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PERSPECTIVE

Acupuncture for Pain Management in Evidence-based Medicine

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Abstract
Pain is an enormous and prevalent problem that troubles people of all ages worldwide. The effectiveness of acupuncture for pain management has been strongly verified by large randomized controlled trials (RCTs) and meta-analyses. Increasing numbers of patients with pain have accepted acupuncture treatment worldwide. However, some challenges exist in establishing evidence for the efficacy of acupuncture. A more applicable and innovative research methodology that can reflect the effect of acupuncture in the settings of daily clinical practice needs to be developed.

1. Introduction

Pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" [1]. The prevalence of pain has become an enormous global problem in the field of medical and public health. In the world, 60 million people (approximately 10% of the world's population) experience chronic pain [2]. According to reliable investigations in various countries and regions, 10–20% adults experience chronic pain. In the United States, a chronic pain prevalence of 11% has been reported [3]. The estimated prevalence of chronic pain for adults is 18.9% in Canada [4]. Furthermore, the prevalence of chronic pain among respondents in Europe [5] and Australia [6] are reportedly 19% and 20%, respectively.

For pain management, many research studies indicate that acupuncture effectively treats pain and is a reasonable referral option [7]. In recent years, acupuncture has rapidly developed and gradually become part of mainstream medicine in the West and globally [8]. According to a survey, 2.13 million Americans reported the recent use of acupuncture in the 2002 NHIS sample [9]. This number increased to 3 million in 2007 [10]. In Australia, the examining statistics in 2005 indicate that there were 10.2

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million visits to acupuncturists in the 12-month period [11,12]. In the United Kingdom [13,14] and Canada [15], the rapid development of acupuncture has also occurred during the last few decades.

Acupuncture has been widely practiced; however, its mechanisms of action remain unanswered [16,17]. This is a barrier for the full acceptance of acupuncture by the medical community [18]. Hence, evidence-based medicine become a key scientific method to evaluate the effect of acupuncture [19]. In 1996, evidence-based medicine (EBM) was briefly defined by Sackett et al [20] as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. Evidence-based medicine has been applied in all fields of medical research in the world since it was first presented in 1990 by a clinical epidemiologists study group at McMaster University (Hamilton, Ontario, Canada) [21]. In the past 2 decades, EBM has been widely used to evaluate the efficacy and safety of acupuncture [8]. A large number of published controlled RCTs promote having acupuncture as a mainstream journal category in Science Citation Index (SCI) [22].

2. Individual patient data meta-analysis and large RCTs of acupuncture for pain conditions

In recent years, studies have increasingly provided some evidence for using acupuncture for pain management. In 2012, an individual patient data meta-analysis was conducted by Andrew et al to evaluate the effectiveness of acupuncture for four types of chronic pain: back and neck pain, osteoarthritis, chronic headache, and shoulder pain. The result reflects that acupuncture was superior to sham acupuncture controls and to the usual care controls in all four chronic pain conditions ($p < 0.001$, for all comparisons). The effect sizes of the comparison between acupuncture and sham controls were 0.23 (95% CI, 0.13—0.33), 0.16 (95% CI, 0.07—0.25), and 0.15 (95% CI, 0.07—0.24) standard deviations (SDs), and the scores of acupuncture in comparison to the no acupuncture controls were 0.55 (95% CI, 0.51—0.58), 0.57 (95% CI, 0.50—0.64), and 0.42 (95% CI, 0.37—0.46) SDs. In a meta-analysis, the data of 17,922 patients from 29 of 31 eligible RCTs were analyzed, and each of these RCTs determined that allocation concealment was unambiguously adequate. This work provides the most robust evidence data to determine the effectiveness of acupuncture for chronic pain and indicate that acupuncture is a reasonable referral option for pain management [23].

To build robust evidence of acupuncture for pain management, high-quality RCTs are essential. In 2010, a pragmatic, controlled, patient-blinded, multicentered, randomized acupuncture trial for chronic shoulder pain in an outpatient care environment was completed by Albrecht et al. This trial consists of 424 outpatients who suffered from chronic shoulder pain for 6 weeks or longer and with an average visual analog scale pain score of 50 mm or greater. All patients were randomly allotted to receive Chinese acupuncture (verum), sham acupuncture (sham), or conventional conservative orthopedic treatment. The results of intention-to-treat and PPP analysis for the primary and secondary endpoints all suggest the effect of the verum treatment was superior to the sham treatment and conservative orthopedic treatment ($p < 0.01$). Descriptive statistics showed that acupuncture is an effective orthopedic treatment for chronic shoulder pain [24]. In addition, Joon-Shik et al (2013) reported a multicenter, randomized, controlled, comparative effectiveness trial that was conducted to assess the effects of motion style acupuncture treatment (MSAT) in acute low back pain (aLBP) with severe functional disability. Fifty-eight aLBP patients participated in this trial and receive one session of conventional diclofenac injection or MSAT at random. The numerical rating scale and Oswestry Disability Index of the MSAT group decreased 3.12 (95% confidence interval = 2.26, 3.98; $p < 0.0001$) and 32.95% (95% confidence interval = 26.88, 39.03; $p < 0.0001$) more than the injection group, respectively. These results suggest that MSAT is an effective treatment for aLBP patients with severe disability in immediate pain relief and in functional recovery [25].

