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The Chiropractic Hospital-based Interventions Research Outcomes (CHIRO) Study: a randomized controlled trial on the effectiveness of clinical practice guidelines in the medical and chiropractic management of patients with acute mechanical low back pain

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Abstract

BACKGROUND CONTEXT: Evidence-based clinical practice guidelines (CPGs) for the management of patients with acute mechanical low back pain (AM-LBP) have been defined on an international scale. Multicenter clinical trials have demonstrated that most AM-LBP patients do not receive CPG-based treatments. To date, the value of implementing full and exclusively CPG-based treatment remains unclear.

PURPOSE: To determine if full CPGs-based study care (SC) results in greater improvement in functional outcomes than family physician–directed usual care (UC) in the treatment of AM-LBP.

STUDY DESIGN/SETTING: A two-arm, parallel design, prospective, randomized controlled clinical trial using blinded outcome assessment. Treatment was administered in a hospital-based spine program outpatient clinic.

PATIENT SAMPLE: Inclusion criteria included patients aged 19 to 59 years with Quebec Task Force Categories 1 and 2 AM-LBP of 2 to 4 weeks' duration. Exclusion criteria included ''red flag'' conditions and comorbidities contraindicating chiropractic spinal manipulative therapy (CSMT).

OUTCOME MEASURES: Primary outcome: improvement from baseline in Roland-Morris Disability Questionnaire (RDQ) scores at 16 weeks. Secondary outcomes: improvements in RDQ scores at 8 and 24 weeks; and in Short Form-36 (SF-36) bodily pain (BP) and physical functioning (PF) scale scores at 8, 16, and 24 weeks.

METHODS: Patients were assessed by a spine physician, then randomized to SC (reassurance and avoidance of passive treatments, acetaminophen, 4 weeks of lumbar CSMT, and return to work within 8 weeks), or family physician–directed UC, the components of which were recorded.

RESULTS: Ninety-two patients were recruited, with 36 SC and 35 UC patients completing all follow-up visits. Baseline prognostic variables were evenly distributed between groups. The primary outcome, the unadjusted mean improvement in RDQ scores, was significantly greater in the SC group than in the UC group ($p=.003$). Regarding unadjusted mean changes in secondary outcomes, improvements in RDQ scores were also greater in the SC group at other time points, particularly at 24 weeks ($p=.004$). Similarly, improvements in SF-36 PF scores favored the SC group at all time points; however, these differences were not statistically significant. Improvements in SF-36 BP scores were

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similar between groups. In repeated-measures analyses, global adjusted mean improvement was significantly greater in the SC group in terms of RDQ (p=.0002), nearly significantly greater in terms of SF-36 PF (p=.08), but similar between groups in terms of SF-36 BP (p=.27).

CONCLUSIONS: This is the first reported randomized controlled trial comparing full CPG-based treatment, including spinal manipulative therapy administered by chiropractors, to family physician–directed UC in the treatment of patients with AM-LBP. Compared to family physician–directed UC, full CPG-based treatment including CSMT is associated with significantly greater improvement in condition-specific functioning.

Keywords: Clinical practice guidelines; Acute low back pain; Nonoperative treatment; Chiropractic; Spinal manipulation

Introduction

Current clinical practice guidelines (CPGs) for the treatment of acute low back pain (AM-LBP) have been derived from independent systematic reviews carried out on an international scale [1–12]. Their recommendations have been shown to be highly consistent and based on sound scientific evidence rather than on consensus [13]. The knowledge translation of these guidelines to primary health-care providers has, to date, been unimpressive [14–16]. Multiple studies have demonstrated a poor correlation between what primary health-care providers think is an effective treatment and what has actually been shown to be an effective treatment [17–20]. Without widespread implementation of guideline-recommended treatments, the degree to which otherwise extensive scientific research (which the guidelines are based on) is actually helping this patient population remains to be determined.

The Chiropractic Hospital-based Interventions Research Outcome (CHIRO) initiative was designed to evaluate the outcomes of spinal pain patient management strategies that involve a component of chiropractic assessment and/or spinal manipulative therapy, administered in a hospital-based spine program outpatient clinic. This CHIRO framework was used in the present study to examine the effectiveness of current evidence-based CPG-recommended treatments for patients with AM-LBP pain.

The specific objective of the present study was to compare the short-term outcome of treatment comprised exclusively of guideline-recommended therapies on the one hand, with family physician–directed ''usual care (UC)'' on the other hand, for patients with AM-LBP. Our primary hypothesis was that guideline-concordant treatment would result in greater improvement in condition-specific quality of life than physician-directed UC at 16 weeks. One of our secondary goals was to advance the process of knowledge translation by directly involving community-based clinicians in research and thereby exposing this clinician population (and their patients) to a culture of evidence-based care.

