SAFETY OF SPINAL MANIPULATION IN THE TREATMENT OF LUMBAR DISK HERNIATIONS: A SYSTEMATIC REVIEW AND RISK ASSESSMENT

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ABSTRACT

Objective: To provide a qualitative systematic review of the risk of spinal manipulation in the treatment of lumbar disk herniations (LDH) and to estimate the risk of spinal manipulation causing a severe adverse reaction in a patient presenting with LDH.

Data Sources: Relevant case reports, review articles, surveys, and investigations regarding treatment of lumbar disk herniations with spinal manipulation and adverse effects and associated risks were found with a search of the literature.

Data Synthesis: Prospective/retrospective studies and review papers were graded according to quality, and results and conclusions were tabulated. From the data published, an estimate of the risk of spinal manipulation causing a clinically worsened disk herniation or cauda equina syndrome (CES) in patients presenting with LDH was calculated. This was compared with estimates of the safety of nonsteroidal anti-inflammatory drugs (NSAIDs) and surgery in the treatment of LDH.

Results: An estimate of the risk of spinal manipulation causing a clinically worsened disk herniation or CES in a patient presenting with LDH is calculated from published data to be less than 1 in 3.7 million.

Conclusion: The apparent safety of spinal manipulation, especially when compared with other accepted treatments for LDH, should stimulate its increased use in the conservative treatment plan of LDH. (J Manipulative Physiol Ther 2004;27:197-210)

Keywords Indexing Terms: *Chiropractic Manipulation; Intervertebral Disc Herniation; Cauda Equina Syndrome; Low Back Pain; Safety; Adverse Reactions*

INTRODUCTION

The lifetime prevalence of symptomatic herniated disks is estimated at 1% to 3%,[1,2] although anatomic evidence of disk herniation is said to be found in 20% to 40% of imaging tests among asymptomatic persons.[3,4] Most clinically relevant herniations occur between the ages of 30 and 50 but can also occur in adolescents and older people.[5] Two percent to 5% of patients seeking help are thought to suffer from a disk herniation,[6] while others think that in about 40% of low back pain (LBP) patients the cause is internal disk disruption.[7] Conservative care, or natural history, is beneficial in more than 50% of patients with disk herniation and sciatica[6,8,9] and is associated with a low complication rate.[6] Ten percent of LBP patients account for more than 80% of the total health care and social costs. It is estimated that the 1% to 2% of low back pain patients who undergo surgery for disk herniation account for as much as one third of the costs, yet the evidence for most surgical procedures is still unclear.[10] Surgery has not been proven to be more effective than conservative care[11] and has a complication rate of 24%, almost half of which are major complications.[12]

Even though 70% of patients will recover adequately, 30% of patients with lumbar radiculopathy in one study continued to have back pain, reduced capacity in work, and

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Table 1. *Evidence table for adverse effects of lumbar spinal manipulation*

Year	Author	Quality score	Study type	No. of Patients / Txs
1978	Evans et al[44]	43%	*Randomized crossover	32Pts/96 Txs
1981	Laderman[37]	48%	Review	
1985	Kirkadly-Willis and Cassidy[42]	49%	*Prospective	283Pts / > 2830Txs
1987	Hadler et al[43]	50%	*Controlled trial	26 pts
1987	Nyiendo and Haldeman[47]	28%	*Prospective	888 LBP (22 disc) / 4706 Txs(116 disc)
1991	Patijn[40]	32%	Review	
1992	Haldeman and Rubinstein[33]	84%	Review	3720 million est.
1992	Shekelle et al[34]	86%	Review	More than 1500
1992	Terret and Kleynhans[38]	60%	Review	
1993	Michaeli[46]		Survey	228,050 Txs All spinal areas
1993	Powell et al[31]	40%	Review/2 Cases	2
1995	Stern et al[6]	39%	*Retrospective	59pts / 1274Txs
1996	Assendelft et al[30]	74%	Review	
1996	BenEliyahu[21]	38%	*Prospective	16pts / avg 25 Txs each
1996	Rivet and Milburn[28]		Survey	
1997	Senstad et al[45]	36%	*Prospective	1058pt / 4712Tx/102DCs
1999	Rydell Raf[29]		Review(Swedish)	
2000	Barrett and Breen[48]	29%	*Prospective	108pts / 9 DCs
2000	Burton et al[41]	71%	*Blind RCT	20pts / 220txs

Pooled data	*Total of *lumbar patients* in Prospective/ retrospective studies Patients	Treatments
Evans et al[44]	32	96
Kirkaldy-Willis and Cassidy[42]	283	>2830
Hadler et al[43]	26	26
Nyiendo and Haldeman[47]	888	4706.....
Stern et al[6]	59	1274.....
BenEliyahu[21]	16	400.....
Senstad et al[45]	1058×75%=793	4712 × 75% = 3534
Barrett and Breen[48]	108×51%=55	55 (× Txs = ?)
Burton et al[41]	20	220.....
	2164 pts	>13,141 Txs

See Appendix 1 for legend of abbreviations.

restriction of leisure activities, and 19% were still out of work after 1 year in both the nonsteroidal anti-inflammatory drug (NSAID) and control groups.[13] Because the natural history of lumbar disk herniation (LDH) is favorable in the majority of patients, the goal of care must be to accelerate recovery beyond natural history itself, improve the quality of life during and after the recovery process,[11] and provide relief when natural history is not favorable. Any treatment that can be shown to do this safely and cost-effectively should be utilized more often.

