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P Jüni,[1,2] M Battaglia,[1,3] E Nüesch,[1,2] G Hämmerle,[4] P Eser,[1,5] R van Beers,[3] D Vils,[3] J Bernhard,[6] H-R Ziswiler,[5] M Dähler,[1] S Reichenbach,[1,5] P M Villiger[5]

[1] Division of Clinical Epidemiology and Biostatistics, Institute of Social and Preventive Medicine, University of Bern, Bern, Switzerland; [2] CTU Bern, Inselspital, Bern University Hospital, Bern, Switzerland; [3] Praxis Bubenberg, MediX General Practice Network, Bern, Switzerland; [4] Department of Rheumatology, Schulthess Clinic, Zürich, Switzerland; [5] Department of Rheumatology, Clinical Immunology and Allergology, University Hospital Bern, Bern, Switzerland; [6] Department of Internal Medicine, Cantonal Hospital Solothurn, Solothurn, Switzerland

Correspondence to: Professor P Jüni, University of Bern, Institute of Social and Preventive Medicine, Division of Clinical Epidemiology and Biostatistics, Finkenhubelweg 11, 3012 Bern, Switzerland; juni@ispm.unibe.ch

PJ and MB contributed equally to this paper

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ABSTRACT

Objective: To determine whether treatment with spinal manipulative therapy (SMT) administered in addition to standard care is associated with clinically relevant early reductions in pain and analgesic consumption.

Methods: 104 patients with acute low back pain were randomly assigned to SMT in addition to standard care (n = 52) or standard care alone (n = 52). Standard care consisted of general advice and paracetamol, diclofenac or dihydrocodeine as required. Other analgesic drugs or non-pharmacological treatments were not allowed. Primary outcomes were pain intensity assessed on the 11-point box scale (BS-11) and analgesic use based on diclofenac equivalence doses during days 1–14. An extended follow-up was performed at 6 months.

Results: Pain reductions were similar in experimental and control groups, with the lower limit of the 95% CI excluding a relevant benefit of SMT (difference 0.5 on the BS-11, 95% CI −0.2 to 1.2, p = 0.13). Analgesic consumptions were also similar (difference −18 mg diclofenac equivalents, 95% CI −43 mg to 7 mg, p = 0.17), with small initial differences diminishing over time. There were no differences between groups in any of the secondary outcomes and stratified analyses provided no evidence for potential benefits of SMT in specific patient groups. The extended follow-up showed similar patterns.

Conclusions: SMT is unlikely to result in relevant early pain reduction in patients with acute low back pain.

Acute low back pain is a frequent reason for consultations in primary care or emergency departments.[1] The majority of consultations leads to the prescription of analgesics,[2] with or without additional non-pharmacological treatment modalities. Spinal manipulative therapy (SMT) plays a prominent, but inconsistent role in different treatment guidelines.[3] British[4] and American[5] guidelines, for example, recommend early referral to SMT to reduce the proportion of patients developing chronic complaints, whereas Dutch guidelines[6] discourage it. Similarly, the conclusions of systematic reviews that inform these guidelines are discordant.[7–12] The most recent Cochrane Review[11 13] concluded that for the treatment of acute low back pain SMT may be superior to sham therapy, but not to other treatment modalities. Most of the published trials of SMT in patients with acute low back pain[14–21] were hampered either by poor methodology,[22 23] including inadequate concealment of allocation[14–18 20] and co-interventions that were insufficiently controlled or recorded,[15 17–20] or very small sample sizes with insufficient statistical power to detect clinically relevant effects.[16 17] Early beneficial effects of SMT occurring within the first few days after the initial consultation may have been missed if pain assessments were performed too late during the course of the pain episode.[14 17–19] In addition, the design of most trials ignored current clinical practice[2] to prescribe analgesic treatment in the majority of patients with acute low back pain,[15 17–19] irrespective of the decision to refer patients to non-pharmacological interventions such as SMT.

We performed a randomised controlled trial in patients undergoing standard care comparing standard care in combination with SMT with standard care alone. Reflecting clinical practice, we allowed the prescription of analgesics in all patients, but ensured that their use was carefully monitored. The objective of the trial was to determine whether treatment with SMT in addition to standard care is associated with clinically relevant reductions in pain and analgesic consumption within 14 days of the initial consultation.

PATIENTS AND METHODS

Patients

Eligible for trial participation were men and non-pregnant women aged 20–55 years who presented with acute low back pain (duration of current episode <4 weeks) at the emergency department of the University Hospital Bern, or at mediX Practice Bubenberg, a general group practice in the centre of Bern, Switzerland. Exclusion criteria were: signs of nerve root irritation or compression; pain radiating below the knee; cauda equina syndrome; suspected specific cause of low back pain such as fracture, tumour or infection; blood coagulation disorder; severe renal or hepatic dysfunction; severe osteoporosis; allergy or intolerance to an administered medication; or epidural corticosteroid injections in the preceding 3 months. The trial was conducted in accordance with the Declaration of Helsinki and was approved by the research ethics committee of the Canton of Bern. All patients gave their written informed consent. The trial is registered with clinicaltrials.gov, number NCT00294229.

