# Adverse effects of spinal manipulation: a systematic review

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#### **SUMMARY**

Objective To identify adverse effects of spinal manipulation.Design Systematic review of papers published since 2001.Setting Six electronic databases.

**Main outcome measures** Reports of adverse effects published between January 2001 and June 2006. There were no restrictions according to language of publication or research design of the reports.

**Results** The searches identified 32 case reports, four case series, two prospective series, three case-control studies and three surveys. In case reports or case series, more than 200 patients were suspected to have been seriously harmed. The most common serious adverse effects were due to vertebral artery dissections. The two prospective reports suggested that relatively mild adverse effects occur in 30% to 61% of all patients. The case-control studies suggested a causal relationship between spinal manipulation and the adverse effect. The survey data indicated that even serious adverse effects are rarely reported in the medical literature.

**Conclusions** Spinal manipulation, particularly when performed on the upper spine, is frequently associated with mild to moderate adverse effects. It can also result in serious complications such as vertebral artery dissection followed by stroke. Currently, the incidence of such events is not known. In the interest of patient safety we should reconsider our policy towards the routine use of spinal manipulation.

Spinal manipulation or adjustment is a manual treatment where a vertebral joint is passively moved between the normal range of motion and the limits of its normal integrity, though a universally accepted definition does not seem to exist. It is occasionally used by osteopaths, physiotherapists and physicians, and it is the hallmark treatment of chiropractors. Practically all chiropractors use spinal manipulation regularly to treat low back and other musculoskeletal pain. It often involves a high velocity thrust, a technique in which the joints are adjusted rapidly, often accompanied by popping sounds. This results in

transient stretching of joint capsules which, according to chiropractic belief, resets the position of the spinal cord and nerves, allowing the nervous system to function optimally and improving the body's biomechanical efficiency.<sup>3</sup> The thrust is exerted through either a long lever arm, in which force is applied distant from the joint, or a short lever arm, when force is applied close to the joint. Many experts see spinal manipulation as an effective form of treating back pain:<sup>4</sup> the evidence from randomized clinical trials (RCTs), however, remains contradictory and often unconvincing.<sup>5</sup> For conditions other than back pain, there is no good evidence for the effectiveness of spinal manipulation.<sup>5</sup>

Many authors have voiced doubt about the safety of spinal manipulation. A particular concern is stroke after upper spinal manipulation. The systematic review by Ernst and Stevinson, published in 2002, summarized safety data available up to 2001.<sup>6</sup> Since then, an abundance of new evidence has emerged. The aim of this article is therefore to identify adverse effects of spinal manipulation published since 2001.

#### **METHODS**

Computerized literature searches were performed using MEDLINE (PubMed), EMBASE, Amed, CINHAL, the British Nursing Index and the Cochrane Library up to June 2006. The search terms used were 'adverse effects', 'adverse events', 'arterial injury', 'cervical manipulation', 'chiropractic', 'complications', 'manual therapy', 'osteopathy', 'risk', 'safety', 'spinal manipulation', 'stroke', 'vascular accident', and 'vertebral artery dissection'. In addition, our departmental files were searched, and other experts were consulted. The bibliographies of relevant papers were scanned for pertinent articles. All reports, irrespective of language of publication, which contained data about risks associated with spinal manipulation were included, regardless of the profession of the therapist or the research methodology used for the report. Articles from 2000 or earlier, dual publications of the same material<sup>7</sup> and cases of spinal manipulation for non-therapeutic purposes<sup>8</sup> were excluded. All relevant reports were obtained in full. Key data were extracted by the author according to predefined criteria, tabulated and also described narratively.

# **RESULTS**

# **Case reports**

The search strategy located 28 articles reporting a total of 32 case reports (Tables 1 and 2). In 22 cases (published in 20 articles) the therapists were chiropractors (Table 1), 9-28 while in 10 cases (published in nine articles) they were other health-care professionals (Table 2).13,29-36 In the majority of cases, the problem related to upper spinal manipulations including rotational movements. The patients were mostly young healthy individuals treated for benign, self-limiting conditions such as neck pain or headache. There was no clear over-representation of one sex over another. Dissection of the vertebral arteries was the most common problem; other complications included dural tear, oedema, nerve injury, disc herniation, haematoma and bone fracture. The symptoms were frequently life-threatening, though in most cases the patient made a full recovery. In the majority of cases, spinal manipulation was deemed to be the probable cause of the adverse effect.

