



Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/eujim

Editorial

Evidence is in the eye of the beholder: The case of the 2016 draft NICE guidelines for low back pain



As the paradigm of evidence-based medicine reaches its adolescence, it is appropriate to acknowledge how the systematic surveying of evidence on a particular clinical topic has constituted a positive advancement in healthcare decision making [1]. But for all the benefits rigorous review methods have to offer, we must remember that no matter how many controls we have in place to minimise bias from the process, ultimately the appraisal and synthesis of research remains a purely human endeavour and with that comes interpretation consistent with a particular, subjective world-view [2].

The recent publication of the UK's National Institute for Health and Care Excellence (NICE) new draft guidelines for the management and treatment of low back pain and sciatica offers a prime example (<https://www.nice.org.uk/>). Unlike the 2009 guideline which recommended a course of acupuncture, the updated draft, published in March 2016, recommended against acupuncture [3]. This is not remarkable in itself: the evidence base is continually changing, which is why guidelines are and should be routinely updated. However, Lai suggests that this is not the issue here (page 329). In terms of simple pain reduction, compared to usual care, acupuncture's benefits were found to be above the threshold for clinical relevance (defined as a visual analogue scale difference greater than one, on a scale 1 to 10). The guideline development committee, before recommending against its inclusion in the guidelines, acknowledged that compared to usual care, acupuncture demonstrated "clinically important benefits" in pain reduction, improved function and increased quality of life [3]. The same cannot be said of some treatments that were recommended, such as massage therapy or self-management. For cost-effectiveness too, acupuncture (£3598 per QALY) compared favourably to other interventions [4]. Why then did NICE decide not to recommend it?

The guideline development group (GDG), following the NICE precedent with osteoarthritis, decided to base its acupuncture recommendation on performance over sham before considering its effectiveness compared to usual care page 337. This stipulation, set out at the beginning of the recommendations section in the draft guideline, was not an explicit requirement for any other of the 11 non-invasive interventions. For all of these interventions placebo/sham/attention controls, usual care/waiting list and any other treatment were all designated as allowable comparators. Only for manual therapies was there any other explicit indication of possible preference amongst comparators, where it was noted that the complex nature of the intervention and difficulties with

blinding have prompted researchers to opt for pragmatic trials. And herein lies one of the key issues: acupuncture too exhibits these characteristics but nevertheless a substantial amount of its RCT evidence comes from sham controlled trials. Is this sufficient reason for the GDG to have followed this unique approach for acupuncture? As Lai points out, such a decision requires at least a proper explanation, if not a prior statement of intent (page 329). Merely to cite the osteoarthritis guideline as precedent is insufficient, for its latest version did not update most of the interventions (page 337).

The rejection of acupuncture in the draft guidelines has been contentious, for it turns on the interpretation, rather than the existence, of scientific evidence. Lai commented on the preponderance of hospital-based medical professionals in the GDG. We might also look to the absence of acupuncture and acupuncture research expertise as a critical factor in the interpretive route followed. Hence the requirements for the acupuncture profession may be more about developing a pool of researchers and research leaders, and working with NICE to ensure that their voices are heard, rather than just producing more evidence.

This issue therefore comprises of two sections, a freely accessible Section on Acupuncture and Evidence (2 evidence summaries, 9 original articles and 2 study protocols) and a general section with 24 articles and the CAMSTRAND conference abstracts. Continuing on with this focus on acupuncture, there are two reputable Evidence Summaries on the use of acupuncture, both of which are based on critical review and appraisal (pages 324, 326). Evidence from the Cochrane database tends to be used by policy makers and guideline developers as the gold standard for decision making. The Cochrane summary of findings in this issue reports on the evidence base for the use of acupuncture for the prevention of tension-type headache. It demonstrates that there is some evidence that people with frequent tension headaches are likely to have fewer headaches as a result of a course of acupuncture (6 treatments, 1 per week) but there was little/no difference in their intensity page 324. This is of interest as it supports the Scottish Intercollegiate Guidelines Network (SIGN) guidelines which since 2008 have recommended that acupuncture should be considered for preventive management in patients with migraine but not for chronic tension headaches <http://www.sign.ac.uk/pdf/sign107.pdf>

The Point-of-Care Application column shows how DynaMed Plus, an evidence-based clinical reference, analyses and summarises the evidence for acupuncture for treating low back pain page 326. This evidence analysis provides a decision aid for clinicians to

inform their patients' care though clinicians undoubtedly vary in how they convey information to their patients.