Interventions

Patients were randomly allocated to receive standard care with SMT or standard care alone for 2 weeks. Standard care consisted of general advice on rapid return to normal activities and the avoidance of bed rest in the acute phase[24] and the use of paracetamol, diclofenac or dihydrocodeine according to local guidelines as required. Patients

were provided with all three study medications by treating physicians; they were instructed about the maximum daily dosages and advised to use paracetamol as a first-line drug. The actual schedule and daily dosage was left at the discretion of patients. To avoid performance bias,[22] other analgesic drugs or non-pharmacological treatments (eg, physiotherapy) were not allowed. SMT was performed by a specialist in manual medicine, chiropractice and rheumatology (GH), a specialist in physical medicine (DV) or an osteopath (RvB), all proficient in SMT. SMT was initiated within 24 h of randomisation, with patients undergoing a maximum of five sessions within 2 weeks; it included a combination of high velocity low amplitude thrusts, spinal mobilisations and muscle energy techniques.[25–27] Whenever possible, high velocity low amplitude thrusts were applied, combined with the other techniques as considered necessary in view of the clinical presentation of the patients.

Randomisation

Patients were assigned on a 1 : 1 basis to treatment with standard care with SMT or standard care alone. Randomisation was performed on-site using sealed, opaque, sequentially numbered allocation envelopes, which were produced at the trial coordination centre (ISPM Bern) and were only opened by the recruiting physician after a patient had definitely been registered in the trial. Envelopes were monitored by the trial coordination centre to ensure that they were not tampered with. The allocation schedule was based on computer-generated random numbers, blocked and stratified according to trial centre with randomly varied block sizes of eight and 12. Recruiting physicians were unaware of the block sizes.

Outcomes

The two prespecified primary outcomes were changes in pain intensity as determined by the 11-point box scale (BS-11) for pain evaluation[28] and analgesic use based on calculated equivalence doses[29] up to day 14. BS-11 is a patient-administered numeric rating scale ranging from 0 to 10, with higher values indicating more severe complaints.[28] Equivalence doses were calculated using diclofenac as a reference (50 mg diclofenac equivalent to 2000 mg paracetamol or 62.5 mg dihydrocodeine). With maximum daily dosages of 150 mg diclofenac, 4000 mg paracetamol and 250 mg dihydrocodeine, the maximally possible daily equivalence dose was 450 mg. Diclofenac equivalence doses follow an approximate normal distribution with a typical standard deviation (SD) of 80 mg. A difference between groups of 16 mg (corresponding to 0.2 SD units) represents a small, 40 mg a moderate and 64 mg (0.8 SD units) a large effect.[30] Secondary outcomes were disability as determined by the Roland Morris Questionnaire[31] at day 14, the proportion of pain-free patients and the proportion of patients without analgesic intake up to day 14 and at the extended follow-up at 6 months, pain intensity at 6 months and the proportion of patients experiencing at least one serious adverse events up to 6 months. The Roland Morris Questionnaire ranges from 0 to 24, and higher values indicate more severe disability. Outcomes were assessed daily during days 1–14 using a patient-administered diary, a postal questionnaire at 6 months and, if necessary, telephone calls by a blinded interviewer (MD). Two investigators (PJ, MB), who were blinded to the assigned treatment, adjudicated all suspected serious adverse events based on relevant medical records.

Statistical analysis

This was a superiority trial with two equal primary outcomes, pain intensity and analgesic intake during days 1–14. Assuming SD of 2.2 points for pain intensity on the BS-11 and 80 mg for diclofenac equivalence doses, we estimated that 51 patients per group undergoing repetitive daily assessments of pain and analgesic consumption during days 1–14 would provide more than 80% power in a multilevel model adjusted for baseline values to detect a moderate difference between groups of 0.5 SD units[32] with p set at 0.025 for both outcomes after Bonferroni correction.[33] 0.5 SD units correspond to a difference of 1.1 points on the BS-11 and to 40 mg diclofenac equivalents.