# **Retrospective case series**

Haldemann *et al.* analysed 64 cases in which a cerebrovascular ischaemic event had occurred after spinal manipulation.<sup>37</sup> All cases had been referred to Haldemann for medico legal review during a 16-year period, and none had previously been reported in the medical literature. The patients were predominantly women (mean age 39 years) who had consulted a chiropractor for neck pain or headache. In 48 cases, the onset of the stroke was within 30 minutes after spinal manipulation. The authors were unable to identify any risk factors that would discriminate high risk from low risk patients. Neurological status one year after the stroke was available for 46 patients: eight had made a full recovery, two had died, and the rest were still suffering from persistent neurological deficits.

Young and Chen described nine patients who were admitted for acute vertigo after spinal manipulation by chiropractors or practitioners of Traditional Chinese Medicine. Magnetic resonance angiography showed that the clinical symptoms were due to vertebral artery occlusion (n=1), stenosis (n=1), slow blood flow (n=1) or associated with normal findings (n=6). The average time between spinal manipulation and onset of symptoms was 17 hours (range 1–24 hours). All patients made a full recovery after treatment.

Hansis *et al.* published an analysis of 57 patients who had been referred during 28 years to the North Rhine General Medical Council for alleged malpractice. <sup>39</sup> In 20 patients who had experienced a disc prolapse after spinal manipulation, the Council attested five instances of malpractice. In six cases of bone fractures, the Council attested one instance of malpractice. In nine cases of

cerebrovascular accidents, seven of which were due to dissection of the vertebral artery, the Council attested malpractice four times. In 22 instances, patients had complained that spinal manipulation had no effect or had worsened the presenting condition: the Council attested malpractice in two of them.

Oppenheim *et al.* conducted a chart review of 18 patients (nine men and nine women aged 31–72 years) who suffered non-vascular adverse effects after receiving spinal manipulation by chiropractors.<sup>40</sup> The injuries occurred in the cervical (33%), thoracic (22%) and lumbar spine (44%). In nine cases, they were associated with spinal cord injuries (myelopathy, quadriparesis, central cord syndrome or paraparesis); two patients experienced cauda equina syndrome; six patients developed radiculopathy; and three patients had pathological fractures related to cancer which the chiropractors had failed to diagnose. Sixteen patients required surgery; half of them subsequently made an excellent recovery, and 31% a good recovery.

Reuter *et al.* reported 36 cases of vertebral artery dissection seen within three years in 13 neurological centres. 41 On admission, 30 of these patients had neurological deficits; on discharge this figure had decreased to 18. Spinal manipulation had been administered by orthopaedic surgeons (50%), physiotherapists (14%), chiropractors (11%) or other health-care professionals. In 14% of all cases, the onset of symptoms was during treatment, while in a further 12% it was within one hour. All patients had been treated with spinal manipulation for benign conditions such as neck or back pain.

#### Prospective case series

Cagnie et al. invited 59 Belgian physiotherapists to recruit a total of 465 new patients treated by them with spinal manipulation. All patients were subsequently asked to complete a questionnaire about adverse effects. 61% of all patients reported at least one adverse effect, most of which were mild and transient, such as headache (20%), stiffness (20%), local discomfort (15%), radiating discomfort (12%) and fatigue (12%). 63% of these patients noted more than one symptom. In 61%, the problems had started within four hours after manipulation, and 64% had resolved within 24 hours. 21% of post-manipulative effects were experienced as 'severe', and 27% of patients felt impaired in their daily activities. No complications with long-lasting consequences were reported.

Hurwitz *et al.* reported adverse effects documented in a randomized controlled trial comparing spinal manipulation with spinal mobilization as treatments of neck pain. <sup>43</sup> Of 280 patients, 30% reported at least one adverse effect. Patients receiving spinal manipulation were more likely to experience adverse effects than patients treated with

