Available online at www.sciencedirect.com
ScienceDirect
International Journal of Osteopathic Medicine 11 (2008) 3–6
www.elsevier.com/locate/ijosm

Editorial

Towards an osteopathic understanding of evidence

The evidence-based medicine (EBM) culture in medicine today seems to have regrettably polarised the osteopathic profession, in relation to both cranial osteopathy[1,2] and practice as a whole.[3–6] The words "research" and "evidence" seem to conjure up for some a nightmare vision of the profession being swallowed up into a single manual therapy profession, comprising an army of white-coated technicians robotically performing set treatment protocols for specific symptom pictures based on scientific evidence! At the other extreme are those whose nightmare is the use of patient-centred techniques[2] such as cranial osteopathy, for which there is no plausible biological model and an absence of scientific evidence of effect, despite positive clinical experience and patient feedback.

Research may seem a dry, dusty and rule-based discipline but its findings can investigate and support the subtler aspects of holistic practice which embraces the art of palpation, the therapeutic relationship and the mysteries of the body's own healing powers. Moreover, EBM is not a straightjacket on individual practice,[7] scientific evidence is only one piece of the jigsaw of information gathered and synthesised by a practitioner while interacting with a patient.

Evidence and research need not polarise the profession. Andrew Taylor Still managed to embrace both poles. He was a true researcher of his day, always questioning traditional views, searching for the truth, keenly observing and testing new ideas. He was also deeply aware of the mysteries of life, the human spirit, magnetism and emotions. Perhaps his vision can help to lead us to a new vision for osteopathy as a discipline of the twenty-first century, can help us to avoid becoming either fossilised in blind adherence to tradition or technical slaves to scientific evidence. But, the challenge for osteopaths is how do we evolve a model of practice that embraces the holistic aspects as well as utilising scientific evidence?

The blueprint we need for a more holistic concept of evidence will take time to evolve. This quest has already been underway for two decades in complementary and alternative medicine (CAM); and was highlighted at a recent influential UK conference on research methods and evidence in complementary medicine.[8] All delegates were invited to submit written evidence in response to the three questions below. A Consensus Statement based on the written evidence and the conference proceedings are scheduled for publication in March 2008. The three questions were the following:

1. What research methods should funders support to generate high quality and influential evidence into complementary practice?
2. What criteria would you suggest to guide the limited funds of complementary research funders and why?
3. In terms of health priorities, where would investment in complementary practice research produce the biggest health dividend? And why?

The conference provided a forum for constructive debate on how to move the political agenda forward. An issue which became a major theme at the conference was the mismatch between the high patient (consumer) spending on CAM and the research commissioners' spending priorities towards reductionist science – testing 'magic bullet' remedies (e.g. pharmaceuticals) in highly selected patient groups. The need for regulation of therapists to protect patients was emphasised, particularly given the nature of some touch based therapies practised in isolation; although it was acknowledged that regulation should not be allowed to disempower patients by removing choice. Presentations about placebo effects and the patient experience raised some important issues about the way in which research evidence was used in clinical practice, and the challenges these posed for researching therapies or healthcare systems which were radically different from the Western biomedical model. The issue of 'ring-fenced' funding or positive discrimination for funding research into complementary therapies was extensively debated at the conference. Of great interest to those involved in organising research funding in CAM is that the UK Medical Research

1746-0689/$ - see front matter
doi:10.1016/j.ijosm.2008.01.002

Council has a 'highlighting' process that encourages research in an area without having to create a separate funding stream.

Do randomised controlled trials have a role in osteopathy?

Is it possible to conduct a randomised controlled trial (RCT) in osteopathy that has real clinical meaning and value? The classical RCT is widely considered to be the best way to obtain an estimate of the efficacy of a specific therapy or technique, if the trial is well designed, with proper randomisation, appropriate controls and blinding of patients and assessors. A widely acknowledged limitation of RCTs is that the results from a highly selected trial population are not necessarily applicable to a heterogeneous clinic population.[9] Evidence from trials is inevitably limited and simplistic – about as much like the patient in front of you as an architect's model is like the actual building. Randomised controlled trials generally aim to compare two treatments which appear identical to the patient, so that the patient is "blinded" to the treatment they are receiving. None of the options for control therapies in osteopathy – such as no treatment, advice only, exercise, touch or massage, and sham electrotherapy – satisfies this condition. The patient is never adequately blinded to their treatment in osteopathy (or in any manual therapy or any medical procedure in which the patient can observe and feel the treatment given). If researchers cannot define the 'active ingredient' in treatment, as is the case in both acupuncture and osteopathy, this poses a problem when deciding on active and control treatments.[10,11] We can conduct comparative RCTs to compare two therapies, but explanatory trials which investigate specific efficacy will be weakened by the current absence of a convincing and acceptable sham (or placebo) 'treatment'. There has been some work that has recently emerged in this area with respect to osteopathic manipulative treatment but there is much still to do.[12]

