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Effects of acupuncture and sham acupuncture in addition to physiotherapy in patients undergoing bilateral total knee arthroplasty – a randomized controlled trial

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Objective: To compare the acute effects of acupuncture with sham acupuncture on knee pain, range of motion and ambulation in patients with knee osteoarthritis undergoing bilateral total knee arthroplasty, when added to a standard postoperative physiotherapy programme.
Design: Prospective patient- and assessor-blinded randomized controlled trial.
Setting: Acute inpatient physiotherapy department.
Patients: Thirty patients (24 women and 6 men) undergoing bilateral total knee arthroplasty were included for final analysis in the study.
Interventions: Both groups received a standard postoperative physiotherapy programme. Each patient was also given either 10 sessions of acupuncture or sham acupuncture within two weeks.
Main outcome measures: The primary outcome measures were the levels of pain at rest and at maximum after exercise measured by the numeric pain rating scale. Other outcome measures included active and passive ranges of knee motion measured by standard goniometer, and ambulation measured by the timed up-and-go test.
Results: Thirty-six patients were recruited at the start of the study with 18 patients allocated to the acupuncture group and another 18 patients to the sham acupuncture group. On postoperative day 15, there were 30 patients with complete data; three patients in each group dropped out from the study. The mean differences (95% confidence interval (CI)) in overall averages of postoperative mean pain levels were 0.4 (–0.6 to 1.3) and –0.8 (–2.0 to 0.4) at rest and at maximum respectively. There were no significant differences in the active and passive ranges of knee motion and the time for the timed up-and-go test between the two groups.
Conclusion: There is no difference between the acute effects of acupuncture and sham acupuncture in addition to standard postoperative physiotherapy programme in patients with knee osteoarthritis undergoing bilateral total knee arthroplasty.

Introduction

Knee osteoarthritis is a common condition in elderly people. The prevalence rates of knee osteoarthritis with severe radiographic changes range from 1% in people aged 25–34 to 30% in

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those aged 75 and above.[1] Various non-operative treatments[2] are available for knee osteoarthritis but currently there is no cure.[3] With disease progression, some patients may develop severe pain and major limitations in ambulation. In these severe cases, total knee arthroplasty may be recommended. Postoperatively, patients undergoing total knee arthroplasty would experience significant pain and swelling,[4] which can affect their compliance to exercise programmes and limit their progression in range of knee motion and ambulatory status. It is reported that up to 44% of patients undergoing total knee arthroplasty had a pain score on a visual analogue scale greater than 40 out of 100 at one month post operation.[5]

Acupuncture has been used to treat knee osteoarthritis with some evidence of effectiveness.[6] Based on the perspective of western medical acupuncture,[7] acupuncture is considered and used as a kind of sensory stimulation. The analgesic effect of acupuncture can be explained by the use of needle stimulation to small-diameter nerve fibres and activation at spinal level and higher brain centres to release endogenous opioids and neurotransmitters.[8] However, there is a paucity of information of the use of acupuncture in treating patients with knee osteoarthritis after undergoing total knee arthroplasty.[9]

The aim of this study was to examine the acute effects of acupuncture compared with sham acupuncture, in addition to a standard postoperative physiotherapy programme, with respect to pain relief, knee ranges of motion and ambulation in patients with knee osteoarthritis undergoing bilateral total knee arthroplasty.

Method

Subjects

Patients had to meet the following inclusion criteria: (1) being diagnosed with bilateral primary knee osteoarthritis and having undergone bilateral total knee arthroplasty in the orthopaedic wards of the Queen Mary Hospital; (2) being able to complete daily postoperative physiotherapy programme for 10 sessions within two weeks; and (3) being aged 60 years or above. Patients were excluded if any of the following exclusion criteria were present: inability to give consent; postoperative complications such as unstable haemodynamics and deep vein thrombosis; history of neoplasm or stroke or having associated rheumatological conditions or psychiatric disorders; deranged clotting profiles or currently taking anticoagulants; skin diseases; unstable cardiac conditions; sensory deficit at lower limb; fear of acupuncture; and previous experience with acupuncture. Approval by the Ethics Committee of the Queen Mary Hospital was obtained and all patients who participated in the study gave informed consent.