Causation\* Possible Possible Possible Possible Possible Certain Certain Certain Certain Certain Likely Fibrinolysis resulted in complete recanalization Likely 225 Complete recovery after epidural blood patch Residual left-side hemianaesthesia and Permanent, severe neurological deficit Complete recovery after laminectomy Residual headache and stiffness on Significant recovery after surgery Full recovery after surgery No information provided discharge from hospital Residual dyspnoea Complete recovery Complete recovery Complete recovery Not mentioned Not mentioned Not mentioned Not mentioned Not mentioned Not mentioned dysaesthesia Full recovery Not reported of the artery Paraplegia Outcome Phrenic nerve injury, diaphragmatic paralysis, haemorrhagic infarction and visual impairment Epidural haematoma extending from cervical Dissection of right carotid artery followed by Bilateral internal carotid and vertebral artery Dissection of extra-cranial port of the right Dissection of left vertebral artery followed Dissection of right internal carotid artery, Dissection of vertebral artery followed by Dissection of vertebral artery followed by schaemia of caudal spinal cord followed Haematoma of ligamentum flavum at the Bilateral dissections of vertebral arteries Bilateral dissection of vertebral arteries Vertebral artery dissection followed by followed by bilateral occipital-parietal posterior inferior cerebellar artery Dissection of left vertebral artery evel of C3-C4 with hemiparesis Multiple cervical disc herniation Dissection of left carotid artery Dural tear, positional dizziness Wallenberg's syndrome Wallenberg's syndrome Subdural haematoma by Dejerine syndrome Horner's syndrome Horner's syndrome severe dyspnoea to sacral spine Adverse event tetraparesis dissection Dural tear Table 1 Case reports of adverse events after spinal manipulation administered by chiropractors 34-year-old man with neck pain after whiplash injury 36-year-old woman with neck and shoulder pain 26-year-old woman with headache and sinusitis 47-year-old man with neck and shoulder pain 44-year-old woman with low back pain 44-year-old man with shoulder pain 33-year-old woman with headache 31-year-old woman with headache 46-year-old woman with neck pain 42-year-old woman with neck pain 72-year-old man with neck pain (1) 31-year-old woman (2) 64-year-old man 3) 51-year-old man 40-year-old woman 37-year-old woman 27-year-old woman 40-year-old patient 33-year-old patient 38-year-old man 46-year-old man 34-year-old man Patient(s) Menendez-González Stevinson (2001)<sup>13</sup> First author (year) Schram (2001)<sup>12</sup> Morandi (2004)<sup>24</sup> Parwar (2001)<sup>11</sup> Wojcik (2003)<sup>18</sup> Yokota  $(2003)^{22}$ Nadgir (2003)<sup>20</sup> Siegel (2001)<sup>10</sup> Izquiedo-Casas Saxler (2004)<sup>25</sup> Oehler (2003)<sup>21</sup> Sédat (2002)<sup>15</sup> Tomé (2004)<sup>26</sup> Jeret (2002)<sup>14</sup> Beck (2003)<sup>19</sup> Chen  $(2005)^{27}$ Jeret (2001)<sup>9</sup> Suh (2005)<sup>28</sup> Jay (2003)<sup>16</sup>  $(2003)^{17}$  $(2004)^{23}$ 

 $\mathit{Tab}$   $\mid$  2 Case reports of adverse events after spinal manipulation performed by non-chiropractors

First Author (Year)	Patient(s)	Therapist	Adverse event	Outcome	Causation*
Kraft (2001) <sup>29</sup>	43-year-old man with tinnitus	Orthopaedic surgeon	Intracapsular oedema of facet joints C2/C3, severe neck pain	Not reported	Likely
Stevinson (2001) <sup>13</sup>	Woman (age not reported)	No information provided	Vertebral artery dissection occlusion, stroke	Permanent deficit (after surgical decompression)	Possible
Tsuboi (2001) <sup>30</sup>	80-year-old man	Shiatsu practitioner	Retinal artery embolism, multiple infarctions in right frontal lobe	Permanent ocular symptoms	Possible
Quintana (2002) <sup>31</sup>	62-year-old woman	'Bonesetter'	Dissection of left vertebral artery, infarction of middle left cerebellar hemisphere and vermis	Residual deficit at five months	Possible
Chung (2002) <sup>32</sup>	46-year-old man	'Bonesetter'	Cervical cord oedema followed by tetraplegia	Residual deficits	Certain
Gamer (2002) <sup>33</sup>	37-year-old man	Not mentioned	Dissection of carotid artery followed by Horner Syndrome	Not mentioned	Likely
Tseng (2002) <sup>34</sup>	(1) 37-year-old man with shoulder pain	Not mentioned	Disc herniation at C4-C5	Complete recovery	Likely
	(2) 38-year-old man with upper back pain	Not mentioned	Disc herniation at C6-C7	Complete recovery	Likely
Licht (2003) <sup>35</sup>	39-year-old man with neck pain	General practitioner	Large infarction in the left cerebellar hemisphere (presumably due to arterial dissection)	Complete recovery	Likely
Schmitz (2005) <sup>36</sup>	37-year-old patient		Displaced odontoid fracture in the presence of an aneurismal bone cyst	Complete recovery after surgery	Likely

