

Lower limb complications

DIABETIC MEDICINE



Available evidence for infection diagnosis methods is weak

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

- The diagnosis of infection in diabetic foot ulcers involves its identification by laboratory analysis or clinical judgement.
- This systematic review aimed to summarise and assess the evidence on the diagnostic ability of clinical examinations, microbiological sampling techniques and microbiological analysis techniques.
- A variety of electronic and other sources were searched. Three criteria had to be met by all studies included in the analysis. Each study had to: compare the results of an independent reference standard with an alternative diagnostic method; have, as its target population, people older than 18 years with a diabetic foot ulcer; have enough data to compile a 2x2 diagnostic table (with true and false positives and negatives).
- Three studies were identified that met all of the inclusion criteria. One on clinical examination, another on sample collection and a final on sample analysis. None of the studies had the best possible reference standard.
- Other problems were also identified with the studies' methodologies, for example results were not interpreted blind, or the index and reference samples were not always taken at the same time.
- The authors concluded that the available evidence is insufficient and too weak to allow any implications for practice to be elucidated.

O'Meara S, Nelson EA, Golder S et al on behalf of the DASIDU Steering Group (2006) Systematic review of methods to diagnose infection in foot ulcers in diabetes. *Diabetic Medicine* **23**(4): 341–7

A lack of systematic reviews for diabetic foot care: Anarchy in the UK?



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The most vexed questions when it comes to treating diabetic foot ulceration are 'is it infected?' and 'does it need antibiotics?' In truth the answers may not be found in O'Meara and colleagues' (summarised on left) and Nelson and colleagues' latest systematic reviews (summarised below and on page 176) but some interesting insights come through.

The methodology behind systematic reviews is robust for determining whether a clinical question can be answered by the published available studies, but relies on randomised controlled trials (RCTs) as its gold standard, and has to dismiss a lot of smaller studies which may be biased or flawed in some way but might actually reflect real life practice. The RCTs that are available do not always do this and few of us would follow the recommendations they throw up, for example that granulocyte colony stimulating factor is cheaper than standard care.

It is, therefore, not surprising that only three studies that satisfied the inclusion criteria were used to determine the best method to diagnose

infection and 23 for treating infection. The full decision-analysis model for attempting to inform sampling and treatment of foot ulcer infection runs to more than 200 pages (Nelson and colleagues, summarised on page 176) and has no firm conclusion because of this lack of appropriate or comparable studies.

So, what do we need? As with many such reviews the overwhelming conclusion is that we need more evidence. The diabetic foot is a hugely expensive area of health care – where we work with experience and knowledge but no true practical RCTs, unlike for conditions such as hypertension and post-myocardial infarction care. I have previously, in a sister journal to this publication, *The Diabetic Foot* (Young, 2005), suggested that the pharmaceutical industry or government might want to sponsor a nationwide database of foot care. This would not constitute RCT-type data but, with enough patients, should allow valid case-controlled information to be extracted without a mass of expense and paperwork. There still seems to be a need but until then individuality, and sometimes consensus, will have to rule.

Young M (2005) An evidence base for diabetic foot care: A step forward? *The Diabetic Foot* **8**(3): 108

DIABETIC MEDICINE



More robust research needed for antimicrobial agents

Readability	✓✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 In parallel with the Health Technology Assessment document (summarised on page 176) this paper was also published. It outlines the systematic review and its aim of reviewing the evidence for antimicrobial intervention for diabetic foot ulcers.

2 From a variety of sources searched, 23 studies that investigated the

effectiveness or cost-effectiveness of antimicrobial agents were found. The trials were not standardised enough or were too weak to be pooled.

3 The authors stated that there is no strong evidence for any particular antimicrobial agent for the prevention of amputation, the resolution of infection or ulcer healing.

4 Therefore, the authors concluded, large well-controlled studies are needed in order to make informed judgements, with regard to effectiveness of treatment and cost-effectiveness, when prescribing antimicrobial agents for the treatment of the infected diabetic foot ulcer.

Nelson EA, O'Meara S, Golder S et al on behalf of the DASIDU Steering Group (2006) Systematic review of antimicrobial treatments for diabetic foot ulcers. *Diabetic Medicine* **23**(4): 348–59

‘An increase in the diabetic ulcer severity score reduced the chance of healing by 35%.’



