

Acupuncture Treatment for Knee Osteoarthritis, an Experience from Egypt

Research Article

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Osteoarthritis of the knee is a major cause of pain and functional limitation worldwide, often treated by medical, physical, or surgical intervention. There are many treatment options, there is no single definite effective treatment. In patients in whom standard medical practice is ineffective and who are not candidates for surgery (or who reject it), other pain management procedures, as acupuncture should be considered. The aim of our study was to determine the efficacy of acupuncture for treatment of OA of the knee. We conducted a randomized, controlled trial with blinded evaluation and statistical analysis of results. It was carried out at the Rheumatology, Rehabilitation and Physical Medicine Department, Mansoura University Hospital, Egypt, over a period of two years. Sixty patients were randomly assigned and instructed to stop all treatment and only paracetamol was allowed for 2 weeks when patient followed weekly. Patients were divided into three groups each is of 20 patients; an intervention group treated with acupuncture plus manual needle stimulation (group I), second intervention group had electric stimulation (group II), and a control group given sham acupuncture (group III). Treatment were given twice weekly for 8 weeks, then stopped for another 5 weeks, when patients were followed on weekly basis. Our study results showed that patients in group I, II and III reported improvement of their pain, stiffness, and function domains of the WOMAC score, VAS and CI (clinical index) total. Regarding the safety of acupuncture for treatment of knee OA, we found that it is a safe and well tolerated modality with negligible adverse effects. We recommend that future studies in the area of pain and acupuncture must pay particular attention to; use of larger sample sizes, longer follow up periods to determine optimum maintenance regimes and treatment decay patterns.

Keywords: Acupuncture; Knee osteoarthritis

Abbreviations: OA: Osteoarthritis; CI: Clinical Index; VAS: Visual Analogue Scale; RCT: Randomized Control Trial ACR: American College of Rheumatology; ROM: Range-of-Motion Testing; WOMAC: Western Ontario and McMaster University OA Index; CNT: Clean Needle Technique; RA: Rheumatoid Arthritis

Introduction

Osteoarthritis of the knee is a major cause of pain and functional limitation worldwide, often treated by medical, physical, or surgical intervention [1]. There are many treatment options; there is no single definite effective treatment. In patients in whom standard medical practice is ineffective and who are not candidates for surgery (or who reject it), other pain management procedures, as acupuncture should be considered. The aim of our study was to determine the efficacy of acupuncture for treatment of OA of the knee.

Materials and Methods

This study is a prospective, three-Armed, randomized, control trial (RCT), conducted on 60 adult patients with knee OA to determine the efficacy of acupuncture for treatment of OA of the knee and its relation to clinical outcome measures of OA. Those patients were recruited from the outpatient clinic of Rheumatology and Rehabilitation Department at Mansoura University Hospital.

Two groups received verum (real) acupuncture either with manual manipulation (group I), or with electroacupuncture (group II), and the third sham (control) acupuncture (group III). Each group had 20 patients randomly assigned from the included patients.

Patients were included if they

- Agreed to participate in the study by written, informed consent [2]
- Fulfilled the American College of Rheumatology (ACR) criteria for knee OA [3]

Patients were excluded if they

- Had a history of drug abuse or non-compliance
- Had not sufficient skills to complete the assessment tools
- Had a severe or uncontrolled illness as terminal cancer, chronic heart failure, asthma requiring continuous oxygen treatment; diabetes
- Had positive pregnancy test
- Had history of gout or ra or been treated from either
- Had acupuncture before (must be acupuncture naïve)

- g) Had hip or ankle complaints
- h) Had local steroid injection into the knee within the past 4 weeks
- i) Had intra articular hyaluronidase within the past 6 months
- j) Had bleeding disorder or current use of anticoagulants or had
- k) Other causes of joint pains, including torn meniscus or ligament injury.

During follow up, patients were excluded if they

- a) Refused further participation
- b) Underwent a joint arthroplasty
- c) Had severe illness
- d) Died

Information sheet, and ethical and legal aspects

Patients received information leaflet about the study and signed the informed consent and were told that they can quit of the study at any time. Then the patient became formally enrolled in the study, receiving a unique study number.

