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Chronic Spinal Pain Syndromes: A Clinical Pilot Trial Comparing Acupuncture, a Nonsteroidal Anti-inflammatory Drug, and Spinal Manipulation

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ABSTRACT

Objective: To compare needle acupuncture, medication (tenoxicam with ranitidine), and spinal manipulation for managing chronic (>13 weeks duration) spinal pain syndromes.

Design: Prospective, randomized, independently assessed preintervention and postintervention clinical pilot trial.

Setting: Specialized spinal pain syndrome outpatient unit at Townsville General Hospital, Queensland, Australia.

Subjects: Seventy-seven patients (without contraindication to manipulation or medication) were recruited.

Interventions: One of three separate, clearly defined intervention protocols: needle acupuncture, nonsteroidal anti-inflammatory medication, or chiropractic spinal manipulation.

Main Outcome Measures: Main outcome measures were changes (4 weeks vs initial visit) in the scores of the (1) Oswestry Back Pain Disability Index, (2) Neck Disability Index, and (3) three visual analogue scales of local pain intensity.

Results: Randomization was successful. After a median intervention period of 30 days, spinal manipulation was the only intervention that achieved statistically significant improvements (all expressed as percentages of the original scores) with (1) a reduction of 30.7% on the Oswestry scale, (2) an improvement of 25% on the neck disability index, and (3) reductions on the visual analogue scale of 50% for low back pain, 46% for upper back pain, and 33% for neck pain (all $P < .001$). Neither of the other interventions showed any significant improvement on any of the outcome measures.

Conclusions: The consistency of the results provides, in spite of several discussed shortcomings of this pilot study, evidence that in patients with chronic spinal pain syndromes spinal manipulation, if not contraindicated, results in greater improvement than acupuncture and medicine. (J Manipulative Physiol Ther 1999;22:376-81)

Key Indexing Terms: Spine; Acupuncture; Chiropractic Manipulation; Medicine; Clinical Trial; Chiropractic

INTRODUCTION

The high incidence of chronic spinal pain syndromes, their recurrent nature in many patients, and their contribution as a main cause of absence from work is well documented.[1] It is a disconcerting situation that the undisputed immense public health impact of chronic spinal pain syndromes and their enormous cost for health care budgets world wide stand in sharp contrast to the sparse knowledge about absolute and relative efficacy of different interventions. Very little research with respect to thoroughly planned prospective studies has been performed to date. There is controversy in the literature regarding the most effective treatment, although Meade et al[1,2] showed that when chiropractors and hospital therapists treat patients with low back pain as they would in day-to-day practice, those treated by chiropractic practice derive more benefit and long-term satisfaction. The trial by Meade et al,[1] proclaimed to be "one of the better trials in this field,"[3] was a "pragmatic" trial that tested what happens in day-to-day practice and in which details of the type, frequency, and duration of intervention were at the discretion of the treating clinician. However, a "pragmatic" trial may not identify the components of the more successful intervention that were responsible for improvement, but a "fastidious" trial may.[1]

To shed some light on the comparative efficacy of common treatment regimens, a prospective, randomized, independently assessed preintervention and postintervention clinical pilot trial was established at the specialized spinal pain syndrome outpatient unit at Townsville General Hospital. In this "fastidious" trial approach, three separate and clearly defined intervention protocols, (1) needle acupuncture alone or in conjunction with low voltage electrical stimulation (depending on patient tolerance), (2) spinal manipulation, and (3) nonsteroidal anti-inflammatory medication (using tenoxicam with ranitidine) were tested to compare the efficacy of these standardized intervention protocols.

METHODS

Patients

A prospective, randomized, independently assessed preintervention and postintervention (treatment period 4 weeks) clinical pilot trial at the Townsville General Hospital outpa-

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tient Spinal Pain Unit was conducted from July 1995 to June 1998 in cooperation with medical and other health care practitioners who referred patients to the unit for diagnosis and management of their spinal pain syndrome; patients were also allowed to self-refer. Townsville has a population of approximately 127,000 and is the largest community in tropical Australia, with a large catchment area; the next major medical community is 1250 km south.

Inclusion criteria were (1) suffering from spinal pain for at least 13 weeks and (2) age of at least 18 years. Exclusion criteria were nerve root involvement, spinal anomalies, pathology other than mild to moderate osteoarthrosis, previous spinal surgery, and leg length inequality of >9 mm with postural scoliosis. The detailed description of patients is shown in the results; of the total of 875 patients seen, 77 patients were randomized into the study. Ethical approval was granted by the Northern Regional Health Authority's Townsville General Hospital Institutional Ethics Committee (reference 32/94).