Population / Intervention	Length/Follow-up	Adverse effects/Conclusions
Back pain > 3Wks / Rotational thrust	3 wks tx, 3 wks control	2 'deteriorated' / relief quicker with manipulation
Spinal manipulation in general	1911-1980	30 cases aggravation of disc; 20 CES-12 with MUA
Tertiary Back Pain Clinic-chronic LBP Avg 9.4 Yrs / Side lying lumbar manipulation	Avg 10.7 Mos	No Pts made worse
1 long-lever high velocity thrust	2 wk follow-up	None made worse
90% SMT,44% soft tissue, 33% modalities 15% exercise	92% follow-up	No major complications
Manipulative therapy	93 papers	8 cases LDH; 16 cases CES
Chiropractic patients in general	30 years	29 cases of CES-16 with MUA
Chiropractic patients in general		No adverse effects
Spinal manipulation	1911-1991	35 cases CES-24 with MUA 30 cases disc injury-3 with MUA
153/250 'manual PTs'/ spinal manipulation	Recall 1971-1989	1 minor transient complication per 38,137 lumbar SMT Txs
'Spinal Manipulation Therapy'		Mod. high risk of SMT for LDH
LBP+radiating leg pain / side lying lumbar Manipulation, electro, exercise, massage, backschool	3 years	No adverse effects
Chiropractic patients in general		Less than 1 CES per 1 million Txs
MRI documented disk herniations / Traction, IFC, US, Spinal Manipulation, Exercise	9 months avg	No adverse effects
SMT Pts seen by specialists for complications	5 year recall	6 lumbar, 3 with radiculopathy
Chiropractic patients in general (75%incl. Lumbar SMT)	12 NP/DC	No permanent complications
Insurance claims regarding manipulation	2 year period	6 LDH - 3 persistant and severe
Chiropractic patients in general (51%lumbar)	1 Hr.-2days post-Tx	No serious adverse effects
Sciatica due to LDH / stretching, mobilisation, manipulation by osteopath	12-month follow up	No serious complications/ No evidence to question safety

Total of *LDH patients* in Prospective/retrospective studies

Patients	Treatments	
22	116	
59	1274	
16	400	
20	220	
117 pts	2010 Txs.....	No major or permanent adverse reactions

There is a general consensus among contemporary orthopedists that for most patients with LDH, a trial of conservative treatment is preferable initially over surgical intervention.[5,10-12,14-18] Some feel the goal of diskectomy is to provide more rapid relief of sciatica[10] or reduce pain and disability[12] in patients who have failed to resolve with conservative management, but others do not feel that failure of passive conservative care is an appropriate criterion for proceeding to surgical intervention,[11] since appropriate criteria and optimal timing of surgery are unknown.[10] Conservative treatment of LDH by medical doctors and physical therapists usually does not include spinal

Table 2. *Number of reported cases of disk herniation or CES following manipulation*

Author	Quality score %	All cases	Excluding manipulation under anesthesia
1. Ladermann[37]	48%	30 cases of aggravation of "disk syndrome" in French, German, and English literature; 20 cases of CES	8 cases CES; 5 cases ruptured or sequestered disk (13 total)
2. Terrett and Kleynhans[38]	60%	65 cases of disk-related complications; 37 cases of CES	13 cases CES; 18 disk-related complications (31 total)
3. Haldeman and Rubenstein[33]	84%	29 cases of CES found in world literature and in malpractice claims	13 cases CES
4. Assendelft et al[30]	74%	56 LDH or CES found in literature	27 cases LDH or CES

CES, Cauda equina syndrome; *LDH*, lumbar disk herniation.

manipulation,[11,12,18-20] while chiropractors commonly treat LDH with spinal manipulation. The efficacy and the risk of this treatment are not known; however, a number of case studies show spinal manipulation to be effective in the treatment of LDH, even after other treatments have failed to provide relief.[2,6,14,21-27] There is evidence that spinal manipulation has a beneficial effect on pain, straight-leg raising (SLR), range of motion, size of disk herniation, neurologic symptoms, and H-reflex. Detractors, however, suggest spinal manipulation is responsible for causing disk herniations and cauda equina syndrome (CES),[28-31] and disk herniation is the leading cause of claims against chiropractors.[32]

There are no large prospective studies published on the use of spinal manipulation on patients with LDH with which to measure the outcome and complications accurately and compare with natural history or other treatments. Estimates of the risk of causing LDH or CES with lumbar spinal manipulation performed for any reason range from one in 1 million to one in over 100 million.[30,33,34] CES consists of neurogenic bowel and bladder disturbances (usually urinary retention), saddle anesthesia, bilateral leg weakness, and sensory changes[33] and is the most serious sequela of LDH. It has been reported to occur in 1% to 16% of all reported cases of LDH.[35] Manipulation of any sort is contraindicated in the presence of CES,[16] as this represents a surgical emergency. The only estimate of the risk of spinal manipulation in patients presenting with probable LDH calculated the risk to be between 0% and 5%.[6] The purposes of this article are to review the literature and to estimate the risk of spinal manipulation causing a clinically worsened disk herniation or CES in a patient presenting with LDH.

Methods

Databases, including MEDLINE and MANTIS, were searched from 1966 to present. Search terms included lumbar disk herniation, intervertebral disk, back pain, cauda equina syndrome, spinal manipulation, and complications. References from articles retrieved were reviewed for additional articles. Tables of contents of some journals were reviewed for relevant articles.

Table 3. *Risk of lumbar disk herniation or cauda equina syndrome from spinal manipulation (any diagnosis)*

Authors	Quality score %	Estimated risk
1. Haldeman and Rubinstein[33]	84%	One (CES) in 128 million manipulations
2. Shekelle et al[34]	86%	One (CES) in 100 million manipulations
3. Assendelft et al[30]	74%	Less than one (CES or herniation) in 1 million manipulations
4. Patijn[40]	32%	One (LDH or CES) in 2,789,709 manipulations* (One LDH in 8,369,129 manipulations; 1 CES in 4,184,564 manipulations)

CES, Cauda equina syndrome; *LDH*, lumbar disk herniation.
*1/518,886 for any complication, 6.2% of which were LDH and 12.4% CES.