Methods

Patient population

This study was designed as a two-arm, prospective, pragmatic, randomized controlled clinical trial using blinded outcome assessment. All study patients were recruited from the patient population currently referred for assessment at the International Collaboration on Repair Discoveries, Combined Neurosurgical and Orthopaedic Spine Program (CNOSP) Outpatient Clinic at Vancouver General Hospital. This university-based teaching hospital is located within a large Canadian metropolitan center. Eligible patients for this study included those aged 19 to 65 years with a chief complaint of AM-LBP. All patients included in the study satisfied the Quebec Task Force Classification of Spinal Disorders criteria for Categories 1 or 2 and had symptoms of 2 to 4 weeks in duration. Patients were excluded if they had signs of a spinal ''red flag'' condition (eg, cauda equina syndrome, fracture, malignancy, systemic signs of infection, and active inflammatory process), any spinal nerve root irritation or deficit, or were pregnant. Patients were also excluded if they had persisting pain in any other areas of their spine (eg, chronic neck pain), had previous spinal surgery, or were involved in a third-party insurance claim (workers compensation or other personal injury insurer).

Randomization

Patients were randomized to receive either CPGs-based study care (SC) in the CNOSP outpatient clinic or UC from their family physicians. As this study was conceived originally to be conducted at multiple centers, block randomization using a computer-generated randomization chart was used to ensure equal numbers of subjects between the groups throughout the recruitment period. To prevent foreknowledge of the allocation sequence before recruitment, variable blocks of four, six, and eight were used. Furthermore, treatment assignment was conducted through a central research office, where the allocation sequence was accessible only to an independent research assistant.

Treatments

All study patients were assessed initially by a physician in the CNOSP outpatient clinic to confirm that they met the inclusion and exclusion criteria of the study. Patients randomized to receive SC then received reassurance regarding the natural history of AM-LBP; advice to avoid passive treatment approaches (eg, bed rest, heat, or the use of back supports/corsets/braces); advice to carry out

a progressive walking program (two walks a day, each with an initial duration of between 5 and 15 minutes depending on the patient's tolerance increasing by 2 minutes each walk per week); acetaminophen, 650mg every 6 to 8 hours as required for 2 to 4 weeks, unless medically contraindicated (eg, because of allergy, compromised liver function, or acute porphyria); and a maximum 4 weeks of lumbar spinal manipulative therapy using conventional side-posture, high-velocity, low-amplitude techniques. Spinal manipulative therapy was specifically limited to the lumbar spine (ie, no treatment was directed to the cervical or thoracic regions) and was administered by a registered chiropractor.

Hospital privileges were granted to four community-based chiropractors specifically for the purpose of completing the present study. Chiropractic treatment was conducted in the CNOSP outpatient clinic at a frequency of two to three times per week, for a maximum period of 4 weeks at the discretion of the attending chiropractor. Study care patients were also advised to avoid guideline-discordant treatments, including muscle relaxant and opioid-class medications, passive physiotherapy modalities, bed rest, and ''special'' back exercise programs (eg, ''core stability'' or extension exercises).

Patients randomized to the UC treatment arm were advised of their diagnosis (ie, mechanical low back pain) and referred back to their referring family physician with a letter explaining the protocol of the present study. The attending family physicians were also provided with a standardized consultation report containing information that confirmed a diagnosis of acute mechanical low back pain (AM-LBP). Family physicians were not offered specific treatment recommendations but were simply advised to treat at their own discretion. They were also informed that their patients would be followed up at 8, 16, and 24 weeks after their initial consultation and that the content of their UC treatment would be recorded.

EVIDENCE & METHODS

Context
Multiple practice guidelines have been proposed for the treatment of acute low back pain. In this randomized trial, the authors compare outcomes of an evidence-based guideline approach, including nonopioid medication, a progressive walking program, and short-term lumbar manipulation, versus family physician ''usual care.''

Contribution
The evidence-based care group demonstrated significantly greater improvements in reported function through 6 months follow-up. There were high rates of opioid use (80%) and passive modalities (60%) employed in the family physician ''usual care'' group, but much less aerobic exercise or spinal manipulation was used.

Implication
This study offers some insight into high rates of opioid and passive methods for acute low back pain employed in ''usual care'' at a university-based hospital. The results of avoiding some well-documented treatment pitfalls and using the evidence-based guideline method appear promising. This study also provides evidence that the actual implementation of guideline recommendations may be truly beneficial to patients, themselves, and not just to payers' strategy to minimize costs. The outcome of the ''outcomes movement'' is, to some extent, still unclear, and even in this well-designed study limitations preclude identifying individual ''effective'' interventions or dosages, as well as confounding preference and nonblinding effects in study subjects.

—*The Editors*

Chiropractic treatment

The chiropractors participating in this study agreed in advance to modify their typical patterns of practice (if necessary) to conform to the guidelines-based treatment protocol. Four chiropractors participated, with each completing multiple 4-week clinical rotations in turn until the completion of the study. Chiropractic spinal manipulative therapy was administered only to the lumbosacral spine region, again at a frequency of two to three times a week for a maximum of 4 weeks. No patients in the SC group received neck manipulation or any form of chiropractic treatment other than conventional side-posture, high-velocity, low-amplitude, lumbar spinal manipulations. Study care patients were advised that participation in any of the treatments provided was entirely optional and that they could decline any individual component of treatment.

