TANG [HUMANITAS MEDICINE]

Review

Evidence based practice within the complementary medicine context

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ABSTRACT

Evidence based practice (EBP) is a system of applying the most current and valid high quality evidence to support clinical decision making in a healthcare setting. In the twenty five years since its inception, EBP has become the accepted benchmark for excellence in healthcare. Although the system emerged within the biomedical sciences, in the years since EBP has become normative across all healthcare modalities from dentistry, allied health to complementary and alternative medicine (CAM). Practicing evidence based medicine within any modality potentially offers the patient the best available care based on high quality evidence. Yet it is the nature of the evidence that provokes some questions about the suitability of EBP across all modalities of healthcare. The meta analysis of randomized controlled trial (RCT) stands at the pinnacle of the hierarchy of evidence in EBP. This forms a challenge to CAM due to the difficulty in reducing the elementals of a holistic naturopathic assessment of a patient into an answerable question to be tested within a RCT. On one level this makes EBP paradigmatically incompatible with CAM, yet on another level it presents the opportunity to redefine the parameters of what is considered high level evidence. EBP has become a tool, and at times a weapon wielded by governments and health insurance companies to direct healthcare funding and policy. The implications of the nature of accepted evidence are becoming far reaching. The pursuit of the best available healthcare for each individual is the focus of EBP. However, the injudicious use of this system to direct health policy is fraught with biomedical bias and dominance. This issue raises the challenge to CAM to present high level evidence according to the rules of evidence, or face the annihilation of centuries of empirical knowledge.

Keywords Evidence based practice, complementary and alternative medicine, randomized controlled trial

INTRODUCTION

The emergence of evidence based practice (EBP) as the accepted gold standard in medicine has its genesis in work by Chalmers et al. (1989) in association with a review of clinical practices used in the management of pregnancy and childbirth. Following this, a physician at McMaster University in the early 1990s first used the term "evidence based medicine" (EBM), describing it in the context of applying an attitude of enlightened scepticism (Guyatt, 1991) towards the application of diagnostic, therapeutic, and prognostic technologies. Sackett et al. (1996) further defined the system of EBM, suggesting that clinical decisions for individual patients should be made based on the judicious use of current best evidence, exploring explicitly and conscientiously the clinical relevance of the evidence. Two decades on, it has become the "love child" of the biomedical sciences and methodological reductionism. This paper seeks to explore the role of EBM, and in particular EBP in complementary and alternative medicine (CAM). It will also explore the implications of EBP and how it relates to the current practice of CAM in Australia, identifying the strengths and weaknesses of the system, and its political, societal and ethical implications.

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Received May 12, 2016; **Accepted** August 16, 2016; **Published** August 31, 2016
doi: http://dx.doi.org/10.5667/tang.2016.0014

What is EBP?

EBP is a rigorous system aimed at ensuring the best available evidence is being used to treat a patient presenting for care. It sets out a hierarchy of evidence to use in the decision process, with a systematic review considered the gold standard, followed by, in descending order, randomized controlled trials (RCTs), controlled cohort studies, uncontrolled cohort studies, case studies and case series, qualitative and descriptive studies, EBP implementation and quality improvement (QI) studies, and finally expert opinion (Melnyk et al., 2015). Practitioners of EBP adhere to the principles of integrating their own clinical expertise, which is considered internal or intuitive evidence, with external or scientific evidence drawn from research. This evidence is then applied to the patient, with consideration of their preferences and local context (Rycroft-Malone et al., 2004).

The cochrane collaboration

The Cochrane database of systemic review was launched in April 1995 by the Cochrane collaboration. Its stated mission is to "promote evidence-informed health decision-making by producing high-quality, relevant, accessible systematic reviews and other synthesized research evidence" (Cochrane Collaboration, 2015). Since its inception it has become synonymous with EBP, authenticating biomedical evidence, validating the authority of the biomedical health care model, and strengthening the power and dominance of biomedicine in the global health care debate. In addition to the Cochrane collaboration, many journals publish dedicated review volumes,

providing a valuable resource of high level evidence.

Benefits of EBP for CAM

EBP has become normative in Western health care systems, in both practice and policy. The Australian government Health Care Reform of 2015, alongside the NPS Medicine Wise organization and Choosing Wisely Australia all use EBP to guide policy and procedures in healthcare (COAG, 2015; NPS, 2015; Choosing Wisely Australia, 2015).