mobilization, a more gentle manual technique preferred by many osteopaths. The most frequently noted adverse effects were increase of pain, headache, tiredness and radiating pain. 80% of the adverse effects began with 24 hours after treatment and were of moderate or medium severity. No serious complications were noted.

#### Case-control studies

Dziewas et al. studied 126 patients with carotid or vertebral artery dissections. 44 Compared to patients with carotid artery dissections, patients with vertebral artery dissections more frequently reported having previously had chiropractic upper spinal manipulation (6% versus 30%). Bilateral vertebral artery dissection was also significantly related to a preceding chiropractic manipulation. Five cases of carotid artery dissection were associated with prior spinal manipulation, and all had a good clinical outcome. Fourteen cases of vertebral artery dissection were linked to spinal manipulation, of which ten had a good, three a moderate and one a poor clinical outcome. The authors concluded that 'this study emphasizes the potential dangers of chiropractic manipulation of the cervical spine.'

Rothwell *et al.* studied hospital records in Ontario to identify all cases of vertebrobasilar accidents within a five-year period.<sup>45</sup> They found 582 such cases and matched them by age and sex to four controls each who had no history of stroke. In patients younger than 45 years, the odds of having a vertebrobasilar accident within one week of visiting a chiropractor were increased by a factor of five. In this age group, cases were five times more likely to have had more than three chiropractic consultations with a cervical diagnosis in the month before the event.

Smith *et al.* conducted blinded chart review and face-to-face interviews with 51 patients under the age of 60 years from two stroke centres in the USA. 46 They were age- and sex-matched to 100 controls. In univariate analysis, cases were more likely than controls to have had spinal manipulation within 30 days of the vascular accident (14% versus 3%). In multivariate analysis, vertebral arterial dissections were independently associated with spinal manipulations within 30 days (odds ratio [OR] 6.62). For carotid dissection, no significant association was noted. The authors conclude that spinal manipulation 'is independently associated with vertebral arterial dissection, even after controlling for neck pain.'

A systematic review of case control studies of potential risk factors for cervical artery dissection found 'a strong association for manipulative therapy' (OR 3.8, 95% confidence interval [CI] 1.3–11).<sup>47</sup> However, these results were based only on two studies. The authors therefore urge caution until further evidence becomes available.

### Surveys

Adams and Sim posted a questionnaire about adverse effects of spinal manipulation to 300 UK manipulative therapists. 48 Of the respondents, 129 used spinal manipulation. Anxiety about complications was a prominent reason for not using manipulation. Cervical rotary manipulations were thought by some respondents to be potentially dangerous. Overall, respondents felt 'uncertain as to whether its benefits outweighed its risks.'48

Dupeyron *et al.* surveyed 240 French doctors with a diploma in 'manual medicine' asking them to provide details of all complications after spinal manipulation during the preceding two years. <sup>52</sup> 93 such cases were disclosed, none of which had previously been reported in the medical literature. 69% of them related to radiculopathies and 15% to cerebrovascular accidents, and 53% of the problems became symptomatic within 24 hours after treatment.

Egizii *et al.* posted questionnaires to 234 French doctors with 'Manual Medicine' or 'Osteopathy' diplomas from Strasbourg University between 1985 and 2002.<sup>49</sup> Responses were obtained from 140 physicians. Most of them used spinal manipulation in their daily practice. 24% of the respondents stated that they had caused one or more adverse effects through spinal manipulation; no further details were supplied.