There were two prespecified primary analyses, one for pain and one for analgesic intake: repetitive assessments of pain intensity and analgesic intake obtained between day 1 and day 14 were analysed using a multilevel model adjusted for baseline values, with random effects at the level of patients and groups.[34] The primary analyses of pain intensity and analgesic intake were based on an intention-to-treat approach, with all randomly assigned patients included in the analysis in the group they were originally allocated to. In secondary per-protocol analyses of the primary outcomes, we excluded four patients with protocol violations (two patients with symptom durations of 6 and 12 months and two patients who did not receive the allocated treatment). Data on pain and analgesic intake were incomplete, therefore we performed sensitivity analyses based on an imputation of missing values using two different approaches: multiple imputation,[35] with gender, age, type of occupation, pain duration at baseline, pain severity and disability, daily dose of analgesic drugs and setting entered as predictor variables, and imputation of data by carrying forward the most recent non-missing value observed in an individual.[36] In an additional sensitivity analysis of pain scores, we adjusted for the concomitant use of analgesic drugs. Then, we stratified analyses of the primary outcomes according to gender, age, type of occupation, pain duration, pain severity, disability and dose of analgesic drugs at baseline and setting, and performed formal tests of interaction between treatment and stratum.[37] We plotted Kaplan–Meier curves for patients becoming permanently pain free and patients permanently without analgesic intake up to day 14 and used log-rank tests to compare groups. We used analysis of covariance adjusted for baseline values[38] to analyse pain (days 1, 3, 7 and 14) and disability (day 14); results can be interpreted as differences in changes between baseline and follow-up. Proportions of pain-free patients and of patients without analgesic intake at 6 months were compared using Fisher's exact test. Pain scores at 6 months were analysed using analysis of covariance adjusted for pain scores at baseline. For all continuous outcomes, negative values indicate a benefit of SMT compared with standard care alone. Data entry, management and analysis were performed by CTU Bern; study personnel performing data entry, query and data management were blinded as to the allocated intervention. The data analyst (EN) was blinded to the allocated interventions for primary analyses. p Values are two-sided. Analyses were performed using Stata 9.2.

RESULTS

Between March 2003 and April 2006, 104 patients were included in the trial, 52 were randomly allocated to standard care with SMT (experimental group) and 52 to standard care alone (control group). Figure 1 presents the flow of participants through the trial, table 1 presents the characteristics of patients. Two of the 52 patients allocated to the experimental group

were erroneously included in the trial, despite symptom durations of 6 and 12 months; these patients were treated, followed up and analysed according to protocol. Two other patients in the experimental group did not receive the allocated treatment: one was pain free when the first SMT session was scheduled, the other was diagnosed with a herniated disk before the first SMT session. None of the patients allocated to the control group received SMT. The median number of SMT sessions in the experimental group was three (interquartile range (IQR) two to four); High velocity thrusts were applied in an estimated 80% of all sessions, in at least 38 patients allocated to SMT (73%). Four (8%) and three patients (6%) were lost to follow-up before reaching day 14. Data were more complete for pain (median completeness across days 1–14, 91%, IQR 88%–92%) than for analgesic consumption (median 75%, IQR 69%–79%).

Pain

Figure 2 (top left) presents the results of the primary analysis: the difference in pain scores was 0.5 points on the BS-11 (95% CI −0.2 to 1.2, p = 0.13) with the lower limit of the 95% CI at −0.2 excluding a relevant benefit of SMT. Results were much the same in sensitivity analyses using data imputations (fig 2), after the adjustment for analgesic use (difference 0.5, 95% CI −0.1 to 1.1, p = 0.07) and after the exclusion of four patients with protocol violations from the analysis (difference 0.3, 95% CI −0.3 to 1.0, p = 0.28). Figure 3 (top left) shows pain scores at days 0–14 and table 2 presents secondary analyses of differences in pain scores at days 1, 3, 7 and 14. At each of these time points, the 95% CI of differences between groups excluded a clinically relevant benefit of SMT. Stratified analyses provided little evidence for differential effects across various groups (fig 4, left). Figure 3 (bottom left) shows that the cumulative probability of being pain free was similar between groups (p = 0.24); 15 patients in the experimental group (31%) and 22 patients in the control group (45%) were pain free at day 14.

Analgesic consumption

Figure 2 (top right) presents results of the primary analysis: the difference in analgesic consumption was −18 mg diclofenac equivalents (95% CI −43 to 7 mg, p = 0.17). Results were much the same in sensitivity analyses using data imputations (fig 2), and after the exclusion of four patients with protocol violations from the analysis (−16 mg, 95% CI −42 to 9 mg, p = 0.20). Stratified analyses provided no evidence for differential effects across various groups of patients (fig 4, right). The proportion of patients who reported not using analgesics was similar between groups (fig 3, bottom right, p = 0.20). At day 14, 36 patients in the experimental group (69%) and 29 patients in the control group (56%) reported not using analgesics. Most patients had used paracetamol and diclofenac combined (43% of days with study medication use) or diclofenac only (40%). Less frequently used regimens included paracetamol only (8%), paracetamol, diclofenac and dihydrocodeine combined (6%), dihydrocodeine only (2%) and diclofenac and dihydrocodeine combined (1%). Regimens were similar in the experimental and control group.

