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Research article

Effectiveness of True Acupuncture as an Adjunct to Standard Care or Electro-Physiotherapy in Osteoarthritis of the Knee

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Abstract

Recently there has been considerable academic debate about the effectiveness of true acupuncture as an adjunctive treatment in osteoarthritis of the knee. The results from acupuncture studies are inconclusive. The aim of the present research is to find out the effectiveness of two treatment approaches: 2 weeks standard care followed by 2 weeks classical true acupuncture (group A) compared with 2 weeks electro-physiotherapy followed by 2 weeks classical true acupuncture as well (group B). The primary outcomes were the changes in pain intensity measured by visual analogue scale (VAS) and the changes in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain and physical function scores. The secondary outcomes were patients global assessment of treatments and total non-opioid analgesic consumption. Sixty-four consecutive patients with chronic symptomatic knee osteoarthritis were assessed before (baseline) and after treatments, at 1 month and at 3 months follow-up. Our results revealed greater VAS pain relief, improved WOMAC function scores and less non-opioid analgesic consumption after the implementation of electro-physiotherapy combined with true acupuncture, and no between-group differences in WOMAC pain scores and patients global assessment. The results demonstrate the potential of an integrative approach including the complementary treatment of knee osteoarthritis with a combination of electro-physiotherapy and true acupuncture in a consecutive and more intense manner (according to our local practice). Further research in the conventional and alternative management of knee osteoarthritis should focus not only on the quality of patients' life after treatments, but on the quality of available pharmacological and non-pharmacological treatment options as well.

Keywords: *Acupuncture; Knee osteoarthritis; Adjunctive therapy; Physiotherapy; Chronic pain; NSAIDs*

Abbreviations: OA: Osteoarthritis; VAS: Visual analogue scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; NSAIDs: Non-steroidal anti-inflammatory drugs

Introduction

Recently there has been considerable academic debate about the effectiveness of true acupuncture as an adjunctive treatment in osteoarthritis (OA) of the knee [1]. The results from acupuncture studies are inconclusive [2]. Current guidelines highlight the lack of strong evidence of the acupuncture effectiveness in patients with knee OA. The American College of Rheumatology (ARS) conditionally recommends acupuncture for knee OA [3], while the American Academy of Orthopedic Surgeons (AAOS) does not recommend acupuncture [4], and the Osteoarthritis Research Society International (OARSI) guidelines provide an "uncertain" recommendation regarding its use [5]. On the other hand, in the same update guidelines, the AAOS gives strong recommendation for the use of NSAIDs in all patients with symptomatic knee OA [4], the ARS elevates NSAIDs to a first-line option [3], while the OARSI recommends NSAIDs only in patients without co-morbidities, including cardiovascular risk factors [5]. In addition, the latest research in the field suggests that for the patients

with knee OA, long-term, but not short-term, NSAIDs use is associated with an a priori–defined minimally important clinical change in stiffness, physical function, and joint space width, but not pain [6]. Thus the necessary long-term administration of NSAIDs in knee OA, and its associated undesired side effects, makes highly relevant new evidence in the field concerning the NSAIDs-sparing effect of the non-pharmacological treatment options and their combinations [7]. A recent study suggest that the use of true electro-physiotherapy in knee OA (TENS, or interferential currents, or shortwave diathermy), in addition to exercise and education, may reduce the paracetamol intake compare with sham interventions, in addition to exercise and education [8]. To date, there are no published data on the combined effect of acupuncture and electro-physiotherapy in the field. The aim of the present research is to find out prospectively the extent of pain relief and improved function in patients with knee osteoarthritis after the implementation of 2 weeks standard care treatment followed by 2 weeks classical true acupuncture treatment compared with 2 weeks physiotherapy treatment followed by 2 weeks classical true acupuncture as well.

