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Title **A Series of Systematic Reviews to Inform a Decision Analysis for Sampling and Treating Infected Diabetic Foot Ulcers**

Agency **NCCHTA, National Coordinating Centre for Health Technology Assessment**
Mailpoint 728, Boldrewood, University of Southampton, Southampton SO16 7PX, United Kingdom;
Tel: +44 2380 595586, Fax: +44 2380 595639

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Aim

To systematically review the evidence on diagnosing and treating infection in diabetic foot ulcers (DFU) and to use findings from the systematic reviews to create a decision analysis model.

Conclusions and results

We found three studies on diagnostic tests in chronic wound populations (including DFU). These studies indicated that:

- Single items on a clinical examination checklist are not reliable for identifying infection in chronic wounds
- Wound swabs perform poorly against wound biopsies in detecting infection in chronic wounds
- Semi-quantitative analysis of wound swabs may indicate the presence of infection in chronic wounds.

We found 21 RCTs and 2 CCTs examining the effect of antimicrobials on DFU. Most trials were too small to detect clinically important differences in outcomes as statistically significant. There is no strong evidence for recommending any particular antimicrobial agent for preventing amputation, resolving infection, or healing ulcers. Topical pexiganan cream may be as effective as oral antibiotic treatment with ofloxacin for resolution of infection. Findings, each from one small study, indicated that a growth factor (GCSF) was less costly than standard care, cadexomer iodine dressings may be less costly than standard care (daily dressings), and a combination of ampicillin and sulbactam was less costly than imipenem and cilastatin.

A decision analytic model was derived for people for whom diagnostic testing would inform treatment. Information was insufficient to populate aspects of the model with transition probabilities, and hence to inform the most effective diagnostic and treatment strategy.

Recommendations

Clinical assessment of the presence of infection and wound swabbing perform poorly in diagnosing infection in chronic wounds, and their performance in DFU is unknown. Semi-quantitative analysis may be useful in quantitative analysis of wound swabs. The evidence does not allow us to determine whether any particular antimicrobial agent is more effective than either another antimicrobial agent or standard care. An (unlicensed) antimicrobial cream may be as effective as oral antibiotics at resolving infection, but the impact on healing is unknown. Small, single studies indicate that lower treatment costs might be associated with GCSF vs standard care, cadexomoer iodine vs daily gauze dressings, and ampicillin and sulbactam vs imipenem and cilastatin.

Methods

Systematic reviews of the diagnostic, effectiveness, and cost-effectiveness literature with decision analytic modeling were used.

Further research/reviews required

1. To investigate the characteristics of infection in people with DFU which influence healing and amputation outcomes, eg, examining the importance of critical colonization on healing, cell density, and biofilm formation on healing and amputation.
2. To determine if detecting infection prior to treatment yields benefits over empirical therapy and, if so, to identify the most effective and cost-effective methods for detecting infection.
3. To determine the relative effectiveness and cost effectiveness of antimicrobial interventions for DFU infection.

Written by Dr E Andrea Nelson, University of Leeds, United Kingdom

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