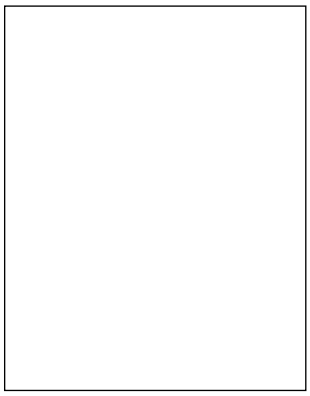

Ewan Masson

Is foot care evidence based?

Evidence-based medicine (EBM) sounds like a good idea; indeed, it is hard to argue that any management decision in medicine should be based on anything else…or is it? The main problem is the common assumption that the randomised controlled trial (RCT) is king, and nothing else will do.

However, in the real world all clinicians face management decisions for which there is no hard evidence; and even in situations where evidence is available there may be compelling reasons why it is not followed in a particular case. Individuals make decisions based on personal clinical experience (which, inevitably, is highly variable).

For example, a senior colleague with considerable experience of removable casting recently expressed the opinion that 'total contact casting was contraindicated in neuropathic patients'. This statement was based on the valid local evidence of two individuals with Charcot arthropathy whose casts caused considerably more harm than good. However, those working in centres with more experience of total contact casting may hold the opposite opinion. Both points of view may be valid, depending on local expertise and access.

The problems with RCTs

I would like to explain why I believe that RCTs are not the only acceptable evidence. The protocols are always tightly written in an attempt to eliminate confounding variables that may muddy the waters in which the hypothesis to be tested floats. Anyone with experience of trying to recruit for such trials will know how difficult this can be, as most of the real world clinic population is excluded for one reason or another.

This highly selected subgroup is then randomised to receive a treatment or an identically packaged placebo. Standardisation of practice is essential between participating centres, and even internationally in some cases, in order to recruit sufficient numbers to give a clear statistical answer.

Most such trials are run by the pharmaceutical industry, which, at the end of the day, is motivated by commercial pressures, however ethical the standards of the individuals involved. RCTs with negative end-points are rarely published in peer-reviewed journals, and it seems increasingly common for such results to be published in supplements to journals. These are often 'proceedings of a conference' sponsored by the industry, and reprints that may have escaped the normal peer review process can then be distributed.

When a number of trials fail to answer a question without equivocation, meta-analyses have been used. These pool the published (and therefore preselected) evidence of different trials, which will have recruited different populations and were probably designed to answer subtly different questions. After much heavy number crunching, a conclusion may seem clearer.

But consider this: if hundreds, or even, in some recent trials, thousands of patients need to be included in drug trials for several years before an answer is clear, the benefit to individuals must necessarily be small. Beware the statement 'X% improvement' in the treatment arm — a percentage of a small outcome is even smaller! It's not like the question of whether to give a patient with meningitis penicillin – if you don't the patient dies, if you do he/she may live.

Where does this leave foot care?

With regard to management of the foot, RCTs are uncommon, usually only concern the newest biotechnologies, and the results can be confusing for various reasons. It is important to look at all the data in context. Several new innovations, although appealing in concept, are currently presented in glossy brochures without any objective evidence of efficacy.

All sorts of other evidence are available and relevant. Indeed, relevance of evidence is probably much more important than the method by which it was gathered.

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'All ulcers intrinsic to foot dysfunction or due to extrinsic forces have a removable cause, but how can one devise a randomised controlled trial to prove it?'

Careful clinical observation can reveal a lot.

One of my interests is medical history and many very old observations in textbooks of medicine were controversial in their day, but obvious to us in the context of new knowledge. My favourite example is the suggestion in an 1829 *Textbook of Physic,* before there was any such thing as microbiology, that idiopathic tetanus did not exist:

> **'A friend with much experience asserts that all cases, if examined carefully enough, have evidence of injury, even if it be only a minor rope burn.'**

Left alone, neuropathic foot ulcers do not heal, but with pressure relief they do. We all know this – but where's the evidence, other than consensual experience? All ulcers intrinsic to foot dysfunction or due to extrinsic forces have a removable cause, but how can one devise an RCT to prove it?

There are many different types of dressings for open wounds – some strongly advocated or denigrated – but very few have any evidence of efficacy. Eusol, for example, not surprisingly is not good for growing cells, but vascular surgeons use it all the time for packing large wounds because 'it's cheap and it works'; and if it is not good for growing cells then it will not be good for growing bugs. The cell division that heals wounds is not confined to the surface, but the colonising bugs that cause invasive infection are. Logical, maybe, but not EBM as advocated by the purists.

One must therefore examine critically the evidence with which one is presented, looking carefully at the source, context and relevance of any data, the methodology by which the data were obtained and, most importantly, the interpretation (or in current political jargon 'spin') put upon the evidence. I would recommend all those who are not natural cynics to read Professor Sir Douglas Black's (1998) view on EBM as conventionally promoted. ■

Black D (1998) The limitations of evidence. *Journal of the Royal College of Physicians of London* **32**: 23-6