



A protocol for developing a clinical practice guideline for the intra-articular injection of knee osteoarthritis

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ABSTRACT

Introduction: Osteoarthritis (OA) is the most prevalent disorder of articulating joints in humans. As one step of advanced pharmacological management, intra-articular treatment is applied in Knee OA. However, there was no clinical practice guideline (CPG) involving intra-articular injection of knee OA. Here, we will conduct a CPG according to recognized methodology.

Methods and analysis: We will develop the new CPG according to the Institute of Medicine (IOM), the Appraisal of Guidelines for Research & Evaluation II (AGREE II) and WHO guideline handbook, and make recommendations based on systematic reviews. We will establish a Guideline Working Group (including a Guideline Steering Subgroup, a Guideline Development Subgroup and a Guideline Secretary Subgroup), and formulate clinical questions in the form of Population, Intervention, Comparison, Outcomes (PICO) and complete a literature search. The consensus will be developed via evidence syntheses and the Delphi method. We will also consider patients' values or preferences, peer review results and declaration of interests in making CPG. The present CPG was registered on International Practice Guidelines Registry Platform (<http://www.guidelines-registry.org/>), and the registration number is IPGRP-2016CN004.

Ethics and dissemination: The protocol will provide us a roadmap to systematically develop evidence based CPG for the intra-articular injection of knee osteoarthritis. The work will be disseminated electronically and in print. The guideline would be the first CPG developed primarily by orthopedics in China, strictly based on systematic methodology.

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1. Background

1.1. Description of condition

Osteoarthritis (OA) is the most prevalent disorder of articulating joints in humans and represents a major burden on public health worldwide [1–4]. It causes of disability among the older people. In epidemiology, half of the world's population aged 65 years or older has OA. Specifically, knee OA involves the largest synovial joints in human, which is prevalent in middle aged or older people [5]. In estimate, the prevalence of knee OA is more than 250 million patients worldwide [6]. Knee OA involves the following pathological features, including cartilage degeneration,

bone remodeling and inflammation. The clinical features of knee OA is mainly characterized by pain, swelling and joint dysfunction [7]. The symptomatic knee OA affects 24% of the general population [8]. Furthermore, symptomatic knee OA may be associated with an increased risk of all-cause mortality [9–11]. Thus, the purpose of the treatment for knee OA is to alleviate pain and to improve joint function and life quality.

1.2. Description of interventions

A large number of primary studies were conducted to evaluate the knee OA treatments in non-pharmacological, pharmacological and surgical therapy [12]. However, many limitations, such as study design, risk of bias, sample size and individual characteristics, hindered the transformation from literature to practice. Therefore, recommendations for the treatment of knee OA have been developed by academic societies, including the American Academy of Orthopaedic Surgeons (AAOS) [13], UK National Institute for Health and Clinical Excellence (NICE) [14], the Osteoarthritis

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Research Society International (OARSI) [12], the American College of Rheumatology (ACR) [15] and the European League Against Rheumatism (EULAR) [16]. However, Feuerstein et al. [17] used AGREE II instrument to assess the quality of 13 guidelines and concluded that the lowest score was recorded in the domains of comment on conflicts of interest. Thus, optimal clinical practice guidelines (CPGs) are defined as recommendations which are informed by an evaluation of evidence, a development of recommendation strength and an assessment of the benefits and harms of alternative care options by the Institute of Medicine (IOM) [18]. Unfortunately, the Chinese medical evidence was not evaluated or used in the above mentioned guidelines. Furthermore, no evidence-based guideline of knee OA was developed in China currently.

1.3. Description of intra-articular interventions

As one step of advanced pharmacological management in the persistent symptomatic OA patients, intra-articular treatment may be applied in the condition that contraindications to NSAIDs, or if the patient is still symptomatic despite the use of NSAIDs or was severely symptomatic [19]. Traditionally, hyaluronic acid (HA) and corticosteroids have been the most commonly used intra-articular interventions [20]. Recently, regenerative medicine products, including mesenchymal stem cells (MSCs), platelet-rich plasma (PRP), autologous conditioned serum (ACS), and other agents such as intra-articular morphine, present promising outcomes in treating knee OA.