At the baseline visit, patients were submitted to the following

Thorough history taking [4], with special concern to knee pains; clinical examination: which was carried out blind to subsequent treatment allocation & included general and local examination of the chest, heart, abdomen and CNS & local assessment of the knee joint (at base-line visit, 8th and 13th week of follow up) including:

- a) A careful inspection of the knee
- b) Palpation of the knee
- c) Assessment for joint effusion
- d) Range-of-motion testing (ROM)

- e) Evaluation of ligaments for any signs of injury or laxity
- f) Assessment of the menisci
- g) Assessment of pain by VAS (Visual Analogue Scale)
- h) Clinical index (CI) including (tenderness, swelling, effusion and ROM)
- i) WOMAC (Western Ontario and McMaster University OA) index

Acupuncture Treatment

A standard for verum acupuncture is defined to treat osteoarthritis. This treatment is based on recommendations for an optimized acupuncture treatment in clinical studies and based on the most distinguished German textbooks [5], as well as from International Studies [6,7]. Furthermore, the therapy was discussed with experts in the field of acupuncture. The most important and most cited local points in literature are chosen as obligatory points. Therefore the following local points [8] have to be used for every treatment on the affected knee: ST 34, ST 36, Xiyan (including 2 needles), SP9, SP 10 and GB 34, (Figure 1) [8]. Points of this combination can be omitted only in exceptional cases with documentation, e.g. needling was not tolerated, inflammation or skin injury covering the acupuncture point [9]. The most important distant points to treat knee pain were used (Figure 2) [8], two distant points bilaterally (four needles) are used, namely; LI 4, and SP6. In every treatment, the knee and adjoining musculature are examined for further, pressure-sensitive points (Ahshi Points), in addition to the obligatory points, one to four of these Ahshi points per knee may also be treated with acupuncture [9]. For electroacupuncture, an electrical stimulation using a battery-operated, four channel electro stimulator (ITO, Japan), with low frequency, square-wave pulses of 1ms duration. Needles were attached to the apparatus in the following pairs; Xiyan points, SP9 and ST36. The electrical stimulation was delivered at 6Hz for 20 minutes, at intensity just below the pain threshold [9]. Treatment was performed with sterilized disposable steel needles, 30×0.3 mm.

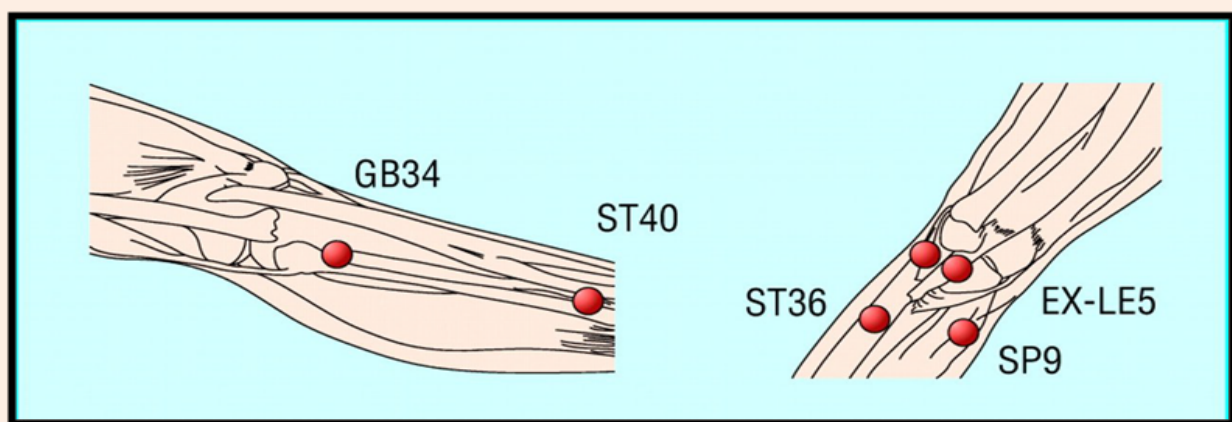


Figure 1: Local Points of prescription for Treatment of knee OA (quoted from Cobos & Vas 2000).