Materials and Methods

Sixty-four patients were included in our study if they were aged ≥ 50 (range 50-75 years) and had been diagnosed with chronic symptomatic knee OA (in the presence of radiological alterations in the knee joint of grade ≤ 2 according to Kellgren-Lawrence criteria and an average pain intensity of ≤ 40 mm on a 100 mm VAS in the week before baseline assessment). The exclusion criteria were the following: knee pain from inflammatory, malignant or autoimmune origin; severe deformity of the knee joint requiring surgical repair; undergone surgery or arthroscopy of the affected knee joint in the past year; implemented corticosteroid or hyaluronic acid intra-articular injections in the past 4 months; implemented acupuncture treatment in the past 1 year; implemented physiotherapy or other treatment for OA knee pain (with the exception of non-steroidal anti-inflammatory drugs or simple analgesics) in the past 4 weeks. Patients were randomly allocated (by the name of the interventions) to received either a course of standard care followed by classical true acupuncture (Group A, n = 31), or a course of physiotherapy followed by the same true acupuncture treatment (Group B, n = 33).

Interventions

The standard care included 14 consecutive days of regular oral intake of patients' current non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics only. The acupuncture was implemented according to the Traditional Chinese Medicine within 10 working days as 10 consecutive treatment sessions of 30 min unilateral or bilateral manual acupuncture only, by needling at least 8 out of 12 proposed acupoints (the local points Sp 9, St 34, St 35, St 36, GB 34 as well as Xiyan extra point and the distal points Sp 6, Liv 3, UB 57, UB 60, GB 39, Kid 3) and eliciting De Qi. The physiotherapy was implemented within 10 working days as 10 consecutive electrotherapy treatment sessions of 15 min interferential currents and 20 min low frequency pulsed magnetic field. Within the courses of physiotherapy and acupuncture and during the 3 months follow-up patients were allowed to take their oral NSAIDs/simple analgesics as needed only, i.e. as a rescue medication when implemented treatments failed to prevent pain.

Outcome measures

The primary outcomes were the changes in pain intensity measured by 0-100 mm visual analogue scale (VAS) and the changes in the Western Ontario and McMaster Universities OA Index (WOMAC) pain (0-20) and physical function (0-68) scores. The secondary outcomes were patients global assessment of treatments (1-5) [worse(1), no change(2), better(3), much better(4), complete recovery(5)] and total non-opioid analgesic consumption (number of pills taken). Patients were assessed by blinded observer before (baseline) and after treatments, at 1 month and at 3 months follow-up.

Statistical analysis

Analysis was performed according to the intention-to-treat principle with the baseline (or the last recorded) values used in place of any missing follow-up values. Categorical data were compared with the χ^2 test or Fisher's exact test (as appropriate). Continuous variables were compared with Independent Samples T-test in normal distribution or Mann-Whitney U-test for distribution different from the normal (between-group comparisons), and with Paired Samples T-test or Wilcoxon Signed Ranks Z-test, respectively (within-group comparisons). All statistical analyzes were performed at $\alpha = 0.05$.

Results and Discussion

No baseline differences existed between Group A and Group B with respect to demographics, Kellgren-Laurence grades or pain and function outcome variables.

	Acupuncture + Standard Care (n = 31)	Acupuncture + ElectroPhysiotherapy (n = 33)	p
Age (years)	63,7 ± 7,3	62,6 ± 7,4	0,589
Gender (male/female)	4/27	7/26	0,511
Kellgren-Laurence grade 2 (n)	4	6	0,409
Kellgren-Laurence grade 3 (n)	24	24	0,435
Kellgren-Laurence grade 4 (n)	3	3	0,669
VAS pain (0-100 mm)	61,1 ± 11,8	60,6 ± 10,1	0,989
WOMAC pain (0-20)	9,2 ± 2,4	9,1 ± 2,01	0,994
WOMAC function (0-68)	32,6 ± 6,9	32,6 ± 6,9	0,829