Disability

At day 14, mean Roland Morris scores were 5.8 in the experimental group (95% CI 3.9 to 7.7) and 5.2 in the control group (95% CI 3.7 to 6.8). After adjustment for baseline values, the difference in Roland Morris scores was 0.8 (95% CI −1.5 to 3.2, p = 0.49). Results were robust to data imputation.

Extended follow-up

Fifty patients in the experimental group and 51 patients in the control group were followed up at 6 months. Pain intensities were similar (difference 0.6, 95% CI −0.4 to 1.6, p = 0.22). Twenty-two patients (44%) reported being pain free in the experimental group and 30 (59%) in the control group (difference −15%, 95% CI −34% to 4%, p = 0.17), whereas seven patients in the experimental group (14%) and four

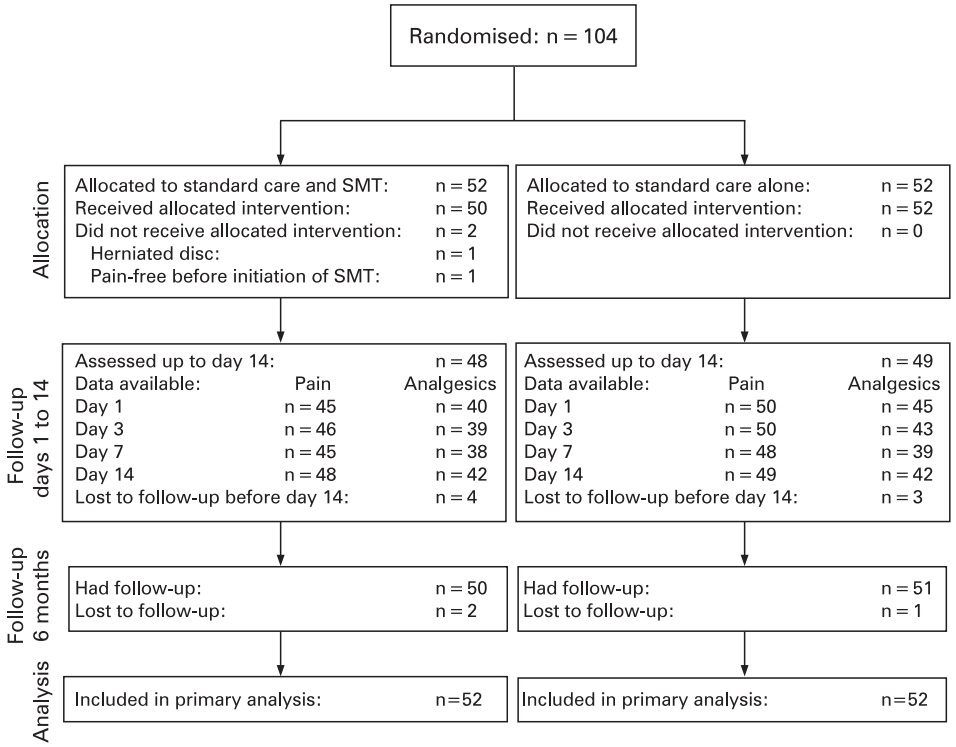

Figure 1 Flow of patients through the various stages of the trial. SMT, spinal manipulative therapy.

Table 1 Characteristics of patients at baseline

	Standard care and SMT (n = 52)	Standard care alone (n = 52)
Gender, n (%)		
Women	18 (35%)	19 (37%)
Men	34 (65%)	33 (63%)
Age, n (%)		
<35 years	29 (56%)	25 (48%)
⩾35 years	23 (44%)	27 (52%)
Age, years (SD)	34.3 (9.4)	36.5 (8.2)
Type of occupation, n (%)		
Non-manual	30 (57%)	33 (63%)
Manual	22 (43%)	19 (37%)
Pain duration, n (%)		
<7 days	28 (54%)	39 (75%)
⩾7 days	24 (46%)	13 (25%)
Pain duration, days (SD)*	8 (10)	5 (5)
Pain intensity, n (%)		
BS-11 score <7	22 (42%)	27 (51%)
BS-11 score ⩾7	30 (58%)	25 (48%)
Pain intensity, BS-11 score (SD)	6.8 (2.2)	6.3 (2.2)
Disability, n (%)		
Roland Morris score <14	25 (48%)	22 (42%)
Roland Morris score ⩾14	27 (52%)	30 (58%)
Disability, Roland Morris score (SD)	12.8 (5.1)	14.3 (4.9)
Type of analgesic drug, n (%)		
NSAID	36 (69%)	40 (77%)
Paracetamol	21 (40%)	34 (65%)
Opioids	7 (13%)	6 (12%)
Dose of analgesic drugs, mg, n (%)		
Diclofenac equivalence dose <125	22 (42%)	16 (31%)
Diclofenac equivalence dose ⩾125	30 (58%)	36 (69%)
Diclofenac equivalence dose, mg (SD)	116 (87)	131 (88)
Fitness for work, n (%)		
Fully	27 (53%)	19 (37%)
Partly	0 (0%)	3 (6%)
Unfit	24 (47%)	30 (57%)
Healthcare setting, n (%)		
Emergency department	21 (40%)	21 (40%)
Primary care	31 (60%)	31 (60%)