Study design

The study was a patient-blinded and assessor-blinded randomized controlled trial with two groups: the acupuncture group received a standard physiotherapy programme and acupuncture, and the sham acupuncture group received a standard physiotherapy programme and sham acupuncture. The standard physiotherapy programme is described in the Appendix. Block randomization was used to randomly allocate patients to the acupuncture group or the sham acupuncture group using blocks of four[10] by the first author (RCCT). Allocation concealment was maintained using opaque sealed envelopes. Three physiotherapists (PLT, CYK and HTY) who held a diploma in acupuncture and had 2–3 years of experience in acupuncture were responsible for applying the acupuncture or sham acupuncture to the patients. They were only aware which group each patient was assigned to when they opened the envelope during the intervention. These three physiotherapists did not participate in the provision of the standard physiotherapy programme and subsequent outcome evaluation of the patients.

Acupuncture interventions

All patients received acupuncture or sham acupuncture to both legs as allocated on postoperative day 4 after the patient control analgesia was removed. In the acupuncture group, the following acupoints were selected as recommended

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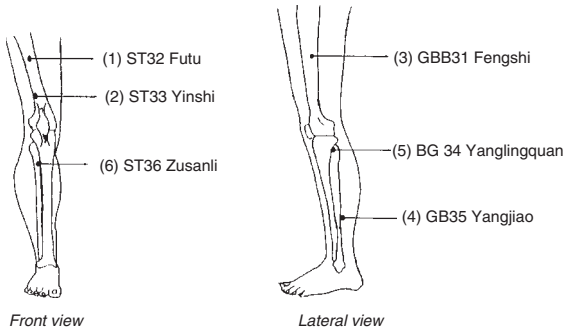

Figure 1 Location of selected acupuncture points.

from the textbooks[11,12] and positive trials for treating osteoarthritis knee pain[13,14]: ST32 (Futu), ST33 (Yinshi), GB31 (Fengshi), GB35 (Yangjiao), GB34 (Yanglingquan) and ST36 (Zusanli) (Figure 1). The four commonly used acupoints ST35 (Dubi), Xiyan (extra point), SP10 (Xuehai) and ST34 (Liangqiu) for treating knee osteoarthritis were not chosen because of potential risk of introducing infection into the knee joint. The acupuncture needles (sterile, single-use, size 0.3×40 mm, manufactured in China) were inserted to a depth of 13–25 mm, and manipulated until the patient had the feeling of numbness, tingling or heaviness for both knees. The needles were left for 20 minutes and the manipulation of needles to achieve the feeling of numbness was repeated every 5 minutes. In the sham acupuncture group, the needles were inserted less than 5 mm superficially and about 2 cm away from the same acupoints selected as in the acupuncture group. No manipulation of the needles was given and no feeling of numbness, tingling or heaviness was asked about and elicited in the sham acupuncture group.

Before the trial started, the three physiotherapists who were responsible for applying the acupuncture had a session of revision of the acupuncture points and their application to achieve standardization. No electrostimulation was given to the needles in either group to avoid the potential risk of concentration of currents in the metal prosthesis inside the knee joint.

Outcome measures

The Chinese version of an 11-point numeric pain rating scale[15] was used to measure the average pain level of patients of both legs at rest before the start of acupuncture and the exercise programme (pain at rest) and that was maximally experienced during exercise (pain at maximum). The Chinese numeric pain rating scale had excellent test–retest reliability (ICC = 0.92, 95% confidence interval (CI) 0.86 to 0.95).[15] Active and passive ranges of motion of both knees were measured using a standard goniometer. The ambulation status was assessed by the timed up-and-go test.[16]

Sample size estimation

The primary outcomes were the average pain levels of both legs experienced by patients measured at rest and at maximum. The minimum clinically important difference in pain level was set to 2.0 between the two groups, with a hypothesized standard deviation of 2.0. The estimated sample size was about 16 patients in each group, with the level of significance set at 0.05 and a statistical power of 80%, based on calculations using the independent *t*-test.

Data collection

The pain level was assessed preoperatively, on postoperative days 4–8 and postoperative days 11–15. Active and passive ranges of motion of both knees were measured preoperatively, on postoperative days 4, 8 and 15. The daily number of analgesic tablets (Dologesic 500 mg or diclofenac SR 100 mg) taken by each patient was recorded from the day of operation to postoperative day 15. Demographic data including age, sex and body mass index of patients were collected. All outcome assessments were performed by another two physiotherapists (BCHK and WYL) who were blinded to the group status of the patients.