Randomization and Intervention Regimens

After informed written consent was obtained, patients were randomized by drawing an envelope out of a box with 150 well-shuffled envelopes, each containing one of three color codes (50 envelopes per intervention). This sample size per group was calculated as being sufficient to find an improvement of 10% of the initial score in the main outcome indexes as significant at a 5% alpha level with a power of 80% (taking into account published means and variability).

Fees for medical services were largely covered by Medicare Australia. To exclude any "financial bias" against a specific intervention, costs not covered by Medicare were absorbed by the hospital and a donor (Green Projects Donation Fund Limited).

Once patients were randomized, those undergoing acupuncture or spinal manipulation were examined by their treating clinician, who performed a physical examination to decide which form acupuncture or spinal manipulation would take. Acupuncture was performed by one of four experienced medical acupuncturists using sterile HWATO Chinese disposable acupuncture guide tube needles 50 mm long with a gauge of 0.25 mm for 20-minute appointments. For each patient, an average total number of 8 to 10 needles were placed in local tender points and in distant acupuncture points according to the "near and far" technique, depending on the condition being treated. Once patients could satisfactorily tolerate the needles for 20 minutes, low-volt electrical stimulation was applied to the needles with a battery-operated Multipurpose Health Device Model G6805-2 (Shanghai Medical Electronic Instruments Factory) at the patient's comfortable tolerance level. Six treatments applied in a 3- to 4-week period defined this intervention.

Spinal manipulation was performed as judged to be safe and appropriate by the treating chiropractor for the spinal level of involvement only; a high-velocity, low-amplitude spinal manipulation was performed.[4] Six treatments applied in a 3- to 4-week period defined this intervention. Patients treated with medication were given pills for the defined 3- to 4-week treatment period. Treatment times were standardized by arranging 15- to 20-minute appointments for all visits to eliminate a potential placebo effect originating from different lengths of "exposure" to the clinician.

Outcome Measures

Patients were asked to complete a questionnaire on sociodemographic basic data. For measuring the initial preintervention status and the postintervention outcome after the 4-week treatment period, the following questionnaires were self-administered: subjective Oswestry Questionnaire[5] (Couper, Eisenstein, Fairbank, O'Brien, written communication, June 1995) for low back and thoracic spine pain, and the Neck Disability Index[6] for neck pain. Both questionnaires are well tested and established and consist of 10 different items, such as pain intensity, lifting, and traveling. Each section has a scale ranging from 0 to 5. The overall score (0 to 50) is then transformed into a disability percentage (0% to 100%). If one or more single items are not answered, the overall score is computed from the available information.[5] Three visual analogue scales[7] were used to assess subjective pain (10-cm long scales marked "no pain" to "pain as bad as it could be" for "low back," "upper back (thoracic)," and "neck" pain, respectively.

Pain frequency was recorded on a scale with 5 ordered categories (once/month, once/week, once/day, frequent, and constant). Additionally, it was recorded whether patients had to be crossed over to another intervention after the study period (because of inefficiency or side effects) or whether they could be discharged.

Data Handling and Analysis

The data input person was provided with "color-coded" data and thus was unaware of which intervention was represented by the codes. Data were analyzed with the statistical software package SPSS. Because the frequency distributions of the main outcome measures proved to be skewed, quartiles were used for descriptions (ie, medians for measures of central tendency and 25th/75th percentiles for measures of dispersion). Consequently, all bivariate statistical test procedures used were nonparametric approaches. Initial scores from the different questionnaires were compared between treatment groups by the unpaired Kruskal-Wallis test. Preintervention/postintervention changes were tested by the paired Wilcoxon signed rank test within the treatment groups. Categorical variables between the groups were assessed with χ^2 or exact tests. Checking for possible confounding effects and interactions was performed by multiple regression models and respective logistic regression approaches. For all tests a P value less than .05 was regarded as statistically significant.

Deviations from the Study Protocol

Pilot study funding restrictions and resulting understaffing caused (1) randomization to be stopped before all envelopes were used, (2) difficulties in optimal follow-up of