Presented are means and standard deviations (SD) or numbers and percentages.
*Two patients allocated to experimental treatment with SMT were excluded for the calculation of the mean duration of symptoms; these patients were erroneously included in the trial, despite symptom durations of 6 and 12 months.
BS-11, 11-point box scale ranging from 0 to 10, with higher values indicating more pain; NSAID, non-steroidal anti-inflammatory drug; SMT, spinal manipulative therapy; Roland Morris scores range from 0 to 24, with higher values indicating more disability.

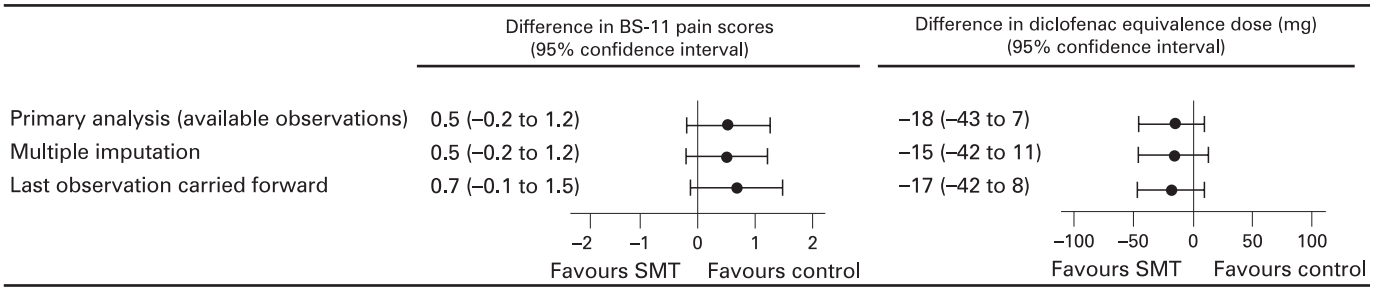

Figure 2 Differences in 11-point box scale (BS-11) pain scores and diclofenac equivalence doses between patients allocated to standard care with spinal manipulative therapy (SMT) and patients allocated to standard care alone during days 1–14. Results are presented based on available observations (prespecified primary analysis), imputation using multiple imputation and imputation using last observation carried forward. All analyses are based on all randomised patients according to the intention-to-treat principle, with repetitive measures of pain and analgesic intake during days 1–14 analysed using a multilevel model (see Methods section).