Papers were included if they discussed lumbar spinal manipulation and lumbar disk herniation, CES, or other complications of lumbar spinal manipulation or if they included estimates of the number of people attending a chiropractor, the number of those chiropractic patients who present with symptomatic lumbar disk herniation, or the number of chiropractic patients who receive spinal manipulation.

Prospective and retrospective studies and review papers that included adverse effects were scored for quality according to specific criteria modified from Koes et al.[36] The findings of these papers were summarized and tabulated, and the numbers of patients, treatments, and adverse reactions of the patients of the prospective and retrospective

Table 4. *Quality scores of adverse effects of lumbar spinal manipulation: prospective / retrospective studies (with respect to lumbar disk complications)*

	Methods criteria																	
Author	A 2	B 5	C 4	D 3	E 4	F 12	G 10	H 5	I 5	J 5	K 5	L 5	M 10	N 10	O 5	P 5	Q 5	Total score 100
Evans et al[44]	2	3	2	1	3	0	1	0	5	0	2	2	8	6	5	0	3	43
Kirkaldy-Willis and Cassidy[42]	2	0	0	0	4	12	5	0	2	0	5	2	2	2	5	5	3	49
Hadler et al[43]	2	3	0	3	4	0	10	3	0	0	1	3	4	4	3	5	5	50
Nyiendo and Haldeman[47]	1	0	0	3	3	12	2	0	0	0	5	0	0	0	2	0	0	28
Stern et al[6]	2	0	0	3	3	6	5	0	0	0	5	2	6	0	3	5	5	39
BenEliyahu[21]	2	0	0	3	4	0	5	0	0	0	5	0	6	0	5	5	3	38
Senstad et al[45,*]	1	0	1	0	4	12	1	0	0	0	5	0	4	0	3	0	5	36
Barrett and Breen[48,*]	1	0	1	0	2	6	1	0	0	0	5	0	4	4	3	0	2	29
Burton et al[41]	2	4	4	3	3	0	10	5	5	0	5	4	8	8	5	0	5	71

Modified from Koes et al[36] with permission from the BMJ Publishing Group.
Refer to Appendix 2 for definitions of the letters A to Q.
* Studies whose primary purpose was to look at adverse reactions of spinal manipulation. Other studies had different main purpose and mentioned complications (or lack of) as an outcome variable or as an aside.

papers were pooled. A summary of papers reporting on effectiveness of spinal manipulation was presented, and a possible mechanism of disk injury from spinal manipulation was provided.

Using the best available evidence, an estimate of the risk of lumbar spinal manipulation on patients presenting with LDH causing serious worsening of the disk herniation or CES was calculated.

Review of Literature

Eight review articles, 9 prospective/retrospective studies, and 2 surveys that included discussions of adverse effects of lumbar spinal manipulation were found (Table 1). In 1981, Ladermann[37] reviewed the available literature published in French, German, and English and found 30 cases of aggravation of a "disk syndrome" by manipulation. Among 20 cases of CES, 12 resulted from "manipulation under narcosis."

Terrett and Kleynhans[38] augmented and updated Ladermanns' review[37] and found a total of 65 disk-related complications from spinal manipulation from 1911 to 1991. In 4.6% of cases, the practitioner was an osteopath; 6.1% involved physiotherapists; in 7.7%, the therapy was "chiropraxis" but the practitioner was not identified; in 17%, the practitioner was not identified; in 20% the practitioner was a chiropractor; and nearly half (44.6%) were medical manipulation under anesthesia. Sixty-seven percent of the cases involved male patients.

Haldeman and Rubinstein[33] found a total of 29 cases of CES following spinal manipulation from 1911 to 1989 (Table 2) and used the 1975 estimate of 124 million patient visits to chiropractors per year[39] as the estimate for 30 years. This equates to one CES per 128 million patient visits (Table 3). Sixteen of the 29 reported cases were manipulation under anesthesia (MUA), which is said to involve very strenuous manipulation without the natural guarding forces of muscular spasm or the feedback of patient complaints and is considered a separate procedure, not analogous to normal chiropractic methods. [33,37] If you exclude MUA, the risk falls to about one episode of CES in 286 million patient visits. These authors also state that manipulation does not appear to be contraindicated for patients with bulging disks or herniation, and the rare occurrence of CES should not be a reason to avoid such treatments.[33]

Shekelle et al[34] estimated the rate of occurrence of CES as a complication of spinal manipulation to be about one per 100 million manipulations (Table 3).

Assendelft et al[30] reviewed the literature and estimated the risk of the most frequently reported complications. Out of the 295 complications of spinal manipulation found, there were 56 cases of lumbar disk herniation or progression to CES, and 49% of the complications occurred during manipulation under anesthesia. They estimated the incidence of CES to be less than one per 1 million treatments (Table 3).

Patijn[40] also reviewed the literature and calculated the risk of all complications of spinal manipulation to be one in 518,886. He found 8 cases of LDH (6.2%) and 16 cases of CES (12.4%), and from his numbers, this equals a risk of one in 8,369,129 for LDH and one in 4,184,564 for CES (Table 3).