Educational institutions, governments, health care practitioners and consumers have all embraced and legitimized the method, which is understandable since it facilitates excellence in health care on many levels. CAM has also been swept up in the tide of EBM along the way, and is now met with the challenge of scrutinizing and validating its traditional knowledge within the paradigm of the scientific method of EBM (Holmes et al., 2006). There are advantages to this shift, including the opportunity to empirically test traditional knowledge without negating the assumptions of holism and vitalism; also the opportunity to legitimize and educate the public and the biomedical community on the methodologies and epistemologies of CAM (Jagtenberg et al., 2006). This also offers a potential for true medical pluralism if CAM can validate its methods and evidence within this model, although there are significant methodological incongruences preventing the realisation of this utopic health care system (Jagtenberg et al., 2006).

Disadvantages of EBM for CAM

The scientific reductionist principles of EBM are essentially paradigmatically irreconcilable with CAM (Jagtenberg et al., 2006). The complexity of the CAM consultation, therapy and context is multi-interventional and individualistic in nature, and becomes problematic to reduce it to a single testable hypothesis, rendering it impotent within the reductionism of the EBM methodology (Jagtenberg et al., 2006). As Churchill (1999) points out, reductionism is an inappropriate methodology for studying systems with feedback mechanisms. He cautions that CAM will lose its autonomy through EBM, joining with Ernst et al. (2004) in warning of the violation of the rights of individuals to choose a healing modality due to the increasing biomedical dominance of EBM. While EBM superficially presents CAM with an opportunity to establish efficacy and acceptance into the wider, legitimized health care system, it comes at a cost.

The tyranny of EBM

Sackett et al. (1996) prophetically warned of the "tyranny of EBM", referring to over reliance on EBM, without integrating the essential component of clinical knowledge as the internal evidence of the EBM model. This underscores the need to examine the nature of evidence in CAM within the model of EBM, and to recognize the paradigmatic differences between these two healthcare models (Jagtenberg et al., 2006). Within EBP, the benchmark of systemic reviews of primarily RCTs stands as the prevailing standard which seeks to reduce the complexities of health care into a single testable hypothesis (Dawes, 2005). This methodological criteria essentially eliminate the possibility of validating CAM through EBM, as the fundamental nature of the practice of CAM defies the constraints of a RCT (Barry, 2006). EBM is based on the biomedical model and its reductionist scientific methodology. This methodology fails to provide the platform for the illumination of the complexity of the various modalities of CAM, including herbal medicine, homeopathy and energetic healing modalities to name just a few (Barry, 2006). Barry calls for a more expansive model of evidence, suggesting the anthropological and ethnographic form of evidence is more suited to measuring the effects and benefits of CAM therapy. The subtle, yet significant transformation of the experience of living and existential shifts cannot be measured within a RCT, although they do resonate more closely with anthropological notions of evidence such at embodiment theory (Barry, 2006). The author goes on to propose deep political motivation in biomedicine's standardization of RCTs as evidence, pointing to a need to establish a form of evidence that truly measures what actually works in CAM. The methodologies of RCTs focus on what is easily measured, however, in the process overlook the often subtle and complex effects. This essentially limits CAM's ability to validate its evidence through EBM and the highly constructed evidence of the reductionist biomedical paradigm (Barry, 2006).

Prejudices and biases of EBM

EBP sits as the jewel in the crown of the biomedical model's hegemonic cultural movement (Jagtenberg et al., 2006). The recent and ongoing reviews of homeopathy and CAM in Australia by the National Health and Medical Research Council (NHMRC) has used EBM as a weapon to delegitimize homeopathy through the selective use of systematic reviews (NHMRC, 2015). In their submission to the review, the National Institute for Complementary Medicine (NICM) urged the review committee to consider the nature of evidence in CAM, suggesting traditional knowledge is not simply anecdotal, but can be considered a form of empirical knowledge. To dismiss it as invalid is to ignore the underlying science of systematic observation tested by experiment (NICM, 2013; Myers, 2002). This review process is highlighting the biases and prejudices inherent in EBM, demonstrating the therapeutic nihilism in the absence of RCTs that comply with the NHMRC's rules of evidence. This is the playing field at present, although it is not even. If CAM wants to participate in the health care sector at all, it has to work within the system that is attempting to corrupt and annihilate its fundamental principles.

