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Acupuncture for chronic low back pain in older patients: a randomized, controlled trial

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***Objective*. To determine if acupuncture is an effective, safe adjunctive treatment to standard therapy for chronic low back pain (LBP) in older patients.**

***Methods*. The inclusion criteria for subjects were: (i) LBP $\geq$12 weeks and (ii) age $\geq$60 yr; the exclusion criteria were (i) spinal tumour, infection or fracture and (ii) associated neurological symptoms. The subjects were randomized to two groups. The control group of subjects continued their usual care as directed by their physicians, i.e. NSAIDs, muscle relaxants, paracetamol and back exercises. Subjects in the acupuncture group in addition received biweekly acupuncture with electrical stimulation for 5 weeks. Outcome was measured by the modified Roland Disability Questionnaire (RDQ) at weeks 0, 2, 6 and 9. The primary outcome measure was change in RDQ score between weeks 0 and 6.**

***Results*. Fifty-five patients were enrolled, with eight drop-outs. Twenty-four subjects were randomized to the acupuncture group and 23 were randomized to the control group. Acupuncture subjects had a significant decrease in RDQ score of 4.1 ± 3.9 at week 6, compared with a mean decrease of 0.7 ± 2.8 in the control group ($P = 0.001$). This effect was maintained for up to 4 weeks after treatment at week 9, with a decrease in RDQ of 3.5 ± 4.4 from baseline, compared with 0.43 ± 2.7 in the control group ($P = 0.007$). The mean global transition score was higher in the acupuncture group, 3.7 ± 1.2, indicating greater improvement, compared with the score in the control group, 2.5 ± 0.9 ($P < 0.001$). Fewer acupuncture subjects had medication-related side-effects compared with the control group.**

***Conclusions*. Acupuncture is an effective, safe adjunctive treatment for chronic LBP in older patients.**

KEY WORDS: Acupuncture, Chronic low back pain, Elderly patients, Randomized controlled trial.

Back pain is a common disorder, affecting 65–80% of the population [1] and is a major item in health-care expenditure, costing the United States $25 billion annually [2]. Back pain is common in the elderly, with a prevalence of up to 49% of the population [3]. Patients aged 75 and over reported back pain as the third most common complaint overall and their most common musculoskeletal symptom [4]. Back pain is a prevalent, significant cause of morbidity in older patients, including depression [5], functional disability [6] and decreased quality of life [7].

Chronic, non-specific back pain refers to back pain not due to a specifically recognized disease process [8]. The literature describes inflammatory, degenerative, structural or traumatic aetiologies. Conclusive causal evidence, however, is lacking.

Acupuncture is a method of stimulating specific points on the body surface with fine needles. Acupuncture is derived from traditional Chinese medicine (TCM) and has been used for over two thousand years to treat disease. In the USA, it is a widely used treatment for pain [9] and has a favourable safety profile [10, 11].

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Acupuncture stimulates release of β-endorphins into the cerebrospinal fluid, and its analgesic effect can be reversed by naloxone and antiserum against endorphins [12].

There is inconclusive data on the effect of acupuncture for back pain [13, 14]. The acupuncture literature focusing on older patients is more limited [15]. Grant *et al*. [16] performed a study comparing acupuncture to transcutaneous electrical nerve stimulation (TENS) for chronic back pain in the elderly. To date, no other randomized trials on acupuncture for back pain have specifically targeted older patients. The purpose of this study was to determine if acupuncture is an effective and safe adjunctive therapy to standard therapy for chronic, non-specific low back pain in older patients.

Subjects and methods

Subjects had to meet the following inclusion criteria: (i) having chronic, non-specific, low back pain of at least 12 weeks' duration; if there was associated buttock and/or leg pain, back pain must be the chief complaint; (ii) being aged 60 yr and over and (iii) having an imaging study (plain radiograph, computed tomography or magnetic resonance imaging) of the lumbar spine within the past year.

Patients were excluded if any of the following exclusion criteria were present: a spinal tumour, infection or fracture; a bleeding diathesis; epilepsy; a cardiac arrhythmia or pacemaker [17]; dementia; any serious, active medical condition that precluded safe participation (i.e. myocardial infarction within the past 3 months); neurological involvement (loss of sensation, motor weakness or loss of reflexes); planned or scheduled lumbar surgery; a history of lumbar surgery; a significant psychiatric disability; inflammatory arthritis; the prior use of acupuncture for back pain; the current use of systemic corticosteroids; the current use of muscle relaxants; the current use of narcotic medications; the current use of anticoagulants; the use of epidural steroid injections within the past 3 months; the involvement in litigation related to back pain; or refusal to be randomized.

Subject recruitment

Subjects were screened first by telephone and then via a physical examination performed by a physician. Our primary sites of recruitment were the private surgeries and clinics of the Hospital for Special Surgery (HSS), an orthopaedic and rheumatic disease referral centre, and at the New York-Presbyterian Hospital. Approval by the Institutional Review Boards (IRB) at both these institutions was obtained. All subjects signed an IRB-approved consent form at enrolment.