Powell et al,[31] after reviewing the literature, feel the risk/benefit ratio in patients with acute midline lumbar pain is

Table 5. *Quality scores of adverse effects of spinal manipulation: review papers (with respect to lumbar disk complications)*

		Methods criteria								
		A	B	C	D	E	F	G	Total score	Total score
Year	Author	10	5	5	10	10	5	5	50	%
1981	Laderman[37]	9	5	5	3	0	1	1	24	48
1991	Patjin[40]	5	3	1	2	4	0	1	16	32
1992	Terrett and Kleynhans[38]	9	5	5	3	5	2	1	30	60
1992	Haldeman and Rubenstein[33]	10	5	4	10	8	0	5	42	84
1992	Shekelle et al[34]	10	4	5	10	9	0	5	43	86
1993	Powell et al[31]	5	1	0	8	3	2	1	20	40
1996	Assendelft et al[30]	9	5	3	5	10	0	5	37	74

Refer to Appendix 3 for definitions of letters A to G.

sufficiently low to recommend spinal manipulative therapy (SMT) as an alternative treatment.

A single-blind randomized controlled trial of manipulation versus chemonucleolysis in patients presenting with sciatica due to LDH by Burton et al[41] found there were no serious complications and no evidence to question the safety of spinal manipulation. Kirkaldy-Willis and Cassidy,[42] in a prospective study of manipulation of 283 patients and more than 2800 treatments for 7 different diagnoses of low back pain averaging 9.4 years duration, found no patients were made worse. Stern et al[6] retrospectively reviewed their clinic files from 1990 to 1993 and found 59 patients who had received spinal manipulation for low back and leg pain diagnosed as lumbar disk herniation; none reported an increase of back or leg pain. They stated they were 95% confident that the risk of complication of manipulation for patients with back pain and sciatica was between 0% and 5%.

BenEliyahu[21] prospectively investigated the effect of chiropractic management on 27 magnetic resonance imaging (MRI)-documented disk herniations (16 in the lumbar spine) and none of the patients were made worse. In a stratified controlled trial of manipulation versus mobilization for low back pain, Hadler et al[43] found none of the 26 patients in the manipulation group were made worse. In a randomized crossover of 32 patients and 96 treatments over 3 weeks, Evans et al[44] found 2 patients "deteriorated," which seemed to indicate mild aggravation of symptoms.

Senstad et al[45] performed a prospective study of more than 1000 new patients and 4700 treatments and found no permanent complications. Michaeli[46] surveyed 153 of 250 South African manipulative physiotherapists who reported one minor or transient complication and no serious or permanent complications per 38,137 lumbar spinal manipulations.

A prospective evaluation of 2000 patients attending a chiropractic college clinic failed to reveal even one major complication.[47] Barrett and Breen[48] prospectively studied 68 patients of 9 chiropractors and found no serious adverse effects reported.

Table 6. *Number of patient visits to chiropractors in the last 40 years*

Author	Patient visit estimate
1. Haupt[39] (1975 estimate)	124 million visits per year
2. Frymoyer[4] (1988 publication)	75 - 120 million visits per year
3. Shekelle et al[34] (Average of 1980 + 1991 estimates)	50 visits per 100 person-years
4. Hurwitz et al[51] (1991 estimate)	101.2 visits per 100 person-years

Calculation of estimate of chiropractic patient visits 1960-2000:
(1960-1990) 124 × 30 = 3720 million
+
(1990-2000) 101 × 250 million × 10 / 100 = 2525 million
= 6245 million

Powell et al[31] suggest the presence of a herniated nucleus pulposus as a risk factor to spinal manipulation; however, these authors seem to base their opinion on 2 cases presented and some cases of disk herniation following manipulation reviewed from the literature, without regard for the total number of spinal manipulations performed.

Rivett and Milburn[28] surveyed medical specialists in New Zealand regarding complications of spinal manipulation they recalled in the last 5 years, with 3 in the lumbar spine and 3 in the lumbar spine with radiculopathy reported. They admit that some of the outcomes (eg, disk prolapse, radiculopathy) may have manifested as part of the progression of the patient's disorder or were not caused by manipulative therapy, and since the number of manipulations performed over this time period is, again, unknown, incidence cannot be calculated.

In a review of injuries for which claims were submitted to 3 insurance companies during a 2-year period in Sweden[29] and which had arisen in conjunction with manipulation, there were 6 cases of lumbar disk herniation, 3 of which had persistent severe problems. Again, the incidence is not known, and the submission of insurance claims does

Table 7. *Percentage of chiropractic patients with low back pain, low back pain of discogenic origin, and receiving spinal manipulation*

Author	% with LBP	% with discogenic LBP	% receiving spinal manipulation
1. Hurwitz et al[51]	68% (1310 / 1916 patient files randomly reviewed from 131 chiropractors from 5 US and 1 Canadian city presented for low back pain)	6% of low back pain patients presented with sciatica (the most common cause being disk herniation)	84% of 1310 low back pain patients (83% of 1916 total patients)
2. Schwartzer et al[52]		40% of low back pain thought to be caused by disk herniation or internal disk derangement	
3. Senstad et al[45]	75% of chiropractic patients received treatment to the lumbar spine, but presenting complaint is not listed		74% - 99%* of 1058 patients
4. Shekelle et al[34]	32% - 45% of chiropractic patients thought to present with low back pain		61% - 92% of chiropractic patients
5. Stern et al[6]		2.2% of all new patients attending 1 chiropractic clinic over a 4-year period presented with LBP and radiating leg pain clinically diagnosed as lumbar disk herniation	

LBP, Low back pain.
* It was not clear whether 25% of patients who were recorded as receiving "a combination of several methods" of treatment received spinal manipulation.

not equate to spinal manipulation being the cause of the disk herniation.

