Moving from Anecdote to Evidence

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Evidence based medicine (EBM)¹ and evidence-based practice (EBP)² have become the major driving force impacting clinical practice education, policy making and scientific medical research. EBM and EBP has therefore become of direct interest and relevance to the majority of health teaching and research in universities.

I have to admit that I was initially excited by the goals of EBM and EBP, which seemed to bring hope for a new level of objectivity. However, this hope was clearly a premature evaluation and has been upset by the preeminent professional application of evidence based practice, which breaks down to simply finding the best evidence within a paradigm, without questioning the paradigm itself. The emphasis on hard science tends to devalue multifaceted highly developed clinical expertise largely derived from experience and a detailed study and understanding of individual patients.³

Sometimes there may be no evidence. Regardless, the absence of evidence of effectiveness is not the same as absence of effectiveness.⁴ Clearly, not all spinal or musculoskeletal treatments are studied or can be studied to the same magnitude as in EBM. Non-pharmacological methods of treatment that pertain to manual medicine, specifically spinal manipulation, cannot readily participate in EBM or EBP studies.⁵ Manual medicine has an underdeveloped research culture. Randomized and controlled studies to date have not been satisfactorily designed to prove effectiveness or ineffectiveness of manual medicine in terms of EBM.⁶

The sum of evidence has to be more than a Cochrane type meta analysis of randomized and controlled trial studies.⁷ To date the data do not include many types of treatments or patients seen in daily clinical manual medicine practice. We need to recognize the subjective nature of clinical decision making as the fundamental aspect of human assessment. Imperatively, we need to acknowledge the subjective meaning of pain and disability to the patients we serve. The laudable goal of making clinical decisions based on evidence will be further impaired unless we include patient values and beliefs and incorporate this invaluable perspective.

Randomized trial information is not very often available for issues in etiology, diagnosis, prognosis and for clinical judgments that rely on pathophysiologic changes, psychosocial factors and personal preferences of patients and direction for providing comfort and reassurance.⁸

Simply we require a new and more applicable design development for studies in order to do justice to nonpharmacological treatments based on evidence and effectiveness.

Randomization and blinding becomes problematic in non-pharmacological studies. The randomized controlled trials (RCT's) have an important place in the assessment of the efficacy of manual medicine. However, the RCT's address only one limited question, whether an intervention has statistically an effect.9 The RCT does not address why the intervention works, how the participants are experiencing the intervention or how they give meaning to these experiences. It may be argued that the addition of qualitative research methods to RCT's can further understanding of manual medicine interventions. Qualitative research is able to assist in understanding the meaning of a specific intervention to the patients as well as the patient's beliefs in respect to the treatment and the expectations of the outcome. Qualitative research may aid in understanding the impact of the context and the process of the intervention.¹⁰ Qualitative research is helpful in the development of appropriate outcome measures for manual medicine. A greater understanding of manual medicine intervention will have the potential to improve health care delivery and further acceptance of non-pharmacological therapies.

The aspect of EBP raises important issues about our fundamental role and how the chiropractic profession will choose to practice and appropriately define our profession in the future. The Cochrane library is not the exclusive answer, nor is tradition and anecdotal evidence.

Historically non-pharmacological therapeutic intervention such as spinal manipulation lack the established research infrastructure of conventional medicine. Unfortunately, research respective to spinal manipulation has attracted only a limited number of manual medicine high caliber researchers. The field suffers from a durst of research expertise.

Randomized and controlled studies in manual medicine simply do not align with the evidence based medicine paradigm. This fact has resulted in present situations where relatively little scientific research has occurred. Methodology and design in EBM have neglected nonpharmacological treatments. One of the under researched areas in manual medicine is spinal manipulation. By concentrating the design methodology on drug trials, EBM has prejudiced the patient population suffering from chronic diseases in need of complex multi-modal management and non-pharmacological interventions. Clearly, it is much easier to do an RCT for a drug treatment than it is for a physical manual intervention.

What is not readily measurable tends to be denied existence in medical science. This fact creates a questionable bias within the evidence based medicine paradigm when weighed against areas of research in spinal manipulation where outcomes, to date, cannot be effectively quantified. Therapeutic benefits of spinal manipulation unquestionably occur on levels not accessible by quantitative measurement.

This profession needs to utilize techniques that consolidate judiciously definable and defensible parameters. There is a vast difference between randomized controlled clinical validated studies and 'vitalistic' charisma. Bronfort et al. have over sixty well researched random controlled trials buttressing spinal manipulation.^{11,12,13} Therapeutic techniques that are neither defensible, valid nor reliable will pursue 'legendary subluxations' in lieu of scientific accountability. Reliability and validity studies will not permit mixed and inconclusive evidence. Confusion abounds ...

The evidence issue protracts and the question becomes ... Is chiropractic a profession or a procedure? Bumper stickers and posters such as 'Chiropractic Works' or 'Chiropractic Healing' discredit the profession. When it comes to defending what this profession does ... for patients, patient advocacy, ministries of health, insurance companies and courts of law, 'innate restoration and the nerve rule' will blanch in evidence based clinical practice.