Data analysis

Baseline comparisons of the two groups with reference to demographics, preoperative pain level at rest and at maximum, active and passive

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ranges of knee motion, timed up-and-go test and postoperative consumption of analgesic tablets were performed using independent *t*-test or Fisher exact test among completers. Only the descriptive statistics were presented for drop-outs and statistical comparisons were not performed as recommended.[17] The overall averages of the mean pain level at rest and mean pain level at maximum of both knees from postoperative day 4 to day 15 were computed as summary measures[18] for comparison among completers between the two groups using independent *t*-test. Repeated-measures analyses of variance were performed for postoperative active and passive ranges of knee motion, and the timed up-and-go test. Baseline score of the timed up-and-go test was used as the covariate for the repeated-measure analysis of variance as it was observed that there was significant difference in the preoperative timed up-and-go test scores among completers between the two groups. The level of significance for all statistical tests was set at 0.05. All statistical tests were performed using SPSS 11.5 (Chicago, IL, USA). All the data were analysed according to the principle of intention-to-treat.

Results

Patients were recruited from October 2001 to October 2004. A total of 60 patients were screened and 36 patients were enrolled with informed consent obtained. Figure 2 shows the flow of patients through the trial. There were 30 patients with complete data for analysis at postoperative day 15, with three drop-outs in each group. Among these 30 patients, 15 patients were randomized to the acupuncture group and 15 were randomized to the sham acupuncture group.

Table 1 lists the baseline data of the completers and drop-outs of the two groups. There were no significant differences in the demographic and clinical characteristics among the completers between the two groups except the performance in preoperative timed up-and-go test.

Table 2 and Figure 3 show the mean pain scores of both legs from postoperative day 4 to 15. The overall averages of the postoperative mean pain scores and analgesics consumption are shown in Table 3. The overall averages (SD) of mean pain scores were 2.2 (1.4) and 2.6 (1.2) at rest, and 6.5 (1.5) and 5.7 (1.7) at maximum from postoperative day 4 to 15 in the acupuncture group and sham acupuncture group respectively. The mean differences in the overall averages of mean pain scores were 0.4 (95% CI −0.6 to 1.3) at rest and −0.8 (95% CI −2.0 to 0.4) at maximum between the two groups. No significant differences in overall averages of mean pain scores at rest ($P = 0.463$) and at maximum ($P = 0.177$) were found. The mean number of analgesic tablets consumed (SD) was 28.3 (11.6) and 24.7 (13.8) for the acupuncture group and sham acupuncture group, respectively. There was no significant difference in the analgesic consumptions between the two groups ($P = 0.447$).

The mean postoperative active and passive ranges of motion of both knees from postoperative day 4 to days 8 and 15 are shown in Table 4. The results of repeated-measures analysis of variance for the postoperative active and passive ranges of motion of both knees, and the timed up-and-go test did not show any significant interaction effect (*P*-values ranging from 0.098 to 0.930). There were significant changes in the active and passive ranges of motion of both knees from postoperative day 4 to day 15 ($P < 0.001$).

The mean (SD) scores of timed up-and-go test of the acupuncture group and sham acupuncture group were 78.4 seconds (30.7 seconds) and 67.5 seconds (48.8 seconds) on postoperative day 8, and 45.8 seconds (31.1 seconds) and 39.8 seconds (33.4 seconds) on postoperative day 15 respectively.

No significant change was found in the timed up-and-go test from postoperative day 8 to day 15 ($P = 0.152$). There were no significant differences in the postoperative active and passive ranges of motion of both knees and the timed up-and-go scores between the acupuncture group and sham acupuncture group (*P*-values ranging from 0.213 to 0.990).

