



Evidence-based medicine is not all randomised controlled trials and systematic reviews

Is there evidence to support the popular belief that pregnancy results from sexual intercourse? Puliyel and colleagues¹ set out to test this hypothesis by conducting a Medline search of the literature from 1966 to 2004 using ‘sexual intercourse’ and ‘pregnancy’ as keywords, and found ‘no relevant or irrelevant paper’ and certainly no systematic reviews or randomised controlled trials (RCTs) on this question. They accordingly drew the *reductio ad absurdum* conclusion that there is no evidence to support the belief that pregnancy results from sexual intercourse.

In a thrilling yet provocative mock investigation published in the *BMJ*, Smith and Pell² searched the literature for RCTs on ‘parachute use to prevent death and major trauma related to gravitational challenge’. Concluding that parachute use ‘has not been subjected to rigorous evaluation by using RCTs’ and has therefore not been shown to save lives, they suggest that ‘everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute’.

The advent of the notion of evidence-based medicine (EBM) in the early 1990s has profoundly influenced medicine and medical practice, and Puliyel’s and Smith and Pell’s farcical exercises should not be construed as detracting from its value and validity. Rather, they should be seen as cautioning against EBM becoming an evangelical orthodoxy whereby other sensible methods of identifying the relative harms and benefits of medical diagnosis and intervention are relegated to heresy.

Strictly speaking, EBM – perhaps best defined as ‘the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions’³ – is not a new notion. Medical schools have always taught, and good practitioners have always strived, to practise medicine according to the best available research-based knowledge.

What is new is EBM’s exclusive identification with systemic reviews and RCTs that has led to perceptions that diagnostic approaches and interventions not validated by RCTs have little or no validity. Furthermore, EBM zealots have tended to understate its limitations, such as the fact that RCT evidence relevant to many clinical situations simply doesn’t exist; that many clinical questions do not lend themselves to evaluation by RCT; that RCT evidence is population-based, and ‘does not answer the primary clinical question of what is best for the patient at hand’;⁴ that patient management choices are governed as much by evidence as by the limitations of time, space and resources; and that the EBM approach itself is not evidence based, there being no RCT evidence showing that it improves patient care.

RCTs are by no means always reliable or consistent. Bastian⁵ stopped prescribing neck collars for whiplash in 2001 in response to an RCT suggesting that neck rest was perhaps not such a good thing, only to start using them again in 2003 when a subsequent Cochrane review cast doubt on the first. On another occasion, her consumer coalition group abandoned a campaign to ban the use of bromocriptine for lactation suppression on the strength of a systematic review that concluded that the drug was effective and safe. Subsequently the agent was found to cause serious harm, and even death.

EBM is more than RCTs and systematic reviews

To equate EBM exclusively with RCTs and systematic reviews is a misrepresentation. EBM encompasses best evidence from all sources – observational studies, cohort studies and case studies of rare events, as well as RCTs. Sackett, a founder of the EBM movement, and colleagues⁶ have written a succinct elaboration on the ambit of EBM worth quoting at some length: ‘Good doctors use both individual clinical expertise and the best available external evidence, and neither alone is enough. Without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients ...’

‘(S)ome questions about therapy do not require randomised trials (successful interventions for otherwise fatal conditions) or cannot wait for the trials to be conducted. And if no randomised trial has been carried out for our patient’s predicament, we must follow the trail to the next best external evidence and work from there.’

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4. Tonelli RM, cited in Wikipedia.org/evidence_based_medicine (accessed 13 December 2006).
5. Bastian H. Learning from evidence based mistakes, 2004. www.bmj.com/cgi/content/full/329/7473/1053 (accessed 13 December 2006).
6. Sackett DL, Rosenberg WMC, Gray JAM *et al*. Evidence based medicine: what it is and what it isn’t. *BMJ* 1996; 312: 71-72.