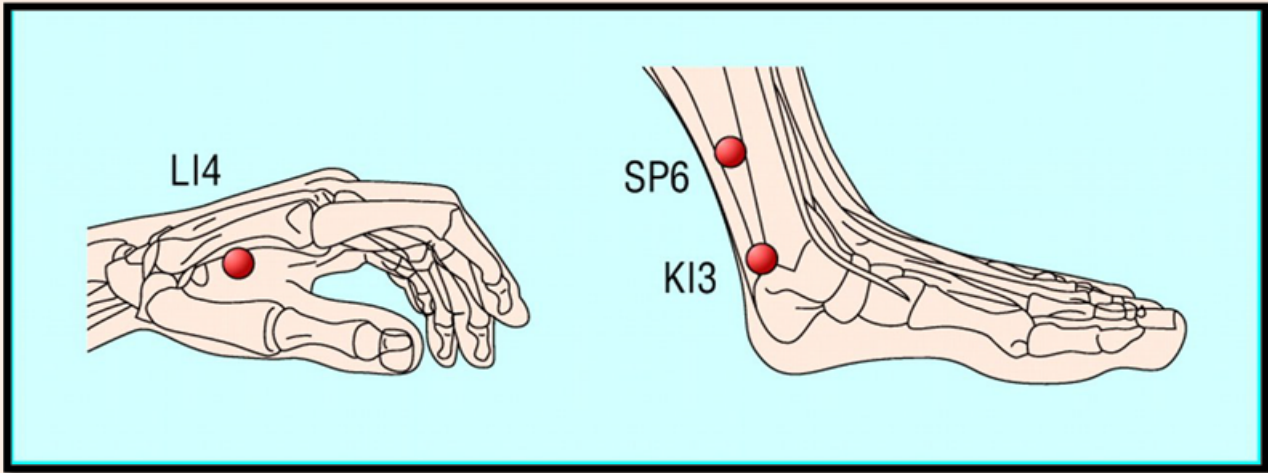


Figure 2: Remote Points of prescription for Treatment of knee OA (quoted from Cobos & Vas 2000).

The depth of needling was about 0.5 - 3.5 cm according to the localization of points. After needle insertion Qi has been tried to trigger in the verum group, followed by a manual stimulation of the needle, which has to be repeated twice (group 1), and electro

acupuncture (group 2), the electrical stimulation was delivered at 6Hz for 20-30 minutes, at an intensity just below the pain threshold [4] (Table 1).

Table 1: Demographic characteristics of the studied groups.

		Group I	Group II	Group III	One way ANOVA	
					F	P
Age (Years)	Range	36.0-61.0	38.0-60.0	36.0-59.0	0.12	0.89
	Mean± SD	46.9 ±7.65	46.0±6.8	46.9±6.1		
Disease Duration(- Years)	Range	1.0-15.0	3.0-16.0	2.0-10.0	0.18	0.84
	Mean± SD	6.75±4.0	6.15±3.57	6.3±2.15		
BMI Kg/m ²	Range	21.0-42.0	21.-44.0	24.0-42.0	1.11	0.37
	Mean± SD	31.2±6.2	29.2±5.7	31.75±5.07		
					Chi- Square test	
					X ²	P
Sex	♂	3	4	3	0.24	0.89
	♀	17	16	17		

BMI: Body Mass Index; SD: Standard Deviation P value ≤0.05

Control Intervention

The treatment with sham acupuncture is standardized too [10]. Aiming to trigger only a minimal unspecific physiological stimulus, sham acupuncture was applied with a minimal depth of needling (not exceeding 5 mm), avoiding real acupoints. A manual stimulation of needles was not allowed.

Schedule of Interventions

Patients randomized to one of the 3 acupuncture arms to get 16 acupuncture treatments within the 8 weeks on biweekly basis with duration of needling of 20-30 minutes.

Outcome Measures & Endpoints

If only one knee of the patient was afflicted, the assessment of the WOMAC related to this knee. If the patient had two afflicted knees, of which only one meets the ACR-criteria, only this knee was considered. In case that both knees were afflicted in accordance to inclusion criteria, one knee was randomly chosen and assigned for the score [11].