Discussion

The results of the present study suggested that acupuncture was no better than sham acupuncture in pain relief, improvement of ranges of knee motion and ambulation in patients with knee

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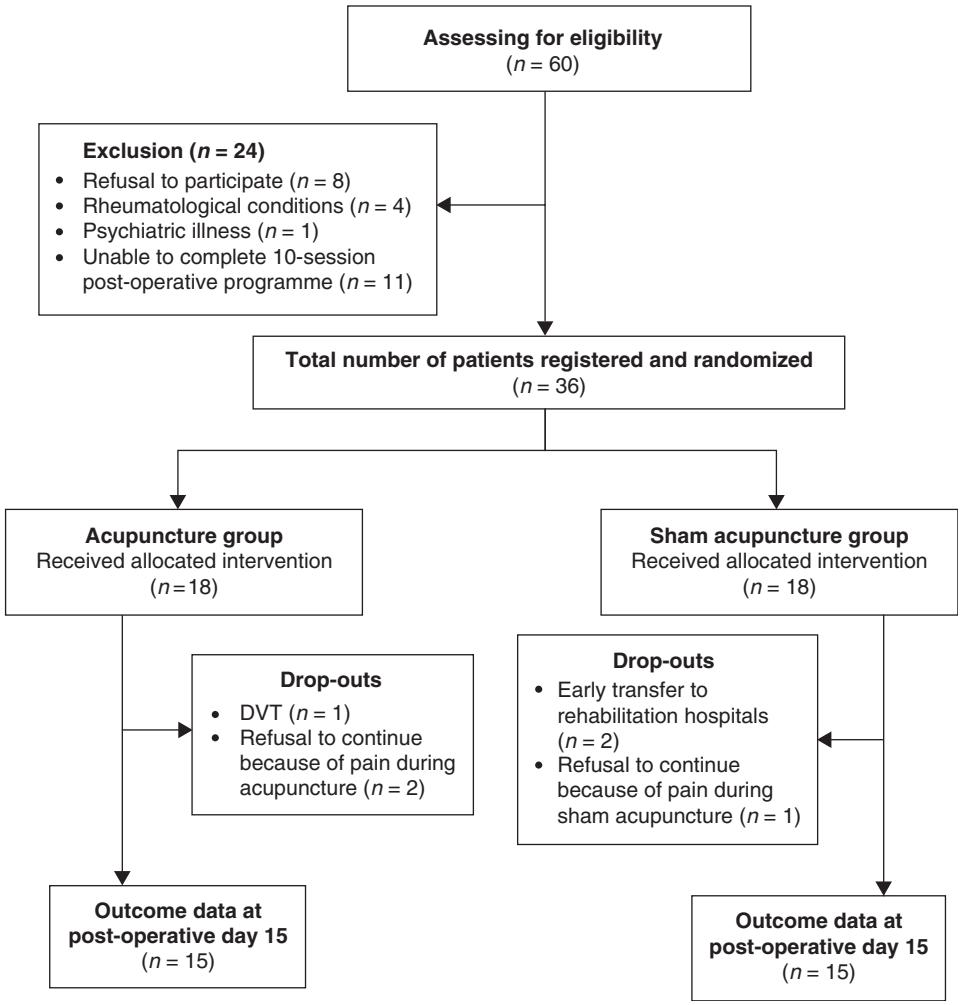

Figure 2 Flow of patients through the trial.

osteoarthritis undergoing bilateral total knee arthroplasty in the first two weeks after surgery. From the literature search, there is only one abstract of a randomized controlled trial reporting the effect of acupuncture on pain, stiffness and functional status of patients following total knee arthroplasty at six weeks after surgery in 2004.[9] The results of that study suggest that the inclusion of acupuncture as an adjunct to rehabilitation of patients with total knee arthroplasty may be of little benefit. In our study, the focus was on the acute effects of acupuncture in reducing pain in patients with bilateral total knee arthroplasty with the aim of achieving better compliance with a postoperative rehabilitation programme in the immediate postoperative period.

In the present study, the acupoints were chosen according to recommendations from the acupuncture textbooks to treat pain in the knee areas and from positive clinical trials of acupuncture to treat pain in knee osteoarthritis. It could be argued that the exclusion of the classical acupoints such as ST35 (Dubi), Xiyan (extra point), SP10 (Xuehai) and ST34 (Liangqiu) might have reduced the

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Table 1 Baseline demographics and clinical characteristics

