Acupotomy combined with intra-articular injection of sodium hyaluronate in the treatment of knee osteoarthritis

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Abstract
This retrospective study aimed to compare the effects of acupotomy combined with intra-articular injection of sodium hyaluronate (IA-SH) for the treatment of knee osteoarthritis (KOA). Eighty electronic medical records of patients with KOA were retrospectively analyzed. The patients were divided into an intervention group (n = 40, acupotomy plus IA-SH) and a control group (n = 40, IA-SH). Outcome measures included the visual analog scale, the Western Ontario and McMaster Universities Arthritis Index (WOMAC), and adverse events. Outcome data were collected and analyzed before and after treatment. The results of this study showed that there was a greater reduction in the visual analog scale (P < .01) and WOMAC scores (pain, P < .01; stiffness, P < .01; function, P < .01; total, P < .01) in the intervention group than in the control group. In addition, there were no significant differences in adverse events between the 2 groups. In this study, the effects of acupotomy plus IA-SH were superior to those of IA-SH alone for the treatment of patients with KOA. Further prospective studies are required to confirm these findings.

Abbreviations: IA-SH = intra-articular injection of sodium hyaluronate, KOA = knee osteoarthritis, VAS = visual analog scale, WOMAC = The Western Ontario and McMaster Universities Arthritis Index.

Keywords: acupotomy, efficacy, intra-articular injection, knee osteoarthritis, sodium hyaluronate

1. Introduction
Knee osteoarthritis (KOA) is a chronic degenerative disease of the knee joint that is influenced by a variety of factors.[1–4] It often causes pain, restricted motion, and disability of the knee joint, eventually leading to a poor quality of life in patients with KOA.[5–7] Studies have reported that over 600 million people are affected by this disorder, and it accounting for about 85% of all osteoarthritis worldwide.[6–8] Its prevalence is estimated to be approximately 22.9% in individuals aged ≥ 40 years.[6,7] It ranks 10th among global disability-causing diseases, and its prevalence has doubled over the last 10 years.[8–11] Therefore, KOA incurs a very large cost and spirit burden on patients, families, and society.

Current KOA modalities often comprise nonsteroidal anti-inflammatory drugs, glucosamine, chondroitin sulfate, hyaluronic acid, and other medication.[12–17] Pharmacological treatment benefits patients with KOA in the short-term, and its long-term efficacy is still unsatisfactory.[18] In addition, it is often accompanied by a variety of adverse events, such as gastrointestinal ulcers. Thus, adjunctive therapy with pharmacological modalities is important. Studies have reported that alternative treatments, such as acupuncture, moxibustion, and acupotomy, benefit patients with KOA.[19–24]

Sodium hyaluronate is an important component of normal joint synovial fluid and cartilage matrix. It plays a lubricating role in preventing wear and tear of the cartilage and decreasing the friction between the tissues in the knee joint cavity after injection. Previous studies have reported that the intra-articular injection of sodium hyaluronate (IA-SH) can benefit patients with KOA.[25,26] However, data on acupotomy combined with IA-SH in the treatment of KOA are limited. This retrospective study aimed to investigate the efficacy and safety of acupotomy combined with IA-SH in patients with KOA.

2. Methods
2.1. Ethical statement
Ethical approval for the present study was waived because it was conducted based on electronic medical records, and written informed consent was obtained from all patient records.

2.2. Study design
This was a retrospective study. All electronic medical records of patients with KOA were collected from the Ankang Hospital of Traditional Chinese Medicine and the High-tech Branch of...
the Ankang Hospital of Traditional Chinese Medicine between April 2019 and March 2021. We analyzed 80 eligible records and divided them into an intervention group (n = 40) and a control group (n = 40) based on the different treatment schedules they received. All patients in both groups received IA-SH. In addition, the patients in the intervention group underwent acupotomy. The researchers and analysts of the data harvest were blinded to the study.

2.3. Eligibility criteria
The inclusion criteria were as follows: age > 18 years, confirmed diagnosis of KOA, complete medical records, and no prior fractures. The exclusion criteria were as follows: age ≤ 18 years; presence of knee fracture, tumor, or cancer; previous knee surgery; inability to communicate; severe organ diseases; and incomplete medical records.

2.4. Treatment methods
All patients in both groups received IA-SH (2 mL, Shandong Boshilun Company Frieda Pharmaceutical Co., Ltd., Shandong, China) in the attacked knee joint cavity once weekly for a total of 5 weeks.

In addition, patients in the intervention group also underwent acupotomy according to the principles of acupotomology. The procedure was as follows: (a) Identifying the lesion location by physical examination, the A-shi point, and confirmation by ultrasound. (b) Determine the operating points (less than 5 points each time) based on ultrasound inspection. (c) Patients in the supine position underwent surgery using a needle-knife (Hanzhang Type 1, No. 4). (d) After the operation, the attacked area was kept dry and cleaned for 3 days to avoid infection. Each patient was treated once weekly for a total of 3 weeks.

2.5. Outcome measurements
The primary outcome was knee pain, measured using a visual analog scale (VAS, 0–10). It ranges from 0 (no pain) to 10 (worst pain), with a higher score indicating a greater severity of knee pain. The secondary outcome measurements were the Western Ontario and McMaster Universities Arthritis Index (WOMAC) and adverse events. The WOMAC tool consists of 24 items, and it is categorized into 3 subscales to respectively assess the pain, stiffness, and physical function. Of those, pain subscale has 5 items, with a total score ranging from 0 (no pain) to 20 (worst pain). The stiffness subscale comprises of 2 items, with a total scale ranging from 0 (no stiffness) to 8 (worst stiffness). The physical function subscale consists of 17 items, ranging from 0 (normal physical function) to 68 (poorest physical function). We analyzed the outcomes before and after treatment.

