Clinical Study of Electro-acupuncture at the Top Ten Highly Selected Acupoints in the Treatment of Knee Osteoarthritis

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Abstract

Objective: The objective of this study is to assess the clinical effectiveness of the ten most often used acupoints, chosen through literature review, for treating knee osteoarthritis (KOA). Additionally, the study aims to monitor and analyse the therapeutic effects of combining electro-acupuncture with these acupoints in the treatment of KOA. **Methodology:** A total of 80 patients were randomised in a random manner to either the treatment group or the control group, with an equal distribution of 40 patients in each group. The treatment group was administered a combination of electro-acupuncture (EA) and traditional acupuncture (TA), targeting the top ten acupoints often used. A comparative analysis was conducted to assess the clinical effectiveness, WOMAC scores, VAS ratings, and SF-36 scores before and after treatment in both groups. **Results**: Prior to treatment, there were no statistically significant variations in the three scores between the two groups ($P>0.05$). Following the therapy, both groups exhibited noteworthy decreases in WOMAC and VAS scores. Notably, the treatment group displayed considerably lower values compared to the control group ($P<0.05$). In addition, the SF-36 ratings for physical health and mental health showed a significant increase in both groups after treatment. The treatment group achieved significantly higher scores than the control group ($P<0.05$). Furthermore, the treatment group exhibited a more significant enhancement in scores in comparison to the control group ($P<0.05$). Significant differences in WOMAC, VAS, and SF-36 scores were seen in the within-group comparisons ($P<0.05$). The treatment group demonstrated a significantly higher overall success rate of 92.50% (37/40) compared to the control group's success rate of 75.00% (30/40) ($P=0.035<0.05$). **In conclusion**, the combination of EA and TA, along with the use of the top ten high-frequency acupoints, effectively enhanced clinical symptoms and signs in patients with KOA, indicating promising therapeutic outcomes. EA had higher clinical efficacy and had a good influence on patients' quality of life, compared to the other strategy. The acupoint prescription was carefully determined by analysing available literature to investigate the patterns of acupoint selection in the treatment of knee osteoarthritis (KOA). This study led to the identification of the 10 most often used acupoints, which were then confirmed through clinical practice. The novel methodology employed by EA, in conjunction with the utilisation of the top ten high-frequency acupoints, holds significant value in terms of its potential for promotion in Malaysia.

Keywords: Electroacupuncture, Highly Selected Acupoints, Knee Osteoarthritis (KOA), Clinical Study.

Knee Osteoarthritis (KOA) is a condition where the cartilage in the knee joint breaks down, leading to damage in the bone, synovial tissue, joint capsule, and other tissues. [1-3] The condition manifests with symptoms including swelling, discomfort, deformity, and restricted mobility in the knee joint. It has a lengthy and progressive course. This disease not only induces physical and psychological suffering in patients but also places a substantial strain on healthcare systems and public health.[4-6] The warm and humid temperature of Malaysia, combined with the need for fans or air conditioning, produces a distinct geographical environment and lifestyle that leads to a

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relatively high occurrence of KOA in the local population.[7] Prior to undertaking clinical study, a comprehensive evaluation of the existing literature was undertaken, involving the examination, extraction, and analysis of previously published studies on the use of acupuncture as a treatment for knee osteoarthritis (KOA). Furthermore, an examination was conducted on the acupoint selection patterns for acupuncture therapy of knee osteoarthritis (KOA), resulting in the identification of the 10 most commonly utilised acupoints. Consequently, we devised a randomised controlled experiment that integrated electro-acupuncture and traditional acupuncture, employing a carefully chosen set of the ten most effective acupoints, to address knee osteoarthritis (KOA). The primary aims of this study were to examine the clinical effectiveness of the top ten meticulously chosen acupoints and to monitor and analyse the therapeutic outcomes of electro-acupuncture when paired with these acupoints for the treatment of knee osteoarthritis (KOA). The study sought to enhance the treatment modalities for knee osteoarthritis (KOA) in Malaysia and offer valuable scholarly references and scientific data.

Case Source and Grouping

Case Source

The cases were sourced from Malaysia Traditional Chinese Medicine (TCM) clinics between June 2020 and June 2021. A total of 80 participants with KOA were randomly assigned into two groups using transparent randomization: the treatment group (EA + top ten highly selected acupoints treatment) and the control group (TA + top ten highly selected acupoints treatment), with 40 participants in each group.