EBM within CAM and naturopathic practice

Within a naturopathic practice, EBM is an important guiding principle and practice, together with the principles of the Hippocratic Oath to first do no harm. An experienced naturopathic practitioner accumulates a body of internal evidence through clinical experience, which is considered when reviewing, analyzing and implementing external evidence from the literature. The challenge to keep up to date with current and emerging evidence in CAM is no less a burden and a responsibility for a naturopath than it is for practitioners within the biomedical model of health. The search for the best possible evidence to address clinical questions arises from the common desire to offer each individual patient the most efficacious treatment, regardless of the modality of healing used by the practitioner of EBM. There are, however, subtle and at times striking differences in the application of EBM within a naturopathic context in comparison to a biomedical context.

On a daily basis naturopaths are confronted with clinical questions, some of which are easily answered through internal evidence, while others will lead the practitioner on a search of the literature. At times this can be an uncomplicated process with an easily defined question, leading to the most efficacious treatment option for the patient. More often the complexity of the naturopathic case, with multifactorial influences and a diverse array of presenting clinical manifestations and complaints, can leave the naturopath seemingly directionless in the face of EBM. These are the times when the true art of

naturopathic practice can shine. It is the deciphering of the complete picture of a presenting case, exploring the emotional, physical, spiritual and existential elements which allow possible causation to arise. Thus the corresponding corrective course of treatment becomes evident by addressing the totality of the case (Sarris, 2011). Clinical questions do arise within this process, however it is impossible to reduce the complexity of a multifactorial case into a single answerable question defined within the limits of a RCT. There are, however, many opportunities to turn to the literature to address issues and questions arising within a naturopathic consultation.

The CAM practitioner is presented with a plethora of information on a daily basis, including professional education seminars, commercial advertising of naturopathic products, patient questions arising from internet searches, and information from the patient's local context. All of this information needs to be assessed for validity and applicability to the naturopathic practice. Seminars can be a valuable source of current discussion, however it must be viewed through the lens of professional scepticism until the sources of evidence are reviewed. Regularly the studies used to underpin new products would not meet the requirements of good evidence within the general hierarchy of evidence. Yet this does not invalidate the findings. It simply calls for more detailed studies, with larger study cohorts and a more focused methodology. This highlights an issue central to the evidence of CAM when compared to evidence within the biomedical models. The cost of financing large studies can be exorbitant, beyond the capacity of independent practitioners and small to medium sized businesses. Manufacturers of CAM products in Australia tend to allocate possible research funding into marketing for commercial reasons and intellectual property right considerations (Bensoussan et al., 2004). This leaves research funding in the hands of individual CAM practitioners and a small number of academic researchers. The Australian government funding of CAM is partially directed through the NHMRC which is focusing their resources on seeking to either validate or discredit CAM through EBM, within their reviews of homeopathy and complementary medicine. Their guidelines of evidence limit systematic review of studies to those with more than one hundred and fifty subjects (NHMRC, 2015), amongst other restrictions. The NICM (2013) in their submission to the NHMRC review of CAM, points to the gradual emergence of scientific validation of the properties of many botanical medicines. They cite the 1985 work of US pharmacognosist Professor Norman Farnsworth (1985), who shows that of the 119 plant derived drugs used internationally, 75 percent share the same use in folklore as has been found to be effective in conventional medicine. Thus the evidence to support traditional knowledge of CAM is slowly emerging, a CAM practitioner draws on this evidence, and the patients benefit from the evidence, yet in the healing process, it is the medicines that do the work.

CAM practitioners can appreciate the benefits of EBM, however questions arise regarding the ethics of the manipulation and hijacking of the model for commercial, political and hegemonic purposes. Holmes et al. (2006) express an extreme view suggesting EBM's use of scientific knowledge is exclusionary and normative, verging on micro-fascism in the contemporary scientific arena. This is no reason to discredit EBM; rather it points the way to develop and expand the epistemology of science, including phenomenological and experimental data (Baer, 2004). Churchill (1999) advises CAM practitioners to advocate for full recognition and acceptance of the CAM paradigms within EBM, and to question the implicit intention of biomedicine to subjugate CAM modalities within an environment of biomedical dominance of EBM. In less radical terms Barry (2006) advocates for a transformation within the health care system, creating a new paradigm through the synthesis of science and spirituality. This is one of the challenges facing CAM practitioners in Australia today.

