Supervised exercise plus acupuncture for moderate to severe knee osteoarthritis: a small randomised controlled trial

Anushka Soni, Abhay Joshi, Nicola Mudge, Matthew Wyatt, Lyn Williamson

Abstract

Objectives Although total knee replacement (TKR) is cost effective and successful in most cases, patient-reported outcome measures demonstrate 20% of people remain unsatisfied at 1 year after a technically successful procedure. Our group has previously shown that patients with severe knee osteoarthritis (OA) awaiting surgery can achieve a short-term reduction in symptom severity when treated with acupuncture, and that a trend towards improved walking distance, as a measure of function, is achieved with preoperative supervised exercise. The aim of this study was to evaluate the effect of combined acupuncture and physiotherapy on preoperative and postoperative pain and function.

Methods A total of 56 patients awaiting TKR surgery were randomised to receive either combined physiotherapy and acupuncture or a standardised exercise and advice leaflet. Pain and function were measured primarily using the Oxford Knee Score (OKS), with assessments at baseline prior to intervention, 6 and 12 weeks after intervention and at 3 months postoperatively.

Results Due to the introduction of the 18-week waiting times target during this study, the required sample size was not achieved. There were no significant differences demonstrated between the control and treatment groups for OKS. Seven patients withdrew from surgery because of symptomatic improvement in their knees: six from the treatment group and one from the control group (OR 7.64, 95% CI 0.86 to 68.20).

Conclusions This study demonstrated that the use of combined acupuncture and physiotherapy in the treatment of patients with moderate to severe knee OA preoperatively did not improve patient outcome postoperatively. As the study was underpowered, a larger trial is required to examine this result further.

INTRODUCTION

Osteoarthritis (OA) is a major public health problem and the leading cause of pain and disability in the Western world. It results in significant loss of productivity (£3.2 billion in 1999/2000). Knee OA is common and rising rapidly due to the combination of an aging population and the obesity epidemic.

Guidance issued by the National Institute for Health and Clinical Excellence (NICE) emphasises the importance of adopting a holistic approach to the assessment and management of symptoms in OA and encourages the use of exercise in knee OA in order to reduce pain, disability, medication intake and improve mental health and physical functioning. Although insufficient evidence was available to provide formal guidance on the use of acupuncture in OA, there is some suggestion that acupuncture may be beneficial in a subgroup of patients with symptomatic knee OA and further research is recommended.

Current treatment of knee OA follows a generic stepwise approach, starting with conservative measures and ending with knee surgery (reserved for those with severe disease). Total knee replacement (TKR) is cost effective and successful in most cases, yet patient-reported outcome measures demonstrate 20% of people remain unsatisfied at 1 year after a technically successful procedure. Given the increasing load of TKR (in 2002 approximately 44 645 TKRs were performed in the UK), the associated burden of this unsuccessful group is significant. As patients with marked functional limitation and severe pain before total knee arthroplasty are more likely to have poor outcome postoperatively, interventions ameliorating symptoms preoperatively may in turn be associated with improved postoperative outcome.

Our group has previously shown that patients with severe knee OA can achieve a short-term reduction in symptoms (as measured using the Oxford Knee Score (OKS)), when treated with acupuncture, and that a trend towards improved walking distance, as a measure of function, is achieved with preoperative supervised exercise. This study also demonstrated that both interventions could be delivered effectively in an outpatient setting, within the National Health Service (NHS). Recent studies have explored the
potential benefit of combining exercise therapy and acupuncture in the management of symptomatic knee OA, but not in patients with severe knee OA prior to surgery. The aim of this study was to evaluate the effect of combined acupuncture and physiotherapy on preoperative and postoperative pain and function. As in the previous study treatment was delivered in a group setting by a single therapist and compared to standard care. The acupuncture protocol was adapted to avoid needling into the knee joint prior to surgery.

METHODS

Trial design

This randomized controlled trial (RCT) was conducted using a parallel design with equal ratio allocation.

Study participants

The study took place between May 2007 and August 2008. Patients who were listed for knee replacement surgery were invited to take part by letter and those eligible to participate were randomised after written consent was obtained, according to the Declaration of Helsinki.

The study inclusion criteria were: patients listed for knee arthroplasty due to OA who had unilateral or bilateral knee pain lasting more than 3 months. Patients were excluded if they were: taking anticoagulants or diagnosed as having a bleeding diathesis, needle-phobic, allergic to metal, experiencing any skin disease around the knee, within 3 months of receiving an intra-articular steroid injection, experiencing back or hip pain, diagnosed as having rheumatoid arthritis, within 12 months of receiving acupuncture or physiotherapy, or if they were pregnant.