Outcomes assessment

The primary outcome of interest was the improvement (ie, change) in back pain–specific function at 16 weeks compared with the start of treatment, as measured on the modified Roland-Morris Disability Questionnaire (RDQ) [21]. We were primarily interested in the outcome of patients at 16 weeks as this approximates the end of the acute phase of the patient's clinical course. Because patients who have demonstrated poor treatment outcomes at this point are thought to be at a significant risk for going on to develop chronic low back pain, improvements in functional capacity at this time are critically important. The secondary outcomes of interest included the change in RDQ scores at other time points (8 and 24 weeks) and in normalized Short Form-36 (SF-36) bodily pain (BP) and physical functioning (PF) domain scores at 8, 16, and 24 weeks.

Baseline historical, demographic, RDQ, and SF-36 questionnaires were administered by the study coordinator at the time of the initial clinical evaluation. With the exception of the initial demographic questionnaire, these same questionnaires were readministered by mail at 8, 16, and 24 weeks' (after the baseline) follow-up. In addition, patients in the UC group had the composition of the treatment that they received, recorded, and scored on a guideline concordant scale based on a standardized format previously described in the literature [14]. Briefly, the guideline concordance of the treatment received by each patient was scored on a scale of 0 to 7. In this regard, the points were given for recommending any of the following four guideline-concordant treatments: reassurance of the favorable natural history; nonsteroidal anti-inflammatory drugs (NSAIDs) or acetaminophen if the patient requested medication; spinal manipulative therapy involving the lumbar spine for a period of up to 4 weeks; and aerobic exercises. Points were also added/subtracted if any of the following three guideline-discordant treatments had specifically been discouraged or encouraged: more than 7 days' use of narcotic medication; bed rest for longer than 3 days; and passive physiotherapy or massage therapy. Patients receiving SC were also asked at the time of their 8, 16, and 24 weeks' follow-up assessments if they had received any other forms of treatment during their participation in the study. Subjects not returning their questionnaires within 3 weeks of the required dates were contacted once a week by phone, for a maximum of three times.

Statistical analysis

For the primary analysis, the unadjusted mean change in RDQ scores at 16 weeks was compared between treatment groups using the *t* test for independent samples. We planned to use an analysis of covariance in the event that a clinically significant difference in baseline RDQ scores was observed between groups. In accordance with an intention-to-treat analysis, patients were analyzed according to the treatment group they were allocated to. Missing responses were handled using the last observation carried forward method. For the secondary analysis, pairwise comparisons in the mean changes in RDQ scores at 8 and 24 weeks and in normalized SF-36 BP and PF scale scores at all points of follow-up were also conducted. Finally, for all outcome measures, the adjusted mean change at each time point and the average adjusted mean change across all time points (global change) were compared between groups in repeated-measures analyses. All analyses were implemented in SAS version 9.1 (SAS, Carey, NC, USA). For the adjusted analyses, the Proc Mixed procedure was used to fit a mixed-effects model in which correlation between repeated measures within subjects over time was accounted for. Akaike's information criterion statistic was used to assess optimum model fit and the appropriateness of different variance-covariance structures.

Calculation of sample size

Bombardier et al. [22] and Roland recommended the use of 2 to 3 points as the minimal clinically important difference on the RDQ in clinical trials of low back pain. Assuming a difference in mean RDQ scores between groups of 5 points, a standard deviation of 4.4 (as per Constant et al. [23]), power of 0.80, and a significance level of 0.05 (two sided), the estimated sample size for each arm of the study was 35. Also, assuming a potential dropout and/or loss to follow-up rate of 25%, a total required sample size of 88 (35+35+18) was estimated.

Ethics approval was obtained from the University of British Columbia Clinical Research Ethics Board (certificate number H04-70588). The study was registered with ClinicalTrials.gov (http://clinicaltrial.gov; identifier number: NCT00135239).

Results

Chiropractic care

Two patients randomized to SC expressed mild apprehension about receiving lumbar spinal manipulation treatment from a chiropractor, but none actually declined this component of their treatment. There were no instances of patients reporting adverse effects or requesting that their chiropractic treatment be discontinued.

Patient baseline characteristics

As shown in Fig. 1, a total of 96 eligible patients were needed to fulfill the required study sample of 88 patients. All patients who declined to participate in the study (8%) did so because of lack of interest and were not otherwise followed up. No patients crossed over between treatments within the 24-week study period. There was a 20% loss to follow-up in both treatment arms at 24 weeks.

The demographic features, clinical characteristics, and baseline health status measures of the patients enrolled in this study are summarized in Table 1. There were no statistically significant differences in baseline demographic, clinical, or questionnaire measurements (RDQ and SF-36 BP or PF scale scores) between groups. Furthermore, as is shown in Table 2, the baseline characteristics of the patients who did not complete the study did not differ significantly from those who completed the study.