Table 1: *Participant demographic and baseline data (mean ± SD, unless otherwise specified).*

The between-group differences at end of treatments and during the follow-ups revealed greater VAS measured pain relief (p = 0,01) (Figure 1), improved WOMAC function scores (p = 0,01)(Figure 3) and less non-opioid analgesic consumption (p = 0,048) in Group B compared to Group A, but not in WOMAC pain scores (p = 0,15)(Figure 2) and in patients global assessment of treatments (p = 0,06). According to the patients perspective (the latter comparison) there was only a trend in favour of physiotherapy combined with true acupuncture treatments. The within-group differences (baseline vs. follow-up values) revealed significant reductions in all measured primary outcomes scores, which were in favour of both combined treatments (p < 0,0001).

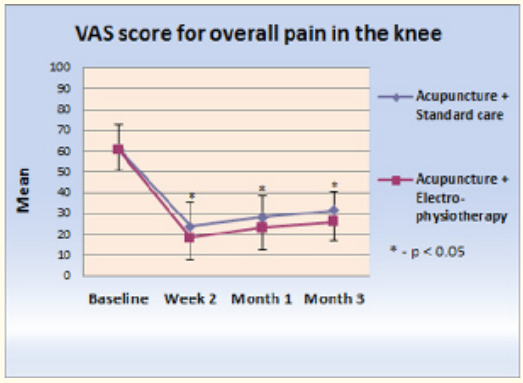

Figure 1: *Changes from baseline in participant VAS pain scores (0-100 mm) (mean ± SD).*

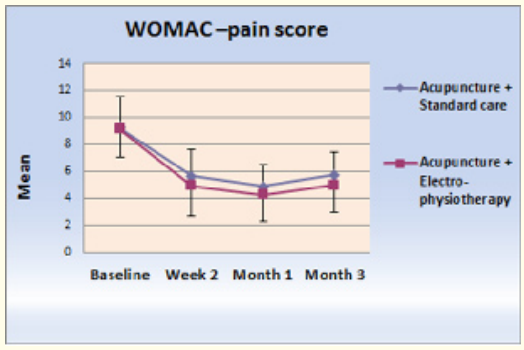

Figure 2: *Changes from baseline in participant WOMAC pain score (0-20) (mean ± SD).*

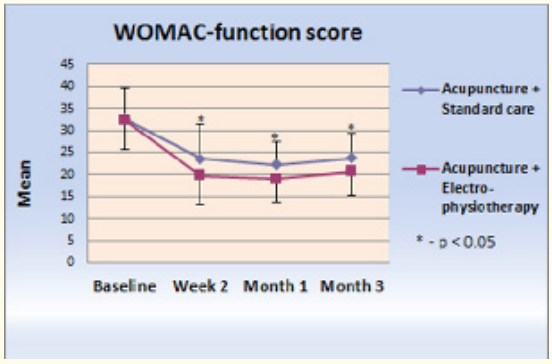

Figure 3: *Changes from baseline in participant WOMAC function scores (0-68) (mean ± SD).*

Despite the observed significant reductions in primary outcomes, one could not say with certainty that these improvements *per se* are clinically meaningful. The clinically relevant outcomes were defined by OMERACT-OARSI criteria (Scenario D) [9], using data from individual patients responses at different levels of WOMAC pain/function reductions (Table 2) and from absolute change in pain intensity (Figure 1). Scenario D was defined as a moderate improvement in either pain or physical function (≥ 20 % relative improvement from baseline with absolute change ≥ 10 mm on a 100 mm VAS), or as a large improvement in either pain or physical function (≥ 50 % relative improvement from baseline with absolute change ≥ 20 mm on a 100 mm VAS) [9]. All patients had absolute change ≥ 20 mm on a 100 mm VAS (Fig.1). The vast majority of patients in Group A and Group B (≥ 90 %) have responded with moderate improvements in both pain and function (Table 2, $p > 0,05$). About one third of Group A and half of group B patients have responded with large improvement in pain (Tabl.2, $p > 0,05$), but only 2 patients in Group A and 9 patients in Group B have responded with large improvement in function (Tabl.2, $p = 0,045$). The proportion of responders (patients with a decrease of at least 50% in their WOMAC index scores) was 51% (WOMAC pain score, Table 2) in electro-physiotherapy combined with true acupuncture group, which complies with the responder rates reported by others [10, 11].