Grouping Method

The random sequence was created in the following manner: Prior to commencing the trial, sequential numbers ranging from 1 to 80 were issued to the patients' visit orders. Afterwards, the "Random Number Generator" feature in IBM SPSS Statistics 22 software was employed to produce random numbers. Next, the variable "Group" underwent transformation using the "Visual Binning" function in data analysis. This resulted in assigning each integer from 0 to 80 to either 1 or 2, where "1" represents the treatment group and "2" represents the control group. Patients were assigned to their respective therapy groups based on the number they were given on their initial appointment.

The utilisation of this random allocation approach was implemented in order to minimise biases and guarantee dependable and comprehensible comparisons between the two groups. The 1:1 allocation ratio ensured an equal number of participants in both the treatment and control groups, making future analyses more comparable and statistically significant. Given the inherent characteristics of acupuncture therapy, it was not feasible to attain complete blinding throughout the trial. Consequently, the study did not entirely adhere to rigorous blinding requirements. All participants who were enrolled successfully finished the treatment without any dropouts or exclusions owing to non-compliance with the research protocol.

Research Methods

Diagnosis and Inclusion Criteria

① The diagnostic criteria for knee osteoarthritis (KOA) from "Guidelines for the Diagnosis and Treatment of Osteoarthritis (2007 edition)".[8] ② Pure KOA. ③ Age between 40 and 80 years.

Exclusion Criteria

① Patients who do not meet the diagnostic and inclusion criteria. ② Patients with rheumatoid or rheumatism knee arthritis, acute or traumatic KOA. ③ Patients with knee joint tuberculosis, tumor, osteomyelitis, or synovitis. ④ Patients who have not received non-steroidal anti-inflammatory drugs or related medications, acupuncture, needle knife, or other treatments in the past month. ⑤ Patients with a history of knee joint surgery or localized skin infection in the knee joint area. ⑥ Patients with implanted metal devices, cardiac pacemakers, or other devices unsuitable for electroacupuncture treatment. ⑦ Patients with severe primary diseases of the heart, liver, kidney organs, or blood diseases. ⑧ Patients with needle phobia or pregnant women. ⑨ Patients with poor compliance.

Treatment Methods

Acupoint Selection: Based on previous literature research, the top ten high-frequency acupoints for acupuncture treatment of KOA were selected. These acupoints are as follows: Dubi (ST35), Neixiyan (EX-LE4), Xuehai (SP10), Yanglingquan (GB34), Liangqiu (ST34), Zusanli (ST36), Yinlingquan (SP9), Heding (EX-LE2), Xiyangguan (GB33), and Sanyinjiao (SP6).

Control Group (CG): The conventional technique of acupuncture was utilised. Patients were positioned in a supine posture, with their feet resting flat and a cushion put beneath the affected knee to provide a small flexion of the knee joint. The positions of the acupoints were determined and marked, and the nearby skin was regularly cleaned with 75% medicinal ethanol. 0.35×50mm disposable sterile acupuncture needles were placed vertically into the acupoints at a depth of approximately 30-40mm. The needling procedure involved the administration of supplements and reductions until the local Deqi sensation, characterised by soreness, heaviness, and fullness, was obtained.

Treatment Group (TG): The technique of electroacupuncture was utilised. Furthermore, following the attainment of the Deqi sensation, the Huatuo SDZ-II electronic acupuncture device was employed for dense-disperse wave treatment, with the stimulation intensity being customised according to the patient's tolerance.

Each group underwent a 30-minute treatment once a day for a total of 6 sessions, which comprised one complete course of treatment. There was a single-day interval between the two courses, during which a total of two treatments were given.

Outcome Indicators

Primary Outcome Indicators: The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)[9] scores before and after treatment were the main outcome measures.

Secondary Outcome Indicators: Visual Analog Scale (VAS),[10] Short Form 36 (SF-36) health survey scores, and adverse reactions such as fainting and hematoma during the treatment were the secondary outcome measures.