The dichotomy within the profession in the approach to clinical knowledge should not be irreconcilable. There needs to be a consilient approach to the interpretation of the evidence and the integration of intervention in clinical practice. The EBP approach will rely on the linking of interdisciplinary cooperation and facilitate collaboration and the development and alliance with other relevant manual medicine organizations.¹⁴

Internationally there is a growing interest in manual medicine therapies and EBP. An increasing number of respected medical researchers are designing trials to study the efficacy of spinal manipulation and manual medicine modalities addressing the complaints for which they have traditionally been advocated.¹⁵ The chiropractic profes-

sion has developed a small dedicated group of researchers who have actively published results in highly respected journals.^{16,17} This profession must learn to adopt and utilize evidence based medicine or evidence based practice approaches in daily clinical practice. Failure to do so will further polarize this profession.

A degree of professional consensus is necessary so that an intervention is consistent based on evidence based practice simultaneously having an enduring impact in the delivery of health care in the future. EBM, EBP clinical expertise needs to be balanced with evidence of cost-effectiveness. Many interventions/treatments are clinically effective but exceptionally expensive. Cost-effectiveness: Is the additional health expenditure justified by the improvement in health? Manual medicine, specifically spinal manipulation intervention is cost-effective.¹⁸ The ongoing spine patient outcome research trial (SPORT) will possibly shed light in their findings and will begin to appear in the literature. Rates of spinal surgery have increased sharply over time. Despite these trends, there is little evidence proving the effectiveness of surgical intervention over non-operative management. Such a multicentered, randomized and controlled trial, for the first time will provide scientific evidence as to the relative effectiveness of surgical versus non-surgical treatment.¹⁹

The majority of manual medicine providers use interventions with high evidence of clinical effectiveness, however much of clinical practice is spent on interventions that are not well reported in the literature. Some of these interventions ought to be revisited in light of the design of the SPORT trial.²⁰ Future results will probably indicate the need for improvement in the quality of the clinical research as well as the dissemination and implementation in a manner that is acceptable to all health care providers. Manual musculoskeletal medicine should be approached in a more evidence based manner. This profession needs to become a partner in the delivery of health care of Canadians and a referral specialty for physicians for neuromusculoskeletal disorders.

References

- 1 Sackett DL, et al. Evidence based medicine: What it is and what it isn't. BMJ 1996; 312:71–72.
- 2 Muir G. Evidence based health care: How to make health policy and management decisions. London. Churchill Livingstone, 1997.

- 3 Green S, Buchbinder R, Glazier R, Forbes A. Systematic review of randomized controlled trials of interventions for painful shoulder: Selection criteria, outcome assessment, and efficacy. BMJ 1998; 354:316.
- 4 Trinh K. Medical acupuncture. An evidence based approach to traditional Chinese medicine. 2000: McMaster University.
- 5 Beyer KH. Manuelle Medizin. Band 43. Nummer 6. Dezember, 2005. p. 400–403.
- 6 Beyer WF, Weber KP. Manuelle Medezin. Band 43. Nummer 1. February, 2005. p. 7–12.
- 7 Williams DDR, Garner J. The case against 'the evidence': A different perspective on evidence based medicine. Br J Psych 2002; 180:8–12.
- 8 Meyer J. Qualitative research in health care: Using qualitative methods in health related active research. BMJ 2000; 320:178–181.
- 9 Dieppe P, Szebenyi B. Evidence based rheumatology. J Rheum 2000; 27(1):4–7.
- 10 Feinstein AR, Horwitz RI. Problems in the "evidence" of "evidence-based medicine". Am J Med 1997; 103:529–535.
- 11 Devocht, JW. History and overview of theories and methods of chiropractic: A counterpoint. Clin Orth Rel Res 2006; 444:243–249.
- 12 Breen A, et al. Improved early pain management for musculoskeletal disorders. www.hse.gov.uk/research/rrhtm.
- 13 Breen A, Van Tulder M, Bronfort G, et al. Monodisciplinary or multidisciplinary back pain guidelines? How can we achieve a common message in primary care? European Spine J. Online Issue, June 2005.
- 14 Palmer R, Patijn J. Thoughts regarding evidence based medicine. International Federation for Manual/ Musculoskeletal Medicine. June 19, 2004.
- 15 Santilli V, et al. Chiropractic manipulation in the treatment of acute back pain and sciatica with disc protrusion: A randomized double-blind clinical trial of active and simulated spinal manipulations. The Spine. 2006; 6:131–137.
- 16 Herzog W. Forces required to cause cavitation during spinal manipulation of the thoracic spine. Clin Biomech 1993:3:16–18.
- 17 Giles L, Muetter R. Chronic spinal pain: a randomized clinical trial comparing medication, acupuncture, and spinal manipulation. Spine 2003; 28; 1490.
- 18 Manga P, et al. The effectiveness and cost effectiveness of chiropractic management of low back pain. Ontario Ministry of Health. 1993.
- 19 Gunzburg R, et al. Editorial: European Spine J 2005; 14:919.
- 20 Reference: http://sport.dartmouth.edu/hsn/