Ernst[49] searched all language literature for prospective investigations into the safety of spinal manipulation and found 5 cases, 4 of which were related to the lumbar spine and are reviewed above.

A number of studies have found increased symptoms in the first week or so of manipulation [42,44,45] and this has generally been thought to be a part of the treatment or healing process,[36] but this finding has not been adequately compared with other treatment, placebo, or control groups and may not be unique to spinal manipulation. Gibson et al[10] found that the incidence of increased symptoms following spinal manipulation (11%) was similar to that following placebo treatment of detuned short wave diathermy (12%) and may therefore represent normal fluctuations in pain intensity or be inappropriately attributed to the treatment given.

Pooling of Trial Data

When all the subjects of the prospective and retrospective studies that discuss adverse effects of lumbar spinal manipulation are pooled, there is a total of over 2100 patients and over 13,100 treatments and no major, serious, or permanent complications have been reported (Table 1). Four studies focused specifically on spinal manipulation of probable disk herniations and together included 117 patients diagnosed as having LDH and over 2000 treatments without complication.[6,21,41,47] In Koes et al[36] review of trials of effectiveness of manipulation for acute and chronic low back pain, few papers specifically mentioned the absence of adverse effects,[40,43,44] but most did not mention adverse effects at all. This may be because none occurred during these trials involving over 1500 patients[34] or simply they were not recorded as part of the data. However, if any significant complications had been known to occur, they would probably have been mentioned, at least as a reason for dropout.

Quality Reviews

All prospective and retrospective studies were analyzed and graded for quality with respect to adverse effects of lumbar spinal manipulation, using a modification of a method previously used by Koes et al[36] and again by Shekelle et al[34] to assess studies of efficacy (Table 4). As per Vernon et al,[50] a rating of 0% to 40% was deemed to indicate "poor" quality; ratings of 40% to 60% were deemed to indicate "moderate" quality; and ratings above 60% were deemed to indicate "high" quality. Burton et al,[41] with a quality score of 71% (71/100), was the only high-quality study with respect to adverse effects. Hadler et al,[43] Kirkaldy-Willis and Cassidy,[42] and Evans et al[44] all scored in the moderate range with scores of 50%, 49%, and 43%, respectively, while the other studies scored from 28% to 39%, in the poor range.

All review papers were scored for quality in regard to adverse effects of lumbar spinal manipulation using criteria

Table 8. *Risk of manipulation worsening LDH or CES in patients presenting with LDH*

No. of patient visits from Table 6	Estimate of no. of patients presenting with LDH from Table 7	% getting manipulation from Table 7	Number of cases reported from Table 2	Risk
Excluding MOA 6245 million	× 2.2%	× 84%	/ 31	= 1 in 3.72 M
Including MUA 6245 million	× 2.2%	× 84%	/ 65	= 1 in 1.78 M

LDH, Lumbar disk herniation; *CES*, cauda equina syndrome; *MUA*, Manipulation under anesthesia.

assigned by this author, modeled after the method used by Koes et al[36] to assess studies of efficacy (Table 5). There were 3 review papers in the high quality range; the papers by Shekelle et al,[34] Haldeman and Rubenstein,[33] and Assendelft et al[30] scored 86% (43/50), 84% (42/50), and 74% (37/50), respectively. Terrett and Kleynhans,[38] Ladermann,[37] and Powell et al[31] scored in the moderate range with 60% (30/50), 48% (24/50), and 40% (20/50), respectively, while the paper by Patijn[40] scored in the poor range with 32% (16/50).

Calculation of Risk

To estimate the risk of spinal manipulation causing a (clinically worsened) disk herniation or CES in a patient presenting with LDH as the cause of their LBP, the number of patients who received spinal manipulation for lumbar disk herniation needed to be calculated and then divided by the number of cases of disk herniation or CES following lumbar spinal manipulation. The number of patients that received spinal manipulation for lumbar disk herniation was calculated using the number of people who attended a chiropractor, the percentage of those presenting with lumbar disk herniation as the probable cause of their symptoms, and the percentage of those people who received lumbar spinal manipulation (excluding MUA). These numbers were taken from the literature and are found in Tables 2, 6, and 7. For each of the numbers needed for this calculation, the number used was that which was most recent or was thought to be the most accurate or most erred on the side of calculating a higher risk.

For the number of people who have attended a chiropractor, the 1975 estimate by Haupt[39] of 124 million office visits to chiropractors per year (Table 6) was used as the average for the years 1960 to 1990, since 1975 falls in the middle of that 30-year period (124 million × 30 = 3720 million). The 1991 estimate of 101 visits per 100 people years[51] was used for the years 1990 to 2000 (101 × 250 million 1990 United States population/100 × 10 years = 2525 million). These two numbers were added to get a total of 6245 million chiropractic office visits in the United States in the last 40 years (Table 6). Office visits were calculated for only the last 40 years because a reliable estimate of chiropractic use prior to this could not be found, and this also errs on the side of overestimating the risk.

The number of patients presenting to a chiropractor with LDH was estimated in 2 papers. Stern et al[6] calculated 2.2% of all new patients presenting to their clinic had symptoms attributable to a disk herniation (LBP and sciatica), and Hurwitz et al[51] found about 4% of the patients in their study had sciatica (6% of the 68% of total patients who had LBP), of which disk herniation is considered the most common cause (Table 7).[6] These two estimates are similar to the estimate of 5% of patients attending a medical doctor having LDH.[6] The Schwartzer et al[52] estimate of 40% of LBP being caused by internal disk derangement is based not on physical examination findings but on injection provocation testing. LBP alone can be caused by any structure in the back, including disk derangement or prolapse. Leg pain can be caused by disk prolapse compressing an inflamed nerve root, but it also can be caused by disk disruption passing into the outer layer of the annulus without resulting in deformation of the annular wall[53]; injury to ligaments, zygapophyseal joints, musculature, or sacroiliac joints; or a combination of these. There is no clinical test that definitively distinguishes the source of pain in LBP patients. Therefore, the Stern et al[6] estimate was used in this calculation, since it is based on findings in the chiropractic office setting, and being the lowest of the 3, will also give the highest final estimate of risk.