To add to our problems, osteopathy as practiced is never a single 'magic bullet', it is a complex and integrated intervention comprising touch, advice and delivery of a number of manual techniques selected by the practitioner in consultation with each specific patient. Not only is our treatment complex, but the patients we serve are complex too. The most frequent presenting condition in osteopathic practice, non-specific low back pain, is for the most part, diagnosed from patient reported pain and tenderness rather than objective tests. Progress and outcome are measured subjectively too, by the patient's report of pain, disability, and more recently, using psychological outcomes.[13] Symptoms are often self-limiting, yet are also recurrent rather than stable and chronic. Back pain, like many musculoskeletal complaints, is a multifaceted biopsychosocial phenomenon that may require a multifaceted research approach.

The physiotherapy profession has over the past decade conducted many RCTs but there is growing unease with studies which may be methodologically excellent but may not adequately reflect practice[14] and also unease with the way researchers or journal editors report or interpret their results. For example, one trial by physiotherapists which concluded that routine physiotherapy was no more effective than one session of assessment and advice,[15] was headlined by the media as "physiotherapy no better than a chat". More recently, a trial published in *The Lancet* concluded that "patients with acute low back pain receiving recommended first-line care do not recover more quickly with the addition of diclofenac or spinal manipulative therapy".[16] This conclusion is potentially misleading. The trial did not compare manipulation, diclofenac or placebo with a group that only received first-line care (advice and paracetamol); therefore, the authors could not know whether patients receiving additional treatment had different recovery rates to those patients who only received first-line care. Perhaps the more correct interpretation of the data is that none of the active treatments performed better than placebo.

The standard RCT design does have a place in osteopathy, as it can be used to compare the efficacy of one technique with that of another. The benefits of such designs are mainly internal to the profession, to help us refine our treatment protocols. We urgently need to answer the bigger question as to whether osteopathy as practiced, in the context of all this complexity, is clinically effective and cost-effective. We need this information in order to promote osteopathy in the market place.[7] The bigger question implies use of a pragmatic RCT design, based on a growing understanding of the complexity of the setting, the intervention and the outcomes from mixed methods research.[17–19]

In a pragmatic randomised trial,[19–21] one health service model is compared to another, to assess effectiveness of a package of care rather than specific efficacy of one ingredient of the care. For example, patients are randomised to receive either 'best' standard GP care only or GP care plus referral for six sessions with an osteopath. The BEAM trial and the ROMANS trial are examples of pragmatic trials.[22,23] The results of such trials are useful to clinicians and to purchasers of healthcare services. Pragmatic trials reflect the real world and the cost-effectiveness of including this type of service in a care package can be evaluated.[24,25] Both the BEAM and ROMANS trials showed that osteopathy was a cost-effective addition to back pain services. Another study in Plymouth NHS Trust[26] showed substantial savings for GPs: a service offered treatment for patients who were not making progress and who would have been referred elsewhere; only 3% were referred to secondary care. Yet

despite the accumulating evidence on cost-effectiveness, UK health service commissioners are purchasing very few osteopathy services. Perhaps this is because trials which investigate effectiveness rather than efficacy are often excluded from systematic reviews; which can impact strongly on the conclusions.[9] However, acupuncture has 'ticked all the boxes' with positive results in large trials of efficacy,[27] effectiveness, cost-effectiveness, safety, and understanding biological mechanisms – and is still not being purchased by health authorities. The number of NHS contracts for complementary services has been reduced as government pressure to balance NHS budgets has tightened. It appears that commissioners see complementary therapies as a luxury that can be trimmed, rather than a solid and dependable way of getting people back to work.[29] While research shows that patients view some complementary therapies as a "treat" rather than "treatment",[28] it also shows patients view osteopathy as conventional rather than complementary! The views of the general public on osteopathy are also reflected by their willingness to pay for services from their own pocket.

