



Health Technology Assessment of Homeopathy in Treatment of Knee Osteoarthritis: Comparison with Non-Steroidal Anti-Inflammatory Drugs

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ABSTRACT

Background: Osteoarthritis is the most common joint disease in humans, which is the greatest cause of physical disability among the elderly in developed countries. Homeopathy is a specific therapy that treats patients based on precise stimulation of the immune and vital systems by certain homeopathy medications. Given the widespread use of this technology, in this article, we compared homeopathy Health Technology with non-steroidal anti-inflammatory drugs in the treatment of osteoarthritis.

Methods: In this study, Health Technology Assessment (HTA) was employed to compare homeopathy treatment with non-steroidal anti-inflammatory drugs (NSAIDs), by reviewing clinical trials. The study population included patients with knee osteoarthritis; the intervention group included homeopathy, and the control group comprised routine medical treatment (NSAID) and outcomes measured included efficacy, safety, and cost effectiveness. The most important electronic medical databases were searched for relevant articles published from 2000 to 2016, including The Cochrane Library, Cochrane Central Register of Controlled Trials (CENTRAL); Center for Reviews and Dissemination, University of York (CRD; NHS EED), Trip; PubMed; EMBASE and Google Scholar.

Results: Effectiveness was measured by indicators of pain and motor function. Total changes in VAS index revealed about 34 units decrease in the intervention group, while there was 12 units reduction in the control group. Reducing the consequences of pain and knee function problems were 10 points more in the intervention group in comparison to the control group. Safety outcomes were measured via skin reactions (and sensitivity) which were lower in the intervention group. In terms of cost-effectiveness, the results revealed that for each unit of pain relief, more cost was spent in homeopathy method.

Conclusion: Given that the overall costs of both treatments were low, even with the higher effectiveness and safety of homeopathy treatment, compared with NSAIDs, homeopathy is preferable.

Keywords: Health Technology Assessment, Homeopathy, Knee Osteoarthritis

Citation

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Introduction

Osteoarthritis is the most common disease of the joints in humans and the greatest cause of disability among the elderly in developed countries. Moreover, the disease is very common in developing countries, including Iran. The main pathological feature of osteoarthritis is the progressive erosion of articular cartilage which also involves synovial joint and connective tissues, such as synovium, and subchondral bone. The main complaint of patients is pain that is relieved with rest in the beginning of the disease; but as the disease progresses, the pain increases and becomes more resistant (1-3).

Given that there is no cure for this disease; one of the main goals of treatment is to reduce symptoms. Treatments include patients' education, exercise, weight control, joint protection, physical therapies, physiotherapy and sometimes medication therapy, such as non-steroidal anti-inflammatory drugs (NSAIDs), topical analgesics, intra-articular injection of hyaluronic acid and glucocorticoids, muscle relaxants, antidepressants, and surgical procedures (4-6).

Homeopathy is a specific treatment that treats patients through precise stimulation of the immune and vital systems by certain homeopathy drugs. According to the basic principles of homeopathy, any substance (or agent) that can cause a series of symptoms of a disease in a healthy body, can also cure patients with the same symptoms, if the patients' symptoms and symptoms of the drug's substance are as similar as possible. In other words, the drugs used for the treatment in this method are those that can cover up the patients' symptoms, in order to treat the disease with appropriate stimulation of the immune and vital systems of the patients and thus alert the immune system. This implies that homeopathic treatment is based on the patient's vital and treatment forces (7, 8).

Homeopathy is a therapy within the field of complementary medicine and is much expanded in today's world. Homeopathy means "the same as disease"; in other words, treatment with the similar or the agent similar to the disease. The most important feature of this treatment is the general

view on people from physical, mental, and emotional aspects. Homeopathic medicines are made of natural substances, 70% of which are generally prepared from plants and 20% from minerals and natural materials (metals, salt, and acids) and the rest from animal sources (poisons of snake, bees, etc.). The important point regarding homeopathy drugs is that very small concentrations of raw material are used and the drugs are diluted, but they are prepared by specific pharmaceutical methods. Accordingly, the homeopathic drugs have tremendous medicinal benefits, such that the homeopathic drugs are generally prescribed at small size, amounts, and frequency of administration, but have a lot of wonderful therapeutic effects (9, 10).