Analysis of UC composition

Patients randomized to the UC group received treatment from a variety of professionals including family physicians, massage therapists, kinesiologists, and/or physiotherapists. As is shown in Fig. 2, none of the UC patients received treatment with a guideline-concordant score greater than 4 of 7, whereas 77% had a score of 2 of 7 or less. By definition, all patients in the SC group received treatment with a guideline-concordant score of 7 of 7. At the primary follow-up point of 16 weeks, 78% of patients in the UC group were still taking narcotic analgesic medications on either a daily or as needed

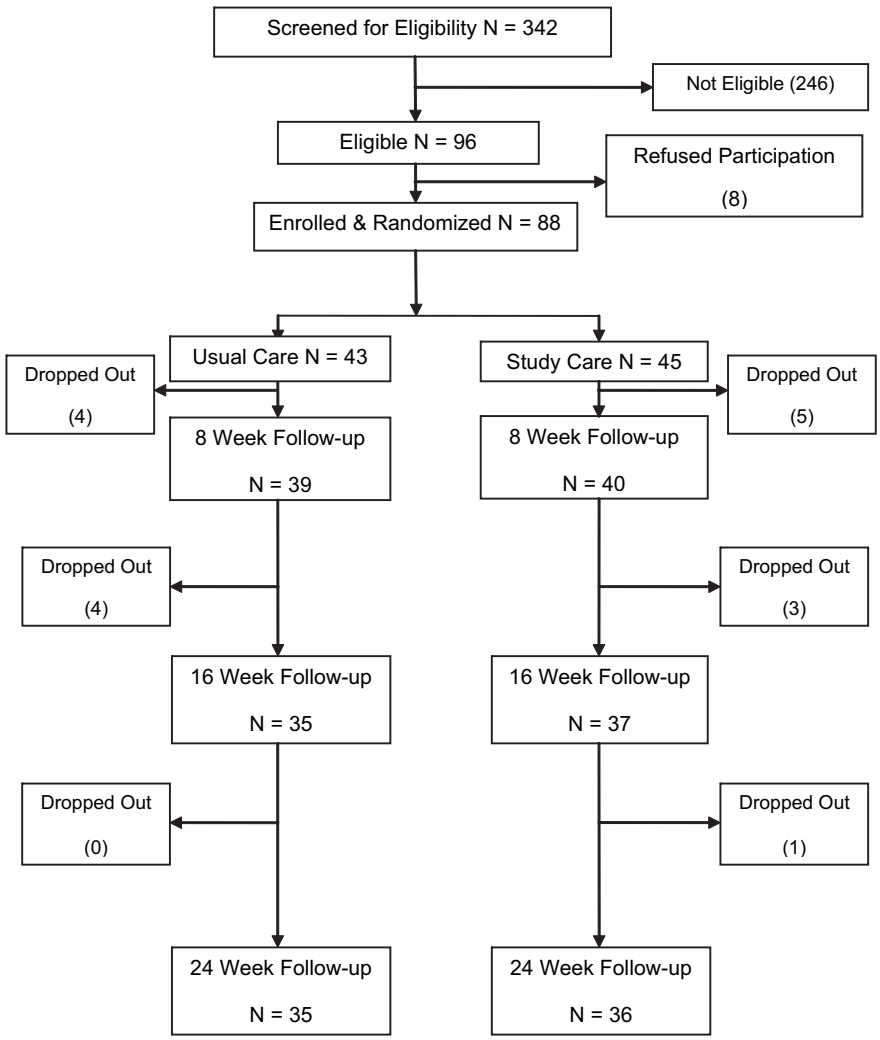

Fig. 1. Patient flow diagram.

basis. Only 6% of patients in the UC group had received chiropractic spinal manipulative therapy (Table 3).

Primary outcome

The primary comparison of interest involved the mean change in RDQ score between treatment groups at 16 weeks. The plots in Figs. 3 and 4, respectively, depict mean unadjusted RDQ and SF-36 (BP and PF) scale scores over time for each treatment group. As shown in Table 4 (unadjusted results), condition-specific improvement at 16 weeks clearly favored the SC group, with mean RDQ improvement scores of 2.7 in the SC group compared with only 0.1 in the UC group ($p=.003$). Mean RDQ scores at baseline were comparable between groups, and therefore an analysis of covariance was not performed.

Secondary outcomes

In Table 4, it is evident that the unadjusted pointwise improvements in RDQ scores also favored the SC group at 8 and 24 weeks. The difference favoring SC treatment was not quite significant at 8 weeks ($p=.07$) but clearly significant at 24 weeks of follow-up (0.004).

Unadjusted pointwise differences in SF-36 BP change scores were not significant between groups at either 8, 16, or 24 weeks' follow-up. Unadjusted differences in SF-36 PF change scores slightly favored the SC group at all time points, and the difference was nearly significant at 8 weeks ($p=.07$) but not at 16 ($p=.11$) or 24 weeks ($p=.32$).

