dressings

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there were no trials of size or meaning. This is not surprising. Modern dressings are certainly more than mere covers for wounds but the actual effects of a dressing on wound healing are swamped by the much larger influence of the variables outlined. Therefore, case studies are often used to illustrate effectiveness, even though single cases or mini-case series may have selection bias. Until there are better, larger studies, or the theoretical basis for a dressing is borne out by practice, dressings will remain to be chosen by experience and not by evidence. Therefore, there is an obligation for specialist foot care teams to choose dressings responsibly, for community teams to follow their advice, and for neither to choose the latest product on a whim.

Mortality

The mortality of diabetic foot patients does not appear to have altered over the years despite studies (e.g. Turner et al, 1998) showing that blood pressure, lipid and anti-platelet therapies can improve outcomes in diabetes overall and particularly in patients with ischaemic heart disease. Is it autonomic neuropathy, or is the burden of vasculopathy irreversible in our patients? Until we know, should we maximise cardiovascular risk reduction to try to give foot ulcer patients every opportunity to live longer? We do this in our clinic but can I justify it by evidence? Possibly not yet, but it might be the most useful thing we do.

Conclusion

To practice evidence-based care, answering the big questions will require considerable numbers of patients. Each centre is unlikely to recruit quickly enough, or in large enough numbers, to solve them alone. Collaborations between units, such as CDUK (see page 57), are the best way forward and together perhaps we will find the answers. ■

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