Assessment Criteria for Therapeutic Effect

Based on the "Diagnostic and Therapeutic Efficacy Criteria for Syndromes and Diseases in Traditional Chinese Medicine",[11] and in combination with the nimodipine method, clinical assessment criteria for therapeutic effect were formulated.

The WOMAC scores were used as the calculation data for the clinical efficacy index. The difference between the pre-treatment and post-treatment WOMAC scores was calculated (pre-treatment WOMAC score - post-treatment WOMAC score). The difference was divided by the pre-treatment score and then multiplied by 100% to obtain the clinical efficacy index. The total effective rate was calculated as follows: (number of cured cases + markedly effective cases + effective cases) / total number of cases x 100%.

①Cure: Clinical efficacy index ≥ 80%;
②Markedly effective: 50% ≤ Clinical efficacy index < 80%;
③Effective: 25% ≤ Clinical efficacy index < 50%;
④Ineffective: Clinical efficacy index < 25%.

Statistical Analysis

The data were analyzed using IBM SPSS Statistics 22 software, with a significance level set at α=0.05. Normally distributed continuous data were expressed as $\pm s$, and categorical data were presented as percentages, analyzed using the χ^2 test. For comparisons before and after treatment between groups, independent samples t-test was used. For within-group comparisons, paired samples t-test was employed.

Results

Baseline Characteristics of Patients in Both Groups

There were no significant differences in baseline data, including gender, age, and clinical course, between the two groups before treatment (P>0.05), indicating comparability (see Table 1).

Table 1: Baseline Characteristics of Patients in Both Groups before Treatment.

Group	n	Gender		Age (Years)	Clinical Course (Months)
		Male	Female		
TG	40	16	24	56.25±3.67	36.75±2.82
CG	40	17	23	55.23±3.91	36.83±3.67
P value		0.820		0.231	0.919

Comparison of WOMAC and VAS

Comparison of WOMAC and VAS scores between the two groups before and after treatment (Refer to Table 2 and Table 3)

Table 2: Comparison of WOMAC Scores between the Two Groups before and after Treatment (value, $\bar{X}\pm s$).

Group	n	Before Treatment	After Treatment	Difference
TG	40	58.98±4.82	24.38±3.23•	34.60±6.05
CG	40	58.35±5.15	40.23±3.83•	18.13±6.55
t value		0.560	-20.014	11.687
P value		0.577	0.000	0.000

Note: Compared with the Pre-treatment Group, •P < 0.05.

Table 3: Comparison of VAS Scores before and after Treatment in the Two Groups (value, $\bar{X}\pm s$).

Group	n	Before Treatment	After Treatment	Difference
TG	40	6.75±0.44	3.25±0.44•	3.50±0.60
CG	40	6.70±0.46	4.00±0.00•	2.70±0.46
t value		0.495	-10.817	6.676
P value		0.622	0.000	0.000

Note: Compared with the Pre-treatment Group, •P < 0.05.

Comparison of SF-36 Scores

Comparison of SF-36 scores in the two groups of patients before and after treatment (see Table 4 and Table 5)

Table 4: Comparison of SF-36 Scores (physical health) before and after Treatment in the Two Groups (value, $\bar{X}\pm s$).

Group	n	Before Treatment	After Treatment	Difference
TG	40	26.50±3.11	34.75±4.13•	8.25±1.34
CG	40	27.90±4.90	32.88±3.09•	4.98±2.08
t value		-1.525	2.299	8.376
P value		0.132	0.024	0.000

Note: Compared with the Pre-treatment Group, •P < 0.05.

Table 5: Comparison of SF-36 Scores (mental health) before and after Treatment in the Two Groups (value, $\bar{X}\pm s$).

Group	n	Before Treatment	After Treatment	Difference
TG	40	49. 93±3.40	59.03±3.42•	9.10±1.66
CG	40	51.30±3.63	53.80±4.55•	2.50±1.66
t value		-1.750	5.801	17.753
P value		0. 084	0.000	0.000

Note: Compared with the Pre-treatment Group, ●P < 0.05.

Comparison of Clinical Efficacy

Comparison of clinical efficacy between the two groups of patients (see Table 6)

After the completion of treatment, the total effective rate in the treatment group was 92.50%, significantly higher than that of the control group at 75.00%. Combine the data of the three columns of cure, markedly effective, and effective into the column of "effective", and then form a four-table table with "ineffective" for the Chi-square test (χ^2 test), and get P value = 0.035<0.05. It indicates that the clinical efficacy of electro-acupuncture combined with the top ten highly selected acupoints is better than that of traditional acupuncture.