The number of chiropractic patients who received spinal manipulation was calculated by Hurwitz et al[51] as 84% and by Shekelle et al[34] as between 61% and 92% (Table 7). Since the Hurwitz et al[51] number is more recent and was specifically calculated for patients presenting with low back pain and since it falls within the Shekelle et al[34] range, 84% is the number that was used. The Senstad et al[45] finding, which implies 99% had spinal manipulation, was not used because the authors did not clearly state whether 25% of patients who received "a combination of several methods" had spinal manipulation, and the Hurwitz et al[51] study reviewed almost twice as many files. As well, 84% leads

to a higher risk estimate than 99%. This calculation also assumes an average of only one manipulation per visit, which is unlikely,[45] but this will again overestimate the risk of spinal manipulation in patients presenting with LDH.

The highest number of cases of LDH or CES following spinal manipulation reported in the literature, excluding MUA, is 31 (Table 2).[38]

Using the most accurate, recent, and/or conservative numbers found in the literature for manipulation of LDH patients and the highest number of LDH and CES reported following office manipulation in the following formula

$$Risk = \frac{\begin{array}{l}\#\ of\ patient\ visits \\ \times\%\ of\ low\ back\ pain\ patients\ presenting\ with\ LDH \\ \times\%\ of\ those\ getting\ spinal\ manipulation\end{array}}{number\ of\ cases\ of\ LDH\ or\ CES\ reported}$$

calculates the greatest risk of developing a disk herniation or CES attributable to treatment of LDH by spinal manipulation to be one in 3.72 million manipulations (Table 8).

Discussion

Many authors recommend the use of spinal manipulation in the treatment of LDH,[2,6,8,14,16,21–26,54] while some recommend against it,[5,31,49] and disk herniation is the most common claim against chiropractors.[32] Therefore, it is important to estimate the risk of serious complications of spinal manipulation in the treatment of LDH using the best available evidence. The serious complications that spinal manipulation could cause in a patient with LDH are a significantly worsened LDH or a CES.

By attributing all of the reported cases of LDH and CES following spinal manipulation to patients presenting with LDH, an estimate of the risk of manipulation causing a clinically worsened disk herniation or CES in a patient with LDH can be calculated. The risk is less than 1 in 3.7 million manipulations, according to calculations using published estimates of the number of patients attending chiropractors, the percentage of those with disk herniations, the number of those patients receiving spinal manipulation, and the number of cases of CES or disk herniation following spinal manipulation. This does not, of course, include the kind of temporary or mild symptoms that are commonly reported following manipulation[45,48] and placebo treatments.[10] If complications following MUA are included, the risk doubles (Table 8).

The numbers that these calculations have been based on can be argued to be rough estimates at best, and therefore with each calculation, the accuracy of this risk estimate may have been reduced. However, there has been an increased emphasis on evidence-based care. This risk was calculated according to the best evidence available, and the numbers used err in favor of overestimating the risk. Specifically, the lowest estimate of 2.2% of patients attending a chiropractor having LDH was used (Table 6) and not the estimate of 40% of low back pain patients having pain due to internal disk derangement,[52] which may be a more accurate estimate of those at risk and would have lowered the estimate of risk of spinal manipulation causing LDH or CES in a patient presenting with discogenic pain to one in 46 million (6245 M × 40% × 68% × 84%/31 = 1 in 46 M) (Tables 6, 7, and 8). The estimate of chiropractic visits in the United States over the last 40 years was used to represent worldwide spinal manipulation by all disciplines since 1911 (the date of the first published case of CES). An average of only one manipulation per treatment was also assumed, which is not normally the case.[45]

Finally, the results were compared with another calculation based on estimates from the literature. An estimate of one case of CES in 286 million office manipulations derived from Haldeman and Rubenstein[33] was multiplied by 2.2%, the number of patients who likely presented with a disk herniation,[6] and this suggests a risk of one CES in 6.2 million manipulations. Multiplying this by 13/31 to account for the other disk-related complications, as well as CES (Table 6), gives a risk estimate of one in 2.6 million, which is similar to the estimate presented above.

After the number of patients presenting with disk herniation, the biggest source of error may be the number of LDH or CES which have occurred following spinal manipulation, [30,33] as detractors state that many cases of disk injury following spinal manipulation may go unreported, [28,30,31,49] but this has not been verified.

The safety of spinal manipulation in the treatment of LDH should be compared with other commonly accepted treatments for the same condition. Comparing this, or any treatment, with "no treatment" is not meaningful, because while no treatment may be the safest option, most patients seeking relief will opt for some type of treatment, hoping it will provide more relief than natural history. NSAIDs are the most commonly used medications in the world, and adverse events occur in 25% of patients, with significant complications occurring in 1% to 4% per year.[55] The major side effects include gastrointestinal (GI) ulceration and bleeding, hepatorenal dysfunction, organ failure, and skin reactions, and they may accelerate cartilage destruction.[56] GI complications due to NSAIDs cause more than 100,000 hospitalizations and an estimated 16,500 deaths each year in the United States,[57] and NSAID-related congestive heart failure may exceed the mortality resulting from gastrointestinal tract damage.[58] CES is reported as a sequela of surgeries for LDH in 0.2% to 1%,[59,60] while Kardaun et al[61] found the frequency of CES in 3289 surgically treated LDH patients was about 0.5%. The "any-complication rate" has been estimated to be 3.7% or more, including 1.5% mortality.[61,62] The most recent study comparing surgical with nonsurgical treatment of chronic LBP patients found 24% of the surgical group had complications, almost half being major complications, and