Table 5 shows the results of repeated-measures analyses. The overall adjusted mean improvement in RDQ scores, averaged across all time points, was clearly greater in the SC group than in the UC group ($p=.002$). Pairwise comparisons at each time point showed that the difference between groups was nearly significant at 8 weeks ($p=.07$) and highly significant at both 16 ($p=.002$) and 24 weeks ($p=.002$).

No significant difference between groups was observed in terms of overall adjusted mean improvement in SF-36 BP scores ($p=.27$). However, SC treatment was associated with a trend toward greater overall mean improvement in

Table 1
Baseline characteristics of patients

Characteristic*	Usual care (N=43)	Study care (N=45)
Age (y)	38 (8.9)	37 (11.3)
Female (%)	61	59
Symptom duration at randomization (d)	20.0 (3.7)	18.0 (3.7)
RDQ score	13.1 (5.6)	12.2 (6.0)
SF-36 scores		
PF	46.3 (14.7)	47.5 (12.6)
BP	38.8 (7.4)	38.0 (13.4)

RDQ, Roland-Morris Disability Questionnaire; SF-36, Short Form-36; BP, bodily pain; PF, physical functioning.

* Mean value with standard deviation in parentheses unless otherwise indicated.

Table 2
Baseline characteristics of patients who were eligible but not enrolled, patients with incomplete follow-up, and patients followed-up for 24 weeks

Characteristic	Eligible but not enrolled (N=8)	Incomplete follow-up (N=18)	Followed-up at 24 wk (N=70)
Age (y)	32	35	38
Female (%)	59	60	58
Working (%)	64	63	61
Symptom duration at randomization (d)	18	20	20
RDQ score	N/A	12	13
SF-36 scores			
PF	N/A	49	44
BP	N/A	39	37

RDQ, Roland-Morris Disability Questionnaire; SF-36, Short Form-36; BP, bodily pain; PF, physical functioning.

SF-36 PF scores (p=.08). Correspondingly, post hoc comparisons showed trends toward significantly greater improvement in SF-36 PF scores at 8 (p=.07) and 16 weeks (p=.06) but not at 24 weeks (p=.23).

Discussion

To our knowledge, this is the first randomized controlled clinical trial assessing the efficacy of full, multimodal, CPG-based therapy for patients with AM-LBP. In this respect, it is distinct from previous studies that have evaluated only individual components of guidelines-based therapies in isolation or combinations of relatively few selected guidelines-based treatment elements as a package [24–26]. This study also follows two previous studies conducted by our group that demonstrated that treatments commonly recommended by primary care physicians are often highly guideline discordant [14,15], and other studies that have demonstrated that primary care physicians are highly resistant to changing their patterns of practice for managing patients with AM-LBP [19,20]. An important, although not unique, feature of the design of the present study was that it successfully achieved the cooperation from a diverse group of physicians and chiropractors to modify their preexisting patterns of practice to conform to our specific guidelines-based treatment protocol.

The results of this study demonstrated that in equivalent groups of patients with AM-LBP of less than 4 weeks' duration, carefully controlled and comprehensive CPG-based care was associated with greater improvement in terms of condition-specific functioning (RDQ scores) at 16 weeks after treatment initiation. The study was primarily designed to evaluate treatment outcomes for the entire duration of the acute phase of the patient's clinical course (ie, 16 weeks). The important issue of whether patients in either treatment group later experience reoccurrences of acute back pain or go on to develop chronic low back pain is the subject of

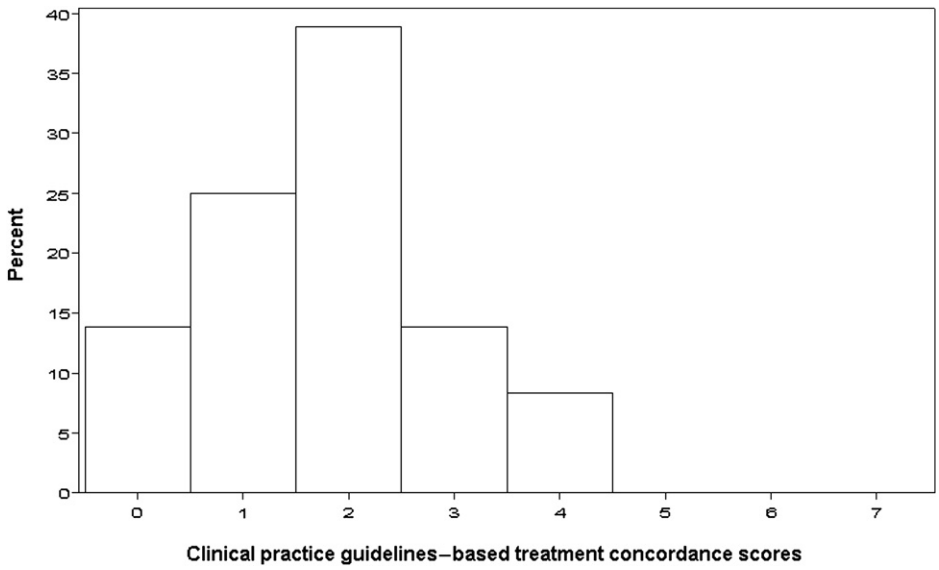

Fig. 2. Clinical practice guideline–based treatment concordance scores.