2.6. Statistical analysis
All data were analyzed using SPSS software (SPSS 17.0, IBM Corp., Armonk, NY, USA). Measurement data were analyzed using Student t-test or Mann-Whitney U test based on data with normal or non-normal distribution. Categorical data were analyzed using χ² test or Fisher exact test. A 2-side P < .05 signifies that a difference is statistically significant.

3. Results
This study identified 174 electronic medical records from KOA. A total of 94 ineligible medical records were excluded. Finally, we analyzed 80 medical records and divided them into intervention and control groups (Fig. 1).

Table 1
General characteristics of eligible patients in 2 groups.

| Characteristics      | Intervention group (n = 40) | Control group (n = 40) | P   |
|----------------------|-----------------------------|------------------------|-----|
| Age (years)          | 65.7 (10.8)                 | 67.1 (11.4)            | .57 |
| Gender               |                             |                        |     |
| Male                 | 25 (62.5)                   | 23 (57.5)              | .65 |
| Female               | 15 (37.5)                   | 17 (42.5)              |     |
| Race (ethnicity)     |                             |                        |     |
| Han                  | 37 (92.5)                   | 39 (97.5)              | .33 |
| Hui                  | 3 (7.5)                     | 1 (2.5)                |     |
| BMI, kg/m²           | 23.8 (3.2)                  | 24.0 (2.9)             | .77 |
| Duration of KOA, years | 5.1 (2.6)                  | 5.4 (3.0)              | .63 |
| K/L grade            |                             |                        |     |
| 2                    | 24 (60.0)                   | 27 (67.5)              | .49 |
| 3                    | 16 (40.0)                   | 13 (32.5)              |     |

Table 2
Comparison of VAS between the 2 groups.

| VAS                  | Intervention group (n = 40) | Control group (n = 40) | P   |
|----------------------|-----------------------------|------------------------|-----|
| Pretreatment         | 5.9 (2.2)                   | 6.1 (2.0)              | .67 |
| Post-treatment       | 1.0 (0.9)                   | 2.4 (1.1)              |     |
| Change from pretreatment | −4.9 (−6.0, −3.9)            | −3.7 (−4.6, −2.8)      | <.01|
| Difference between 2 groups | −1.2 (−1.8, −0.7)            |                       | <.01|

Data are present as mean ± standard deviation or number (%).
BMI = body mass index; K/L = Kellgren-Laurence grade.

The general characteristics of the 80 electronic medical records are summarized in Table 1. We compared the data of age, gender, race, body mass index, duration of KOA, and Kellgren-Laurence grade between the 2 groups (Table 1). No significant differences in any of these general characteristics were detected between the 2 groups (Table 1).

There was no significant difference in the visual analog scale (VAS) scores (P = .67; Table 2) before treatment between the 2 groups. However, a significant difference in the VAS score (P < .01; Table 2) was observed after treatment between the 2 groups.
There were no significant differences in WOMAC scores (pain, $P = .77$; stiffness, $P = .59$; function, $P = .85$; total, $P = .81$; Table 3) before treatment between the 2 groups. However, there were significant differences in WOMAC scores (pain, $P < .01$; stiffness, $P < .01$; function, $P < .01$; total, $P < .01$; Table 4) after treatment between the 2 groups.

Additionally, there were no significant differences in adverse events (local pain, $P = .65$; redness, $P = .50$; swelling, $P = .56$; Table 5) between the 2 groups in this study.

4. Discussion

KOA is a highly prevalent musculoskeletal disorder and leading cause of disability in the elderly population. Various studies have reported the effectiveness of hyaluronic acid injections, and guidelines have recommended its use in the management of KOA. Although previous studies have investigated the efficacy of IA-SH in the treatment of patients with KOA, there is insufficient evidence regarding the efficacy of acupotomy combined with IA-SH in the management of KOA.

In this study, we investigated the efficacy and safety of acupotomy combined with IA-SH in patients with KOA. We compared acupotomy in combination with IA-SH and IA-SH for KOA. This retrospective study collected data from the completed medical records of patients with KOA. We analyzed the medical records of 80 eligible patients with KOA and divided them into intervention and control groups, with 40 patients in each group. The results of this study showed that patients who underwent acupotomy in combination with IA-SH achieved a greater reduction in VAS and WOMAC scores than patients who underwent IA-SH alone. These findings suggest that acupotomy plus IA-SH is superior to IA-SH alone for the treatment of KOA.

In terms of safety, there were no significant differences in adverse events. In the intervention group, 3 and 2 patients reported local pain and local swelling, respectively. In the control group, 2, 1, and 1 patients reported local pain, redness, and swelling, respectively. However, all of these adverse events were treated well.

This retrospective study has several limitations. First, this was a retrospective cohort study with a small sample size. Second, confounding factors and selection bias may have affected the results. Third, because there were limited data on current medical records, the outcome measurements were not comprehensive enough to address this issue. Finally, randomization and blinding could not be applied to the patients and researchers because of the retrospective nature of the study.

5. Conclusion

Our results demonstrated that acupotomy combined with IA-SH benefited patients with KOA more than IA-SH alone did. Further prospective studies are warranted to investigate the efficacy of acupotomy plus IA-SH for KOA in a larger group of patients.

Author contributions

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