Viewpoint

Wound care: the RCT dilemma

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The clinical decision-making process involves the synthesis of knowledge acquired from a number of different sources. Wound care is no different from other fields of practice and typically each healthcare professional bases their day-to-day decision-making on their personal clinical experience.

What does randomised controlled trial (RCT) data and meta-analysis add to this process? It should establish what 'best care', whether it be a health delivery system or specific treatment, can achieve and set standards in terms of healing rates and cost that should be used as the gold-standard against which alternative wound care is judged. Using these criteria, RCTs are necessary to control standards but should not be used to limit care. If a clinical team can consistently demonstrate comparable or improved outcomes for a treatment or device, then that care should not be condemned simply because it has not been assessed in a formal RCT.

Does every treatment, drug or device have to be subjected to an RCT before it can enter into practice? Clearly this is not practical or achievable, particularly for existing treatments or for every subtle variation in a class of product.

As a researcher, I am well aware that data obtained in RCTs is usually derived from a highly selected sub-population of patients and the results and treatment conclusions may not always be transferable to the general 'wound' population. In wound care, a pragmatic approach to clinical trials is probably more realistic and should provide more clinically relevant indicators of product effectiveness across a range of clinical scenarios. The lack of reliable trial data is particularly noticeable when dealing with non-healing wounds, which have already failed to respond to standard therapy. Data is, and probably always will be, lacking when treating these complex wounds where care is often an n-of-1 experiment. In such situations, care effectiveness can still be measured using an alternative therapeutic effectiveness indicator such as TELER (Browne et al, 2004).

Should we demand that only products proven to be effective in 'acceptable' RCTs be used in wound treatment? As such, a policy would remove most, if not all, currently available products from the wound care formulary. This is clearly not practical. What of funding issues? It is unlikely that either manufacturers or healthcare providers would fund studies on already established products to provide the necessary level of evidence to satisfy the requirements of bodies such as Cochrane or the National Institute for Health and Clinical Excellence (NICE).

What of new products? The transition from scientific research through product development to clinical trial and then clinical use is an expensive process and one that the majority of small wound device manufacturers would struggle to afford, even without the additional cost burden of an extensive RCT. By demanding high-level evidence, regulatory and purchasing authorities will inevitably have to be prepared for an increase in the cost of individual dressings, or will have to make major contributions to the cost of such studies. Great care will need to be taken in designing these studies if they are to satisfy the requirements of industry, clinicians, patients and regulatory bodies. The conclusions reached may not be equally applicable or valid across all healthcare systems, or even relate to the management of all patients with wounds, irrespective of the wound's aetiology.

RCTs may also produce conflicting answers. The silver debate is one such example. The conclusion reached from the VULCAN study (Michaels et al, 2009) were that antimicrobial silver dressings were of limited value in the routine management of venous leg ulcers. However, a recent study by Beele et al (2010) showed that such dressings prevented the progression of wounds to infection and improved healing. How do clinicians interpret such contradictory results?

As RCTs are designed to answer very specific questions in a selected patient population, the answers they provide cannot always be simply extended to a general population. We must be careful to look in detail at the trial design before using trial data to defining treatment policy.

The delivery system for wound care in the United Kingdom is not designed to allow widespread high-quality research to be undertaken across a range of clinical settings. The majority of staff delivering wound care are not trained in the rigors of RCTs, and funding is not available for the number of studies that would be required to 'validate' all current treatment. All this would suggest that, at least in the short term, an alternative method is required to demonstrate treatment effectiveness. WUK

References

Beele H, Meuleneire F, Nahuys M, Percival SL (2010) A prospective randomised open label study to evaluate the potential of a new silver alginate/carboxymethylcellulose antimicrobial wound dressing to promote wound healing. *Int Wound J* 7(4): 262–70

Browne N, Grocott P, Cowley S, Cameron J, Dealey C, Keogh A, et al (2004) Woundcare Research for Appropriate Products (WRAP): Validation of the TELER method involving users. *Int J Nurs Stud* 41(5): 559–71.

Michaels JA, Campbell B, King B, Palfreyman SJ, Shackley P, Stevenson M (2009) Randomized controlled trial and cost-effectiveness analysis of silver-donating antimicrobial dressings for venous leg ulcers (VULCAN trial). *Br J Surg* 96(10): 1147–56