Randomization

A computer-generated random allocation sequence was prepared. The assignments were placed in serially numbered, sealed, opaque envelopes. Subjects were randomized after enrolment. The study enroller screened the patient and, if s/he qualified, obtained informed consent and completed the baseline measurement. Then the next envelope was opened and the treatment allocation discussed. No assignment was reused with another patient, once the envelope had been opened. Subjects completed their own assessments, and blinding was not possible.

Intervention

(1) Standard therapy (control group). Both treatment groups continued standard therapy as directed by their primary physician during the 5-week intervention period; non-steroidal anti-inflammatory drugs (NSAIDs), aspirin and non-narcotic analgesic medications were allowed [18]. Patients were asked to remain on the same medications and not start new ones. A medication diary was provided to document medications for back pain, and their dosage, frequency and side-effects. In addition, subjects were allowed to continue their back exercises, i.e. physical therapy or a home exercise regimen. Prohibited therapies were narcotic medications, muscle relaxants, TENS, epidural steroid injections and trigger point injections.

(2) Acupuncture plus standard therapy. In addition to standard therapy as described above, subjects in this group received acupuncture treatments twice a week for 5 weeks at the Hospital for Special Surgery and New York-Presbyterian Hospital. Two anaesthetists certified in acupuncture performed the acupuncture. The protocol consisted of biweekly courses of acupuncture for 5 weeks for a total of 10 sessions, which is a standard frequency and number of treatments for chronic pain [17, 19]. Aseptic technique and disposable, sterile, prepacked 30-gauge needles [20] with electrical stimulation at 4–6 Hz with a pulse duration of 0.5 ms were used [17, 21]. Deqi responses at all points were verified. The probes were connected to four sets of bipolar leads. Between 10 and 14 needles were used per session. Needles were removed after 20 min [17, 20].

(2a) Acupoints core protocol. Our acupuncture protocol followed the modern approach to acupuncture which incorporates neurohumoral theories of acupuncture mechanism. Standard acupoints, according to major acupuncture reference texts [22, 23], were used. Our co-investigator (L.L.), who has an extensive background in acupuncture and TCM research, assisted in the design of this protocol. Each subject received 10 needles in the following local acupoints, traversing the lumbar spine [24]: Shenshu (UB23), Qihai shu (UB24), Dachangshu (UB25) and Pangguangshu (UB28), which are bilateral acupoints, and Yaoyangguan (Du3) and Mingmen (Du4). 'UB' denotes the bladder meridian which traverses the gluteal and paravertebral regions along the back, and the Du meridian starts at the coccyx and passes upward along the midline of the back to the head [25] (Fig. 1).

(2b) Acupoints supplementary protocol. In order to individualize the regimen to treat each subject's specific symptoms while maintaining protocol uniformity, we allowed a maximum of four additional needles in a supplementary protocol. This protocol specified acupoints to treat concomitant buttock or leg pain: UB36, 54, 37, 40, GB30, 31 [25, 26] (Fig. 1).

(3) Cross-over group. Subjects who were randomized to the control group were offered the opportunity, at the completion of their tenure in the control group, to cross over to receive acupuncture in addition to their standard treatments for back pain. The acupuncture treatments were performed according to the same protocol described above.

Outcomes assessment

Baseline history. Demographic information included age, gender and ethnicity. The presence and severity of co-morbid diseases was assessed using the Charlson Comorbidity Index [27]. Activities of daily living, medications and use of other complementary therapies were recorded. A short depression scale was administered [28].

