



Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/eujim



Research paper

Warm needle acupuncture for osteoarthritis: A systematic review protocol[☆]

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ARTICLE INFO

Article history:

Received 10 June 2016

Received in revised form 28 July 2016

Accepted 28 July 2016

Available online xxx

Keywords:

Acupuncture

Warm needle acupuncture

Osteoarthritis

Systematic review

Protocol

ABSTRACT

Introduction: Warm needle acupuncture (WA) is widely used the treatment in the East Asian countries. However, there is no critically appraised evidence of the potential benefits and harms. The purpose of this systematic review will be to evaluate the efficacy of WA for osteoarthritis (OA).

Methods and analysis: Electronic databases will be searched: MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL) and AMED, 6 Korean medical databases (Korea Med, the Korean Traditional Knowledge Portal, OASIS, DBPIA, the Research Information Service System and the Korean Studies Information Service System), 3 Chinese databases (CNKI, VIP and Wanfang) and a Japanese database (CiNii Articles) will be searched from their inception. These will be searched from their inception. Selection of the studies and data extraction and validation will be performed independently by two reviewers. Randomised controlled trials (RCTs) and quasi-RCTs using WA for any type of OA will be considered. The studies will independently undertake study selection, extraction of data and assessment of study quality by two authors. Risk of bias will be assessed using the Cochrane risk of bias standards. All data synthesis and subgroup analyses will be conducted using Review Manager Software.

Dissemination: Findings will be published in a peer-reviewed journals. This systematic review may inform the treatment of OA patients in clinical practice.

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1. Introduction

1.1. Description of the condition

Osteoarthritis (OA) is a structural and functional failure of whole joint [1] and damage to joint cartilage, deterioration of the bone beneath the joint, swelling of the joint with newly formed bone, and mild inflammation of the synovial membrane [2]. Above all, OA is often associated with significant disability and reduction in quality of life [3]. This affects such as the knees, hips, fingers and lower spine. Researchers have reported that the knee joint is affected especially frequently, and the incidence of knee OA is increasing [4]. Unfortunately, the available treatments for OA are not perfect. Therefore, many studies, both pharmacological and

non-pharmacological, focus on reducing pain and limitations to patient's daily functioning [5].

1.2. Description of the intervention

Acupuncture and moxibustion have been used as medical treatments in East Asia, including China, Korea and Japan [6]. Moxibustion includes various techniques. There are two types of moxibustion: predominantly divided into direct moxibustion and indirect moxibustion. When performing direct moxibustion, moxa sticks are burnt at acupoints directly on the skin. In contrast, in indirect moxibustion, the moxa cone does not touch the skin and is burnt while being insulated from the skin by some substance [7]. Warm needle acupuncture (WA) is the combination of acupuncture with moxibustion by stimulating acupoints with a burning moxa (also called Ai Ye) stick on the handle of the acupuncture needle [8]. The use of WA was first documented in *Shang Han Za Bing Lun* ("Discussion of Cold-Induced Disorders"), a classical Chinese medical book by Zhongjing Zhang (Eastern Han dynasty, 25–220 C.E.) [9]. WA is often used to treat painful conditions such as arthritis,

[☆] Trial registration number: PROSPERO 2015: CRD42015024413

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<http://dx.doi.org/10.1016/j.eujim.2016.07.030>

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especially rheumatoid arthritis and OA [10,11] as well as musculoskeletal pain conditions [12,13]. WA treatment is transmitted to the acupoint by radiation, moreover, by direction conduction through the shaft of the needle, thereby stimulating deep tissue within the acupoint and warming the acupoint on the surface [14].

1.3. How the intervention might work

WA for OA is widely used for treatment and prevention [15,16]. Studies on the treatment of WA on OA have also shown a greater pain relief compared to manual acupuncture [17]. Furthermore, WA has reduced joint fluid and abnormally high serum levels of interleukin-1 beta (IL-1 β) and tumor necrosis factor-alpha (TNF- α), two inflammatory factors in patients with knee OA [18].

1.4. Why it is important to do this review

Many studies have been reported treatment using WA treatment for OA in clinical practice [19,20]. One recent review assessed the efficacy of WA for OA but most of included studies have suffered from high risk of bias [21]. The previous review focused on the WA treatment for knee OA and searched Chinese databases only. Furthermore, the review is outdated. Therefore, the aim of this systematic review was to update, complete and critically evaluate the evidence from randomized clinical trials (RCTs) of WA for OA.

