



Research paper

Cupping therapy for Treating Knee Osteoarthritis: A protocol for systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

Introduction: Cupping therapy is widely used in East Asia, the Middle East, or Central and North Europe to manage the symptom of knee osteoarthritis (KOA). The purpose of this systematic review is to evaluate the available evidence from randomized controlled trials (RCTs) of cupping therapy for treating patients with KOA. **Methods:** The following databases will be searched from their inception until January 2017: PubMed, Embase, the Cochrane Central Register of Controlled Trials, AMED, CINAHL, four Chinese databases [WanFang Med Database, Chinese BioMedical Database, Chinese WeiPu Database, and China National Knowledge Infrastructure (CNKI)], and six Korean medical databases (Korean Studies Information, DBPIA, the Korean Institute of Science and Technology Information, KERIS, KoreaMed and the Korean National Assembly Library). Only the RCTs related to the effects of cupping therapy on KOA will be included in this systematic review. A quantitative synthesis of RCTs will be conducted using RevMan 5.3 software. Study selection, data extraction, and validation will be performed independently by two reviewers. Cochrane criteria for risk-of-bias will be used to assess the methodological quality of the trials.

Ethics and dissemination: This systematic review will not use data from individual patients and no privacy will be involved. The results will be disseminated through peer-reviewed publications.

1. Introduction

Knee osteoarthritis (KOA) is a common chronic degenerative disorder of unknown etiology affecting approximately 19.4% of the Chinese elderly [1,2]. It can be the consequence of a pathological process characterized by progressive loss of articular cartilage, peri-articular muscle wasting, subchondral bone thickening, bone hypertrophy, and new bone formation [3]. KOA most frequently presents with clinical symptoms which include loss of physical function accompanied by pain, stiffness, muscle weakness, deformity and instabilities [4]. In addition, with the disease progression, KOA impaired patients' normal quality of life, and increased their heavy economic burden [5].

To date, international and local guidelines recommended that the use of oral nonsteroidal anti-inflammatory drugs (NSAIDs) can be highly beneficial for the management of KOA [6,7]. However, according to recent research, these agents only help to slightly reduce short-term pain and do not modify the natural history or progression of KOA [8]. Moreover, these drugs are frequently associated with some undesired side effects, and increase the risk of serious adverse events

(AEs) involving the cardiovascular, gastrointestinal (GI), and renal systems [9,10]. Therefore, as with most chronic musculoskeletal diseases, KOA patients usually tend to seek complementary and alternative treatment (CAM) therapies for help in managing their pain and discomfort [11].

Cupping therapy is a major integral part of CAM. It is described as a technique that involves a glass, plastic or bamboo cup to create localized pressure on the patient's skin over precise acupuncture points, painful area, or a reflex zone [12]. To date, cupping therapy has widely been utilized and practiced in different cultures like East Asia, the Middle East, or Central and North Europe. In general, wet and dry cupping are the two main types of cupping therapy [13]. Wet cupping, also called *Hijama* in the Middle East, was the most popular cupping method of all used by CAM practitioners. Before suction, CAM practitioners conducted bleeding cupping technique (involves incision, lancing or scarification of the skin) in order to drain excess blood, fluids or toxins, which were considered the source of disease, from the body [14]. In dry cupping, which stimulate the skin by applying cups with a vacuum pressure; the difference lies in whether the skin is punctured to allow blood and other body fluids to flow [15]. In addition to two main

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types of cupping therapy, other subtypes of cupping therapy include retained cupping, quick-cupping, moving cupping, shaking-cupping and balance-cupping.

The mechanism of action of cupping therapy is still not clear, and various theories have been proposed. In modern research, the primary speculation about cupping therapy is that it acts through the system neural network and releases some neurotransmitters and endogenous opioids (nitric oxide, beta endorphins adenosine triphosphate, etc.), which gives euphoria so this may ease the nociceptive painful reception and make patients feel comfortable [16]. Moreover, it was reported that cupping therapy could modulate the inflammatory reactions through the degranulation of the level of tumor necrosis factor in patients who suffered from a headache [17]. Furthermore, Boris et al. [18] and Suleyman et al. [19] revealed that cupping therapy may regulate the immune system via removing oxidants and reducing the cytotoxicity of natural killer cell numbers. Thus, the above basic modern scientific research may partly account for the possible mechanism of cupping therapy, and provide a better understanding of the mechanism of cupping therapy.

In comparison to acupuncture, cupping therapy has not attracted much attention in the West, which is partly due to the lack of sufficient modern scientific evidence. Recently, a bibliometrics analysis of papers published from 1950 to 2010 in China, showed that Cupping therapy has been widely used in the treatment of a wide spectrum of chronic musculoskeletal diseases or the pain-related conditions, especially KOA [20]. According to a 2008 cross-sectional study, cupping therapy was considered as the second most widely used TCM treatment modalities next to Chinese Tuina for the treatment of KOA in Taiwan [21]. What is more, about 71% of TCM practitioners in Taiwan have applied this technique for treating musculoskeletal pain, especially for the keen pain [22]. Furthermore, a community-based survey conducted in Mainland China revealed that almost one-fourth of the general population employed cupping therapy for treating KOA [23]. In addition, Cao, et al. summarized the current clinical evidence for cupping therapy and concluded that cupping therapy was appropriate for 13 pain-related conditions, which included the KOA [24]. Therefore, in the view of modern medicine, cupping therapy is popular and the main therapeutic intervention for treating KOA. Nowadays, numerous systematic reviews have investigated the effects of cupping therapy on stroke rehabilitation [25], hypertension [26], herpes zoster [27] and pain conditions [28]. Nevertheless, there was no systematic review specifically focusing on the cupping therapy of KOA.