Response to treatment was defined as a change at week 8 and week 13 of the study from base-line scores of

- a. The pain assessed by 10-cm VAS

- b. The WOMAC index and
- c. The clinical index parameters

Practitioner Background

The background of acupuncture practitioners influences the nature of the acupuncture treatment given and is therefore a variable that may significantly affect the outcome. For this study the investigator is a registered physician for more than 20 years with MD degree in physical medicine and had duration of relevant documented training of more than 1000 practical training hours in Beijing & Shanxi TCM college, China, followed by acupuncture clinical experience for more than 10 years mostly in governmental hospitals, in rheumatology and physical medicine departments treating all types of arthritis either with western or oriental medicine.

Safety Evaluation

An approach to clean needle technique (CNT) [12] is based on medical protocols for giving injections. It includes the following basic elements:

- a) Sterile disposable needles only
- b) Sterile cotton swabs
- c) Clean hands
- d) Clean field
- e) Surgical, non-latex gloves
- f) Needle disposal container in treatment room

Statistical Analysis

All analyses were completed using SPSS for Windows, version 10. Missing values from patients who dropped out were substituted by base-line data carried forward [13]. Odd results were eliminated from the study. Repeated measures analyses were used to examine mean differences in outcome scores for VAS and WOMAC between baseline and subsequent assessment times at 8 and 13 weeks. Intergroups comparisons of the changes in score from baseline were carried out using ANOVA (analysis of variance) (Table 2).

Table 2: Intergroups comparisons of WOMAC & VAS at base-line, 8 and 13 weeks.

		Group I	Group II	Group III	One Way ANOVA	
					F	P
WOMAC Pain	Base line	68.75±16.88	63.25± 15.49	75.25± 13.9	3.34	0.092
	8 Wks	57.25±17.20	49.00±13.63	70.25±9.52	12.02	0.0001
	13 Wks	59.75±15.34	50.25±12.08	73.25±8.77	17.48	0.0001
WOMAC Stiffness	Base line	67.62±26.36	53.75±23.12	54.37±26.05	2.28	0.11
	8 Wks	48.67±25.50	23.60±24.81	47.87±21.41	4.57	0.014
	13 Wks	51.82±21.57	24.05±20.04	51.87±18.26	9.69	0.0001
WOMAC Function	Base line	60.05±18.85	53.4±17.08	62.45±18.73	1.32	0.27
	8 Wks	51.50±18.38	38.60±12.23	53.70±16.43	8.20	0.001
	13 Wks	52.20±18.24	41.20±12.91	66.45±16.61	10.46	0.0001
WOMAC Total(%)	Base line	67±20.02	59±12.12	66±16.66	4.43	0.08
	8 Wks	52±12.56	39±16.02	60±13.23	6.08	0.004
	13 Wks	56±13.6	40±11.43	66±14.4	4.09	0.022
VAS	Base line	7.45±1.84	6.35±2.2	7.81±1.88	3.86	0.067
	8 Wks	6.300±1.559	4.90±1.29	7.35±1.34	15.30	0.0001
	13 Wks	6.300±1.380	4.65±1.13	7.65±1.18	29.47	0.0001

VAS: Visual Analogue Scale; Wks: Weeks; WOMAC: Western Ontario and McMaster University OA Index; ANOVA: Analysis Of Variance; SD: Standard Deviation *P value* ≤0.05

Evaluating the Quality of the Trials

We judged the adequacy of sample size using guidelines developed by Bellamy and colleagues for the number of participants needed to detect clinically meaningful and statistically significant differences, for frequently used outcomes (as VAS & WOMAC) performed in a standardized manner in osteoarthritis trials [14].

Results and Discussion

Patients were classified as having responded to treatment or relapsed by an independent observer, blinded to the treatment group and results, according to the change at week 8 and week 13 of the study from base-line scores of

- a. The pain assessed by 10-cm VAS

- b. The WOMAC index
c. The clinical index parameters.

There were drop out of cases at follow up at 8 week, as follow; 2 patients in group I and 3 patients in group III, and more 2, 1, 4, patients in groups I, II, and III respectively, at week 13 of follow up.