The World Health Organization (WHO), in a book on the status of complementary/traditional medicine, explains the status of homeopathy in the health care system in different countries, in details. As indicated by WHO, homeopathy is the second medicine's system used globally with over one billion dollars spent for this treatment (11-14).

One of the therapies that can be employed for the treatment of knee osteoarthritis is herbal medicine, commonly known as homeopathy, which has been addressed in this study. In 1985, the Supreme Council of Evaluation of the Ministry of Health and Medical Education considered homeopathy as a therapeutic method and finally in 1988, the guideline of homeopath physician was announced by the Minister of Health at that time to the Department of Education that notified it to the Ministry of Medical Universities. According to the above-mentioned features and extensive application of the technology, the aim of this paper is to assess the efficacy, safety, and cost-effectiveness of homeopathy in treatment of various diseases.

Materials and Methods

In this study, the Health Technology Assessment (HTA) was used. In order to compare homeopathy treatment with nonsteroidal anti-inflammatory drugs (NSAIDs), clinical trials were reviewed.

The most important medical electronic databases were searched, including The Cochrane Library,

Cochrane Central Register of Controlled Trials (CENTRAL); Center for Reviews and Dissemination, University of York (CRD; NHS EED), Trip; PubMed; EMBASE and Google Scholar for articles, published from 2000 until the end of the year 2016. For the search, the strategy listed for each database was used. Screening and selection of articles were based on the following inclusion and exclusion criteria:

- P) Study population: patients with osteoarthritis;
- I) Intervention: treatment with homeopathy;
- C) Comparison with nonsteroidal anti-inflammatory drugs (NSAIDs)

O) Outcomes, including safety, efficacy and cost-effectiveness

D) Type of studies: Randomized clinical trials (RCTs) were enrolled in the study.

In the first phase, we aimed to study the articles on HTA of homeopathy in treatment of patients with knee osteoarthritis. For this purpose, the following steps were performed: defining search strategy, search in the literature, quality assessment, screening and selection of articles. These steps are described separately below.