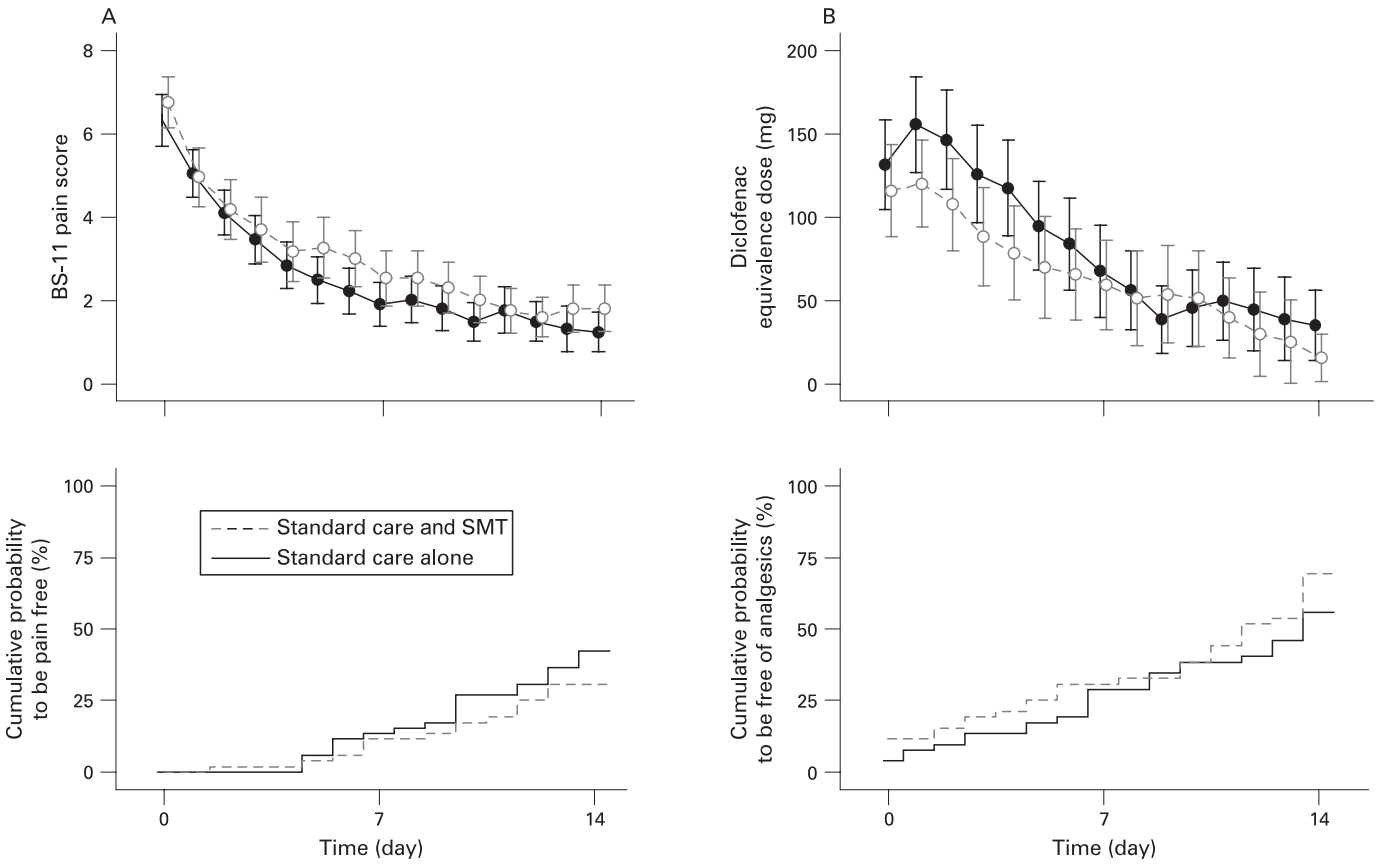

Figure 3 Means and 95% CI for 11-point box scale (BS-11) pain scores (upper left) and diclofenac equivalence doses in milligrams (upper right) at days 0–14 in the standard care plus spinal manipulative therapy (SMT; dotted lines and open circles) and standard care (solid lines and black circles) groups. Analyses are based on all randomly assigned patients, using all available observations.

patients in the control group (8%) reported not using analgesics (difference 6%, 95% CI −6% to 18%, p = 0.36).

Safety

Two serious adverse events occurred in the experimental group (4%) and two in the control group (4%). In the experimental group, there was one patient with an acute pancreatitis and one patient with an acute loss of motor and sensory function of the left lumbar segment L5 due to a herniated disk after randomisation, but before any SMT treatment was initiated (fig 1). In the control group, there was one patient with a symptomatic cholelithiasis and one patient with a femoro-acetabular impingement syndrome. Neither of these events appeared to be related to the allocated treatment strategies.

DISCUSSION

We found no evidence for a clinically relevant benefit of SMT in addition to standard care in patients with acute low back pain. In terms of pain reduction, the 95% CI excludes any clinically relevant benefit of SMT; the lower boundary of the confidence interval, which delineates the most beneficial effect of SMT compatible with results of our trial, corresponds to a difference in pain decrease of 2 mm on a visual analogue scale ranging from 0 to 100 mm. In terms of analgesic use, differences between groups were small and diminishing over time.

This trial included several measures to reduce the risk of bias, including adequate concealment of random allocation, careful control and monitoring of co-interventions and an intention-to-treat analysis.[22] Serious adverse events up to 6 months were actively monitored and adjudicated by blinded investigators.[39] Seven per cent of patients were lost to follow-up up to day 14 and data on pain and analgesic use were missing in approximately 9% and 25% of observations, respectively. Using a multilevel model, we included all 104 patients in the primary analysis based on available data. Using different approaches to impute missing data[35 36] we found the results to be robust. The trial was implemented in clinical routine settings, with patients allowed to use paracetamol, a non-steroidal anti-inflammatory drug or an opioid as required. To avoid performance bias,[22] other analgesic drugs or non-pharmacological treatments, such as physiotherapy, were not allowed. Pain and analgesic use was recorded on a daily basis up to day 14, which ensured that the early effects of SMT were not missed. The statistical model, which fully accounted for the correlation of repetitive measures within each patient, ensured adequate power to detect a moderate difference in pain and analgesic intake despite the relatively low number of patients.