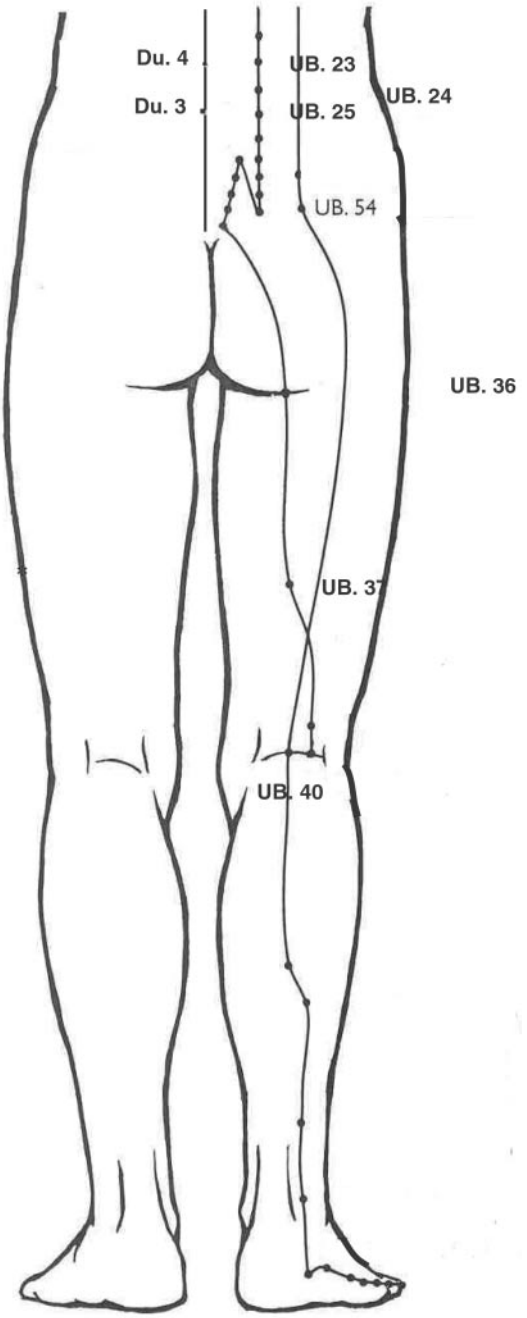

FIG. 1. Acupoints used in study protocol (selected points shown). UB refers to the name of the acupuncture channel, urinary bladder; UB points are bilateral. Du3, Du4, UB23, 24 and 25 are core points. UB36, 37, 40 and 54 are supplementary points. Adapted from Stux G, Pomeranz B. Acupuncture: a textbook and atlas. Berlin, Germany: Springer-Verlag, 1987.

Baseline back pain-specific history. Subjects completed the modified Roland Disability Questionnaire (RDQ), our primary outcome measure. The RDQ documents validity, reliability, reproducibility and responsiveness [29–31], and has frequently been used as a health-related quality of life measure for patients with back pain [32]. Other outcome measures used were the Visual Analogue Scale (VAS) for pain with word anchors [33]. To measure their prior knowledge and expectations of acupuncture, subjects were asked to complete a pretreatment psychological impact profile [34]. All assessments were self-administered.

Follow-up assessments. Follow-up assessments occurred at weeks 0, 2, 6 and 9 during the trial period. The modified RDQ and VAS for pain were administered at these time points. At week 6, a global transition scale and a post-treatment psychological impact profile, which measured patient impressions of acupuncture after treatment, were administered [34]. Subjects recorded the number of tablets taken of NSAIDs, paracetamol, narcotics and muscle relaxants in a diary. Any adverse events were recorded.

Statistical methods

SPSS, SAS and Statxact statistical software were used. All variables were examined using univariate analysis. Means, standard deviations, medians and percentile ranges were recorded. All variables were examined at baseline for statistically significant differences between the groups. Those variables that showed a statistically significant difference were identified as possible confounders.

The primary outcome measure was the difference between the two treatment groups in the change of the RDQ at week 6. Change in the VAS pain score was also analysed. The results were examined to make sure that the change in scores did not correlate with the baseline score. The change in scores was treated as continuous normally distributed data. The Lilliefors significance level for normality was performed. ANOVA with the change in scores as the dependent variable and the treatment group, and any other relevant variables as the independent variables, were performed. Repeated measures ANOVA was used to assess the change in the cross-over group. In examining the side-effects, medications, etc., the non-parametric Mann–Whitney U-test was used to test for differences between groups. The person-week variable indicates for how long a person has been exposed to a risk or treatment, i.e. a person who has side-effects for 1 week contributes 1 person-week. Each subject can have a total of 5 person-weeks.

The data were analysed both as intent-to-treat ($n = 55$) and as completers only ($n = 47$). The intent-to-treat analysis was a conservative analysis in assuming that the patients did not recover from the last measured point, and carried that last value forward.

An analysis was done to mirror the analysis of Berman *et al.* [15] for all subjects who received acupuncture. First the results of the control group after cross over were combined with the acupuncture group to form one group ($n = 50$). A repeated measures ANOVA was used to assess the change in RDQ and VAS scores. A conservative analysis was also performed. The control subjects who did not cross over had their last value carried forward as their score as acupuncture subjects. A new combined group, consisting of acupuncture subjects, subjects who crossed over to receive acupuncture, plus the carried forward values for those who did not cross over, was created ($n = 55$). This combined group was also entered in a repeated measures ANOVA analysis for VAS and RDQ scores.

Results

Study population

Subjects were recruited from July 2000 until April 2001. A total of 205 subjects were screened and 55 (26.8%) were enrolled. The major reasons for exclusion from the

study included the presence of associated neurological abnormalities ($n = 30$, 20%), the primary complaint of pain not in the low back area ($n = 23$, 15%), prior history of lumbar surgery ($n = 15$, 10%), prior use of acupuncture for low back pain ($n = 10$, 6%) and the presence of inflammatory arthritis ($n = 10$, 6%) (Fig. 2). Other reasons for exclusion included planned lumbar surgery, the presence of a cardiac arrhythmia, having a pacemaker, the current use of anticoagulants and not being willing to be randomized.

Of the 55 subjects who enrolled in the study, 31 subjects were randomized to the acupuncture group and 24 were randomized to the control group. There were no significant differences in the demographic and clinical characteristics between the acupuncture and control groups (Table 1). Eight patients dropped out of the study. When subjects who completed the study were compared with those who dropped out, the only significant differences that emerged were in the location of back pain. More subjects who completed the study tended to be on NSAIDs than those who dropped out ($P = 0.05$) (Table 1). Of the subjects who dropped out, seven were from the acupuncture group and one from the control group. Reasons for dropping out included being too busy to comply with the treatment schedule ($n = 3$), receiving an epidural steroid injection during the trial period ($n = 1$) and pain from acupuncture ($n = 1$). The remaining three were excluded from analysis because of not completing the forms properly (Fig. 2). Use of other complementary and alternative therapies were not significantly different between the two groups, although there was a trend to use more dietary supplements in the control group.