3. Challenges and future directions of acupuncture research for pain conditions in EBM

High-quality RCTs and meta-analysis have increasingly produced robust evidence of the effectiveness of acupuncture for pain conditions, although nonspecific physiologic response to the needle insertion and the nature of holistic character of acupuncture treatment lead to many challenges in the research designs that reflect the daily clinical acupuncture practice [26].

The most critical challenge in acupuncture research is the selection of controls and the design of appropriate sham needling. Wait-list, noninsertion sham, and needle-insertion sham controls are commonly used as controls in acupuncture clinical trials. In 2011, the statistics on the result of different acupuncture controls was conducted by Xianze et al. This work included 26 RCTs on pain from the years 2006 to 2007. The percentages of positive outcomes of wait-list, noninsertion sham, and needle-insertion sham controls were 81% (13 of 16 RCTs), 86% (6 of 7 RCTs), and 25% (2 of 8 RCTs), respectively. The data suggest that needle-insertion sham may not be a feasible option for acupuncture clinical trial, especially in pain conditions. Any needle insertion would cause nonspecific physiologic response such as diffuse inhibitory noxious control effect, which can produce an analgesic effect [8]. To evaluate the role of needle-insertion sham control in clinical trials of acupuncture, a critical review of literature that included all acupuncture RCTs during the years 1997—2006 was conducted by Rosa et al. The results indicated that it is difficult to find a significant difference between acupuncture and needle-insertion sham control. In addition to the needle-insertion sham, other types of sham control (e.g. sham laser, sham transcutaneous electrical nerve stimulation) have been reported, but every sham design has its limitation. Because the mechanisms of action of acupuncture have not been fully revealed, it is difficult to design an appropriate sham control that does not have the mechanisms that specifically pertain to acupuncture [27].

Other challenges also exist in the clinical research of acupuncture. One challenge is the involvement of the

acupuncturist. The holistic character of acupuncture theory emphasizes the patient—practitioner relationship. In some way, needles serve as a medium for conversation between patients and practitioners. An acupuncture practitioner is not simply just "someone who inserts needles." The acupuncturist's diagnostic skill, which leads to an adequate treatment plan and acupuncture points selection, and the needling technique skill have a critical role in treating a patient in an actual clinical setting. Therefore, one should be aware of such major difference between acupuncture and medication.

A second challenge is outcome measures. Acupuncture is a complex intervention and focuses on individualized treatment. Some biomarkers used in conventional Western medicine may not be sufficiently sensitive to measure changes induced by acupuncture treatment. Patients' voices and perspectives should be included for the establishment of an evidenced-based approach to evaluate the effect of acupuncture [26].

The previous experience of acupuncture research studies are invaluable for researchers to recognize the limitations and challenges of research designs and would help to move the field forward in future research. For example, the design of an adequate sham control, involvement of skilled and experienced acupuncturists, adequate outcome measures in the clinical trials, and the discovery of physiological effects of acupuncture in basic science are all important tasks for acupuncture researchers to address and solve. A multidisciplinary research team that uses a combined approach, while considering efficacy, effectiveness, and qualitative measures, would strengthen the evidence of acupuncture, which is an ancient and complex intervention. [17].

4. Discussion

As the newest revolution in the field of medical science, EBM has converted the classic authoritarian expert-based medicine and become the fundamental basis for clinical practice [28,29]. The emergence of EBM provides a single, well-defined goal for acupuncture physicians, researchers, and others who wish to develop acupuncture into a fully accepted therapeutic intervention. The establishment and development of evidence-based acupuncture is the key for the future of acupuncture in the modern world [19].

Under the influence of EBM, although some challenges remain, key sets of evidence have been acquired by the research over the past decades. The scientific research community in the field of acupuncture has become more mature by learning lessons from previous failed trials and is able to overcome major challenges and difficulties encountered in the acupuncture trials. Clear evidence for the effectiveness of acupuncture for treating pain conditions has been obtained by hard data through high-quality source types such as RCTs [24,25] and individual patient data meta-analysis [23]. These trials demonstrate that acupuncture is a credible treatment option for a wide variety of conditions. Except for the evidence of the effectiveness shown in these trials, a considerable part of evidence for the mechanisms of acupuncture action was also discovered by advanced neuroimaging technology. Local tissue responses induced by acupuncture can produce profound changes in the central nervous system [30—32]. Based on these robust scientific evidence bases, acupuncture will eventually become a vital part of the modern health care system under an EBM paradigm [19].

5. Conclusion

In recent years, large RCTs and meta-analysis of the effectiveness of acupuncture have greatly advanced our knowledge of acupuncture. Increasingly more patients worldwide now accept acupuncture treatment. Challenges remain in the course of establishing evidence on acupuncture, although under the guidance of EBM, acupuncture will become a standard therapeutic procedure in the modern health care system. However, a more applicable and innovative research methodology that can reflect the effect of acupuncture in daily clinical practice settings is warranted to be further developed.

Disclosure statement

The authors declare that they have no conflicts of interest and no financial interests related to the material of this manuscript.

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