Randomisation

A rheumatology clinical research fellow used computerised block randomisation to generate 120 sealed opaque envelopes. The envelopes were opened by the patient in the presence of the study physiotherapist immediately after recruitment to the study. After randomisation, 28 patients were allocated to each of the control and intervention groups.

Intervention

The intervention group received weekly sessions of combined physiotherapy and acupuncture for 4 weeks followed by fortnightly sessions for 4 weeks and monthly sessions until their surgery. The patients were seen in groups of 6 to 10 by the same study physiotherapist, who has completed the Acupuncture Association for Chartered Physiotherapists foundation course and is experienced in musculoskeletal acupuncture. The patients initially carried out an exercise circuit replicating the previous study. This was supervised by the study physiotherapist and comprised: static quadriceps contractions, inner range quadriceps contractions, straight leg raises, sit to stands, stair climbing, calf stretches,

Figure 1  Acupuncture points selected for intervention group.
theraband-resisted knee extensions, wobble board balance training, knee flexion/extension sitting on a gym ball and free standing peddle revolutions. This was followed by Western medical style acupuncture whereby the needles (1 inch, 0.25 gauge) were inserted and the *de qi* sensation achieved where possible and left in situ for 20 min. The acupuncture points were selected based on the Western medical approach as in the previous study.10 In response to feedback from the orthopaedic department regarding needling over the joint line prior to surgery, the protocol was adapted and the points used were SP9 and SP10, ST34 and ST36, LI3, GB34 and LI8 (figure 1). Up to three further trigger points were needled at the physiotherapist’s discretion.

The control group received an exercise and advice leaflet that had been designed by consensus between the physiotherapy, rheumatology and orthopaedic departments.

**Blinding**
The research fellow carrying out all the assessments was blind to the patient treatment allocation until data collection was completed. The study design did not allow blinding of participants or the study physiotherapist.

**Outcome measures**
Patients completed a questionnaire containing the OKS (which was the primary outcome measure)13, 10 cm pain visual analogue scale (VAS) and the Hospital Anxiety and Depression scale (HAD).14 Patient height was measured at baseline. At each visit patients were weighed, analgesic use was documented and patients undertook a 50 m timed walk. Assessments took place at baseline prior to intervention, at 6 weeks and 12 weeks after the intervention commenced and at 3 months postoperatively. A research fellow collected the data during a dedicated study session held within the physiotherapy department.

**Power calculation**
The mean change in OKS following TKR surgery is 15.9 (SD 10.2), with an estimated minimal clinically important difference of 5 points.15 Patient numbers were therefore calculated to detect a 5-point difference in improvement in OKS between groups at a 5% significance level with 80% power. A total of 60 patients were required in each group.

**Statistical analysis**
Analysis was performed by intention to treat. A repeated measures analysis of covariance (ANCOVA), adjusting for baseline scores, was used to assess for any effects of intervention on OKS, pain VAS, HAD and the 50 m timed walk. Tests of simple main effects were conducted for significant interaction terms, with adjustment for simultaneous tests. This method, rather than analysis of change in scores as per the original power calculation, was selected as it provides greater power.16 A post-hoc analysis of patients who cancelled their surgery due to improvement in symptoms was conducted. All statistical analysis was conducted using Stata V12.0 (StatCorp, College Station, Texas, USA).

**Ethics**
Ethical permission was granted by the Swindon Research Ethics Committee, 06/Q2004/3. The ISRCTN number for this trial is 65723721.

**RESULTS**

**Baseline and dropouts**
The flow of patients through the trial is shown in figure 2. Due to the introduction of the 18-week waiting times target during this study, the required sample size was not achieved and a total of 56 patients were recruited to the study. The control and treatment groups were comparable at baseline apart from pain VAS, which demonstrated significantly higher pain levels in the treatment group at baseline (p 0.004 (table 1)). A total of 44 (79%) patients were assessed at 6 weeks, 25 (45%) at week 12 and 41 postoperatively (73%).

**Follow-up**
There were no significant differences demonstrated between the control and treatment groups for OKS, pain VAS, HAD and 50 m timed walk (table 2). Analgesia use and body mass index did not differ significantly between the two groups at each time point.

A repeated measures ANCOVA, adjusting for baseline scores, did not reveal any significant differences between the interventions at any time point for OKS, pain VAS or HAD. For the 50 m timed walk, a significant interaction effect was seen postoperatively (F=4.38, p=0.02) but this did not remain significant after adjusting for simultaneous tests.

A post-hoc analysis of the patients who withdrew from surgery due to improvement in symptoms was conducted. Seven patients withdrew from surgery: six were from the treatment group and one was from the control group (OR 7.64, 95% CI 0.86 to 68.20, p=0.101(Fisher’s exact test)). At 2 years, the patients in the intervention group had still not required knee surgery but the patient in the control group had undergone bilateral TKR.