Table 1. *Patient characteristics*

Variable	Manipulation (n = 36)	Acupuncture (n = 20)	Medication (n = 21)	All (n = 77)	*P* value (test over groups)
Age (yrs)					
25th percentile	35.5	36.5	29.5	34.5	
50th percentile	42.5	46.5	35.0	42.0	.19
75th percentile	48.5	49.5	48.5	49.0	
% Male sex (no.)	53% (19)	35% (7)	19% (4)	39% (30)	.038
Socioeconomic background					
Retired (no.)	8% (3)	5% (1)	0%	5% (4)	.49 exact test
Blue collar (no.)	47% (17)	70% (14)	57% (12)	56% (43)	
White collar (no.)	33% (12)	15% (3)	24% (5)	26% (20)	
Academic (no.)	11% (4)	10% (2)	19% (4)	13% (10)	
Involved part of spine					
Neck (no.)	50% (18)	35% (7)	33% (7)	42% (32)	.37
Upper back (no.)	36% (13)	35% (7)	29% (6)	34% (26)	.84
Lower back (no.)	86% (31)	75% (15)	81% (17)	82% (63)	.58
Pain duration (yrs)					
25th percentile	2	2	2	2	
50th percentile	6	7.5	5	6	.77
75th percentile	16	10	15	14	
Prior treatment					
Medical (no.)	83% (30)	75% (15)	67% (14)	77% (59)	.35
Manipulation (no.)	47% (17)	35% (7)	38% (8)	42% (32)	.63
Acupuncture (no.)	8% (3)	5% (1)	5% (1)	6% (5)	.83
Physiotherapy (no.)	42% (15)	30% (6)	48% (10)	40% (31)	.50
No. of treatments					
25th percentile	5.0	4.25	2.0	2.0	
50th percentile	6.0	6.0	2.0	6.0	<.0001
75th percentile	6.75	8.0	2.0	6.0	
Intervention period (days)					
25th percentile	14	21.5	14	14	
50th percentile	19	40	15	21	.002
75th percentile	24	65	30.5	35	

patients after the intervention period, resulting in a wide range of differing intervention periods between the first and second questionnaires, even though these differing time periods did not imply a change in the number of treatments, and (3) difficulty in obtaining acupuncture appointments because the acupuncturist treated not only patients randomized into the study but also a large number of other patients, leading to prolonged periods before the defined number of treatments were applied.

RESULTS

In total, 875 patients were seen during the study period. Apart from self-referral (62.7%), there were 204 (34.7%) medical referrals from 126 different medical practitioners, 19 (2.2%) from chiropractors, 3 (0.3%) from osteopaths, and 1 (0.1%) from a physiotherapist; 745 had to be excluded (main groups excluded were disorders other than mild to moderate osteoarthrosis, 360; medicolegal opinion, 97; choosing or refusing treatment, 56). Mainly because of the strict exclusion of any spinal anomalies or bony injuries, only 130 were eligible for randomization. Incomplete questionnaires and dropouts accounted for 49, leaving 77 patients in the study, of which 36 (47%) were randomized to spinal manipulation, 20 (26%) to acupuncture, and 21 (27%) to medication. The proportions of dropouts in the treatment groups were 26% (n = 13) for manipulation, 52% (n = 26) for acupuncture, and 20% (n = 10) for medication and differed significantly (P = .008) with respect to the interventions. Without exception, all dropouts were telephoned at the end of the study to ascertain why they did not return. The reasons found were exclusively unrelated to the outcome (ie, traveling problems because of distance, difficulties in obtaining convenient appointments, having moved location, etc).

Success of Randomization and Description of the Study Population

Table 1 summarizes patient characteristics and the success of randomization by detailing the characteristics in the three intervention groups. Three variables were found to be significantly different between intervention groups: sex, length of intervention period, and number of treatments. The latter difference simply arises from the study protocol: in both manipulation and acupuncture the intervention consisted of 6 treatments in contrast to the medication defined by 2 prescriptions.

Both sex and intervention period were not correlated to any outcome measures and consequently did not introduce any confounding bias. The length of the intervention period does not reflect the number of interventions, which were very close to the planned number of 6 and did not differ between manipulation and the acupuncture groups.

Comparability of groups with respect to initial values of the main outcome measures can be gathered from Tables 2 and 3. All tests for differences of the initial values of the main outcome measures between the groups were not significant (all P values > .28). The P values for initial Oswestry Scale values, the Neck Disability Index, and the visual ana-

Table 2A. *Main outcome measures: Oswestry Disability Index*[*]

Variable	Manipulation (n = 32)	Acupuncture (n = 16)	Medication (n = 20)	All (n = 68)
Initial values				
25th percentile	14.5	18.5	14.5	16.0
Median	28.0	24.0	20.0	26.0
75th percentile	41.5	35.5	39.5	40.0
Change (before minus after intervention)				
25th percentile	–16.5	–7.0	–0.4	–11.7
Median	–8.5 [CI: –14; –4]	+0.5 [CI: –8; +11.8]	0.0 [CI: –4; 0]	–3.5 [CI: –6; –1.1]
75th percentile	–2.0	+12.0	+3.5	+2.00
Test (before vs after)	P = .0004	P = .77	P = .71	P = .007

[*]A negative change means improvement.
CI, 95% Confidence interval of the median.