CONCLUSION

In conclusion, the role of EBP in CAM today is like the skeleton, providing structure and leverage, but failing to explain and account for the 'soul' of the body of knowledge it contains. The Hippocratic Oath is a call for non-maleficence in the art and practice of medicine, and is held as a guiding principle in biomedicine, but also CAM. This paper contends the injudicious use of EBM runs the risk of corrupting and extinguishing the collective and individual art of diagnosis and the holistic practice of medicine, for both the biomedical system and CAM. In essence, the art of the healing practice of medicine can neither be defined nor confined within the present paradigm of evidence, central to the biomedical model of EBM.

ACKNOWLEDGEMENTS

None.

CONFLICT OF INTEREST

The authors have no conflicting financial interests.

REFERENCES

Baer H. Towards and integrative medicine: Merging alternative therapies with biomedicine. (Walnut Creek, USA: Altamire Press), 2004.

Barry CA. The role of evidence in alternative medicine: Contrasting biomedical and anthropological approaches. Soc Sci Med. 2006;62:2646-2657.

Bensoussan A, Lewith GT. Complementary medicine research in Australia: a strategy for the future. Med J Aust. 2004;181:331-333.

Chalmers I, Enkin M, Keirse M. Effective care in pregnancy and childbirth. (Oxford, England: Oxford University Press), 1989.

Churchill W. Implications of evidence based medicine for complementary and alternative medicine. J Chin Med. 1999;59:32-35.

COAG. National Health Reform Agreement. (Canberra, Australia: Commonwealth of Australia), 2015.

Choosing Wisely Australia. What is choosing wisely Australia: Choosing Wisely Australia. 2015. Available at: http://www.choosingwisely.org.au/about-choosing-wisely-australia/what-is-choosing-wisely-australia. (accessed on 10th August 2016).

Cochrane Collaboration. 2015. Available at: http://www.cochrane.org/about-us/our-vision-mission-and-

principles (accessed on 10th August 2016).

Dawes M. Evidence-based practice: A primer for health care professionals. (Edinburgh, Scotland: Elsevier Churchill Livingstone), 2005.

Ernst E, Cohen MH, Stone J. Ethical problems arising in evidence based complementary and alternative medicine. J Med Ethics. 2004;30:156-159.

Farnsworth NR, Akerele O, Bingel AS, Soejart DD, Guo Z. Medicinal plants in therapy. Bull World Health Organ. 1985;63:965-981.

Guyatt G. Evidence-based medicine. ACP Journal Club. 1991;A16:114.

Holmes D, Murray SJ, Perron A, Rail G. Deconstructing the evidence-based discourse in health sciences: truth, power and fascism. Int J Evid Based Healthc. 2006;4:180-186.

Jagtenberg T, Evans S, Grant A, Howden I, Lewis M, Singer J. Evidence-based medicine and naturopathy. J Altern Complement Med. 2006;12:323-328.

Melnyk BM, Fineout-Overholt E. Evidence Based Practice in Nursing and Healthcare. A Guide to Best Practice. (Philadelphia, USA: Wolters Kluwer Health), 2015.

Myers SP. The Nature of Science. J Comp Med. 2002;1:37-51.

NHMRC. Frequently asked questions arising from public consultation: NHMRC advice of the effectiveness of homeopathy for treating health conditions. (Canberra, Australia: National Health and Medical Research Council), 2015.

NICM. Submission to the Australian Government rebate on private health insurance for natural therapies. (Sydney, Australia: National Institute of Complementary Medicine), 2013.

NPS. NPS Medicine Wise. 2015. Available at: http://www.nps.org.au (accessed on 10th August 2016).

Rycroft-Malone J, Seers K, Titchen A, Harvey G, Kitson A, McCormack B. What counts as evidence in evidence-based practice?. J Adv Nurs. 2004;47:81-90.

Sackett DL, Rosenberg WM, Gray JA, Haynes RB, Richardson WS. Evidence based medicine: what it is and what it isn't. BMJ. 1996;312:71-72.

Sarris J. Whole system research of naturopathy and medical herbalism for improving mood and reducing anxiety. Aust J Med Herb. 2011;23:116-119.