Lack of evidence for or against any antibiotic for DFUs

Readability	✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 The authors conducted a systematic review to ascertain the effectiveness of diagnostic tests used to identify infection in diabetic foot ulcers (DFUs) and of methods to treat infected ulcers.

2 Another objective of the paper was to construct a decision-analysis model in order to identify the most efficient method of diagnosing and treating infection in the DFU, and to describe any areas of research that would lead to more certainty when diagnosing and treating the infected DFU.

3 A variety of sources were searched from their date of creation to November 2002. Studies concerned with diagnosis, effectiveness of treatment and the cost-effectiveness of treatment were selected for this study.

4 Three studies dealing with diagnosis and 23 studies dealing with effectiveness, of which two also dealt with cost-effectiveness, were found.

5 Due to a lack of data to populate the decision-analysis model with the specificities and sensitivities of diagnosis of infection in DFUs and a lack of strong data on the probabilities of healing, amputation or death in any of the intervention studies analysed, the most effective diagnostic and treatment strategy could not be described.

6 The authors conclude that the evidence is too weak to draw any reliable implications for practice. With respect to treatment they could not reliably conclude whether systemic or local antibiotics were better, or whether any agent was better than another.

Nelson EA, O'Meara S, Craig D et al (2006) A series of systematic reviews to inform a decision analysis for sampling and treating infected diabetic foot ulcers. *Health Technology Assessment* **10**(12): 1–221. Executive summary also available in same issue.

‘The pole test could play an important, non-invasive role in detecting critical limb ischaemia, especially in people presenting with calcified incompressible leg arteries.’



New scoring system to predict diabetic foot ulcer healing

Readability	✓✓✓✓
Applicability to practice	✓✓✓✓
WOW! factor	✓✓✓

1 The aim of this study was the formulation of a wound-based clinical scoring system that can predict the chances of diabetic foot ulcers healing and also the risk of amputation.

2 The four defined parameters assessed were: palpable pedal pulses; probing to bone; ulcer location; and the presence of multiple ulcers. A score of '1' was assigned if: pedal pulses were absent; probing to bone was a 'yes'; the site of ulceration was foot (as opposed to toe); or the

individual had multiple ulceration. Otherwise a score of '0' was assigned. The total diabetic ulcer severity score (DUSS) was calculated by adding the scores to a theoretical maximum of four.

3 The four parameters were prospectively assessed in 1000 consecutive patients at the authors' hospital. Kaplan-Meier analysis were used to calculate the probability of the ulcer healing and the risk of amputation.

4 Individuals who would score a '0' on any of the parameters had a significantly higher probability of their ulcers healing. An increase in the DUSS score reduced the chance of healing by 35%.

5 The chances of healing and amputation are predicted with high accuracy, conclude the authors. They say that this could be useful in anticipating healthcare costs.

Beckert S, Witte M, Wicke C et al (2006) A new wound-based severity score for diabetic foot ulcers: A prospective analysis of 1,000 patients. *Diabetes Care* **29**(5): 988–92



Pole test offers hope for calcified and incompressible leg arteries

Readability	✓✓✓
Applicability to practice	✓✓✓✓✓
WOW! factor	✓✓✓

1 Sphygmomanometric measurement for the quantification of critical limb ischaemia (CLI) in people with diabetes can be flawed due to, for example, calcification of the blood vessels. the reproducibility of transcutaneous oxygen pressure (TcPO₂) measurement's is questionable because of the different degrees of ischaemia people have.

2 The objective of this study was to assess the effectiveness of the 'pole test' (based on hydrostatic pressure

derived from leg elevation) to detect CLI.

3 Seventy-four individuals (83 legs) with rest pain or gangrene were evaluated by the pole test, cuff-manometry, TcPO₂ and arteriography.

4 Cuff-manometry results were significantly higher than those obtained using the pole test; the difference remained significant for people with and without diabetes.

5 Correlation between TcPO₂ and the pole test was only observed in people with diabetes. No correlation between cuff-manometry and TcPO₂ was observed.

6 An accuracy of 88%, a sensitivity of 95% and a specificity of 73% was observed for the detection of CLI.

7 The pole test could play an important, non-invasive role in detecting CLI, especially in people presenting with calcified incompressible leg arteries.

Paraskevas N, Ayari R, Malikov S et al (2006) 'Pole test' measurements in critical leg ischaemia. *European Journal of Vascular and Endovascular Surgery* **31**(3): 253–7