Change in back pain and disability

Our primary outcome measure was a change in score of the RDQ [31]. Deyo *et al.* [31] have shown that a change in score on RDQ of 4 or more is clinically significant. Subjects in the acupuncture group had a statistically significant decrease in RDQ score of 4.1 ± 3.9 at week 6 (1 week after completion of treatment), compared with a mean decrease of 0.7 ± 2.8 in the control group; the intergroup difference at week 6 was 3.4 ± 6.6 ($P = 0.001$) (Fig. 3). This effect was maintained with slight deterioration 4 weeks after the completion of acupuncture treatment at week 9, with a decrease in RDQ of 3.5 ± 4.4 from baseline, compared with 0.43 ± 2.7 in the control group, with an intergroup difference of 3.1 ± 7.4 ($P = 0.007$). These results indicate a clinically and statistically significant improvement in disability from back pain in the acupuncture group compared with the control group, lasting at least 4 weeks after cessation of acupuncture treatment.

The above analysis looked at the results for subjects who completed the study. When using an intention-to-treat analysis, there was again a significant decrease in back pain disability in the acupuncture group, albeit a smaller one, compared with the control group. The

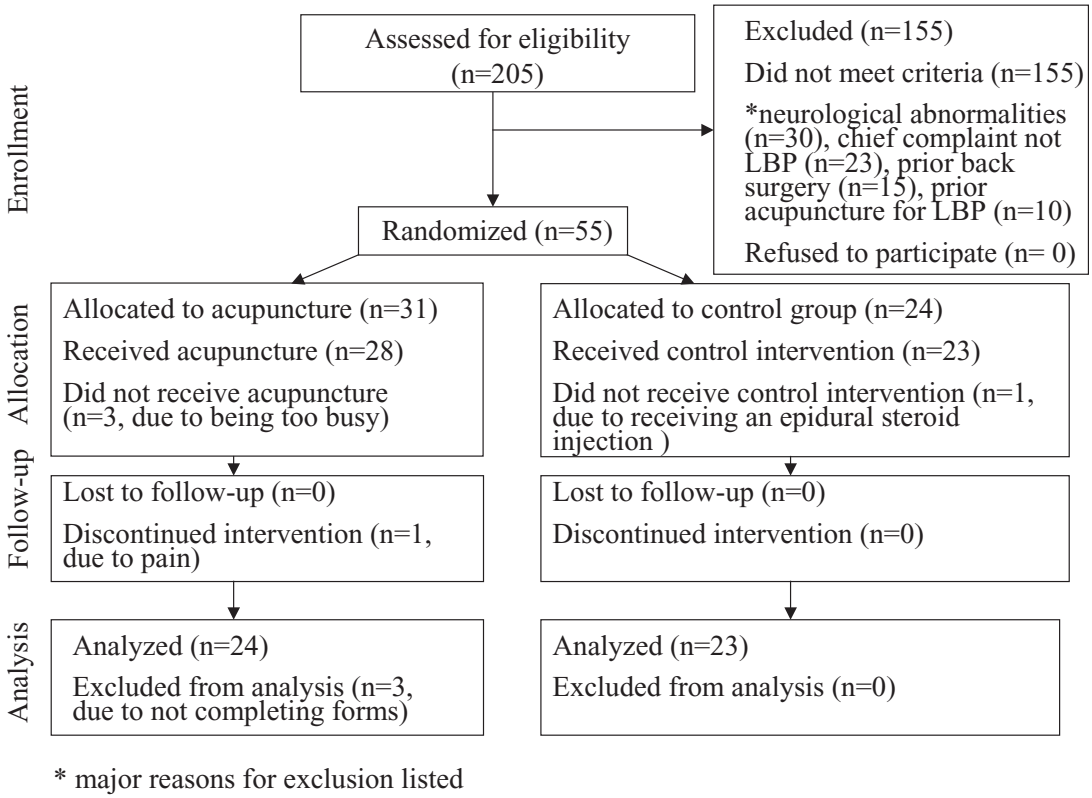

FIG. 2. Flowchart of phases of randomized trial.