Therefore, the aim of this study is to update and critically evaluate the evidence from randomized controlled trials (RCTs) that have tested the efficacy and safety of cupping therapy in treating KOA.

2. Methods

2.1. Study registration

This study will be carried out following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [29]. In addition, the protocol of this systematic review has been registered in PROSPERO funded by the UK National Institute for Health Research (Registration Number: CRD42017057483).

2.2. Data sources

The following databases will be searched from their inception until January 2017: PubMed, Embase, the Cochrane Central Register of Controlled Trials, AMED, CINAHL, four Chinese databases [WanFang Med Database, Chinese BioMedical Database, Chinese WeiPu Database, and China National Knowledge Infrastructure (CNKI)] and six Korean medical databases (Korean Studies Information, DBPIA, the Korean Institute of Science and Technology Information, KERIS, KoreaMed and the Korean National Assembly Library). Search strategies are presented

in Appendix A, and these search terms will be slightly modified for other databases. Additionally, we will also search the reference lists of review articles and identify RCTs for any possible titles matching the inclusion criteria. Furthermore, in order to identify the grey literature/unpublished studies, we will also identify relevant studies via a review of WHO International Clinical Trials Registry Platform (ICTRP) (<http://apps.who.int/trialsearch/>), Registry ClinicalTrials.gov (<http://clinicaltrials.gov/>), and Chinese Clinical Trial Registry (<http://www.chictr.org.cn/>). Cupping devices companies will be also requested to provide relevant published and unpublished data.

As cupping therapy is widely used in the Middle East. Thus, relevant Middle East articles published in *Saudi Medical Journal*, and *Annals of Saudi Medicine* will be also hand searched from 1980 to January 2017.

2.3. Selection of studies

Only the RCTs related to the effects of cupping therapy in KOA will be included in this systematic review. Trials published in the form of dissertations will be also selected as eligible studies. All studies included will meet the following inclusion criteria with the PICOS principle (population, intervention, comparison, and outcome). No language restrictions will be imposed. A flowchart depicting the trial selection process will be shown in the PRISMA flow diagram.

P (population): patients aged over 18 diagnosed with KOA using definitive American College of Rheumatology (ACR) diagnostic criteria will be included.

I (intervention): Studies will be included if cupping therapy is used as the sole intervention or as an adjunct therapy in conjunction with Western medicine therapy for KOA. Therefore, we will exclude studies in which other CAM therapies (e.g. acupuncture, moxibustion, massage, Chinese herbals, Chinese patent medicine) will be utilized as an adjunct treatment in conjunction with the Western medicine therapy.

C (comparison): A sham cupping device/placebo or Western medicine as controls will be included. Conventional Western medicine therapy will be used as a reference standard therapy for KOA in the control group. Studies will be excluded if the control group treatments will not relevant to Western medicine therapy or other CAM therapies (e.g. acupuncture, moxibustion, massage, Chinese herbals, Chinese patent medicine) will be used as an adjunct treatment in conjunction with the Western medicine therapy.

O (outcomes): 1. Primary outcomes: (1) Clinical efficacy measurement (Guiding Principles of Clinical Research on New Drugs-response rate, GPCRND-response rate). (2) Pain (VAS, NRS, McGill pain scale and etc.). 2. Secondary outcomes: Physical function (Western Ontario and McMaster Universities Osteoarthritis Index, WOMAC; Lequesne Algofunctional Index, LAI).

2.4. Data extraction, quality and validation

The complete text of each included article will be read by two independent reviewers (Guo and Tang) who will extract relevant data based on the predetermined criteria. The following data will be extracted from the original manuscripts: (1) Author and year; (2) Sample size; (3) Therapeutic intervention (types of cupping therapy, duration of treatment, treatment acupuncture points, Acupoints' rational theory); (4) Control groups (types of NSAIDs, methods of administration, and the duration of treatment); (5) Follow-up (6) Main outcomes (7) AEs. (Supplement 1 and Supplement 2). Additionally, when reported data are insufficient, we will try our best to retrieve missing information from the corresponding authors. The Cochrane risk-of-bias tool [30] will be used to evaluate the methodological quality of each included trial, and each RCT will be assessed for the following characteristics: (1) selection bias; (2) performance bias; (3) detection bias; (4) attrition bias; (5) reporting bias. The terms 'Low', 'Unclear', and 'High' will be referred to *low*, *uncertain*, and *high* risks of bias, respectively. In most cases, disagreements will be settled by discussion

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