#### **DISCUSSION**

The case reports (Tables 1 and 2) confirm previous reports<sup>6</sup> associating upper spinal manipulation with a range of complications. The most serious problems, which some experts now describe as 'well-recognized',<sup>22</sup> are vertebral artery dissections due to intimal tearing as a result of overstretching the artery during rotational manipulation. This seems to occur most commonly at the level of the atlantoaxial joint.<sup>20</sup> Intimal injury can be followed by intramural bleeding or pseudoaneurysm formation, which can result in thrombosis, embolism<sup>20</sup> or arterial spasm.<sup>22</sup>

The retrospective case series (Table 3) confirm that spinal manipulation is associated with risks such as vascular accidents and non-vascular complications. Such adverse effects are being reported from several countries and often have serious consequences. The therapists involved are mostly chiropractors; this predominance is probably due to the fact that these therapists use spinal manipulation more frequently than other practitioners. Most of the incidents reported in case series or surveys had not been previously reported, indicating that under-reporting may frequently be high.

The two prospective case series<sup>42,43</sup> corroborate the results from several earlier investigations<sup>50</sup> showing that mild to moderate adverse effects occur in a large proportion of patients receiving spinal manipulation. These adverse

 $\mathit{Table}\ 3$  Retrospective case series of adverse events after spinal manipulation

First author (Year)	Patients	Country	Length of observation	Therapist(s)	Nature of adverse effect	Case previously Outcomes published	Outcomes	Causality
Haldemann (2002) <sup>37</sup>	64 mostly young women	USA and Canada	16 years	Not mentioned	Not mentioned Gerebrovascular No accidents	O N	2 deaths. Most patients Cannot be had persistent deficits evaluated	Cannot be evaluated
Young (2003) <sup>38</sup>	9 patients (8 women, 1 man) aged 34-70 years, admitted for acute vertigo	Taiwan	3 years	5 x chiropractor Acute vertigo 4 x TCM practitioner	Acute vertigo	Not mentioned	Complete recovery in all cases after dextram infusions	Likely
Hansis (2004) <sup>39</sup>	57 cases of alleged malpractice referred to the North Rhine General Medical Council	Germany	28 years	Not mentioned Any	Any	Not mentioned	Varied	Cannot be evaluated
Oppenheim (2005) <sup>40</sup>	18 patients from one neurosurgical practice with non-vascular complications after SM and worsening of symptoms immediately after SM	USA	6 years	Chiropractors	Non-vascular	Not mentioned	Not mentioned Mostly excellent or good	In most cases certain or likely
Reuter (2005) <sup>41</sup>	40 cases of vertebral artery dissection after upper SM from 13 neurological departments	Germany	3 years	Any type of health-care professional	Vertebral artery dissection	Not mentioned	Vertebral artery Not mentioned 10 symptom-free, 1 dissection fatality, remaining patients had symptoms of varying severity	In most cases certain or likely

SM, spinal manipulation

effects are transient and non-serious but nevertheless seriously affect many patients. 42,50 Risk—benefit evaluations of spinal manipulation must therefore account not just for serious complications but also for such adverse events.

Case-control and other studies confirm that upper spinal manipulation is associated with risks<sup>44–47</sup> and that spinal manipulation is an independent risk factor for vertebral artery dissection.<sup>46</sup> Many chiropractors insist that a causal link is questionable or unlikely, as the early signs of arterial dissections include neck pain, which could be the reason for a patient to consult a chiropractor, therefore these possible associations could be false.<sup>23,51</sup> Smith *et al.* tried to account for this particular confounder and still found spinal manipulation to be a risk factor.<sup>46</sup>

The three surveys disclose more complications. They suggest that many therapists are now becoming aware of the risks of spinal manipulation. <sup>48,49</sup> Two of the surveys <sup>49,52</sup> also confirm that under-reporting is frequently close to 100%.

It seems unfair to assess the risk of spinal manipulation as practised by well-trained chiropractors alongside that associated with untrained therapists (Tables 1 and 2). Chiropractors may argue that it takes years of experience to learn the fine psychomotor control required for skilled manipulations. Certainly skill and experience are important, and it is relevant to differentiate between different professions, as done in Tables 1 and 2. On the other hand, skill is a quality not easily controlled for in such research; even some chiropractors may be more skilled than others. Moreover, this review is aimed at evaluating the risk of an intervention (spinal manipulation) and not that of a profession (chiropractic). In fact, this review shows that the implicated practitioners are not only chiropractors but also surgeons, shiatsu practitioners, 'bonesetters' and general practitioners (Table 2).