TABLE 1. Baseline demographics of study population

	Acupuncture	Control	*P* value	Completers	Drop-outs	*P* value
Number of subjects (*n*)	31	24		47	8	
Age (yr)[a]	72 ± 5	70 ± 6	0.2	71 ± 6	70 ± 7	0.8
Gender			0.6			
Male	13	9		18	4	0.7
Female	18	15		29	4	
Ethnicity			0.1			0.9
Caucasian	28	19		40	7	
African-American	1	4		4	1	
Hispanic	2	1		3	0	
Depression scale	8	4	0.5	11	0	0.6
Location of back pain						
Central	19	16	0.5	34	2	0.02
Right	9	5	0.7	14	1	0.4
Left	8	3	0.3	5	6	<0.001
Buttock pain	15	6	0.1	19	3	0.9
Episodes of pain last 3 months			0.9			0.4
<10 episodes	2	1		2	1	
>10 and ≤20	4	4		6	2	
>20	25	19		39	5	
Medications for back pain						
NSAIDs	13	14	0.2	26	1	0.05
Non-narcotic analgesic agent	5	5	0.7	10	0	0.3
Muscle relaxing agent	0	1	0.4	1	0	>0.9
Aspirin	1	1	0.9	2	0	>0.9
Baseline RDQ score[b]	9.8 ± 3.6	11.8 ± 5.3	0.08	10.6 ± 4.6	11.0 ± 3.8	0.6
Baseline VAS score[b]	1.6 ± 1.0	1.7 ± 1.0	0.6	1.6 ± 1.0	1.7 ± 1.3	0.9
Disease duration (yr)[b]	12 ± 16	12 ± 14	0.1	11.3 ± 14.3	19 ± 17	0.3
Charlson Comorbidity Index[b]	1.2 ± 1.3	2.1 ± 2.4	0.2	1.7 ± 2.0	1.0 ± 1.2	0.4

Data are frequencies, using χ^2 and Fisher's exact test unless otherwise specified.
[a]*t*-test.
[b]Mann–Whitney U-test.

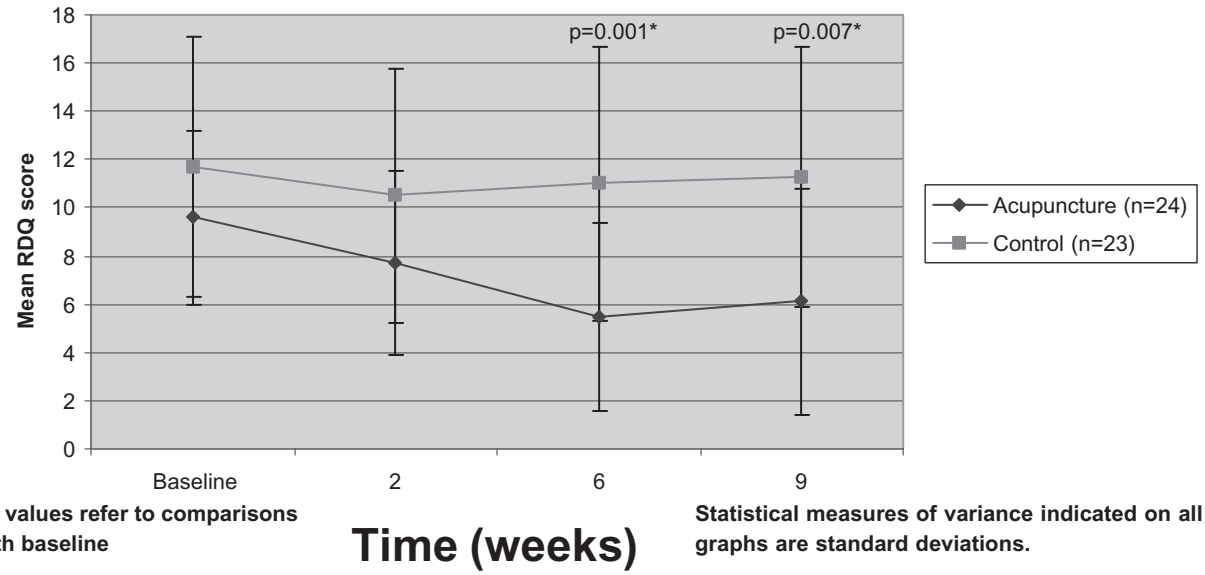

FIG. 3. Mean RDQ scores of acupuncture and control subjects.

acupuncture group had a mean decrease in RDQ of 3.3 ± 3.7 at week 6 compared with 0.6 ± 2.7 in the control group, with an intergroup difference of 2.6 ± 6.7 ($P = 0.006$).

Our secondary outcome measure was a change in pain scores as measured by the Visual Analogue Scale. There was no significant change in pain scores in the acupuncture group at week 6 (0 ± 1.1) compared with an increase in pain score at week 6 of 0.6 ± 1.2 in the control group, the intergroup difference being 0.6 ± 2.3 ($P = 0.1$). However, by week 9, acupuncture subjects showed a significant decrease in pain scores of 0.2 ± 1.3,

compared with control subjects who had an increase of 0.7 ± 1.1, with an intergroup difference of 0.7 ± 2.2 ($P = 0.02$) (Fig. 4).

Global transition scores

The global transition scale ranged from 'much worse' to 'much better', with numerical values of 1 to 5, respectively. The mean global transition score was higher in the acupuncture group, 3.7 ± 1.2, indicating greater improvement, compared with the score in the control group, 2.5 ± 0.9 ($P < 0.001$). Seven out of 22 subjects in the acupuncture group believed they were much better compared with only one out of 23 in the control group. Seven acupuncture subjects believed they were slightly better compared with none in the control group. Eight acupuncture subjects felt the overall status of their low back pain was the same, compared with 13 control subjects. No-one in the acupuncture group believed they were slightly worse, compared with seven in the control group. Thus, the number of patients improving in the acupuncture group was greater than the number improving in the control group ($P < 0.001$).