Out of 20 in each group there were 17, 16 and 17 female

patients in groups I, II and III i.e., 85, 80, &85% respectively. The mean ages of our patients were 46.900 ± 7.649 , 45.950 ± 6.824 and 46.850 ± 6.080 years, respectively with no significant differences among groups. Taking into account the duration of the study (13 weeks), we recorded patients' body mass index at the beginning and the end of the study, to evaluate the possible confounding effect of weight loss or gain. We found no significant differences in, or among the groups at base-line and follow up (Table 3).

Table 3: Intergroups Comparison of Clinical Index Parameters at Base-Line, 8, And 13 Weeks.

			Group I	Group II	Group III	Chi square test	
						X ²	P
Clinical Index	Tenderness	Base-line	1.350±0.670	0.850±0.670	1.050±0.887	2.25	0.11
		8 wks	1.050±0.686	0.550±0.759	0.850±0.670	2.53	0.088
		13 wks	1.550±0.686	0.900±0.788	1.250±0.786	3.71	0.03
	Effusion	Base-line	1.450±0.686	1.000±0.794	1.900±0.967	14.11	0.001
		8 wks	1.300±1.031	0.850±0.988	1.550±0.759	2.00	0.14
		13 wks	1.650±0.670	0.750±0.638	1.350±0.745	6.08	0.004
	Swelling	Base-line	1.900±1.071	0.850±1.136	0.510±0.827	10.19	0.001
		8 wks	0.400±0.598	0.150±0.366	0.490±0.827	1.65	0.20
		13 wks	0.400±0.502	0.5±0.223	0.500±0.753	2.81	0.068
	ROM	Base-line	2.100±1.518	1.900±1.889	2.400±1.535	0.46	0.63
		8 wks	1.400±1.142	1.100±1.372	2.200±1.436	3.69	0.03
		13 wks	1.600±1.046	0.800±1.372	2.400±1.535	7.23	0.002
	Total	Base line	5.800±2.627	4.450±2.818	5.850±2.758	1.68	0.19
		8 wks	4.150±2.254	2.500±2.236	5.100±2.337	5.15	0.009
		13 wks	5.200±1.935	2.800±2.238	5.400±2.370	8.86	0.0001

ROM: Range of Motion; Wks: Weeks. *P value* ≤0.05

The role of acupuncture in osteoarthritis of the knee was a matter of controversy, and some comparative studies of acupuncture and NSAIDs for its treatment have been conducted. A systematic review concluded that a moderate degree of evidence exists that the effect of the acupuncture treatment could be due to the placebo, so further studies are therefore necessary to determine the true role of acupuncture¹⁵. Searching data-base on the world wide web on the internet on the medical database sites and search-engines, mainly on the most popular medical web-sites as pub med site (<http://www.ncbi.nlm.nih.gov/PubMed>) under the key words ACUPUNCTURE+KNEE+OSTEOARTHRITIS revealed many published articles in the world's leading health journals, in all languages, some of them were on humans, the majority were published in English, while other languages included Chinese, German, Japanese, Korean, etc., [15,16].

There is some disagreement among the systematic reviews about the study design of some of the studies. the control of co-interventions, the lack of control over participants' compliance with medical instructions, and the "blinding" of patients and evaluators; and the heterogeneity of follow up periods was also

high [17]. Other methodological problems in some of the studies included heterogeneous samples, infrequent therapy sessions, no formal test statistics, groups not equal at entry and essential details missing [18].

We conducted a randomized, controlled trial with blinded evaluation and statistical analysis of results. It was carried out at the Rheumatology, Rehabilitation and Physical Medicine Department, Mansoura University Hospital, Egypt, over a period of two years on 60 patients divided into three groups each is of 20 patients,

- First group treated with acupuncture plus manual needle stimulation
- Second group treated with acupuncture plus electric stimulation and
- Third control group given sham acupuncture

Assessments were done at baseline (i.e., prior to acupuncture treatment) and weeks 8, and 13 including the VAS, and the WOMAC index (containing separate subscores for pain, stiffness

and disability). In addition, the target knee joint was assessed for clinical index (the presence of a joint tenderness, swelling, effusion and the range of movement).