	Completers, Mean (SD)			Drop-outs, Mean (SD)	
	Acupuncture group	Sham acupuncture group	*P*-value[a]	Acupuncture group	Sham acupuncture group
n	15	15		3	3
Gender			1.000[b]		
Male	3	3		1	0
Female	12	12		2	3
Age (years)	70.6 (5.8)	66.1 (7.5)	0.079	69.3 (5.1)	63.3 (10.7)
BMI (kg/m^2)	29.7 (3.9)	27.6 (5.0)	0.236	26.5 (6.6)	29.0 (6.1)
Preop active ROM					
(R) (deg)	100.9 (27.3)	107.0 (16.0)	0.464	95.0 (13.2)	103.3 (15.3)
(L) (deg)	101.7 (31.9)	109.0 (17.3)	0.441	116.7 (12.6)	98.3 (7.6)
Preop passive ROM					
(R) (deg)	108.8 (29.6)	115.3 (16.5)	0.462	106.7 (18.9)	103.3 (25.2)
(L) (deg)	110.6 (35.4)	118.7 (17.2)	0.434	121.7 (20.2)	96.7 (12.6)
Preop pain level at rest	2.1 (1.7)	1.5 (1.9)	0.424	1.7 (2.9)	2.3 (2.5)
Preop pain level at maximum	6.6 (1.5)	7.0 (2.0)	0.536	8.0 (1.0)	7.0 (1.0)
Preop timed up-and-go test (s)	29.9 (15.6)	19.4 (7.0)	0.028	19.1 (5.2)	18.1 (6.4)

[a]Independent *t*-test.
[b]Fisher exact test.

Table 2 Postoperative mean scores (SD) of pain at rest and at maximum

	Pain level at postoperative day									
	4	5	6	7	8	11	12	13	14	15
At rest										
Acup	2.7 (2.0)	2.8 (1.9)	2.3 (2.0)	2.0 (1.9)	1.9 (1.9)	1.9 (1.6)	2.1 (1.4)	1.9 (1.7)	2.4 (1.7)	2.3 (2.2)
Sham acup	3.1 (2.4)	2.5 (1.7)	3.0 (1.9)	3.3 (2.1)	2.5 (1.9)	2.6 (1.4)	2.3 (1.3)	2.5 (1.5)	2.1 (1.8)	1.9 (1.5)
At maximum										
Acup	7.9 (1.5)	7.2 (1.2)	7.3 (1.8)	6.9 (1.9)	6.8 (2.0)	5.9 (2.0)	5.9 (2.2)	5.7 (2.2)	5.5 (1.9)	6.3 (2.6)
Sham acup	7.3 (2.8)	6.2 (2.7)	6.1 (2.7)	6.0 (2.2)	6.1 (2.1)	5.7 (1.8)	4.9 (2.2)	4.9 (1.9)	4.9 (1.9)	5.2 (2.4)

Acup, acupuncture group; Sham acup, sham acupuncture group.

effectiveness of acupuncture in the present trial. The selection of only six acupoints appeared to be the bare minimum in achieving a positive result in treating knee pain as suggested in a recent systematic review of acupuncture for knee osteoarthritis.[6]

There are many variations in the types of sham acupuncture reported in the literature.[19] Some acupuncture practitioners argue that even superficial needling of acupoints is effective in pain relief.[20] In this study, we applied the superficial needling about 2 cm away from the real acupoints. We sought to answer the clinical question 'Is a normal acupuncture intervention superior to a needling intervention deficient in various aspects considered relevant to good quality acupuncture?' by using the 'superficial needling at non-acupuncture points without an attempt to achieve de-chi and without stimulation' as the sham intervention.[19] The differences in the overall averages of pain level at rest and at maximum between the acupuncture group and sham acupuncture group were only 0.4 (95% CI −0.6 to 1.3) and −0.8 (95% CI −2.0 to 0.4) respectively. These differences were much lower than the hypothesized minimum clinically important difference of 2. As the upper bounds of the 95% CIs of the two differences exclude the prespecified clinically important