Subjects who crossed over from control to acupuncture group

After completing their time in the control group using standard therapies alone, subjects were given the opportunity to cross over to receive acupuncture. The RDQ scores in this group showed similar decreases to those originally randomized to acupuncture (Figs 5, 6).

Global transition scores were obtained twice for those subjects in the control group who later crossed over to receive acupuncture. The mean score for patients after receiving standard therapy alone was 2.54, rising to 3.65 after acupuncture was added ($P = 0.002$). Six patients felt 'much better' after receiving acupuncture, compared with one in the control group prior to crossing over ($P = 0.003$).

Patient expectations and impact on treatment outcome

The pretreatment questionnaire assessed patient experience and expectations of acupuncture, which may potentially have affected treatment outcome (Figs 7, 8). Eight of the 23 subjects (34.8%) in the standard therapy group had tried acupuncture before, compared with three of the 31 subjects (9.7%) in the acupuncture group ($P = 0.04$). There were no other significant differences between the two groups in having friends who had tried acupuncture ($P = 0.5$), impressions of acupuncture ($P = 0.2$), belief that acupuncture could relieve back pain ($P = 0.7$), belief in acupuncture as a reasonable treatment for back pain ($P = 0.7$), willingness to recommend acupuncture to their friends ($P = 0.4$) and expectations of the results of acupuncture treatment ($P = 0.4$).

The impact of prior experience with acupuncture on treatment outcome (change in RDQ at week 6) was studied. There were eight patients who had had neutral or negative prior acupuncture experiences, compared with five who had had positive prior experiences in the study. Subjects with positive prior acupuncture experiences had better outcomes than those who had neutral/negatives experiences, regardless of treatment group ($P = 0.004$). However, after correcting for prior acupuncture experience, acupuncture treatment still resulted in greater improvement in RDQ scores at week 6 ($P = 0.002$) and week 9 ($P = 0.002$) compared with the control group.

The impact of subjects' impressions of acupuncture on treatment outcome was studied. There were 31 patients who had neutral or negative impressions of acupuncture compared with 24 subjects who had positive impressions of acupuncture. Patients with positive impressions of acupuncture had greater benefit from acupuncture compared with those with negative/neutral impressions ($P = 0.03$). Interestingly, in the standard care group,

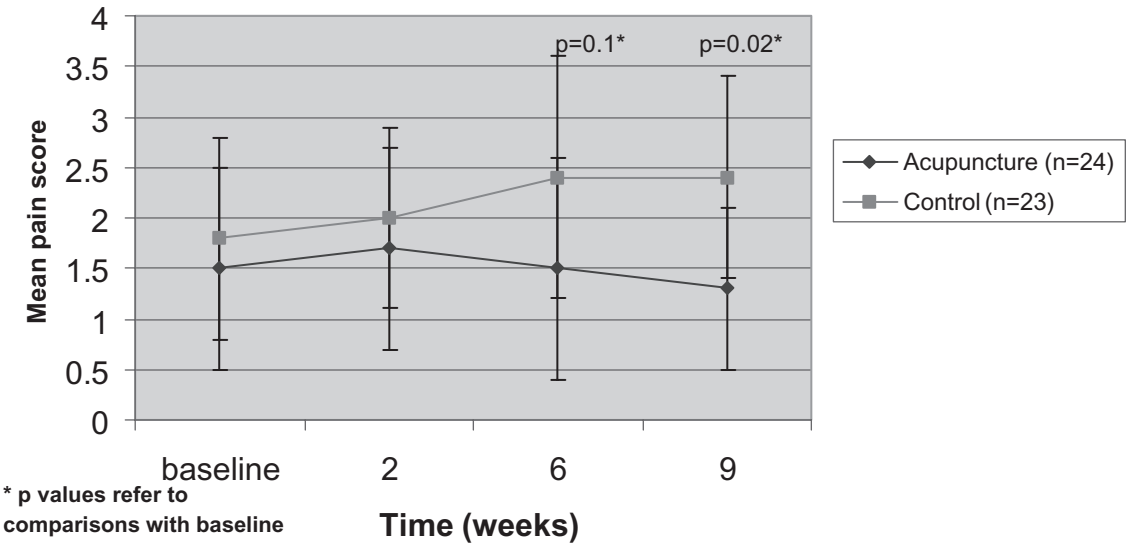

FIG. 4. Mean pain scores of acupuncture and control subjects.