The mean ages for groups I, II and III was 46.9 ± 7.6 , 45.95 ± 6.8 and 46.9 ± 6.1 years respectively, similar results were obtained by [1-4] study, the age range was from 62-83 years simply because their inclusion criteria included age group above 60 years. Also it was found the mean age for the patients in their study is 64.5 ± 11.5 years which is higher than our results [19], most probably because of other risk and predisposing factors in our patients such as majority of cases were females with high BMI (our patients' BMI range was 21-44 kg/m² and the mean was around 30 kg/m² while in Linde et al. [19] study; range was 20-32 kg/m² and the mean was around 26 kg/m²).

From the last item i.e., the BMI, our results for BMI were ranging from 21-44 with mean around 30 kg/m², that also was the case in the results of BMI in many other knee OA studies [1-3] raising the fact of positive association between the obesity and knee OA, not exactly in other [19] study as mentioned.

We followed up our patients for 13 weeks. Many previous acupuncture studies on knee OA did not specify a follow up periods, but others did for periods of: 4 months, 49 weeks, 3 months, 3 weeks, 12 weeks, 12 weeks, 6 months, 9 weeks & 29 weeks [2,5,7,20].

In our study the ACR diagnosis with were the diagnosis and the inclusion base for the patients, and not the Chinese diagnosis. That agreed with almost all the published studies on the same topic as all used the western diagnosis [20].

None of the previous investigators had used the Chinese way to diagnose the patients or what is known as TCM, but all used the western diagnosis based on the ACR diagnosis as inclusion criteria for selection of patients of knee OA [10], and namely the clinical & radiological domains, only one study [21] had used the clinical domain only of ACR criteria for selecting patients.

Regarding the disease duration, the mean of our results was around 6 years for the 3 groups that was the case in a study [22] carried out on the patients' duration of disease mean was 6 years as well. In other study [23] the mean was 10 years (somewhat higher than our results), most probably because the age group was older than ours (mean age was around 60 years while in our patients was around 46 years).

Our study results demonstrated that although patients in group I, II and III reported improvement of their pain either assessed by pain domain of WOMAC or VAS both at 8 and 13 weeks of the study but there were intergroup differences in favor of true either manual or electrical stimulated compared to sham acupuncture at 8 and 13 weeks (WOMAC $P=0.015$, & 0.0001 , and VAS $P=0.058NS$, & 0.0001 respectively).

These results are in agreement with the results of the some other studies [1-8] as they found that treatment group had significant reduction in pain by VAS and analgesic use compared to no treatment group ($p<0.01$) after 6 sessions in 3 weeks, their patients were all initially waiting for arthroplasty; 7 out of 29

patients no longer wanted surgery after acupuncture treatment (at a total estimated saving of \$60,000. Also these results are in agreement with the results [8] that used acupuncture treatment and standard care (as control) and found significant improvement in patients' pains for acupuncture group compared to control at 4 and 8 weeks (WOMAC for pain intergroup difference $P<0.001$). Others [7,22] had similar results. It was demonstrated⁶ that a clear effect of true and sham acupuncture compared to usual care, 73% of patients included in the study showed at least 33% improvement in pain after acupuncture treatment, though groups didn't differ significantly. In other study [24], they found no benefit for acupuncture compared to sham, but they suggest that sham acupuncture may have pain relieving effects and that this may explain the relative equivalence of acupuncture compared to sham acupuncture. They concluded that there is moderately strong evidence supporting adjunctive use of acupuncture.

In our study stiffness and function domains of the WOMAC were improved at 8th & 13th weeks from base-line, this improvement was significantly different among groups as significant differences between group I and II were noticed at week 8 for function WOMAC domain (at 8 week) and stiffness WOMAC domain (at 13 week) that in favor of electroacupuncture, while there were significant differences between either group I and II from one side, and group III (sham) from the other side, i.e., real acupuncture in the 2 treatment groups was more effective than sham group ($P=0.014$ & 0.001 , at week 8, respectively) & ($P=0.0001$ & 0.0001 , at week 13, respectively).