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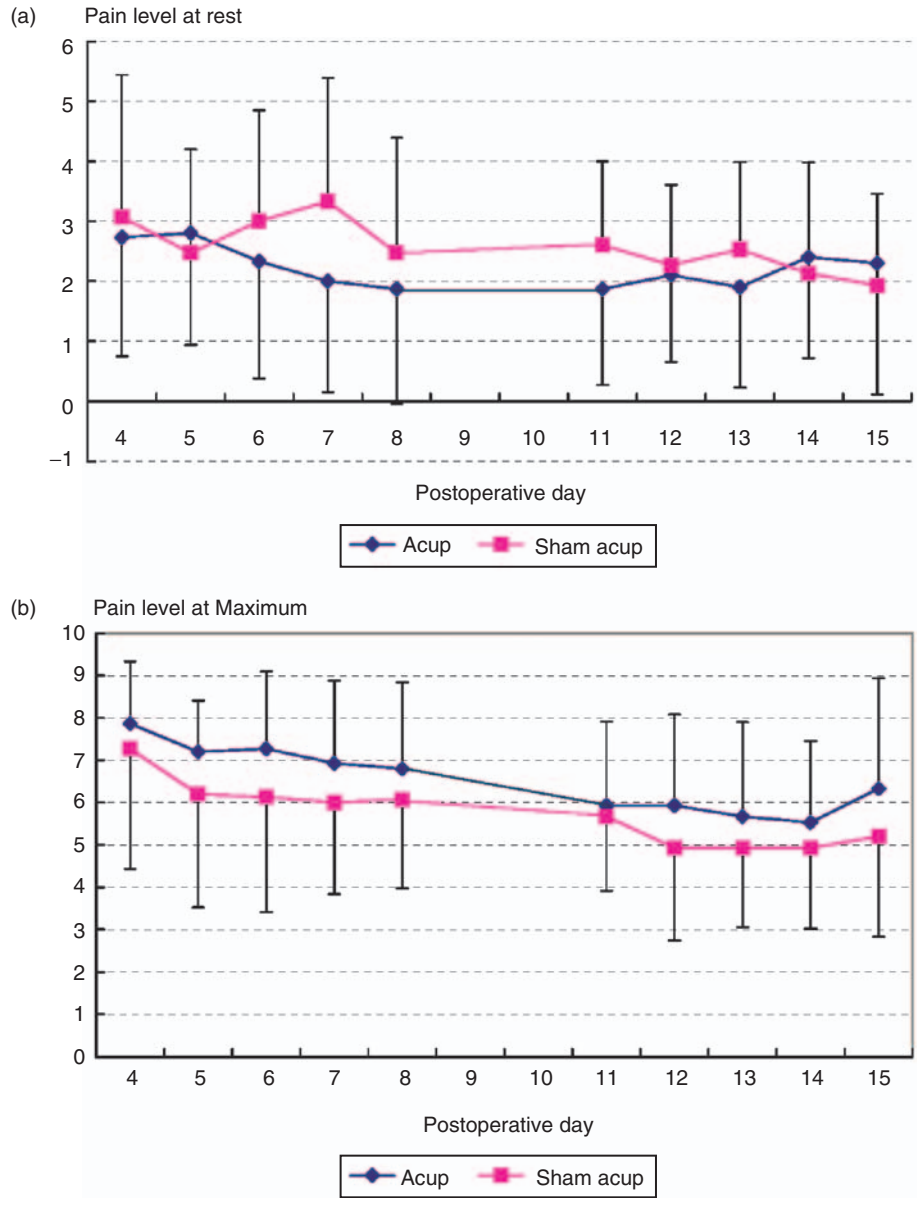

Figure 3 Mean (SD) scores of pain at rest and at maximum from postoperative day 4 to day 15. Acup, acupuncture group; Sham acup, sham acupuncture group. (a) Mean (SD) scores of pain at rest. (b) Mean (SD) scores of pain at maximum.

effect, it is more certain that the present trial was negative.[21]

There were limitations of the present study. The patients' blinding status and their expectation of the helpfulness of acupuncture had not been assessed formally, although no patients in the sham acupuncture group had raised any queries whether they had received

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Table 3 Postoperative overall averages (SD) of mean pain ratings and analgesics consumption

	Average (SD)				
	Acup	Sham acup	Mean difference	95% CI of mean difference	*P*-value[a]
Pain at rest	2.2 (1.4)	2.6 (1.2)	0.4	–0.6 to 1.3	0.463
Pain at maximum	6.5 (1.5)	5.7 (1.7)	–0.8	–2.0 to 0.4	0.177
Analgesics consumption (number of tablets)[b]	28.3 (11.6)	24.7 (13.8)	–3.6	–13.2 to 6.0	0.447

Acup, acupuncture group; Sham acup, sham acupuncture group.
[a]Independent *t*-test.
[b]Dologesic (500 mg) or diclofenac SR (100 mg).