Pragmatic trials provide robust cost-effectiveness data and are politically important for osteopathy. Yet pragmatic trials will never convince the sceptics. In a trial that compares usual care with the addition of a service such as osteopathy, a sceptic will ask – what had the effect? Was it the osteopathic techniques or the advice? Or was it the therapeutic relationship and a heightened placebo effect?[30] The placebo response needs to be distinguished from other non-specific effects and regression to the mean. Would a course of massage or counselling have performed just as well or been cheaper? And therapies such as massage can be accommodated into orthodox services without challenging medical concepts of health and disease! One delegate at the UK research conference chose to phrase this key question – would you get the same result with attention and touch only and "without all the gobbledygook"? Pragmatic trials can be made more specific by methods such as cluster randomisation and a long baseline measurement phase to improve internal validity.[20]

Changing attitudes

Attitudes towards complementary therapy may be so ingrained that even optimal trials of osteopathy will be seen as flawed by its sceptics. Or perhaps only a positive personal experience is likely to convince a sceptic of the benefits.

The philosophical basis of evidence-based medicine has been questioned. Goldenberg called it a male positivist standpoint, the metaphor of the weight of evidence giving the proponent the authority of the moral high ground.[31] The EBM discourse appears not to acknowledge the subjective elements of interpreting research findings. Results are often open to interpretation, as in the diclofenac example above. Research philosophy in the western world grew from the Newtonian concept of an objective reality, an irrefutable truth, before incorporating statistical uncertainties and probabilities. Twentieth century philosophies including phenomenology and quantum physics, have shown the inescapable entanglement of the observer and the observed, the objective and the subjective.[32,33] This post-modernist understanding of truth as a fluid and negotiable entity has yet to permeate the understanding of evidence in medical science.

Why is science needed to prove the glaringly obvious? For example, patients are very impressed if a friend or relative improves or is cured of long-standing symptoms, such as chronic pain. Intuitively, they know that such an improvement was very unlikely to occur by chance just after having treatment, and so they make a causal link. But the evidence-based model regards these observations as weak or anecdotal evidence.

Do patients and chronic conditions hold the key to winning the hearts and minds of funders, maybe even of sceptics? In order to help in chronic benign conditions such as arthritis and obesity, we need to enable and empower a patient-centred approach, including a patient-centred taxonomy. Patient involvement in research is being promoted strongly by funders and government.[34] The osteopathic profession could certainly do more to involve patients in research and training. In chronic disease states there is often a stable baseline of symptoms. The natural history is of a worsening of the condition, and spontaneous remission is rare. Observational studies and case studies[35] can provide additional valuable evidence.

Conclusions

Debate about scientific evidence within osteopathy is tending to polarise the views of the profession. The inspiration of AT Still, who combined research and holistic practice, may help the profession to utilise the passion generated by the debate to move forward to an 'osteopathic' concept of evidence. The EBM model already embraces the patient and the practitioner as well as scientific evidence. However, current concepts of scientific evidence may be limited, especially when applied to a complex practice such as osteopathy. To demonstrate the efficacy of osteopathy we need a more refined understanding of scientific evidence – an understanding that gives some weight to clinical observation, case studies and patients' views. We need a more refined approach to the design of pragmatic clinical trials that allow for context effects and measures specific efficacy. And we could benefit from involving our patients in

research to a much greater extent, not only as subjects but also as researchers.

