

Silver dressings in the light of recent clinical research: what can be concluded?

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Towards the end of 2009 a clinical trial comparing silver-containing dressings with non-medicated dressings in venous leg ulcer treatment was published (Michaels et al, 2009; VULCAN study). This has provoked a remarkable reaction within the UK. Clinicians and scientists have commented on its design and conclusions, and it has led to a subsequent review in the *Drugs and Therapeutics Bulletin* (DTB, 2010). This latter article has been reported in the national press (*Daily Mail*, 2010).

The findings of the VULCAN study do not mean that antimicrobials are not valid for treatment of critical colonisation/local infection which is what some people might erroneously presume from the study results. However, they go some way towards dispelling the belief that topical silver 'aids' wound healing. There are repercussions for the availability and clinical use of silver dressings. For example, there is increasing evidence that the three publications mentioned above are serving to restrict the wider availability of silver dressings. The 'evidence' on silver dressing efficacy is

now so well-publicised that patients are refusing silver on the basis that 'they don't work' — because of what is written in the popular press.

Wound dressings, as medical devices, should not, in our opinion, be judged as if they are pharmaceuticals, they are not. No Regulatory Authority in any of the developed nations currently regards them as such. This does not, however, reduce the need for the development of robust evidence to support and guide dressing use...

From the positive perspective, the VULCAN study confirms that silver should not be used just to get quicker healing, which was a common theme being touted at the time the study was planned. The articles by Michaels et al (2009) and DTB (2010) have served to 'mobilise' wound care experts to make their feelings, and considered opinions, clear. A carefully reasoned article by Gottrup et al (2010) is testimony to this effect. The authors state that:

The extended definition by Sackett (1996) may be more relevant in the wound sector. Evidence-based medicine is not restricted to randomised trials and meta-analyses, but involves exploration

of all types of best external evidence with which to answer our clinical question. Prospective cohort studies may be particularly helpful, especially when cost and resource use are the major outcomes of interest, as background information on the natural progression towards healing can be obtained.

These sentiments echo those of Sir Douglas Black in 1998 about the limitations of evidence.

This approach towards clinical evidence in wound care is certainly not new, correspondence in key journals has posed provocative questions (Maylor, 2007; Cutting, 2008; White, 2008). If confusion exists in what is required as evidence to support wound dressings, it probably stems from the overlapping definitions of medical devices and medicinal products (pharmaceuticals). A medical device can be used for diagnosing, preventing, monitoring, treating or alleviating disease, whereas a medicinal product or pharmaceutical can be used in diagnosis, restoration, correction or modification of physiological functions. Those involved in the appraisal of pharmaceuticals often demand the same level of evidence as required for those products for medical devices used for treatment of wounds.

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nations currently regards them as such. This does not, however, reduce the need for the development of robust evidence to support and guide dressing use to gain the best outcomes for patients in the context of best value. The wider wound care community is now anxious to present their case for 'reasonable' and 'realistic' clinical trials.

Similarly, the wound dressings industry now realises that it too has a responsibility to provide clear, evidence-based instructions for use, and to educate customers in the best practice for use of their products. On this latter point, the NHS must recognise that unless it invests in its own tissue viability workforce to provide impartial evidence-based education to its staff on effective use of dressing products, it will continue to need to rely on wound care company staff to provide training as an essential adjunct to product supply, something which to date has often been viewed with suspicion by those outside the immediate clinical arena.

In the VULCAN trial, antimicrobials were placed on wounds without a justified clinical indication for use and were used for a prolonged period of time, i.e. twelve weeks. This practice can no longer be supported as it is incompatible with current clinical practice (Greenwood et al, 2007; Lo et al, 2009; Carter et al, 2010; Fife et al, 2010). Clinical 'titration' (adjusting therapy to the presence of clinical signs and symptoms of infection) of antimicrobial therapy is not new, it would certainly apply to silver dressings in the hands of informed clinicians. The basic principles of bioburden control in any wound involve debridement, as necessary, and treatment with careful monitoring

up to a defined endpoint. This would never be dictated purely by time elapsed, but rather by sound clinical parameters.

The Michaels et al and DTB articles have now, albeit without intention, led to restrictions in the availability of silver. This could lead to increased morbidity in wound patients; indeed, there is already evidence that arbitrary withdrawal of silver dressings can lead to increased incidence of septicaemia (Newton, 2010). No pertinent questions have been answered by these articles, clinical practice has not been advanced, nor are practitioners better informed through their publication.

Future trends

These controversial publications will ultimately result in responsible use of antimicrobial dressings. The development of associated 'Best Practice Guidelines' is already well-advanced. Manufacturers will be expected to provide more detailed instructions for use, perhaps even to liaise with the wider expertise base in clinical practice before marketing. Clinicians are, as ever, expected to exert greater caution in their use of such dressings, and to educate peers accordingly. Journal editors and reviewers are expected to be much more diligent in their approach to publishing articles which do not advance clinical practice, or, encourage responsible use of treatments. **WUK**

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