Limitations of the trial include restricted resources, which resulted in a limited capacity to monitor self-administered patient diaries and missing data, particularly for the reported use of analgesics. The recruitment rate was unexpectedly low, which meant that an unusual 3 years were required to recruit the necessary number of patients. The limited number of patients prevented us from evaluating the influence of the different components (eg, high vs low impulse manoeuvres) of SMT and their frequency, and from reliably determining whether SMT might be beneficial in specific subgroups of patients. It was impossible for us to blind patients and treating

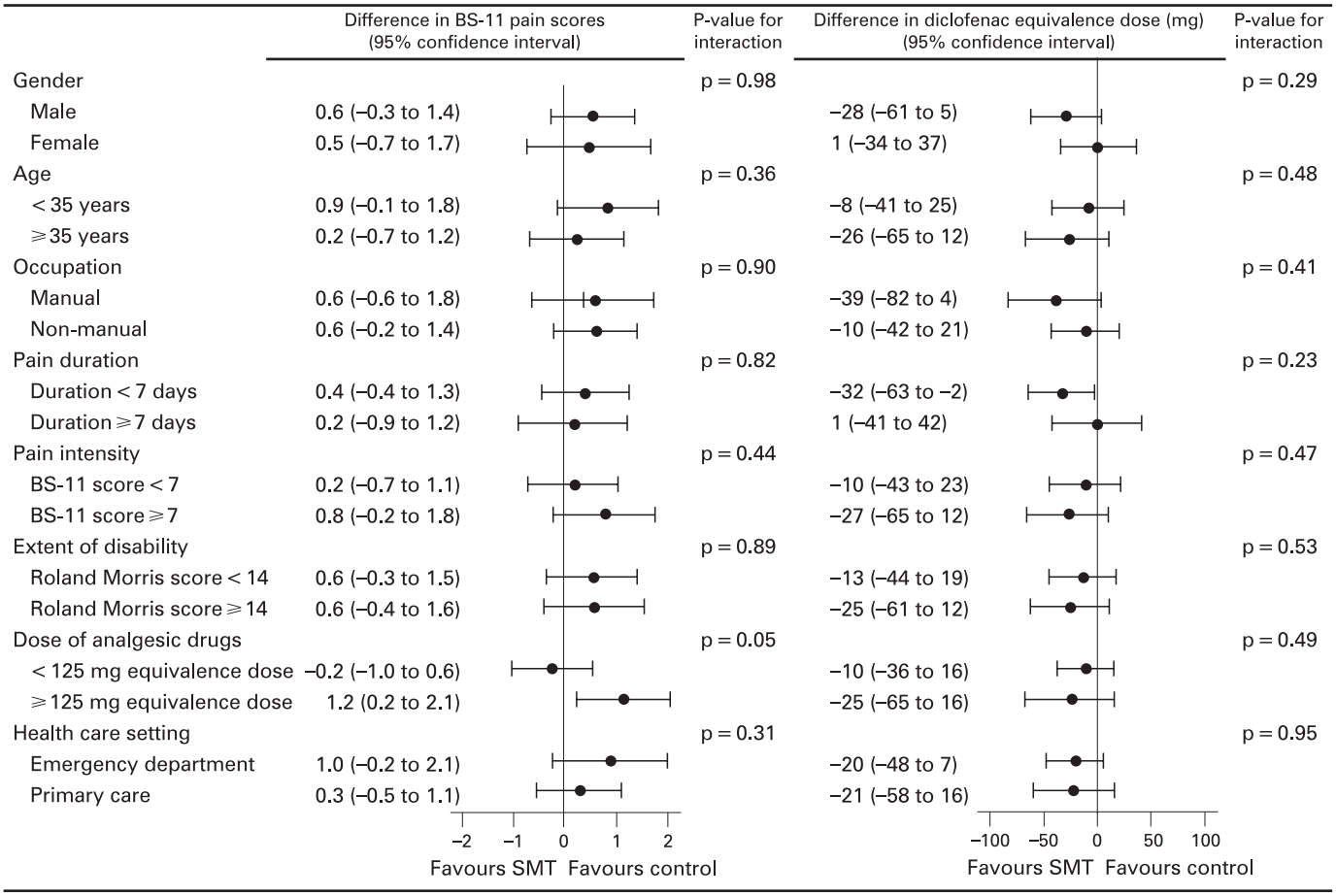

Figure 4 Results from stratified analyses according to baseline characteristics of patients. Values are differences in mean changes between standard care plus spinal manipulative therapy (SMT) and standard care alone during days 1–14. All analyses are based on all available data from all randomly assigned patients according to the intention-to-treat principle, with repetitive measures of pain and analgesic intake during days 1–14 analysed using a multilevel model (see Methods section). p Values are from tests of interaction between allocated treatment and stratum. Refer to table 1 for the numbers of patients per stratum. BS-11, 11-point box scale.

physicians as to the allocated intervention. Therefore, performance or detection bias may have occurred.[22] The small trend towards higher doses of analgesics in the control group (fig 3) may have led to performance bias in favour of the control group. However, when adjusting for analgesic use, we found the results to be much the same. Knowledge of patients about their allocation to experimental or control intervention could have resulted in detection bias, which is likely to favour the experimental group. This would not affect our conclusions; however, even though the benefit of SMT may have been

Table 2 Differences in mean changes of BS-11 pain scores and diclofenac equivalence doses between patients allocated to standard care with SMT and patients allocated to standard care alone