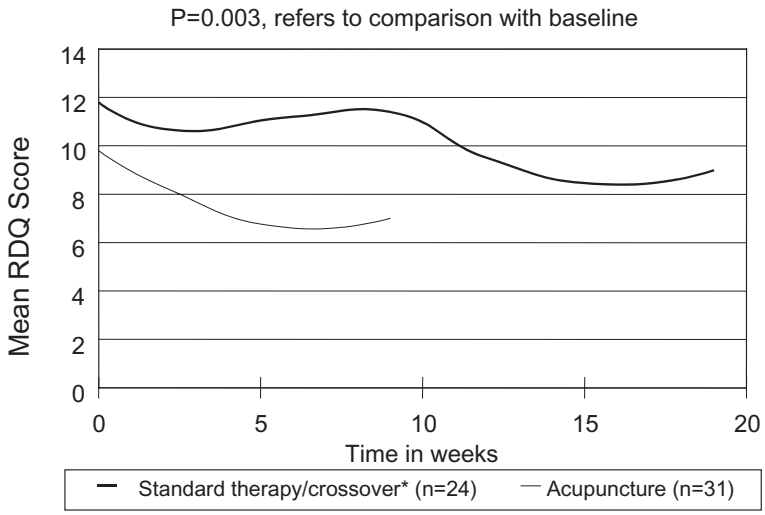

FIG. 5. Mean RDQ scores of acupuncture and standard therapy subjects who then crossed over.

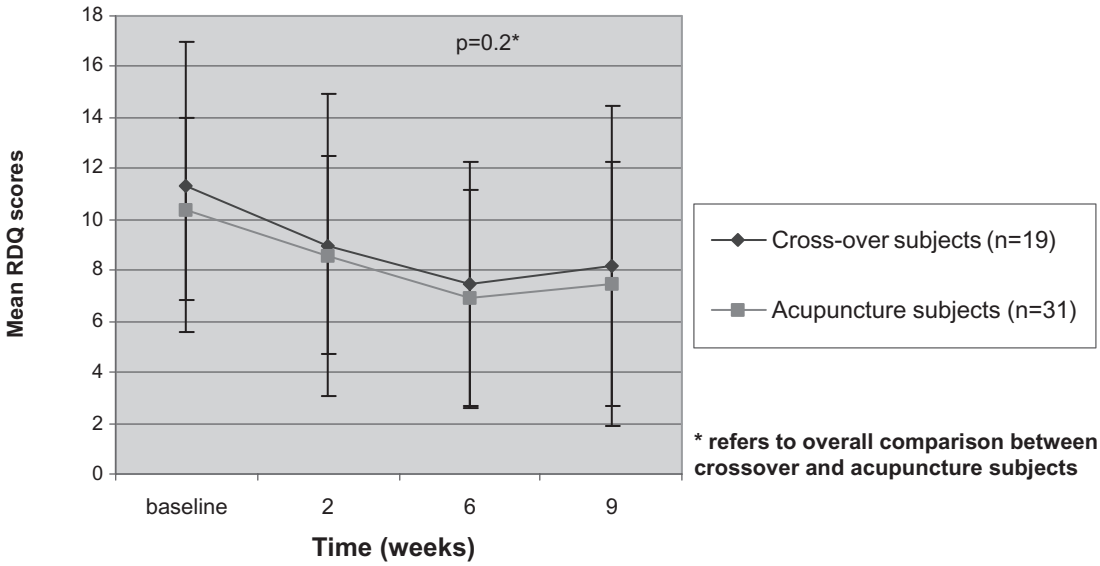

FIG. 6. Comparison of mean RDQ scores of cross-over and acupuncture subjects.

those with positive impressions had no change in baseline, whereas those with negative/neutral impressions had greater relief. When impressions were controlled for, subjects still had greater relief from acupuncture compared with the control group ($P = 0.03$).

Medications

There were 26 subjects in the acupuncture group who took medications for their back pain compared with 23 subjects in the control group. In the acupuncture group, 20 subjects made no changes, five decreased their medication and one increased his medication; in the control group, 13 made no change in their medication, three decreased their medication and seven increased their medications ($P = 0.07$).

Adverse effects

Subjects in the acupuncture group reported minor aching ($n = 5$), bruising ($n = 3$) and light-headedness ($n = 1$). There was one acupuncture subject who withdrew from the study because of pain. Subjects in the control group reported upset stomach ($n = 2$), constipation ($n = 1$), high blood pressure ($n = 1$), dry mouth ($n = 1$) and headache ($n = 1$). Acupuncture subjects did not have more adverse effects when acupuncture was added to standard therapy than those on standard therapy alone. The adverse effects of medications alone were analysed in terms of people-weeks with adverse effects. In the acupuncture group, there were 93 people-weeks without adverse effects compared with 78 people-weeks in the control group; acupuncture subjects had 7

We would like to assess your knowledge of, experience with and expectations of the effectiveness of acupuncture. Please answer the following questions:

1. Do you personally know anyone who is an acupuncturist? 1 (yes) 2 (no)

2. Have any of your friends or family members ever been treated with acupuncture?
1 (yes) 2 (no)

3. If yes, what did they tell you about the effectiveness of the acupuncture treatment?
1 (bad) 2 (fair) 3 (good) 9 (not applicable)

4. In general, what is your impression of acupuncture?
1(very negative) 2(negative) 3(mildly negative) 4(neutral) 5(mildly positive) 6(positive) 7(very positive)

5. Please circle the single most important source of your knowledge of acupuncture:
1 (I have tried acupuncture before)
2 (what friends have told me)
3 (personal reading in books and professional journals)
4 (popular media)
5 (other: _____)

6. If you have tried acupuncture before, what was your experience with it?
1(very negative) 2(negative) 3(mildly negative) 4(neutral) 5(mildly positive) 6(positive) 7(very positive)
9 (not applicable)

FIG. 7. Psychological impact pre-study scale. This questionnaire is adopted with modification from Lao *et al.* [34].

people-weeks with at least one adverse effect compared with 22 people-weeks in the control group ($P = 0.004$). Thus, significantly fewer acupuncture subjects had medication-related side-effects compared with those in the control group.