2. Methods

2.1. Study registration

This protocol review has been registered on PROSPERO 2015 (registration number CRD42015024413) [22].

2.2. Criteria for considering studies for this review

2.2.1. Types of studies

This systematic review will only include RCTs and quasi-RCTs. Observational, cohort, case reports, case series, non-RCT, animal and experimental studies will be excluded. No language restrictions will be imposed.

2.2.2. Types of participants

Patients suffering from OA will be included regardless of joint location (e.g., chronic condition of the neck, near the ends of the fingers, at the base of the thumb, back, hip, and knee). We will also include patients with both sexes and any age. Included patients will have been diagnosed with OA according to the American College of Rheumatology (ACR) criteria [23–25], the equivalent European League Against Rheumatism (EULAR) criteria [26–28], or the Clinical Guideline of New Drugs for Traditional Chinese Medicine [29]. Studies will be excluded if they include patients with rheumatoid arthritis, ankylosing arthritis, joint tuberculosis, purulent arthritis, allergic arthritis, Kashin-Beck disease or Podagra.

2.2.3. Types of interventions and controls

Studies that evaluate WA as the sole intervention will be included. Warm needle will be defined as moxa being attached to the needle once it is inserted. Traditionally, traditional medicine practitioners usually attach burning moxa to the handle of the AT needle to improve the effectiveness of the therapy. Electro-warmed needles and infrared radiation will be excluded. The combined intervention include western medicine or rehabilitation or physiotherapy, but exclude alternative therapy such as

herbal medicine, Tuina, acupuncture. A combined intervention will include western medicine or rehabilitation or physiotherapy, but will exclude any that combines other alternative therapies such as herbal medicine, Tuina, as well as other types of acupuncture.

2.2.4. Type of outcome measures

• Primary outcomes

- 1) Treatment efficacy: the number of patients whose OA symptoms improved and treatment effectiveness.
- 2) Pain: associated scale measured on the visual analogue scale (VAS) [30], Western Ontario and McMaster Universities Arthritis Index (WOMAC) of pain [31], a numerical rating scale (NRS), Verbal Rating Scale (VRS), the Faces Pain Scale-Revised (FPS-R), etc.
- 3) Function of joint: measured by recognized scales including Western Ontario and MacMaster universities arthritis index (WOMAC), Lequesne score, etc.

• Secondary outcomes

- 1) Quality of life (QoL): measured using a validated questionnaire, such as the short-form (36-item) health survey (SF-36) [32] or another validated scale.
- 2) Adverse events.

2.3. Search method for identifying the studies

2.3.1. Electronic searches

Electronic databases will be searched from their inception and will include MEDLINE, EMBASE, the Cochrane Central Register of Controlled Trials (CENTRAL) and AMED, 6 Korean databases (Korea Med, the Korean Traditional Knowledge Portal, OASIS, DBPIA, the Research Information Service System and the Korean Studies Information Service System), 3 Chinese Databases (CNKI, VIP and Wanfang), and the Japanese database (CiNii Articles). The search strategy will include warm needling acupuncture in English, Chinese and Korean.

2.3.2. Searches of other resources

The authors will scan the reference lists and retrieve additional studies. In addition, authors will search the WHO International Clinical Trials Registry Platform (ICTRP) (<http://apps.who.int/trialsearch/>) and Google Scholar (<http://scholar.google.co.kr/>). Dissertations of degrees will be included. The ClinicalTrials.gov registry (<http://clinicaltrials.gov/>) will be searched for any unpublished trials.

2.3.3. Search strategy

The strategy for searching MEDLINE is described in Appendix A. The strategy for searching CNKI is described in Appendix B. Similar search strategies will be applied to other databases.

2.4. Data collection, extraction and assessment

2.4.1. Selection of studies

Two reviewers (JHJ and TYC) will independently screen the titles and abstracts for searched studies, and perform study selection and record their decisions according to predefined criteria. Another reviewers (MSL) will resolve disagreements of section study. Study selection will be documented and summarised in Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) flow diagram [33].

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