Table 4 Postoperative mean scores (SD) of active and passive ranges of knee motion, timed up-and-go test, and results of repeated-measures analysis of variance

	Mean (SD) at postoperative day						Repeated-measures ANOVA *P*-value		
	4		8		15				
	Acup	Sham acup	Acup	Sham acup	Acup	Sham acup	Between-subjects effect	Within-subjects effect	Interaction effect
Active ROM (deg)									
(R)	73.7 (15.1)	76.0 (22.6)	87.7 (14.0)	86.9 (14.2)	94.0 (15.0)	93.0 (13.7)	0.973	<0.001	0.745
(L)	65.7 (21.7)	80.3 (21.6)	87.7 (17.8)	92.1 (14.5)	96.5 (17.1)	99.7 (15.2)	0.213	<0.001	0.098
Passive ROM (deg)									
(R)	94.3 (13.5)	90.7 (19.5)	104.0 (11.5)	99.7 (10.3)	107.9 (11.3)	101.5 (11.9)	0.274	<0.001	0.729
(L)	90.0 (15.9)	93.7 (18.8)	103.0 (13.2)	100.9 (13.4)	107.3 (15.9)	106.0 (14.7)	0.990	<0.001	0.320
Timed up-and-go test[a] (s)	–	–	78.4 (30.7)	67.5 (48.8)	45.8 (31.1)	39.8 (33.4)	0.929	0.152	0.930

Acup, acupuncture group; Sham acup, sham acupuncture group.
[a]Preoperative timed up-and-go test scores as covariate.

sham acupuncture. It is recommended that the assessment of blinding should be routinely incorporated into the design of sham-control randomized controlled trials of acupuncture.[22] Nonetheless, we consider that the success or failure of patient blinding would not have altered the conclusions of the study. When the blinding of patients is successful, the comparison between the acupuncture group and the sham acupuncture group should be valid. If the blinding of patients is not successful and most patients in the sham acupuncture group knew that they had received sham acupuncture only, the results should be biased away from the null. In such a case positive results of acupuncture should be expected, which is contrary to the present results.

It has been reported that patients with low back pain who had higher expectations of acupuncture being helpful to them had better functional outcomes than those who did not.[23] Therefore, a patient's expectation regarding benefit from a specific treatment may be an important confounding factor affecting clinical outcomes.

The results of the present study are consistent with the suggestion that acupuncture analgesia may have a strong non-specific component.[24] Future randomized controlled trials on the same group of patients with the use of placebo needles[25] without skin piercing and the

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Clinical message

- Acupuncture is not superior to sham acupuncture in pain relief and improvements of ranges of knee motion and ambulation in patients with knee osteoarthritis undergoing bilateral total knee arthroplasty in the postoperative two-week period.

assessments of patient blinding with the Credibility of Treatment Rating Scale[26] and expectation of helpfulness of acupuncture[23] are recommended.

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Competing interests

None declared.

Contributors

All authors provided research concept/idea development and consultation (including manuscript review before submission). RCCT provided research design, data analysis and writing. PLT, CYK and HTY provided application of acupuncture. BCHK and WYL provided data collection. RCCT is the guarantor of the report.

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Appendix – Standard physiotherapy programme for total knee arthroplasty

Postoperative days 1–2

(1) Deep breathing exercise (10 times per hour during waking hours)
(2) Ankle and toes exercise (30 times per hour during waking hours)
(3) Active assisted knee flexion and extension exercise (as pain tolerated)
(4) Limb maintenance exercises.

Postoperative days 3–7

(1) Exercises as postoperative days 1–2
(2) Ice therapy to knee for 15 minutes in half lying
(3) Self-assisted knee flexion exercise with the help of towel for 15 minutes
(4) Passive stretching to hamstring when knee flexion contracture is present
(5) Strengthening exercise to quadriceps (neuromuscular electrical stimulation to quadriceps using respond-select for 15 minutes if muscle grading of quadriceps is less than 3)
(6) Full weight-bearing walking exercise with frame (gradual progression to use quadripod and stick as patient's ambulatory ability improves).

Postoperative day 7 onwards

(1) Exercises as postoperative days 1–7
(2) Eccentric control of quadriceps training by mini-squatting and stepping down a step
(3) Stairs ascending and descending training
(4) Proprioceptive training using balance/wobble board
(5) Cardiovascular training using treadmill if patient's physical conditions allow (starting with speed of 1 km/h).

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