	Day 1			Day 3			Day 7			Day 14		
	n		Estimate	n		Estimate	n		Estimate	n		Estimate
	Exp	Ctr	(95% CI)	Exp	Ctr	(95% CI)	Exp	Ctr	(95% CI)	Exp	Ctr	(95% CI)
BS-11 pain score												
Available observations	45	50	−0.2 (−1.1 to 0.6)	46	50	0.2 (−0.8 to 1.1)	45	48	0.7 (−0.2 to 1.5)	48	49	0.6 (−0.1 to 1.3)
Multiple imputation	52	52	−0.1 (−1.0 to 0.7)	52	52	0.4 (−0.6 to 1.3)	52	52	0.9 (0.0 to 1.8)	52	52	0.5 (−0.2 to 1.3)
Last observation carried forward	52	52	−0.1 (−0.8 to 0.7)	52	52	0.4 (−0.6 to 1.3)	52	52	1.1 (0.1 to 2.0)	52	52	0.7 (−0.1 to 1.5)
Diclofenac equivalence dose (mg)												
Available observations	40	45	−22 (−47 to 2)	39	43	−32 (−64 to 1)	38	39	−13 (−50 to 23)	42	42	−13 (−42 to 15)
Multiple imputation	52	52	−22 (−50 to 5)	52	52	−32 (−67 to 3)	52	52	−8 (−42 to 26)	52	52	−8 (−44 to 27)
Last observation carried forward	52	52	−23 (−47 to 1)	52	52	−30 (−61 to 1)	52	52	−10 (−42 to 22)	52	52	−15 (−41 to 11)

Presented are the numbers of patients analysed and the differences in mean changes (95% CI) in pain intensity (top) and diclofenac equivalence doses in milligrams (bottom) between patients allocated to standard care with spinal manipulative therapy (SMT) and patients allocated to standard care alone at days 1, 3, 7 and 14 separately (subsequent columns from the left to the right). For both outcomes, results are shown based on available data (top), data imputation using multiple imputation (middle) and data imputation using last observation carried forward (bottom). Negative estimates indicate that patients allocated to SMT have less pain or lower analgesic intake than patients allocated to standard care alone. BS-11, 11-point box scale ranging from 0 to 10; Ctr, control group allocated to standard care alone; Exp, experimental group allocated to standard care with SMT.

overestimated, 95% CI excluded any clinically relevant benefit of SMT. Finally, some may criticise the use of equivalence doses as one of the two primary outcomes; equivalence doses were introduced more than two decades ago in ankylosing spondylitis,[29] but were never formally validated in patients with low back pain.

A clinical prediction rule was recently derived to identify patients with low back pain who respond best to SMT.[40] The group responsible for the development of the rule performed a validation exercise in a randomised trial and found that patients who met at least four of five clinical criteria were considerably more likely to benefit from SMT than other patients.[20] However, an independently performed analysis by another group failed to confirm these findings: in a preplanned analysis of a randomised trial,[21] the clinical prediction rule performed no better than chance in identifying patients with acute low back pain most likely to respond to SMT.[41]

Results of trials that have assessed the effectiveness of SMT in acute low back pain are conflicting.[14–21] Trials varied with regard to methodological quality, inclusion criteria and choice of control intervention. A recent meta-analysis of 39 trials comparing SMT with other therapies[11 13] concluded that SMT may be superior to sham therapy, but not to other interventions in acute low back pain. At the time of its initiation in 2003, ours was the first trial to determine the added early benefits of SMT in patients with acute low back pain undergoing standard care with analgesics up to 2 weeks. A carefully designed trial initiated in 2005 and published recently by Hancock *et al*,[21] also included patients with acute to subacute low back pain of a duration of less than 6 weeks. Using a factorial design, the trial randomly allocated 240 patients to one of four arms: diclofenac and sham SMT, SMT and placebo drug, diclofenac and SMT, or placebo drug and sham SMT.[21] All patients were given paracetamol 4 g daily until recovery or for a maximum of 4 weeks. Results were fully compatible with those from our trial in terms of pain intensity and cumulative proportion of pain-free patients. Unlike other trials,[14–20] which recorded pain only on a weekly or monthly basis, the trial by Hancock *et al*[21] and our trial are unlikely to have missed early benefits of SMT occurring particularly after the initiation of the treatment. While we cannot exclude that specific subgroups of patients with acute low back pain will benefit from adding SMT to standard care, we believe that the trial of Hancock *et al*[21] and our trial provide reliable evidence that the majority of patients with acute low back pain can be effectively treated without SMT.

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Competing interests: Declared. PMV, GH, H-RZ and SR are members of the Swiss Society for Manual Therapy and RvB is a member of the Swiss Federation of Osteopathy.

Ethics approval: The trial was conducted in accordance with the Declaration of Helsinki and was approved by the research ethics committee of the Canton of Bern.

Patient consent: Obtained.

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