Discussion

The current study was a pragmatic one, intending to study acupuncture as it is commonly practiced, i.e. as an adjunctive therapy to standard therapy. The clinical question the study sought to answer was: does acupuncture add any benefit to older patients with chronic low back pain in addition to standard therapy? Our data indicate that acupuncture plus standard therapy does decrease back pain and disability in these patients compared with standard therapy alone, in a clinically and statistically significant manner. This study is one of the few acupuncture studies that has focused on older patients.

Most standard therapies for back pain frequently carry adverse effects, particularly in older patients, further compromising quality of life. NSAIDs carry a 2- to 5-fold increased risk of gastrointestinal bleeds, which increases with age [35]. NSAID-induced renal, cardiovascular, central nervous system (CNS) and haematological side-effects are also more common in older individuals. Use of narcotic analgesic and muscle relaxing agents results in an increased risk of falls in patients aged 60 yr and over (odds ratio of 1.54) [36], as does polypharmacy with CNS active medications (odds ratio of 2.37) [37]. Bed rest leads to deconditioning and osteoporosis, especially in the elderly, who often are already at risk for these conditions [38].

Prior literature has shown acupuncture to be a safe treatment. Our study likewise documents its safety, with minor aching and bruising being reported by a few patients. There was one patient who withdrew from the study because of pain. This patient also had a diagnosis of fibromyalgia, and her experience is consistent with other reports that acupuncture, as with other physical stimuli, may cause an exacerbation of pain [39]. Fibromyalgia patients should be counselled about this possibility. When acupuncture was added to standard therapy, subjects tended to take fewer medications. Significantly fewer acupuncture subjects had medication-related adverse effects compared with those on standard therapy alone.

The aetiology of back pain is incompletely understood. Back pain studies are challenged by the possibility of variability in characteristics and aetiology within the study population, including ours. We have followed the commonly accepted definition of chronicity and aetiology of back pain used in prior studies and clinical practice. Therefore, our study population is probably representative of that seen in general clinical practice.

Our protocol does not require a standardized regimen for standard therapy, which makes it possible for baseline differences between the two treatment groups to occur. In our study, no significant differences in medications for back pain were found between the two groups. In addition, every subject followed the standard therapy

After your experience here, we would like to know your opinion of the effectiveness of the treatment you received here.

Your responses will not be shown to the acupuncturist, nor will they be used to judge his work. We are only interested in how you feel about the treatment after you received it. All results will be kept anonymous.

Please answer the following questions:

1. I am confident that this treatment can alleviate my complaint.
a) Strongly disagree b) Disagree c) Unsure d) Agree e) Strongly Agree

2. I would be confident in recommending this treatment to a friend who suffered from similar complaints.
a) Strongly disagree b) Disagree c) Unsure d) Agree e) Strongly Agree

3. This treatment seems reasonable.
a) Strongly disagree b) Disagree c) Unsure d) Agree e) Strongly Agree

4. This treatment would be successful in alleviating other complaints.
a) Strongly disagree b) Disagree c) Unsure d) Agree e) Strongly Agree

FIG. 8. Psychological impact post-study scale. This questionnaire is adopted with modification from Lao *et al.* [34].

protocol within defined parameters. The data from this pragmatic study also more closely resembles the clinical setting in which acupuncture is actually used, i.e. an adjunctive therapy to a variety of standard therapies.

The results must be interpreted within the context of the study. This study was limited by a relatively small sample size and high loss to follow-up. The baseline characteristics of the subjects who stayed in the study and those who dropped out did not reveal significant differences other than location of back pain. A conservative, intention-to-treat analysis was done, and still found a statistically significant difference between the two treatment groups.

We had two acupuncturists who performed the study protocol, which made it possible for differences in technique to occur. Both acupuncturists did have similar backgrounds, being trained as anaesthetists and pain management specialists, as well as being certified in acupuncture. Furthermore, both documented at each acupuncture session the same acupoints, achieving deqi at each point and the pattern of electrical stimulation.

Our study also did not have a placebo group to control for the non-specific effects of acupuncture. Placebo effects may occur secondary to the physical aspects of the treatment, attention from the practitioner and *a priori* expectations of the patients about acupuncture [34]. Overall, our study did not show that patient expectations affected treatment outcome. However, the other non-specific effects of acupuncture should also be controlled for. A placebo-controlled study of acupuncture for low back pain in older patients is currently underway.

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Conflict of interest

The authors have declared no conflicts of interest.

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