Results agreed with ours were [6,25] found that there were intergroup difference between the true acupuncture and the waiting list ($P<0.01$) in improving the stiffness and function. as well as found in a study⁵ in 2001 compared acupuncture to waiting for treatment and found benefit for acupuncture compared to the control in the 3 domains of the WOMAC. Some authors had more significant results after cessation of treatment as the case in our study, and in 2008 in an interesting explanation [23] for the more significant difference after cessation of treatment as it might be due to deterioration in the sham group rather than change in the acupuncture group. Also in a meta-analyses [26] also concluded that acupuncture was not better than controls in reducing the WOMAC score of knee OA. Others [18] concluded in disagreement to our study that acupuncture is not superior to sham-needling in reducing stiffness of osteoarthritis; both are equally effective. He suggested that sham-needling had similar specific effects as acupuncture or both methods were associated with considerable non-specific effects. Another disagreement is a meta-analysis [27] who reviewed 11 trials for 3 types of control groups; compared with patients in waiting list control groups, patients who received acupuncture reported clinically relevant short-term improvements in pain and function, while patients who received acupuncture reported clinically relevant short-term and long-term improvements in pain and function compared with patients in usual care control groups, and compared with a sham control acupuncture provided either clinically irrelevant short-term or clinically irrelevant long-term improvements in pain and function some of which may be due to placebo or expectation effects. These all disagreeing results showed that though true acupuncture

group improved but that improvement was not different to sham acupuncture group (i.e., sham acupuncture showed positive effects), intergroup differences, the sham acupuncture was at sites one inch adjacent to the real points, which the authors note may have inadvertently elicited an analgesic response. Other methodological problems in some of the studies included lack of blinding of patients and outcomes assessors and lack of description of dropouts and withdrawals. Unfortunately, needling at sham locations can have analgesic effects almost as large as at "true" locations. As a result of this problem, effects of true and sham become too close, requiring large subject numbers to show a significant difference as generally acupuncture studies do not have a large number of subjects. There is evidence that acupuncture needles placed in non acupuncture points lead to pain reduction because of stimulation of endorphin release via a mechanism called diffuse noxious inhibitory control [20]. Possible explanations of some benefits of sham acupuncture are:

- I. Extensive sham effects as in Japanese acupuncture technique [20].
- II. Missing of (non acupoint) to real acupoint [6].
- III. Percutaneous like therapy effects of electroacupuncture [6].

For the CI parameters we found at 8 week that, the CI total was significantly different from base line ($P=0.009$) and there was intergroups difference as well, then all parameters kept statically improved and were significantly different at 13 week including the CI total ($P=0.0001$) except for the swelling.

Agreement of our results was obtained in a somewhat a study [6] who attempted to treat knee with effusion using acupuncture. In the study, 50 people with the condition were treated using needle insertion and manipulated every 5-10 minutes and retained for 30 minutes, 30 patients were deemed to be cured, which was defined as a disappearance of swelling and pain in the knee joint, a resumption of free movement and range of motion, and no recurrence of the condition in more than six months. Treatment was "markedly effective" in another 18 patients; slight improvement was seen in the remaining two patients. The authors surmised that acupuncture treatment "may produce a quite satisfactory treatment in a relatively short duration. Others [8] agreed that, acupuncture is effective for improving knee function such as ROM. They explained that as it is possible that acupuncture affects tension and blood flow in the muscle.

Comparing electro- to manually stimulated acupuncture we found that group I and II were statistically different regarding WOMAC function at 8 week and WOMAC stiffness, CI total and the VAS at 13 week of the study. Our results as they found that electroacupuncture significantly reduced pain, stiffness and physical disability compared to baseline. Also Berman et al. [6] found same results and he referred it to the percutaneous like therapy effects of electroacupuncture [6]. Electroacupuncture was also significantly more effective than placebo and diclofenac in the symptomatic treatment of OA of the knee in a study [21] in 2002. However, they also found that combination of electroacupuncture and diclofenac was no more effective than electroacupuncture treatment alone. This agrees with Tukmachi et al. [20] who concluded that electroacupuncture causes a significant

improvement in the symptoms of osteoarthritis of the knee, either on its own or as an adjunct therapy, with no loss of benefit after one month [20]. Also others [23] disagreed the superiority of electroacupuncture as both manual and electrical acupuncture were almost equally and compared to sham significantly better in reducing pain and improving function of OA patients.