There were 1 dropout in Group A and 2 dropouts in Group B. All the three patients did not provide information only on the number of pills taken during the last 3 months follow-up. In the calculation of their non-opioid analgesic consumption, the available data on consumption during the first month follow-up were moved forward to replace the missing data.

	Acupuncture + Standard care (n = 31)	Acupuncture + Electro-physiotherapy (n = 33)	p
% reduction in WOMAC pain scores from baseline	Responders yes/no (%)	Responders yes/no (%)	
≥ 20	29/2 (94)	33/0 (100)	0.231
≥ 50	10/21 (32)	17/16 (51)	0.137
% reduction in WOMAC function scores from baseline	Responders yes/no (%)	Responders yes/no (%)	
≥ 20	28/3 (90)	32/1 (97)	0.347
≥ 50	2/29 (6)	9/24 (27)	0.045

Table 2: *Individual patient responses (responders yes/no) in achieving clinically relevant levels of reduction in WOMAC pain/function scores compared with baseline*

Our study has several limitations. The recruited patients assumedly had an interest in acupuncture, possibly introducing a selection effect. The blinding was impossible in implementing alternatively standard care or electro-physiotherapy treatments, possibly leading to patients' biases. Likewise, the observed more intensive practitioner-patient contact (10 + 10 consecutive treatment sessions in Group B vs. 10 consecutive treatment sessions in Group A) may bias the results in favour of electro-physiotherapy combined with true acupuncture treatments (due to placebo effect of a "healing ritual" or patients' expectations) [12, 13].

On the other hand, other data in the same field suggest that after implementing physiotherapy (advice and exercise) or physiotherapy (advice and exercise) plus true acupuncture there was no evidence of a relationship between patients' treatment preferences or expectations and pain reduction [14]. The latest research, using functional magnetic resonance imaging cortical scans, suggests that true acupuncture may achieve its therapeutic effect on knee OA pain by modulating this pain in the descending pain modulatory pathway [15], and thus provides new evidence against the true acupuncture placebo effect.

The more intensive course of treatments did not lead to deviations in compliance with the predefined acupuncture scheme. Apart from minor haematomas, no obvious adverse effects due to acupuncture were detected. This is in accordance with the safety of implementing acupuncture reported by others [12].

Our combined electro-physiotherapy treatments (15 min interferential currents followed by 20 min low frequency pulsed magnetic field) are in line with the needs for further research concerning the combined physiotherapy interventions administered for pain associated with knee OA [7].

There is evidence in favour of the use of acupuncture as an adjunct to pharmacological treatment in patients with knee OA [16]. Our findings support both combined mode of pain treatment in patients with knee OA, but especially that of electro-physiotherapy combined with true acupuncture in patients at high risk of the adverse effects of their NSAIDs/simple analgesics. They are consistent with the data reported by others [16, 17], and provide new evidence of the effectiveness concerning non-pharmacological treatment options. Any future changes in the quality of the prescribed pharmaceuticals would alter the role of these complementary treatments.

Conclusion

These results demonstrate the potential of an integrative approach including the complementary treatment of knee OA with a combination of electro-physiotherapy and true acupuncture in a consecutive and more intense manner (according to our local practice). Further research in the conventional and alternative management of knee osteoarthritis should focus not only on the quality of patients' life after treatments [17, 18, 19], but on the quality of available pharmacological and non-pharmacological treatment options as well.

Conflict of interest

The authors have declared no conflict of interest.

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