Table 3
Frequencies of use of reported treatments and cointerventions in each group among patients completing the study

Type of cointervention	Usual care, n (%)	Study care, n (%)
Bed rest	9 (25)	0 (0)
Passive physical therapy	22 (61)	0 (0)
Narcotic analgesics	28 (78)	0 (0)
Aerobic exercise	3 (8)	36 (100)
NSAIDs	22 (61)	36 (100)
Reassurance	11 (31)	36 (100)
Manipulation	2 (6)	36 (100)

NSAIDs, Nonsteroidal anti-inflammatory drugs.

a future study. However, the importance of improving patient outcomes within the acute phase of the patient's clinical course is important because the development of chronic and often refractory low back pain is commonly preceded by a poor outcome from the management of the patient's AM-LBP.

In regard to other secondary findings, a nonsignificant benefit of guidelines-based care over UC was observed at 8 weeks in both our unadjusted and adjusted analyses. Subsequently, the effect of guidelines-based care on back pain–specific functioning was significantly greater than guidelines-discordant care at 16 weeks, and this benefit was maintained at 24 weeks.

Regarding our SF-36 outcomes, the SF-36 BP subscale did not detect a significant difference between groups, which may reflect lower discriminative ability of the SF-36 BP subscale among some patients with low back pain [27]. On the other hand, 78% of patients in the UC group, compared with 0% of patients in the SC group, were also taking narcotic analgesic medications. This differential use of narcotic analgesics would normally bias the SF-36 BP score results in favor of the UC group; yet, SC patients showed comparable improvement in BP scores.

General PF, as assessed using the SF-36 PF scale, was generally greater in the guideline-concordant treatment group than in the guideline-discordant treatment group. In both adjusted and unadjusted analyses, the superiority of guideline-concordant treatment on general PF was greatest at 16 weeks, then less at 24 weeks' follow-up. A trend toward a statistically significant difference in favor of SC was seen at 8 weeks in both our unadjusted and adjusted analysis and at 16 weeks in our adjusted analysis only.

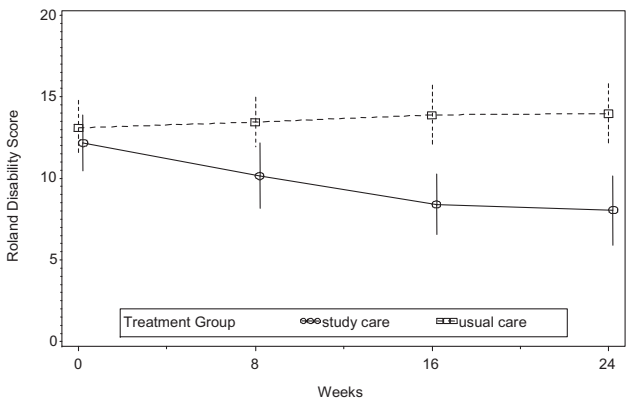

Fig. 3. Higher scores indicate greater disability. Error bars represent unadjusted 95% confidence intervals. Data values for study care are offset to the right to enhance legibility.

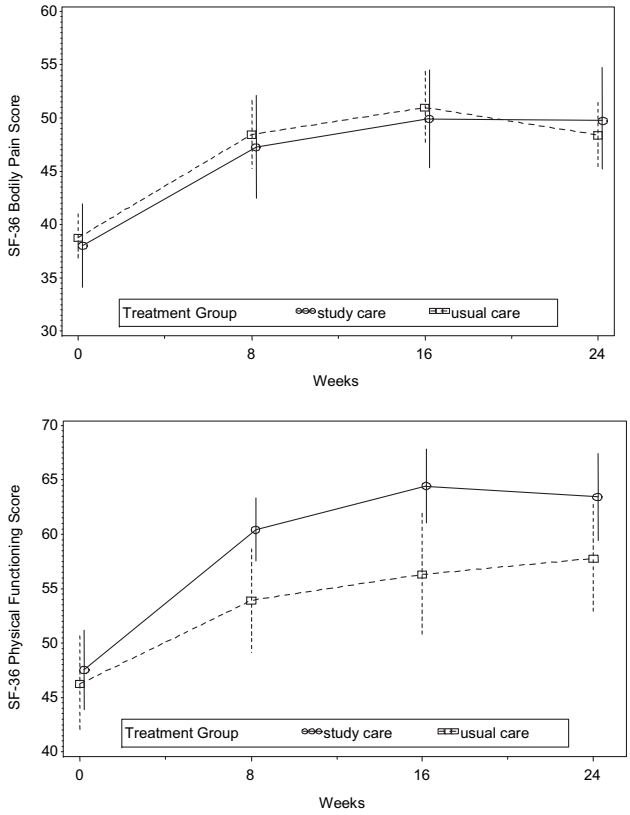

Fig. 4. Observed mean SF-36 bodily pain and physical functioning scale scores over time, by treatment group. Higher scores indicate better health status. Error bars represent 95% confidence intervals. Data values for study care are offset to the right to enhance legibility.