Collectively, these data suggest that spinal manipulation is associated with frequent, mild and transient adverse effects as well as with serious complications which can lead to permanent disability or death. Yet causal inferences are, of course, problematic. Vascular accidents may happen spontaneously or could have causes other than spinal manipulation. A temporal relationship is insufficient to establish causality, and recall bias can further obscure the truth. Moreover, denominators are rarely available. Consequently the frequency of serious adverse effects is currently unknown. Estimates by chiropractors vary (e.g. 6.4 per 10 million manipulations of the upper spine and 1 per 100 million manipulations of the lower spine).<sup>53</sup> These figures, however, may be over-optimistic. Retrospective investigations have repeatedly shown that under-reporting is close to 100%. 13,52 This level of under-reporting would render such estimates nonsensical. At present, there is no sufficiently large and rigorous prospective study to generate

reliable incidence figures; previous studies have failed to investigate those patients which were lost at follow-up. This could be the subgroup which has been harmed. It is therefore essential that future studies follow up close to 100% of the initial patient sample.

The effectiveness of spinal manipulation for most indications is less than convincing. A risk—benefit evaluation is therefore unlikely to generate positive results: with uncertain effectiveness and finite risks, the balance cannot be positive. Cautious attitudes towards upper spinal manipulation are therefore becoming more widespread: 'special caution should be exercised when performing first-line cervical manipulation and simple, honest and easily understandable information about there risks should be included when informed consent is obtained.'54

Some therapists have started advocating screening patients for risk factors before treatment. 55-57 Based on cadaver studies of human vertebral arteries, Cagnie et al.<sup>58</sup> have suggested that, in the presence of arteriosclerotic changes, the stretching and compression effects of rotational manipulation may constitute a risk factor for vascular accidents. These authors concluded that 'therapists should avoid manipulative techniques at all levels of the cervical spine in the presence of any indirect sign of arteriosclerotic disease or in the presence of calcified arterial walls or tortuosities of the vessel.'58 Others have suggested that high homocystein levels constitute a risk factor for arterial dissection.<sup>59</sup> Spinal manipulation might therefore be contraindicated in such individuals. The effectiveness of screening has, however, not been convincingly demonstrated. The chiropractic profession tends to downplay the risks: 'chiropractic services are safe';60 'the healthy vertebral artery is not at risk from properly performed chiropractic manipulative procedures.'61 Others argue that 'the occurrence of cerebrovascular accidents in the chiropractic population is 0.000008%',62 that causality is not proven or even unlikely, 61,63–66 that other interventions are more risky (see below),<sup>67</sup> that the mechanical forces employed for spinal manipulation are too low to cause injury,68 or that there is a ploy from the medical establishment to sideline chiropractors.<sup>69–71</sup> In the light of the evidence summarized above, such attitudes do not seem to be in the best interest of patients.

It is, of course, important to present any risk—benefit assessment fairly and in the context of similar evaluations of alternative therapeutic options. One such option is drug therapy. The drugs in question—non-steroidal anti-inflammatory drugs (NSAIDs)—cause considerable problems, for example gastrointestinal and cardiovascular complications. <sup>72,73</sup> Thus spinal manipulation could be preferable to drug therapy. But there are problems with this line of argument: the efficacy of NSAIDs is undoubted but that of spinal manipulation is

not, and moreover, the adverse effects of NSAIDs are subject to post-marketing surveillance while those of spinal manipulation are not. Thus we are certain about the risks and benefits of the former and uncertain about those of the latter. Finally, it should be mentioned that other therapeutic options (e.g. exercise therapy or massage) have not been associated with significant risks at all.

This systematic review has several limitations. Even though the search strategy was thorough, some relevant published articles might have been missed. High levels of under-reporting or recall bias might distort the overall picture generated. Publication bias could have exerted a similar effect. For instance, it is possible that journals of complementary medicine are unlikely to publish findings which might be considered 'negative'.<sup>74</sup>

In conclusion, spinal manipulation, particularly when performed on the upper spine, has repeatedly been associated with serious adverse events. Currently the incidence of such events is unknown. Adherence to informed consent, which currently seems less than rigorous, 75 should therefore be mandatory to all therapists using this treatment. Considering that spinal manipulation is used mostly for self-limiting conditions and that its effectiveness is not well established, 5 we should adopt a cautious attitude towards using it in routine health care.

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