References

1. Maddick AF. The flawed cranial model. *Int J Osteopath Med* 2007;**10**:80.
2. Hartman SE. Reply to ''The flawed cranial model''. *Int J Osteopath Med* 2007;**10**:81–2.
3. Lamb G. The outer limits of osteopathy. *Osteopathy Today* 2007 April;12–3.
4. Milner R. Letter to the editor about contributions from Lamb and Froud. *Osteopathy Today* 2007 June;19.
5. Froud R. Letter to the editor on article by Gez Lamb. *Osteopathy Today* 2007 May;18.
6. van der Post K. Letter to the editor on evidence-based medicine. *Osteopathy Today* 2007 July/August;21.
7. Lucas NP, Moran RW. Researching osteopathy: who is responsible? *Int J Osteopath Med* 2007;**10**:33–5. doi:10.1016/j.ijosm.2007.08.003.
8. Kings Fund, Prince's Foundation for Integrated Health. Conference: assessing complementary practice: building consensus on appropriate research methods. London; October, 2007.
9. Fritz JM, Cleland J. Effectiveness versus efficacy: more than a debate over language. *J Orthop Sports Phys Ther* 2003;**33**:163–5.
10. Lilford R, Braunholtz D, Harris J, Gill T. Trials in surgery. *Br J Surg* 2004;**91**:6–16.
11. Lilford RJ. Ethics of clinical trials from a bayesian and decision analytic perspective: whose equipoise is it anyway? *Br Med J* 2003;**326**:980–1.
12. Fulda KG, Slicho T, Stoll ST. Patient expectations for placebo treatments commonly used in osteopathic manipulative treatment (OMT) clinical trials: a pilot study. *Osteopathic Med Primary Care* 2007;**1**:3. doi:10.1186/1750-4732-1-3.
13. Williams NH. Optimising the psychological benefits of osteopathy. *Int J Osteopath Med* 2007;**10**:36–41.
14. Moore A, Jull G. The systematic review of systematic reviews has arrived. *Man Ther* 2006;**11**:91–2.
15. Frost H, Lamb SE, Doll HA, Carver PT, Stewart-Brown S. Randomised controlled trial of physiotherapy compared with advice for low back pain. *Br Med J* 2004;**329**:708.
16. Hancock MJ, Maher CG, Latimer J, McLachlan AJ, Cooper CW, Day RO, et al. Assessment of diclofenac or spinal manipulative therapy, or both, in addition to recommended first-line treatment for acute low back pain: a randomised controlled trial. *The Lancet*;**370**:1638–43.
17. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. *Br Med J* 2000;**321**:694–6.
18. Verhoef MJ, Lewith G, Ritenbaugh C, Boon H, Fleishman S, Leis A. Complementary and alternative medicine whole systems research: beyond identification of inadequacies of the RCT. *Complement Ther Med* 2005;**13**:206–12.
19. MacPherson H, Schroer S. Acupuncture as a complex intervention for depression: a consensus method to develop a standardised treatment protocol for a randomised controlled trial. *Complement Ther Med* 2007;**15**:92–100.
20. Godwin M, Ruhland L, Casson I, MacDonald S, Delva D, Birtwhistle R, et al. Pragmatic controlled clinical trials in primary care: the struggle between external and internal validity. *BMC Med Res Methodol* 2003;**3**:28.
21. Macpherson H. Pragmatic clinical trials. *Complement Ther Med* 2004;**12**:136–40.
22. UK BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: effectiveness of physical treatments for back pain in primary care. *Br Med J* 2004;**329**:1377.
23. Williams NH, Wilkinson C, Russell I, Edwards RT, Hibbs R, Linck P, et al. Randomized osteopathic manipulation study (ROMANS): pragmatic trial for spinal pain in primary care. *Fam Pract* 2003;**20**:662–9.
24. Williams NH, Edwards RT, Linck P, Muntz R, Hibbs R, Wilkinson C, et al. Cost–utility analysis of osteopathy in primary care: results from a pragmatic randomized controlled trial. *Fam Pract* 2004;**21**:643–50.
25. UK BEAM Trial Team. United Kingdom back pain exercise and manipulation (UK BEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care. *Br Med J* 2004;**329**:1381.
26. Gurry B, Hopkins M, Peers C, Anderson S, Watts M. A rapid access treatment facility for acute low back pain based in a primary care setting. *J Orthopaedic Med* 2004;**26**:13–8.
27. Haake M, Muller HH, Schade-Brittinger C, Basler HD, Schafer H, Maier C, et al. German acupuncture trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups. *Arch Intern Med* 2007;**167**:1892–8.
28. Bishop F. Treat or treatment: a qualitative study conceptualising patients' use of complementary and alternative medicine (CAM).http://www.cam-research-group.co.uk/detail-publications.php?id = 6 2007.
29. Leech C. *Renaissance project – preventing disability from low back pain*. Eire, Dublin: Department of Family and Social Affairs; 2004. http://www.welfare.ie/publications/renaissance.html.
30. Kaptchuk TJ. The placebo effect in alternative medicine: can the performance of a healing ritual have clinical significance? *Ann Intern Med* 2002;**136**:817–25.
31. Goldenberg MJ. On evidence and evidence-based medicine: lessons from the philosophy of science. *Soc Sci Med* 2005;**62**:2621–32.
32. Hyland ME. Does a form of 'entanglement' between people explain healing? An examination of hypotheses and methodology. *Complement Ther Med* 2004;**12**:198–208.
33. Ladkin D. The enigma of subjectivity: how might phenomenology help action researchers negotiate the relationship between ''self'', ''other'' and ''truth''. *Action Res* 2005;**3**:108–26.
34. INVOLVE. Promoting public involvement in NHS, public health and social care research. http://www.invo.org.uk/ [accessed December 2007].
35. Lewith GT, Jonas WB, Walach H. *Clinical research in complementary therapies: principles, problems and solutions*. Churchill Livingstone; 2001.

Janine Leach
School of Health Professions, University of Brighton, East Sussex, UK
E-mail address: c.m.j.leach@brighton.ac.uk