Another interesting finding in this study is that although patients in both the SC and UC groups showed improvement in general BP scores and general PF scores over time, patients in the UC group uniquely showed no improvement whatsoever in back-specific functioning (RDQ scores) throughout the entire study period. The apparently poorer natural course of low back pain among UC patients is perhaps not surprising, given that patients with AM-LBP referred to a tertiary care hospital-based spine program are more likely to harbor underlying spine pathology (eg, spinal stenosis, disc degeneration, or facet joint arthropathy). A recent study has demonstrated that patients with some forms of underlying spine pathology have less favorable nonoperative treatment outcomes than patients with no identifiable underlying spine pathology [28].

The design of this study carried out in the setting of the Canadian health-care system had some similarities but also some other important differences to other recent studies that have evaluated guideline-based treatment in this patient population in other National health-care environments.

Table 4
Unadjusted mean change scores and differences between treatment groups

Outcome	Time point (wk)	Usual care	Study care	Mean difference (95% CI)	p Value*
RDQ change, mean (SE)	8	−0.07 (0.49)	−1.49 (0.59)	1.42 (−0.12, 2.96)	.07
	16	−0.14 (0.56)	−2.66 (0.60)	2.52 (0.88, 4.16)	.003†
	24	−0.12 (0.35)	−2.68 (0.77)	2.56 (0.82, 4.30)	.004
SF-36 BP change, mean (SE)	8	7.84 (1.42)	7.76 (1.39)	0.08 (−3.87, 4.03)	.97
	16	10.05 (1.52)	11.33 (1.40)	−1.29 (−5.38, 2.80)	.53
	24	8.21 (1.32)	11.04 (1.43)	−2.84 (−6.71, 1.04)	.15
SF-36 PF change, mean (SE)	8	7.30 (1.51)	11.64 (1.86)	−4.34 (−9.12, 0.44)	.07
	16	9.72 (2.22)	14.13 (1.66)	−4.41 (−9.90, 1.07)	.11
	24	10.98 (2.04)	13.62 (1.66)	−2.64 (−7.86, 2.57)	.32

RDQ, Roland-Morris Disability Questionnaire; SE, standard error; CI, confidence interval; SF-36, Short Form-36; BP, bodily pain; PF, physical functioning.

* *t* Tests for independent samples.

† Test of primary hypothesis and outcome of interest.

Using nonrandomized clinical trial methodology, McGuirk et al. [24] evaluated the use of ''special clinics'' established in a single state of Australia, which were staffed by physicians who agreed to ''abide'' by the guidelines to treat a cohort of patients with acute back pain. Although the treatments provided under the umbrella of ''evidence-based care'' did not include all of the current guideline-recommended treatments (eg, chiropractic spinal manipulation), evidence-based care was shown to achieve greater rates of full recovery, result in reduced need for continuing care, and was less expensive. The United Kingdom BEAM [25] study used randomized control study design to evaluate spinal manipulative therapy administered by chiropractors, osteopaths, and physiotherapists as a component of a package of therapies in the treatment of patients with acute and chronic low back pain. The results showed that combined elements of guideline-based treatments resulted in better patient outcomes than treatment based on single guidelines-based elements. The findings of all of these studies are somewhat at odds with the findings of the recent study by Hancock et al. [26] that reported that some components of the current guideline-recommended treatment are superfluous. In particular, using this study design, the addition of NSAIDs and a form of spinal manipulative therapy or mobilization administered by a physiotherapist to the lumbar spine, thoracic spine, sacroiliac joint, pelvis, and hip (compared with a detuned ultrasound as placebo manipulative therapy), to family physician ''advice'' and acetaminophen were shown to have no clinically worthwhile benefit when compared with advice and acetaminophen alone.

Current CPG are derived exclusively from the best available scientific evidence. Research studies that evaluate the efficacy of these guidelines are a desirable and necessary step in the development of more refined guidelines, and it is through this process that optimum treatment strategies will be defined. When evaluating current guidelines, care must be taken to avoid making invalid comparisons. This is particularly the case when evaluating guideline-concordant forms of spinal manipulative therapy. Its inclusion as a component of current guideline-concordant treatment is based on the independent reviews carried out on an international