Acupuncture is also a common choice by patients with osteoarthritis. A review of systematic reviews suggest acupuncture has a small superiority over sham but exhibits a moderate to large benefit compared with usual care page 337. In developing the UK NICE guidelines the guideline developers only considered the sham comparison data. This disparity in interpretation of systematic reviews needs clarity particularly when different comparators are used. In attempt to distinguish specific components operating in acupuncture treatment, the protocol for a pilot study investigating the specific efficacy of the conducted heat of warm needle acupuncture for OA of the knee compared with needling alone is described page 407. Another paper provides a protocol for a systematic review on the use of warm needle acupuncture page 402.

Doctors awareness of and trust in NHS guidance is worth further exploration given that pain management is such a frequent reason for consultation. This may be may not reflect UK acupuncture provision in primary care or in doctors attitudes regarding referring patients as suggested in a small pilot survey by Czarnawska-Iliev page 342. Although it is recognised that Clinical Practice Guidelines are important tools in selecting appropriate treatments for patients, Birch et al. (page 332) suggest they may be limited as they inform more about the clinical utility of a therapy within a broader healthcare context, and may be biased in their inclusion and evidence-selection process.

Last year an article in the BMJ described how both patients and clinicians would like to see a greater focus on nondrug treatment options and also remarked that few drug trials had non drug comparators [5]. It also pointed out that frequently research still fails to reflect the priorities of patients and clinicians. Patients also make decisions about their care and accessing relevant information is key for them to make decisions. Those individuals with intractable pain vary in how they somatise which affects how they perceive pain, this may be related to gender and age (page 394) The need for early psychological management as part of a comprehensive approach to management of chronic pain is emphasised. The internet is often the first point of access to find out about potential treatments. User friendly, accurate, trustworthy and evidence based web based resources are therefore important to guide decisions. Bishop et al. in their qualitative study explore the use of psychological theories and techniques in order to design such an informative website to help engage patients with low back pain, who may wish to consider acupuncture treatment (page 384).

A prospective, single-armed trial explores the use of a mechanical acupressure needle stimulation pad for patients with chronic or recurrent low back pain. (page 368) Although daily use did not affect pain intensity at weeks 2 and 14, significant improvements were exhibited for back pain related disability, some aspects of the quality of life instrument, and number of days taking medication. A small clinical trial demonstrates some significant differences between sham and true acupuncture in reducing shoulder pain after stroke but the long-term effects of acupuncture remains to be assessed (page 373).

Various mechanisms may be operating during an acupuncture intervention. This special section also provides a systematic review of human and animal studies on the evidence for changes in serotonin associated with the use of acupuncture suggesting that symptom improvements may be related to changes in 5-HT (page 355).

Herbal remedies are often used as part of a self help approach and are common throughout the world and information sources are particularly important given the potential for pharmacological interactions. An Italian survey of 54 pharmacies explored patients' choice and utilization of herbal products to manage stress (page 465). Two main herbal therapies were chosen by 63% of users and

there were significant reductions in their perceived stress as measured by the perceived stress scale (PSS).

Such health seeking behaviours will vary depending on culture, geographical location and access to services [6]. One-year therapeutic recall was used by researchers for a population living in NE Brazil in order to obtain information on individual health problems, products used to treat these problems and access to health services (page 471). This paper suggests that both CAM and conventional products were used and that most illnesses appeared to be treated simultaneously by both systems. Women, migrants and those less likely to use primary health-care services (PHCs) were more likely to choose CAM products and were also more likely to prioritize them. Migrants were particularly knowledgeable about medicinal plants and their local (traditional) knowledge may be very useful and should be captured as indigenous knowledge may signpost potential information on phyto-therapeutic activity. Semi-structured interviews on traditional knowledge on the ethnic use of medicinal plants in an area of Pakistan identified 80 medicinal plant species and the traditional uses of these plants (page 560). However as well as demonstrating the decline in indigenous knowledge in younger people, this survey also highlighted the need to ensure that local communities are aware of sustainable use and conservation of flora. Similarly, a cross-sectional study investigating the uses of herbal medicine among 500 patients with type II diabetes in Iran, suggested that 54% used at least one herb in addition to their conventional treatment (page 570). The most common herb used was cinnamon (24%) and family or friends (65.9%) were the main information sources. The influence of traditional knowledge and societal values (especially religion) on the use of traditional remedies is described in a population survey from Zimbabwe suggesting that perceptions were that products were safe and traditional healers were trusted more than conventional medical practitioners (page 484).