**Safety**
No adverse responses occurred in the treatment group.

**DISCUSSION**

**Main results**
This study demonstrates that combined acupuncture and physiotherapy is a pragmatic therapeutic option for patients with moderate to severe knee OA, and can be delivered safely in an NHS outpatient group setting. No significant differences were seen in formal outcome measures preoperatively or postoperatively. A post-hoc analysis showed that patients in the treatment group were more likely to withdraw from the surgical waiting list due to sufficient symptomatic improvement although the effect was not statistically significant (OR 7.64, 95% CI 0.86 to 68.20).
Costs
The estimated cost of providing combined physiotherapy and acupuncture in an outpatient setting with group sizes of 6 to 10, with reusable gymnasium equipment already available, was £30 per patient. There were no additional costs for the control group. The cost of TKR surgery is approximately £5000, assuming a standard length of hospital stay. If the six patients who withdrew from surgery in the treatment group did so because of the effect of the intervention, this would equate to an overall saving of £30 000 in this cohort. Significantly, this was maintained 2 years after the study.

Comparison with existing literature
The effectiveness of acupuncture for rheumatic conditions has attracted more research interest in the past decade than previously. Although numerous studies with contradictory conclusions exist in the literature, a recent systematic review summarising the data for the effectiveness of acupuncture for rheumatic conditions has concluded that a consensus exists that acupuncture is effective for OA, with the majority of the studies included being for knee OA specifically. Data from a previous study by our group has also shown that a short-term reduction in OKS is seen, even in people with severe knee OA, when treated with acupuncture. There are two other studies known to the authors that have assessed the effect of combined acupuncture and physiotherapy in the management of knee OA. The first used acupuncture as an adjunct to standard postoperative rehabilitative care in patients who had undergone bilateral knee replacement. This study concluded that there was no difference between the effects of acupuncture and sham acupuncture in addition to the standard postoperative physiotherapy programme, using the numeric pain rating scale.

Table 1 Baseline characteristics of control and treatment groups

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Treatment</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>69.93 (7.85)</td>
<td>66.89 (9.82)</td>
<td>56</td>
</tr>
<tr>
<td>Sex, percentage male</td>
<td>53.6 (30/56)</td>
<td>46.43 (26/56)</td>
<td>56</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>31.14 (4.85)</td>
<td>31.43 (4.23)</td>
<td>56</td>
</tr>
<tr>
<td>Baseline OKS</td>
<td>39.71 (7.98)</td>
<td>38.67 (9.32)</td>
<td>56</td>
</tr>
<tr>
<td>Pain VAS, mm</td>
<td>5.73 (2.24)</td>
<td>7.63 (2.39)</td>
<td>56</td>
</tr>
<tr>
<td>HAD-A</td>
<td>7.61 (4.45)</td>
<td>7.22 (4.46)</td>
<td>56</td>
</tr>
<tr>
<td>HAD-D</td>
<td>6.57 (3.00)</td>
<td>6.48 (3.56)</td>
<td>56</td>
</tr>
<tr>
<td>50 m timed walk, s</td>
<td>60.36 (19.49)</td>
<td>60.48 (31.54)</td>
<td>56</td>
</tr>
<tr>
<td>Education: school, %</td>
<td>88.2 (15/17)</td>
<td>90 (18/20)</td>
<td>37</td>
</tr>
<tr>
<td>Education: school plus, %</td>
<td>11.8 (2/17)</td>
<td>10.0 (2/20)</td>
<td>37</td>
</tr>
<tr>
<td>Analgesia: none, %</td>
<td>28.57 (8/28)</td>
<td>14.29 (4/28)</td>
<td>55</td>
</tr>
<tr>
<td>Analgesia: simple, %</td>
<td>35.71 (10/28)</td>
<td>53.57 (15/28)</td>
<td>55</td>
</tr>
<tr>
<td>Analgesia: opioids, %</td>
<td>35.71 (10/28)</td>
<td>32.14 (9/28)</td>
<td>55</td>
</tr>
</tbody>
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BMI, body mass index; HAD-A/D, Hospital Anxiety and Depression score for anxiety/depression; OKS, Oxford Knee Score; VAS, visual analogue scale.
scale to assess pain severity. Of note there was no non-acupuncture control group to assess the true combinatorial effect of these therapeutic modalities. The second study in mild to moderate knee OA was designed to investigate the effect of adding sham or true acupuncture to a course of physiotherapy led exercise and advice in patients with a clinical diagnosis of knee OA referred by general practitioners to a physiotherapy department. This study demonstrated small benefits in pain intensity and unpleasantness in both acupuncture groups, but no additional improvement measured on the Western Ontario and McMaster Universities OA index at 6 months and 12 months.