Table 6: Comparison of Clinical Efficacy between the Two Groups of Patients (cases (%)).

Group	n	Cure	Markedly Effective	Effective	Ineffective	Total Effective (%)
TG	40	1 (2.50)	21 (52.50)	15 (37.50)	3 (7.50)	37 (92.50%)
CG	40	0 (0.00)	11 (27.50)	19 (47.50)	10 (25.00)	30 (75.00%)
χ^2						4.444
P value						0.035

Adverse Reactions

Both groups of patients did not experience any adverse reactions during the treatment period.

Discussions

Presently, Western medicine does not possess a cohesive comprehension of the cause and development of knee osteoarthritis (KOA). Nevertheless, the main characteristics of this condition mainly consist of deteriorating alterations and structural abnormalities in the cartilage of the knee joint. These changes are accompanied by thickening of the bone beneath the cartilage, degeneration of the cartilage itself, inflammation of the synovium without infection, and involvement of the joint capsule and nearby structures.[12-14] Traditional Chinese Medicine (TCM) categorises KOA as "Bi Syndrome," "Wei Syndrome," and "Bone Bi," also referred to as "He Xi Feng," "Knee Bi Disease," or "Knee Arthralgia Disease",[15-17] based on the shown symptoms and indicators. In Traditional Chinese Medicine (TCM), the development of knee osteoarthritis (KOA) is believed to be caused by various reasons including the invasion of wind, cold, and dampness pathogens, liver-kidney deficiency, impairment of tendons and bones, spleen deficiency with phlegm stasis, dampness and blood stasis blockage, and joint obstruction.[18]

The condition is age-related, with a higher likelihood of occurrence in individuals of middle-aged and senior demographics. The prevalence of knee osteoarthritis (KOA) in the older population varies across different regions. In the United States, the prevalence is from 13% to 20%,[19] in Europe it ranges from 9% to 17%,[20] in the Middle East it ranges from 22% to 25%,[21] and in Asian countries it ranges from 10% to 38%.[22] Reports indicate that adult patients with KOA in Malaysia make up between 10%-20% of the overall population.[23] Among these patients, approximately 23% are aged over 55 years, while approximately 39% are aged over 65 years.[24,25] Malaysian TCM clinics primarily cater to Chinese patients, followed by Malay patients, with Indian patients being the least served. These findings suggest that TCM in Malaysia primarily caters to Chinese patients. However, its distinctive diagnostic and therapeutic approaches, as well as their efficacy, have also gained recognition from other ethnic groups such as Malays and Indians. This phenomenon may be attributed to factors such as blood recognition, cultural inheritance, and psychological identity. Further detailed research can be conducted in the future to explore this relationship.

Acupuncture possesses the abilities to clear obstructions in the body's energy pathways, eliminate blockages, and restore the equilibrium between opposing forces of energy. Since ancient times, it has been recognised as a significant approach for treating arthralgia condition. Research has demonstrated that it may enhance the restoration and regrowth of supple tissues such skin, muscles, tendons, ligaments, and fascia, as well as nerves, bones, and cartilage tissues. Furthermore, it can significantly enhance the mobility function of the knee joint in patients with knee osteoarthritis.[26-29] Furthermore, acupuncture therapy has the potential to decrease WOMAC scores, boost scores for joint pain, stiffness, and physical function, and improve ratings for physical fitness and psychological functioning.[30] Electro-acupuncture is a therapeutic approach that combines traditional acupuncture techniques with the use of micro-current to enhance the stimulation of certain acupoints. This method aims to effectively treat various ailments. It integrates the functionalities and benefits of conventional acupuncture, electrical stimulation, and mechanical vibration stimulation. Electro-acupuncture can improve blood circulation, enhance the local micro-environment, decrease high pressure within the subchondral bone, and facilitate the circulation,