With complementary and alternative medicine (CAM) increasingly becoming part of health care and self-help, health care practitioners' awareness and knowledge of and attitudes towards CAM should be included within training. A survey page of Hungarian student nurses, midwives and health visitors demonstrates their positive attitudes towards CAM, and their belief that future health care professionals should obtain reliable knowledge and make their work more effective (page 552). The high prevalence herbal use is of particular importance particularly for those already taking medicines and this emphasises how education, accurate information provision, safety and ensuring awareness of health care professionals is needed in order to make them aware of their use.

Safety of an intervention is of critical importance for both patients and practitioners. Moxibustion, or processed mugwort leaves is used in East Asian medicine. Both the smoke and heat generated by burning moxa are considered to have therapeutic effects and the combustion products have been assessed in an article on page 414. Although some potentially harmful substances were released they were found to be safely within the limits for use according indoor environmental standards. However this highlights that there is a need to monitor the provision of a safe practitioner and therapeutic environment.

In the West, patients often pay privately for their treatments from complementary practitioners. The patient experience and their satisfaction with the therapeutic environment is likely to have a strong effect on the outcome of their treatment. In China, the multi bedded delivery is part of routine care. In a European study of over a thousand patients, the use of an open environment for chiropractic care delivery is examined (page 438). Surprisingly, patients reported being highly satisfied with the model of care which they felt maintained privacy and dignity. These findings suggest that the future design and configuration of therapeutic facilities could include open room care.

The benefits of providing integrated care in an Italian public health hospital to women presenting with a range of health issues are described using 11 year follow up data (page 423). Homeopathic treatment was sometimes integrated with diet, botanicals, and psychological counselling and demonstrated positive therapeutic effects, particularly for women with menopausal disorders. Herbal treatment delivered as part of integrative oncology care in Brazil suggests there may have been clinically significant effects for over half of the patients undergoing conventional cancer treatment (page 478). This needs further controlled research for verification.

Clinical studies can contribute to the provision of potential evidence for adoption into future clinical practice. A clinical trial of oral administrations of *Nigella Sativa* on patients with Hashimoto's thyroiditis for on interleukin-23 (IL-23), transforming growth factor β (TGF- β) and thyroid function significantly reduced serum IL-23 concentrations thyroid stimulating hormone (TSH) and anti-TPO antibodies (page 576). These beneficial effects suggest there are possible therapeutic actions of this medicinal plant which need further study. A two armed clinical before and after clinical study of a proprietary Chinese herbal formula, PSP-1, suggested that 3 months supplementation of PSP-1 formulation was able to reduce blood glucose concentration in pre-diabetic subjects and lower blood HbA1c level for both pre-diabetic and diabetic patients (page 458).

The effect of inhalation of essential oil from the root of *Inula helenium* on electroencephalographic (EEG) activity of the human brain appeared to show changes in EEG and enhanced the alertness of the brain (page 453). There may be utility worth exploring for the treatment of psychophysiological disorders. A common formula used in China to treat constipation is MaZiRenWan (MZRW). Zhong et al. present their protocol to assess safety, tolerability, system exposure and its pharmacokinetics in order to explore its mechanism of action (page 581).

Diagnostic concepts used in the treatment of health and disease are problematic to describe and verify. Blood stasis syndrome is a term used in traditional eastern and Asian medicine and is used as a potential descriptor for care and treatment. In Korean Medicine it has been validated for people with musculoskeletal diseases by correlating the diagnosis with biomedical indicators, C-reactive protein (CRP) and serum amyloid P (page 432) Results demonstrate that CRP and SAP levels are potentially associated with the pathogenesis of BSS in Korean medicine and are involved in different aspects of BS symptoms. Rowold proposes and validates a diagnostic tool to verify the human biofield and its association with quality of life (page 446)