It is difficult to make direct comparisons with previous studies in view of the differences in disease severity, acupuncture protocol, choice of control group and outcome measure used. However, the data from this study is also in keeping with the conclusion that the combination of acupuncture and physiotherapy do not make a significant impact on symptoms assessed using a composite disease severity measure, in this case OKS.

The most interesting result from this study was the withdrawal of 21% of the intervention group from surgery, which could be a chance finding but is consistent with findings from our previous study where 5.0% (3/60) and 1.6% (1/61) of the acupuncture and control groups, respectively, withdrew from surgery, because of symptomatic improvement. In a separate study of acupuncture treatment of patients awaiting arthroplasty surgery for knee OA, 24% (7/29) also responded so well that they opted not to go ahead with surgery. In order to establish the relevance of these findings, the rate of patient-initiated cancellation of surgery outside of the context of a clinical trial is required.

**Strengths and limitations**

A major strength of this study is that it was designed in a standardised manner, allowing a single practitioner to deliver reproducible, protocol driven treatment in an NHS outpatient setting with minimal resource costs. Patients were likely to have been a homogenous subgroup of patients with moderate to severe knee OA, due to the fact that they were awaiting surgery. The data on those who withdrew from surgery are available over a 2 year follow-up period.

The main limitation of this study is that fact that it did not gain sufficient power. This is due to the introduction of the 18-week waiting time target during recruitment for the study, which did not allow sufficient time for intervention prior to surgery. Future studies may overcome this by identifying patients at the point of referral for consideration of study. The treatment group also had a significantly higher pain score at baseline, which would result in a tendency towards the null hypothesis.

**Interpretation and implications for future clinical practice and research**

This study has demonstrated that the intervention can be delivered safely, within the current NHS outpatient setting, and could be easily transferred to the community where the management of most rheumatic conditions takes place. Although the study did not show a significant treatment effect, it is underpowered and a larger study is needed. Post-hoc analysis suggests a possible overall cost saving in view of those patients no longer requiring surgery, particularly pertinent the context of the predicted rapid growth in demand for knee replacement surgery.10

This study also highlights the limitations of relying on composite quantitative measures of severity in symptomatic knee OA, such as OKS, alone as a potential discrepancy between the chosen outcome measures and patient-initiated cancellation of surgery was seen. The OKS was originally devised in 1998 as a short, simple questionnaire to assess outcome following TKR surgery, as judged by patients themselves. More recently it has been adopted as the outcome measure of choice as part of the UK Government Patient Reported Outcome Measure Initiative, and is commonly used to select suitable surgical candidates. Qualitative studies have revealed the difficulty in relying on such quantitative measures of symptom severity, without addressing the specific context and expectations pertinent to the individual patient. For example, patients have been found to report a good outcome following TKR, despite ongoing issues of pain and immobility on further questioning. Although the emphasis is placed on capturing a patient-focussed assessment, these measures are likely to be too simplistic, partly due to the close link between pain and activity, strategies employed to adapt to painful activities and the difficulty patients demonstrate in completing such assessments. The waiting list study design used here allows a
further assessment of patient response to intervention, which can be easily followed over an extended period of time. The effect of combined acupuncture and exercise therapy may be mediated by a change in perception of their symptom state rather than an actual change in severity per se. The measurement of patient acceptable symptom state may help to capture this effect.21 22

The discrepancy between guideline advice for the management of OA and actual care is recognised23 and has been indirectly highlighted by this study, with only 11 of the respondents having received recent acupuncture or physiotherapy input. Exercise is a key recommendation of current guidelines for the management of OA, with some evidence in favour of acupuncture in the context of knee OA2; by adopting the infrastructure of this study, both could be provided prior to consideration for surgery or for those in whom surgery is not a safe or desirable option.

In summary this study did not demonstrate any significant intervention effect on OKS, preoperatively or postoperatively. Post hoc analysis suggests that patients in the intervention group showed a possible trend towards cancellation of surgery, due to symptomatic benefit, which was maintained at 2 years follow-up. As the study was underpowered, further study of the use of combined acupuncture and physiotherapy in the treatment of patients with moderate to severe knee OA, prior to consideration for surgery is required.

Summary points

▸ In patients waiting for knee surgery, we compared acupuncture and supervised exercise with an exercise leaflet.
▸ For service operational reasons the sample size was not achieved.
▸ Incidentally, patients in the intervention group were five times more likely to cancel their surgery.

Contributors AS made substantial contributions to acquisition of data, analysis and interpretation of data, drafting the article and final approval of the version to be submitted. AJ made substantial contributions to acquisition of data, revision of the article and final approval of the version to be submitted. NM made substantial contributions to acquisition of data, revision of the article and final approval of the version to be submitted. MW made substantial contributions to conception and design of the study, revision of the article and final approval of the version to be submitted. LW substantially contributed to the conception and design of the study, analysis and interpretation of data, revising the article and final approval of the version to be submitted.

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