Table 2B. *Main outcome measures: Neck Disability Index*[*]

Variable	Manipulation (n = 21)	Acupuncture (n = 9)	Medication (n = 9)	All (n = 39)
Initial values				
25th percentile	27.0	17.0	18.5	24.0
Median	32.0	40.0	28.0	32.0
75th percentile	47.0	60.0	48.0	48.0
Change (before minus after intervention)				
25th percentile	–16.0	–14.5	–12.0	–14.0
Median	–10.0 [CI: –14; –4]	–6.0 [CI: –16; +2]	0.0 [CI: –14; +2.7]	–8.0 [CI: –14; –2]
75th percentile	–2.0	+5.0	+2.5	0.0
Test (before vs after)	P = .001	P = .26	P = .24	P = .005

[*]A negative change means improvement.
CI, 95% Confidence interval of the median.

logue scale for lower back, upper back, and neck were 0.86, 0.71, 0.28, 0.46, and 0.31, respectively. Initial recordings of pain frequency (categorically recorded) did not differ between groups (P = .49).

Main Outcome Measures

Table 2 details the results with respect to Oswestry and Neck Disability Indexes. All changes were calculated as postintervention minus preintervention measurements; therefore an improvement is indicated by a negative change, and a positive change reflects deterioration.

Significant changes with respect to the Oswestry Index were observed for the whole study group where the median decrease was –3.5% or 13.5% of the initial value, and for the manipulated group where the median change was –8.5% or 30.4% of the original disability. Other intervention groups showed no significant change.

Significant changes on the neck disability index could be detected in the whole group (–25% of the initial value) and in the manipulation group, where the median reduction in disability was –10% absolute or 31.3% of the initial disability; other intervention groups showed no significant change.

Table 3 summarizes visual analogue scale results. Significant reductions in pain intensity were found in the whole study group with respect to all three locations: pain intensity in the lower back decreased by 16.6% of the original score; the relative improvements for the upper back and the neck were 32.6% and 25%, respectively. Analysis of intervention subgroups showed significant reductions in pain intensity only in the manipulation group where the relative improvements were 50% (lower back), 46% (upper back), and 33.3% (neck), respectively.

With respect to pain frequency, the overall improvement was not significant (P = .055) but, with manipulation, a significant reduction (P = .007) was observed: 41% (n = 31) improved by at least one category (one by three, four by two, and eight by one category), whereas 45% (n = 14) did not change, and 13% (n = 4) deteriorated by one category. No significant changes for acupuncture or medication were found.

Overall, 33 patients (43%) had to change to another intervention after the study period because of inefficacy or side effects. The percentage of necessary crossing over differed significantly (P = .002) with respect to the three interventions; manipulation 22.2%, acupuncture 60%, and medication 62%. No side effects occurred for acupuncture or manipulation; three medicinally treated subjects had gastric symptoms.

In total, 19 patients (25%) were discharged after the study period. The proportion of discharge was significantly (P = .02) correlated with the type of intervention: manipulation, 39%; acupuncture, 10%; and medication, 14.3%.

For all the above-mentioned outcome measures, multivariate models were built to detect any possible confounding effects. None of the recorded variables—except the type of intervention—proved to be of any significant importance; nor could any effect modification be observed.

Table 3A. *Main outcome measures: visual analogue scale lower back*[*]

Variable	Manipulation (n = 32)	Acupuncture (n = 18)	Medication (n = 19)	All (n = 69)
Initial values				
25th percentile	2.4	0.4	2.0	2.0
Median	5.0	4.3	3.5	4.2
75th percentile	7.4	7.4	5.0	6.7
Change (before minus after intervention)				
25th percentile	–5.0	–1.0	–1.0	–3.8
Median	–2.5 [CI: –5; –21]	+0.8 [CI: –1; +2]	+0.3 [CI: +1.7; –1]	–0.7 [CI: –2; +0.2]
75th percentile	–0.6	+2.6	+2.5	+1.3
Test (before vs after)	P = .0001	P = .33	P = .41	P = .034

[*]A negative change means improvement.
CI, 95% Confidence interval of the median.

Table 3B. *Main outcome measures: visual analogue scale upper back*[*]

Variable	Manipulation (n = 20)	Acupuncture (n = 10)	Medication (n = 10)	All (n = 40)
Initial values				
25th percentile	2.2	0.0	0.8	1.1
Median	5.0	3.5	2.7	4.6
75th percentile	7.0	7.5	7.3	7.0
Change (before minus after intervention)				
25th percentile	–5.0	–4.0	–1.6	–3.4
Median	–2.3 [CI: –4.9; –1.5]	–0.5 [CI: –7; +1]	–1.0 [CI: –1.8; 0]	–1.5 [CI: –2.1; –0.5]
75th percentile	+0.1	+2.5	+0.1	+0.4
Test (before vs after)	P = .003	P = .68	P = .11	P = .0027

[*]A negative change means improvement.
CI, 95% Confidence interval of the median.