Experimental and laboratory research are important precursors to carrying out trials and can provide potential areas for new discovery. This issue of EujIM contains articles on the antioxidant/antibacterial activities of clove (*Syzygium aromaticum*) (page 494), the antioxidant activity of essential oils from *Piper aduncum* and *Cinnamomum zeylanicum* (page 505), the cytotoxic activity and apoptotic effect of the methanolic extract of *Bauhinia racemosa* bark (MEBR) on a cancer cell line (page 513), and the use of liquid chromatograph-triple quadrupole tandem mass spectrometer for Scutellarin (SG) (used in China for treatment of occlusive cerebral vascular diseases) (page 519). A study on the potential effects of Sijunzi Tang Decoction (SJZTD), Si-Wu-Tang Decoction (SWTD), and Liuwei Dihuang Decoction (LWDHD) against oxidative stress and glucotoxic stress-induced neuronal dysfunction and lifespan suggests neuroprotective effects for SJZT decoction resulting from pronounced antioxidant properties (page 526). In South Africa,

Gazania krebsiana was investigated and confirmed for use as an antimicrobial and anthelmintic page while in India, *Triphala*, which is widely prescribed in Indian traditional medicine was shown to significantly decrease gastric ulcers (page 546). Homeopathic treatment using *Lycopodium clavatum* 200dH tested against *Toxoplasma gondii* suggests that its use appeared to delay the conversion of tachyzoites to bradyzoites in the brain of treated mice (page 540).

Finally at the end of this issue there are the 19 peer reviewed accepted conference abstracts from the CAMSTRAND conference held in the UK on 9th June this year at Warwick University (page 587). The conference presented the range of innovative research taking place in the UK on a variety of therapies and conditions.

This issue of EujIM has raised various controversial points around evidence, how it is interpreted, how it is generated, and how it is used to inform patient care. Importantly it also highlights there is a critical need to ensure that high quality studies are conducted and published.

Acknowledgements

The authors would like to thank Mike Cummins and Hugh MacPherson for their comments on this editorial.

References

- [1] T. Greenhalgh, J. Howick, N. Maskrey, for the Evidence Based Medicine Renaissance Group, Evidence based medicine: a movement in crisis? *BMJ (Clin. Res. Ed.)* 348 (4 Jun 13)) (2014) g3725, doi:<http://dx.doi.org/10.1136/bmj.g3725>.
- [2] J.P.A. Ioannidis, Why most published research findings are false, *PLoS Med.* 2 (8) (2005) e124, doi:<http://dx.doi.org/10.1371/journal.pmed.0020124>.
- [3] National Clinical Guideline Centre, 2016. Draft: Low back pain and sciatica: management of non-specific low back pain and sciatica. Assessment and non-invasive treatments. Retrieved from <https://www.nice.org.uk/guidance/GID-CGWAVE0681/documents/draft-guideline>.
- [4] R. Leclaire, L. Fortin, R. Lambert, Y.M. Bergeron, M. Rossignol, Radiofrequency facet joint denervation in the treatment of low back pain: a placebo-controlled clinical trial to assess efficacy, *Spine* 26 (13) (2001) 1411–1416 (discussion 1417).
- [5] Z. Kmietowicz, A focus on drugs over other treatments in studies ignores doctors' and patients' views, *BMJ* 350 (2015) h3375 (27 June 2015).
- [6] A. Lorenc, Y. Ilan-Clarke, N. Robinson, M. Blair, How patients choose to use CAM: a systematic review of theoretical models, *BMC Complement. Altern. Med.* 9 (2009) 9. (22 Apr 2009) <http://www.biomedcentral.com/1472-6882/9/9>.

Mel Hopper Koppelman¹

The Acupuncture Now Foundation, 3827 Emerald Ave., La Verne, CA 91750, United States

Mark Bovey (Research Co ordinator)^{a,b}

^aBritish Acupuncture Council, 63 Jeddo Road, London W12 9HQ, United Kingdom

^bHonorary Research Fellow, London South Bank University, United Kingdom

Nicola Robinson (Professor)^{c,*}

^cTraditional Chinese Medicine (TCM) and Integrated Health, London South Bank University, 103 Borough Road, London SE1 0AA, United Kingdom

¹<https://acupuncturenowfoundation.org/>.

* Corresponding author.

E-mail addresses: melhopkop@gmail.com (M. Koppelman), MarkB@acupuncture.org.uk (M. Bovey), nicky.robinson@lsbu.ac.uk (N. Robinson).