metabolism, and absorption of inflammatory mediators. This is achieved by strengthening the acupuncture sensation and the electromagnetic field produced by the body. The therapeutic goals of electro-acupuncture include clearing blockages in blood vessels, reducing swelling, alleviating pain and stiffness, improving mobility, and repairing damage. The acupoints used for this study were the ten most often used acupoints that we identified and compiled from our previous research. We conducted data mining on previously published material to investigate the patterns of acupoint selection for acupuncture treatment of this particular condition. The lesions were predominantly localised in the vicinity of the knee joint and lower limbs, and have the potential to provide a near-treatment function. By stimulating the acupoints Dubi and NeiXiYan, the circulation of meridians can be enhanced, pain can be alleviated, and the range of motion of the knee joint can be improved. Acupuncture at Xuehai can eliminate blood stasis, stimulate the meridian, regulate the release of vascular active factors, modify the shape of capillaries, accelerate blood flow, and alter the high coagulation state of blood.[31] Acupuncture at Liangqiu, Zusanli, and Sanyinjiao can strengthen the spleen, nourish Qi and Blood, promote the circulation of Qi, relieve pain, and improve the range of motion of the knee joint. Heding is the primary acupuncture point for knee pain and is efficacious in treating Hexifeng; Yinlingquan is efficacious in treating knee pain and lower limb paralysis; acupuncture at Yanglingquan and Xiyangguan can facilitate the flow of Qi and blood in the knee joint and enhance the flexion and extension function of the knee joint. The integration of these specific acupoints can yield a therapeutic outcome by invigorating the liver and kidney, clearing the pathways of energy flow, enhancing the circulation of vital energy and blood, alleviating discomfort, and fortifying the connective tissues and skeletal structure.

The WOMAC, VAS, and Brief Health Status Questionnaire are assessment tools used to measure many aspects of health and well-being. The SF-36 questionnaire, chosen for this study, demonstrates strong test reliability and validity, making it very appropriate for assessing the treatment impact of knee osteoarthritis (KOA). Prior to therapy, there was no statistically significant disparity in the WOMAC, VAS, and SF-36 ratings between the two groups of patients ($P>0.05$), suggesting that they were all similar. Following the therapy, both groups of patients exhibited a significant decrease in their WOMAC and VAS scores compared to their scores prior to treatment. Furthermore, the treatment group demonstrated considerably lower scores in these two evaluation indicators compared to the control group, with P values less than 0.05. The SBrief Health Status Questionnaire SF-36 scores for both physical and mental health showed a significant improvement after treatment. Furthermore, the treatment group had significantly higher scores for these two evaluation indicators compared to the control group, with P values less than 0.05. The treatment group consistently exhibited higher scores than the control group, with all differences in scores between before and after treatment being statistically significant ($P < 0.05$). Paired t-tests were employed to assess the scores before and after therapy within the same group. The P values for the WOMAC, VAS, and SF-36 scores were all found to be below 0.05. The treatment group had a total effective rate of 92.50% (37/40), which was considerably higher than the control group's rate of 75.00% (30/40) ($P=0.035<0.05$). The aforementioned outcomes indicate that: 1. Both electro-acupuncture and traditional acupuncture, when combined with the top ten carefully chosen acupoints, have therapeutic effects on this disease. However, electroacupuncture is more effective than traditional acupuncture in reducing WOMAC and VAS scores, and increasing SF-36 scores of patients. This leads to a greater difference in scores before and after treatment. Electro-acupuncture, when used in conjunction with the top ten carefully chosen acupoints, exhibits superior therapeutic efficacy compared to traditional acupuncture. Furthermore, it effectively enhances the clinical symptoms of patients.

Conclusion

Both electro-acupuncture and traditional acupuncture, when paired with the top ten carefully chosen acupoints, have therapeutic benefits on knee osteoarthritis (KOA). They can successfully relieve the clinical symptoms and signs of patients with KOA. However, the clinical efficacy of electro-acupuncture therapy requires further investigation. It surpasses traditional acupuncture and has the potential to enhance the quality of life for patients. The selected acupoint prescriptions consist of the top 10 acupoints that have been carefully chosen and analysed using data mining of previously published research. These acupoints aim to investigate the patterns of acupuncture treatment for this specific ailment and have been validated through clinical practice. The use of electro-acupuncture therapy, in conjunction with a well chosen selection of the top 10 acupoints, is deserving of endorsement and dissemination in Malaysia.

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