Table 3C. *Main outcome measures: visual analogue scale neck*[*]

Variable	Manipulation (n = 23)	Acupuncture (n = 15)	Medication (n = 12)	All (n = 50)
Initial values				
25th percentile	2.5	0.5	0.4	1.5
Median	4.5	2.0	4.0	4.0
75th percentile	8.0	7.2	5.0	7.3
Change (before minus after intervention)				
25th percentile	–3.0	–2.0	–1.7	–3.0
Median	–1.5 [CI: –3; 0]	–1.0 [CI: –2; 0]	–0.5 [CI: –1.7; +2]	–1.0 [CI: –1.7; 0]
75th percentile	0.0	+0.5	+3.1	0.5
Test (before vs after)	P = .002	P = .35	P = .79	P = .0154

[*]A negative change means improvement.
CI, 95% Confidence interval of the median.

DISCUSSION

At first glance the high proportion of dropouts, which additionally differed significantly between the intervention groups, seems to be a major drawback of this pilot study. It must be emphasized, however, that these dropouts were not related to major improvement or deterioration or side effects (only 3 had side effects) but were simply caused by severe understaffing and the resulting restrictions in the follow-up in an environment where major traveling was included (the catchment area for patients of the Townsville Spinal Pain Unit reaches as far as 1000 kilometers inland). All dropouts were telephoned at the end of the study to ascertain why they did not return. Because all reasons were independent of the outcome of the intervention, the dropouts have no potential for confounding the results. The presented results are also not confounded by any of the specifically recorded potential confounders (eg, sex, age, pain duration, and number and type of previous interventions) because bivariate findings were checked for confounding and found to be invariable.

To the best of our knowledge, these are the first findings reported from such a randomized clinical trial, and they seem to be consistent with the findings of the "pragmatic" study of Meade et al[1,2] that spinal manipulation has an important role to play in the treatment of spinal pain syndromes. The complexity of the field of spinal pain syndromes, as well as political obstacles associated with a multidisciplinary trial, are impediments in this field of research, but they can be overcome, as this pilot study shows.

The most remarkable feature of the results of this pilot study, however, is the absolute consistency: over all outcome

measures, the manipulation group displayed the most substantial improvements that were uniformly found to be significant. In the two other intervention groups, not a single significant improvement could be found in any of the outcome measures. The only other significant results were found in the whole study group. However, a close look at the results easily clarifies that the significant changes in the whole study group are simply a weaker reflection of the more substantial improvements observed in the manipulation subgroup.

It should be mentioned that the relatively short-term nature of this pilot study cannot indicate a guaranteed long-term benefit. The fact that patients could be discharged does not necessarily imply permanent relief from symptoms. To assess long-term effects, additional data collection over several years would have been necessary but was beyond the scope of this pilot study. Nevertheless, it is a noteworthy finding that significantly more patients could be discharged after spinal manipulation as opposed to the other interventions. This finding is consistent with and therefore corroborates the results found in the subjective outcome measurements.

Because a pathologic cause cannot be identified for most episodes of spinal pain,[8] the financial and resource implications of low back pain alone are extensive.[9,10] Therefore clinical guidelines are needed to improve the management of chronic spinal pain in primary care[11] because the proportion of patients with spinal pain who have poor outcomes seems to be higher than generally recognized[12]; research into this major health care problem is essential. At a time when the whole clinical community is implementing evidence-based management of patients, it is imperative that the field of chronic spinal pain syndromes, which vastly impacts on patient suffering and scarce health care resources, should catch up with other health care programs and no longer be characterized by a disproportionate paucity of epidemiologic data and controversy in comparison to its overall impact. In spite of the documented and discussed shortcomings of this pilot study, the consistency of the findings has enabled some light to be shed on the benefit of different interventions on this costly and debilitating condition.

CONCLUSION

Major well-funded prospective longitudinal clinical trials should be undertaken as soon as possible to further investigate this complex issue. These studies should emphasize specifically (1) standardized intervention protocols such as those used in this study, (2) strict monitoring and follow-up of patients in each treatment category, and (3) the long-term effects of treatment that should be evaluated by means of 12-month questionnaires administered over at least 3 years, which was beyond the scope of this pilot study.

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