1.4. Why it is important to do this CPG?

However, there was no CPG involving intra-articular injection of knee OA. Therefore, we aimed to develop a practical and applicable CPG for the intra-articular injection of knee OA using the Grade of Recommendations Assessment, Development and Evaluation (GRADE) [21] to provide evidence-based recommendations regarding intra-articular injection to clinicians, nurses and patients.

2. Objectives

The protocol will provide us a roadmap to systematically develop an evidence based CPG for the intra-articular injection of knee osteoarthritis. The guideline would be the first CPG developed primarily by orthopedics in China, strictly based on the IOM's new guideline definition, WHO guidelines making handbook, GRADE system, AGREE II instrument and RIGHT statement. The guideline will provide standards for treating knee OA and will help conduct intra-articular injection.

3. Methods

3.1. Principle

The CPG will be developed following the new guideline definition from the IOM [18] and AGREE II instrument [22]. We also adhere to the World Health Organization (WHO) handbook for guideline development [23]. We have registered the guideline on International Practice Guidelines Registry Platform (<http://www.guidelines-registry.org/>), and the registration number is IPGRP-2016CN004.

3.2. Guideline development institutions, target users and population

The guideline was launched at the 11th COA International Congress in Beijing by the Chinese Orthopedic Society, Chinese

Orthopedic Journal, and Arthritis Clinic & Research Center, Peking University People's Hospital in Nov 2016. Methodological support will be provided by the Chinese GRADE Center. The title of the guideline will be "guideline for the intra-articular injection of knee osteoarthritis". The target end users of the guideline are orthopedist, physical therapists, rheumatologists and nurses. The target populations are patients with knee OA who could be treated with intra-articular injection. The content of the guideline is about the clinical safety and efficacy of medicine products via intra-articular injection.

3.3. Guideline working group

The Guideline Working Group will be established in Dec 2016 and it will have three subgroups: The Guideline Development Group, the Guideline Steering Group and the Guideline Secretary Group to ensure fair representation by gender and region, the Guideline Working Group will consist of 30 members from multiple fields, as follows: 17 orthopedist (especially majored knee joint surgery), 2 rheumatologists, 1 physical therapist, 2 evidence-based medical experts, 2 medical laboratory scientists, 2 pharmacologist, 1 statistician, and 1 health economist, 1 Chinese medicine practitioner and 1 nurse. The proportion of female numbers will not be less than 10%. The following items will be the mission of the Guideline Development Group: (1) to define the scope of the guideline, draft the Population, Intervention, Comparison, Outcomes (PICOs); (2) to grade the quality of the evidence; (3) to draft preliminary recommendations; (4) to write the draft guideline; and (5) to publish and promote the guideline.

The Guideline Steering Group will consist of 8 members, including 3 orthopedists, 1 evidence-based medical expert, 1 rheumatologist, 2 physical therapists and 1 health economist physician. The mission of the Guideline Steering Group will be as follows: (1) to approve the PICOs; (2) to supervise the literature search and systematic reviews; (3) to check the grade of the evidence; (4) to draft the final recommendations using a modified Delphi approach; and (5) to approve the publication of the guideline.

The Guideline Secretary Group will consist of 6 members, including 3 evidence-based medical experts, 1 statistician and 2 orthopedists. The following two items will be the mission of the Guideline Secretary Group: (1) to perform a literature search and complete systematic reviews; (2) to investigate patients' views and preferences.

3.4. Declaration of interests and funding support

All members of the Guideline Development Group, the Guideline Steering Group and the Guideline Secretary Group will be required to complete declaration of conflicts of interest forms before attending the guideline meetings to judge their potential conflicts of interest.

3.5. Formulating questions and choosing outcomes

After the scope of guideline proposed by the Guideline Development Group and approved by the Guideline Steering Group, we will finalize the Population, Intervention, Comparison, Outcomes (PICOs). The Guideline Development Group will choose the clinical outcomes and will classify them according to their importance by consensus. The scores of the outcomes range from 1 to 9. According to this scale, 7–9 will be considered critical, 4–6 important, and 1–3 not important [21]. After rating the clinical outcomes, we will formulate the clinical questions based on the PICO principle.

For example:

Dose HA intra-articular injection can be used for symptomatic knee OA patients?

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