almost 8% required reoperations.[12] If "significant complications" occur in 1% to 4% of NSAID users,[55] in 1.5% to 12% of LDH surgeries,[12,61,62] and in one in 3.7 million patients receiving spinal manipulation for LDH, then spinal manipulation is at least 37,000 to 148,000 times safer than NSAIDs and 55,500 to 444,000 times safer than surgery for the treatment of LDH. If CES occurs in one in 3.7 million spinal manipulations for LDH and in 0.2% to 1% of surgeries,[59,60] then CES is at least 7400 to 37,000 times more likely to occur as a complication of surgery than of spinal manipulation.

Meanwhile, neither NSAIDs nor surgery has been proven to be more effective in the treatment of LDH than spinal manipulation. There are no data to support the premise that operative intervention will restore neurologic function more rapidly than natural history or nonoperative intervention.[11] Estimates for the effectiveness of surgical procedures for disk herniation range from 30% to 96%,[63] but over 4 years or more, many feel the effectiveness of surgery is the same as natural history.[4,13,63] Rhyne et al,[63] in a study of discogram-positive low back pain patients who were offered surgery but rejected it for various reasons, found their outcome over a mean follow-up of 4.9 years was comparable with, or better than, those reported for surgical treatment of this condition. Weber[19] also found that between 4 and 10 years, there was no difference between those who had surgery for LDH and those who did not, although after the first year, the surgical group reported 66% "good" and 25% "fair" results, whereas the conservative group had 32% "good" and 49% "fair" results. His decade-old paper was recently criticized for not reaching current research standards, but the critics still generally support his conclusions.[64] A 2-year follow-up of surgical and nonsurgical treatment of chronic LBP patients found that 63% of the surgical group rated themselves as "much better" or "better" compared with 29% of the nonsurgical group and showed significantly greater improvements on the Oswestry Low Back Pain Questionnaire, Million Visual Analogue Score, General Function Score, and Zung Depression Scale.[12] These authors were criticized, however, for not specifying or standardizing the nonsurgical treatment and because this group apparently received more of the same care they had all "failed" to be accepted into this study, making this more of a study of surgery versus no treatment.[65] Even so, repeating care the nonsurgical group had all failed once still provided significant relief for 29%. This supports the belief that many operations for LDH could be avoided if energetic conservative management was continued for longer periods before surgery.[18] Or, since one third of patients who found significant relief with the second course of conservative treatment failed the first, perhaps 2 exhaustive courses of conservative care by different providers, including spinal manipulation, needs to be the minimum standard of care before proceeding to surgical treatment. Patients may respond differently to treatment provided by one provider than they do to the same treatment given by another provider.

Furthermore, there is controversy as to whether or not spinal manipulation can actually cause a disk herniation. The reported cases of office manipulation causing CES are poorly documented, and it appears the cause-effect relationship was assumed when there was a temporal association between the manipulation and the symptoms[33] and this may be the subject of bias, as in other reported cases of manipulation iatrogenesis.[2,37] Terrett[66] said that some cases in the literature attributed to chiropractors and spinal manipulation were, in fact, caused by lay people or were reported more than once. Interestingly, only 7 of the 13 cases of CES occurred in the United States, where most of the world's chiropractors are located.[33] Some of the older reports may have been misdiagnosed.[37] It is also interesting that more new cases have not been reported in the literature recently, considering the increased use of chiropractic services.[51]

The only loading conditions known to cause posterior disk prolapse involve a combination of compression, lateral bending, and forward bending,[67,68] and standard lumbar spinal manipulation in the side posture position does not involve a combination of these movements.[2] Many authors agree that the axial rotation of the lower lumbar vertebrae is limited to 2° to 3° by impaction of the zygapophyseal (facet) joints, which prevents tearing of collagen fibers of the annulus within the physiological range of torsion, and torsional stresses just great enough to damage the facet joints do not generate enough torque to rupture the disk.[2,16,69,70]

Others, however, found that annular fibers restrict rotation first, 0.8° before the facets act as a second barrier, and this indicates the annulus can be injured with rotation.[71] Bogduk[72] suggests that after the facets impact and prevent further motion around the normal axis of rotation, sufficient force would then change the axis of rotation of the vertebrae from somewhere within the vertebral body out toward the impacted facet such as to cause a lateral shearing force through the disk. He suggests that 3° rotation of a vertebrae causes 4% elongation of the collagen fibers of the annulus, and collagen fibers suffer microscopic injury at this point. Any further motion, such as flexion or shearing forces, would exceed the 4% limit of collagen elongation and this could cause an annular tear without facet failure. An extra 3° to 4° of rotation may be available at each lumbar joint when the spine is flexed.[69]

When flexion, rotation, and compression are combined over an adequate length of time, annular separation and subsequent prolapse of annular material will occur.[68] Brinckman and Porter[73] concluded that for a disk prolapse to occur, there needs to be both an annular fissure and a fragment within the disk. These researchers sliced from the anterior through the posterior annulus leaving only 1 mm of annulus intact and produced only a small bulge of 0.8 mm

with compression and flexion. But when a small fragment of disk material of the size frequently seen at diskectomy was inserted, it took only a small compression load and flexion of less than 10° to prolapse extruded fragments through a complete annular tear. This type of loading is considered to be well within everyday physiological conditions and could happen with a cough, sneeze, laugh, straining at stool, or a stumble.[37,38,73]

It may be that for spinal manipulation to cause increased symptoms of disk herniation or cauda equina syndrome, the disk must already be fragmented and fissured such that any increased strain, like that imposed by normal daily activities, will cause a rupture and prolapse. Considering CES occurs most of the time in the absence of manipulation, at least some of the cases attributed to spinal manipulation could have had the same outcome without manipulation.[3,37,38] The practitioner in most cases apparently does not actually cause the injury but aggravates a preexisting lesion for which the practitioner is consulted.[38] A clinician who administers treatment during the prodrome of a disk herniation is at risk of being identified as the cause, if leg pain and neurological deficit ensue.[16] Gentle technique and limitation of lumbar flexion during rotational manipulation may further reduce the risk to patients presenting with LDH.