Our results also showed decay in the improvement of all parameters (WOMAC, VAS, & CI) at 13 weeks of the study i.e., 5 weeks after cessation of acupuncture therapy, though true acupuncture groups results were still improved compared to base-line and were still significantly better than sham acupuncture group ($P=0.0001$).

Some authors [28] agreed with our results as their results suggest that treatment with acupuncture sustains the effectiveness in pain reduction. They noticed sustained pain reduction 4 months after an initial 6-week treatment regimen was discontinued. This agrees also with results [20] that concluded that acupuncture causes a significant improvement in the symptoms of osteoarthritis of the knee, with no loss of benefit after one month. Other authors [23] disagreed and stated that benefits from acupuncture were limited to pain intensity not any other parameters such as stiffness and function, and these benefits were unlikely to be clinically significant, were mostly short lived, and could not be attributed to needling effects & found that one month after treatment the between group pain difference had been lost although they stated that the acupuncture group was still benefiting compared to baseline, they suggested that the significant difference that could be found between true and sham acupuncture after cessation of treatment might be due to deterioration in the sham group rather than maintaining improvement in the true acupuncture group [29].

Secondary endpoint was the percentage of cases that had achieved of at least 20% of improvement in pain domain of WOMAC and either 20% of improvement in the function or the stiffness at end of study from base-line, our patients showed that 5 case of group I (25%), while 9 cases in group II (45%) and no case (0%) in group III had fulfilled this end-point, and there was statistical difference between the groups in favor of group II ($P=0.009$).

In agreement for the true acupuncture results but not the shame one Berman et al. [6] compared arthritis education alone to true and sham acupuncture in 570 patients with osteoarthritis of the knee. Acupuncture led to greater improvements in function but not pain after 8 weeks and in both pain and function after 26 weeks (secondary end-point). The proportion of participants who were classified as responders at 26 weeks was 98 of 186 (52%) in the true acupuncture group, 86 of 183 (47%) in the sham group and 52 of 174 (30%) in the education group. These between-group differences were not significant for the true versus sham comparison, but the proportion of responders was significantly greater ($P= 0.001$) in both the true and sham acupuncture groups than in the education control group. The added (under title "caution") that many participants dropped out of the study, so readers should interpret the findings at 26 weeks with caution [6].

Conclusion

The aim of our study was to determine the efficacy of acupuncture for treatment of OA of the knee and its relation to some clinical outcome measures of OA. We conducted a randomized, controlled trial with blinded evaluation and statistical analysis of results. Our results demonstrated that the base-line data of the 3 study groups were statistically matched regarding demographic; age, sex, BMI, disease duration, and clinical findings.

Our study results also showed that patients in group I, II and III reported improvement of their pain, stiffness, and function domains of the WOMAC score, VAS and CI (clinical index) total. This improvement was significantly different among groups that difference was in favor of true acupuncture groups of patients (with some benefits of electroacupuncture group over manual acupuncture group). While sham group showed some improvement especially regarding pain but almost all were insignificant. All these results showed decay at end of the study (week 13) but the true acupuncture groups' results were still better than base-line ones. In brief we concluded that; On basis of the work presented, there is strong evidence on clinical bases that acupuncture is effective in reducing pains and improving function in patients suffering from knee osteoarthritis.

- a) Though manually stimulated needles are effective but coupling.
- b) Electrical stimulation to acupuncture improves the result of this treatment.
- c) Sham acupuncture group of patients showed some clinical improvement but that was an insignificant effect as there was intergroup difference not in favor of sham group.
- d) The improvement obtained by acupuncture showed decline at week 13 of the study, though the results were still better than before treatment, indicating persistence of effect after stopping the treatment.

We may recommend that future studies in the area of pain and acupuncture must pay particular attention to; Use of larger sample sizes, longer follow up periods to determine optimum maintenance regimes and treatment decay patterns. Exploration of underlying mechanisms of action involved in acupuncture treatment, in terms of neurophysiology, neurobiochemistry, endocrinology and immunology. Comparing acupuncture with other modalities used for treating knee OA, such as drugs and physical modalities to omit the dilemma of sham acupuncture.

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