Table 5
Adjusted mean change scores and differences between treatment groups

Outcome	Time point (wk)	Usual care	Study care	Mean difference (95% CI)	p Value*
RDQ change, mean (SE)	8	0.11 (0.68)	−1.33 (0.64)	1.44 (0.18, 3.07)	.08
	16	0.04 (0.68)	−2.50 (0.64)	2.54.3 (0.92, 4.17)	.002†
	24	0.06 (0.68)	−2.52 (0.64)	2.59 (1.4, 5.3)	.002
	Global effect	0.07 (0.60)	−2.12 (0.56)	2.19 (0.96, 4.21)	.002
SF-36 BP change, mean (SE)	8	4.34 (2.03)	4.80 (1.84)	0.46 (−4.30, 3.37)	.81
	16	6.55 (2.03)	8.38 (1.84)	−1.38 (−5.66, 2.00)	.34
	24	4.71 (2.03)	8.09 (1.84)	−3.38 (−7.21, 0.46)	.08
	Global effect	5.20 (1.92)	7.09 (1.73)	−1.89 (−5.2, 1.9)	.27
SF-36 PF change, mean (SE)	8	4.99 (2.53)	9.69 (2.32)	−4.70 (−9.71, −0.31)	.07
	16	7.41 (2.53)	12.18 (2.32)	−4.77 (−9.78, 0.24)	.06
	24	8.67 (2.53)	11.67 (2.32)	−3.00 (−8.01, 2.00)	.23
	Global effect	7.03 (2.44)	11.18 (2.23)	−4.16 (−8.82, 0.51)	.08

RDQ, Roland-Morris Disability Questionnaire; SE, standard error; CI, confidence interval; SF-36, Short Form-36; BP, bodily pain; PF, physical functioning.

* Repeated-measures analysis models using ''treatment'' and ''time'' as fixed effects, ''subject'' as a random effect, and a first-order autoregressive covariate structure.

† Test of primary outcome of interest.

scale of the published high-quality clinical trials that have evaluated spinal manipulative therapy administered virtually entirely by chiropractors. Although spinal manipulative therapy is currently administered by many different health-care professionals, including chiropractors, osteopaths, orthopedic surgeons, family physicians, kinesiologists, naturopaths, and physiotherapists, the levels of training and clinical acumen vary widely. The study design used by Hancock et al., therefore, differs from our study because it did not use *chiropractic* spinal manipulation, and current guideline-based care does not endorse any forms of spinal manipulation administered by any other practitioners. However, this is an issue that certainly requires further study. Similarly, the reported finding that adding NSAIDs to the treatment regimen produced no further benefit to patients is again not guideline discordant, as the guidelines recommend either acetaminophen or NSAID medications and not both.

Our study has several limitations beginning with the comparison of UC, directed by a family physician, to SC provided by medical spine specialists and chiropractors in a hospital-based spine program setting. It may be argued that highly standardized evidence-based care provided by spine specialists is likely to result in improved outcomes when compared with UC provided by a random group of practitioners (eg, family physicians, chiropractors, and physiotherapists) in private offices. Therefore, this study does not necessarily comment on the effectiveness of nonhospital or community-based guideline-concordant care. Furthermore, from the time that treatment actually commences within each study arm, the potential development of higher expectations of benefit (from specialized treatment) within the SC group cannot be ruled out. It should also be noted that neither patients nor health-care providers were blinded in this study. It was not possible to blind health-care providers from the interactive interventions they were administering, particularly in the case of hands-on interventions such as chiropractic manipulation and massage therapy. Furthermore, it was impracticable to blind patients to their respective interventions as this would have required the addition of simulated multidisciplinary health-care visits and corresponding interactive interventions in both study arms. This was deemed unworkable, as it would have required an impractical number of patients and clinician hours. Furthermore, the ethical standards that our institution defined required that the normal patterns of practice for the clinicians and patients in the UC group would not be disrupted in any way.

In the present study, the dropout rate was the same (20%) in each treatment arm. Furthermore, in terms of baseline variables, patients with missing responses were very similar to those with complete response information, and therefore dropouts did not appear to be associated with treatment or other measured confounders. Given the absence of differential dropouts between groups, we suspect that our intention-to-treat analysis—involving a last observation carried forward approach—underestimates the true benefit of CPG-based care. Under the last observation carried forward method, patients with missing responses are assumed not to improve at all after the time of their last follow-up visit. Yet, anecdotally, it is our experience that the few patients at our center who do miss or cancel their follow-up visits do so only in the event that they experience early recovery or some other level of improvement downgrading their need for attention from a spine physician.

It should be noted that although the hospital-based setting of our study intervention potentially limits the generalizability of these results to the community practice setting, the fact that the family practitioners knew they were in a study and that their treatments and results would be reported, potentially makes the observed difference between the two groups even more robust as attending physicians would likely have been inclined to treat study patients more diligently. However, the degree to which the outcomes of this study can be applied to a similar treatment program administered in the community (outside of a hospital-based spine program) is not known. A study addressing this issue is now underway.

Finally, although these results are supportive of CPG-based care, they should not in any way be interpreted as an endorsement or criticism of any one particular health-care profession. The results of this study clearly support the use of multimodal full guidelines-based treatment in this patient population and therefore validate the process of improving quality of care through the implementation of evidence-based care.

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