The evidence debate in wound care: is patient welfare an issue?

Richard White, Steven Jeffery

According to Sir Michael Rawlins, 'evidence, in the present context, has only one purpose. It forms the basis for informing decision-makers about the appropriate use of therapeutic interventions in routine clinical practice. Such decisions have to be made at various levels but, invariably, with critical consequences for patients, families and society' (Rawlins, 2008). Today, the topic of evidence seems more emotive than ever before. Why might this be? And what reaction is appropriate?

For many years we have been told that randomised controlled trials (RCTs) are the 'gold standard' of evidence and that more are required in wound care. The current hierarchy of evidence ranks meta-analyses of RCTs as the highest level. Many do not question this dogma, perhaps to avoid being regarded as 'foolish', but question it we must (see the debate on *pp.114–116* and viewpoint, *p.121* in this issue of *Wounds UK*). We would not be the first, Concato et al (2000) published on the relative value of RCTs with observational studies, drawing surprising conclusions.

We believe that now is the time for those 'luminaries' of wound care to make their position clear, not to prevaricate and avoid this thorny issue. For too long we have heard but one voice, although an authoritative one, pontificating on what clinicians must take heed of. At the heart of the debate lies the spectre of the hierarchy! This alone, in the authors' opinion, is to blame for the confusion — for it is the hierarchy that has decreed that observational studies and outcomes research be ranked lower than the RCT.

... one should not attempt to replace judgement. It is this latter skill, the capacity to assimilate and make decisions about the totality of evidence, which makes a competent clinician or advances medical science.

The status of RCTs has not gone unchallenged. Sir Douglas Black, past President of the Royal College of Physicians, has written on the limitations of evidence (Black, 1998). He does not disparage evidence-based medicine (EBM), rather he 'deprecates any attempt to equate it with the whole of medicine'; that is, to accept that there are pragmatic limits to EBM. Indeed, Rawlins has stated, when claiming an undue weighting for the hierarchy concept: 'the notion that evidence can be reliably placed in hierarchies is illusory. Hierarchies place RCTs on an undeserved pedestal for, although the technique has advantages, it also has significant disadvantages' (Black, 1998). This is not to criticise the RCT *per se*, but rather to emphasise that one should not attempt to replace judgement. It is this latter skill, the capacity to assimilate and make decisions about the totality of evidence, which makes a competent clinician or advances medical science.

We should remember Sackett, who in defining EBM, stated, 'EBM is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients' (Sackett et al, 1996). This means, in the authors' interpretation, that if the best available evidence is an observational study, or a cohort of cases, then that forms the basis for the decision. While this may not be entirely satisfactory, it is the reality. The argument over improving the quality of evidence is not for this commentary. We do not disparage the efforts of those who rely on hierarchies; we merely seek to counsel against this ritualistic practice just as one would rail against ritualistic clinical practices.

There has never been an RCT into whether or not parachutes work. If you are going to jump out of an aeroplane, would you wear one? WUK

Richard White is Professor of Tissue Viability, University of Worcester; Steven Jeffery is Consultant Burns and Plastic Surgeon, Department of Burns and Plastic Surgery, Queen Elizabeth Hospital, Birmingham

References

Black D (1998) The limitations of evidence. J *Roy Coll Phys (Lond)* **32(1)**: 23–6

Concato J, Shah N, Horwitz R (2000) Randomized, controlled trials, observational studies, and the hierarchy of research designs. *N Eng J Med* **342(25)**: 1887–92

Rawlins M (2008) On the evidence for decisions about the use of therapeutic interventions. The Harveian Oration. Royal College of Physicians, London

Sackett DL, Rosenberg WN, Gray JA (1996). Evidence based medicine: what it is and what it isn't. *Br Med J* **312**: 71–2