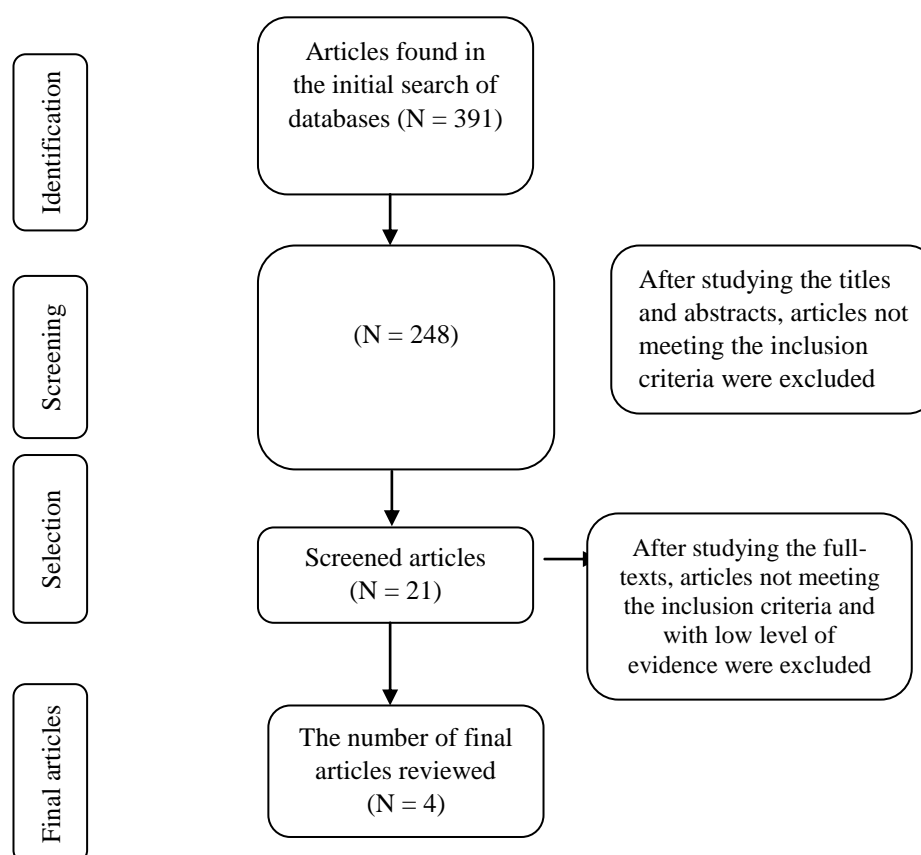


Figure 1. Algorithm of literature search and the results of screening, based on Prisma criteria

In the first step, the title and abstract of articles, found in the literature, were studied and unrelated articles were excluded, based on the research objectives. In the second stage, the full-text of the remaining articles were collected and evaluated for full compliance with the inclusion and exclusion criteria. To assess the quality of clinical trials, CONSORT tool was used. After selection of

articles that could be used to answer the questions, the needed information was extracted. Data collection was done by one person and checked by another person. Search strategy was as follows:

(Homeopathy [Title/Abstract]) AND Osteoarthritis [Title/Abstract]) AND knee [Title/Abstract]



Calculation of cost-effectiveness

To evaluate the cost-effectiveness of homeopathic medicines, in comparison with NSAIDs, two types of data were required. Efficacy data were extracted from studies and cost data were identified by referring to pharmacies and distribution centers of traditional medicines. These data were used in the cost-effectiveness equation.

Further, in the current study all ethical issues were observed based on the Helsinki Declaration.

Results

Effectiveness (clinical efficacy) and safety:

A clinical trial, entitled "The effect of topical joint ointment (herbal) on knee osteoarthritis", published in 2006, a double-blind study that used placebo for the control group. The study samples were randomly assigned into two groups of treatment and placebo. The study was a cross-over study, carried out in two steps. In the first step, ointment or placebo was used three times a day for three weeks. After completing the course, patients were assessed for three criteria, including pain scores, physical function score, and stiffness score. The findings of this study revealed that the joint's topical ointment had greater positive impact than placebo on the treatment of primary knee osteoarthritis (15).

Another clinical trial aimed to assess *Peganum* oil for knee osteoarthritis (OA) in 2015. This study investigated the efficacy of traditional *Peganum harmala* oil in 54 patients in a controlled, double-blind clinical trial. Olive oil was selected as control in this study. Arthritis indices, including WOMAC indices, and VAS questionnaire were completed for the intervention and control groups at the onset of the study and after four weeks. The results demonstrated that pain and knee function significantly decreased after four weeks by *Peganum* oil consumption, but knee stiffness had no significant difference between groups. Overall, VAS indicator changes in the intervention group showed about 34 units reduction, while it was 12 units in the control group. Consequences of pain and knee function problems was reduced more

than 10 points greater in the intervention group compared to the control group (16).

A controlled clinical trial compared piroxicam with a homeopathic gel in knee osteoarthritis in 2000. The results were as follows: In terms of pain outcomes, 16.5 mm reduction in VAS index was observed in homeopathic gel consumers and 1.8 mm decrease in the group using piroxicam. Therefore, the difference between the intervention group and the control group was 1.8 mm (95% CI = 0.8 to 15.9%). In terms of safety, as well, local reactions were observed in both treatment groups, but was more in piroxicam group (16 cases in piroxicam group vs. 12 in homeopathic gel group). The study concluded that in the most pessimistic view, the effectiveness of homeopathic treatment is same as piroxicam treatment (NSAID gels) (17).

A study in 2015 evaluated the efficacy and safety of chamomile oil for knee osteoarthritis. The results revealed that the homeopathic oil, in comparison with topical diclofenac and placebo, significantly reduces acetaminophen requirement (P-value = 0.001), but despite the positive effects of homeopathic oil in motor function and stiffness of the knee, WOMAC inventory demonstrated no significant difference in the studied outcomes. In terms of safety, no reaction was observed in any patient in the homeopathic treatment group. Therefore, homeopathic oil decreases the analgesic requirement in patients with knee osteoarthritis and has a positive impact on outcomes (18).

Cost-effectiveness:

To evaluate the cost-effectiveness of homeopathic medicines, compared to NSAIDs, the efficacy data were extracted from studies (15-18) and the cost of traditional medicines was identified by referring to pharmacies and distribution centers of traditional drugs and was calculated, assuming that 2 packages of both types of drugs (gels) were consumed during a three-week period. These data were used in the cost-effectiveness equation and the results revealed the costs spent in IRR for each unit of effectiveness in the two treatment groups, as follows.

$$\text{cost - effectiveness of piroxicam} = \frac{2.8 \$}{8 (\text{pain reduction})}$$

$$= 0.35 \$ \text{ per pain reduction (1\$ = 35,000 Rials)}$$

$$\text{cost - effectiveness of homeopathy} = \frac{8.5 \$}{16 (\text{pain reduction})}$$

$$= 0.5 \$ \text{ per pain reduction}$$

The results of this calculation suggests that for each unit pain relief in homeopathy, the costs were about 0.35 \$ and 0.5 \$ in routine medical procedure. Although the costs were somewhat more in homeopathy, generally, the costs per unit effectiveness of both methods were low. This implies that both interventions were low-cost interventions.

Discussion

In general, the results of four studies were used to analyze the effectiveness, safety, and cost effectiveness of homeopathy in patients with knee OA. In all of these studies, effectiveness of homeopathy was compared with alternatives, using three components of pain, mobility, and stiffness. The findings of one study revealed that the joint's topical ointment, as a homeopathic product, has a greater positive effect than placebo in the treatment of primary knee OA. Another study compared the effectiveness of Peganum oil and olive oil and showed about 34 units reduction in the total VAS in the intervention group, while this reduction was 12 units in the control group. The consequences of pain and knee function problems in the intervention group reduced about 10 units more than the control group. In another study, comparing homeopathic and piroxicam gels, it was concluded that considering the pain relief index, homeopathic gel was twice more effective. Another study compared the effectiveness of homeopathic oil with diclofenac and placebo and it

was concluded that in terms of motor function and stiffness, it was more effective. Similar foreign studies evaluated the effectiveness and safety of homeopathic herbal medicines in the treatment of osteoarthritis. This study concluded that there is insufficient evidence to confirm the difference in homeopathic treatment with other therapies (19).

Conclusion

In terms of safety outcomes in studies, the studied factor was skin reactions and all studies have consistently noted that the homeopathic treatment showed little reaction.

In terms of the cost-effectiveness outcomes, the results suggest that for each unit pain relief, homeopathy was somewhat more costly. However, given that both procedures have generally low costs, considering the greater effectiveness and higher safety of homeopathy treatment compared to NSAIDs, homeopathy is favorable.

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Conflict of interests

The researchers do not have any conflict of interests.

Authors' contributions

Salari H, Esfandiari A, Akbarisari A and Ravanbod MR designed research; Salari H, Esfandiari A, analyzed data; and Salari H, Esfandiari A, Akbarisari A and Ravanbod MR wrote the paper. Salari H had primary responsibility for final content. All authors read and approved the final manuscript.

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