Conclusion

Evidence-based care, as the term implies, bases the care a patient is given on the best evidence available in the research literature. The risk of spinal manipulation causing a clinically worsened disk herniation or CES in a patient presenting with LDH has been calculated to be less than 1 in 3.7 million manipulations.

Definitive treatment for LDH is currently unknown, but conservative care options should be exhausted prior to surgical treatment. Spinal manipulation is often left out of the conservative care of LDH patients, but many authors suggest a trial of spinal manipulation should be included as part of the conservative treatment plan because there is preliminary data supporting its efficacy. Spinal manipulation for the treatment of LDH appears to be very safe, and there is no sound basis to recommend against a trial of spinal manipulation of patients with LDH, although limited lumbar flexion and gentle technique are suggested to further reduce the risk. Perhaps 2 exhaustive courses of conservative care by different providers, including spinal manipulation, should be the minimum standard of care before proceeding to surgical treatment.

Disk herniation is the number one claim against chiropractors; yet, it appears likely that lumbar disk prolapse could occur only in an already fissured and fragmented disk. Even in patients presenting with LDH, the risk of spinal manipulation appears minimal, especially compared with other common treatments for LDH, such as NSAIDs and surgery, and spinal manipulation may be no more dangerous than activities of daily living, such as a cough or stumble.

More research is needed to determine accurately the incidence of disk injury/increased disk symptoms following spinal manipulation; under what conditions, if any, spinal manipulation can actually cause a disk herniation; the benefit of spinal manipulation in the treatment of LDH compared with natural history, other conservative treatments, and surgery; and which patients will benefit most from which type of treatment.

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References

1. Andersson G. The epidemiology of spinal disorders. In: The adult spine: principals and practice. 2nd ed. Philadelphia: Lippincott-Raven; 1997.
2. Crawford CM, Hannon RF. Management of acute lumbar disc herniation initially presenting as mechanical low back pain. J Manipulative Physiol Ther 1999;22:235-44.
3. Deyo RA, Rainville J, Kent DL. What can the history and physical examination tell us about low back pain? JAMA 1992;268:760-65.
4. Frymoyer JW. Back pain and sciatica. N Engl J Med 1988; 318:291-300.
5. Weber H. The natural history of disc herniation and the influence of intervention. Spine 1994;19:2234-38.
6. Stern PJ, Cote P, Cassidy JD. A series of consecutive cases of low back pain with radiating leg pain treated by chiropractors. J Manipulative Physiol Ther 1995;18:335-41.
7. Schwartzer AC, Aprill CN, Derby R, Fortin J, Kline G, Bogduk N. The relative contributions of the disc and zygapophyseal joints in chronic low back pain. Spine 1994;19:801-6.
8. Cassidy JD, Thiel HW, Kirkaldy-Willis WH. Side posture manipulation for lumbar intervertebral disc herniation. J Manipulative Physiol Ther 1993;16:96-103.
9. Slosberg M. Side posture manipulation for lumbar intervertebral disk herniation reconsidered. J Manipulative Physiol Ther 1994;17:258-62.
10. Gibson JNA, Grant I, Waddell G. The Cochrane review of surgery for lumbar disc prolapse and degenerative lumbar spondylosis. Spine 1999;24:1820-32.
11. Saal J. Natural history and nonoperative treatment of lumbar disc herniation. Spine 1996;21:2S-9S.
12. Fritzell P, Hagg O, Wessberg P, Nordwall A. Swedish Lumbar Spine Study Group. A multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. Spine 2001; 26:2521-34.
13. Weber H, Holme I, Amlie E. The natural course of acute sciatica with nerve root symptoms in a double-blind placebo-controlled trial evaluating the effect of piroxicam. Spine 1983;18:1433-38.

14. King L, Mior S, Devonshire-Zielonka K. Adolescent lumbar disc herniation: a case report. J Can Chiropr Assoc 1996;40: 15-8.
15. Deyo RA, Loeser JD, Bigos SJ. Herniated lumbar intervertebral disc. Ann Intern Med 1990;112:598-603.
16. Quon JA, Cassidy JD, O'Connor SM, Kirkaldy-Willis WH. Lumbar intervertebral disc herniation: treatment by rotational manipulation. J Manipulative Physiol Ther 1989;12:220-6.
17. Croft AC. Appropriateness of cervical spine manipulation in disc herniation: a survey of practitioners. Chiropr Tech 1996; 8:178-81.
18. Postacchini F. Results of surgery compared with conservative management for lumbar disc herniations. Spine 1996;2: 1383-87.
19. Weber H. Lumbar disc herniation: a controlled, prospective study with ten years observation. Spine 1983;8:131-40.
20. Humphreys SC, Eck JC. Clinical evaluation and treatment options for herniated lumbar disc. Am Fam Physician 1999; 59:575-82.
21. BenEliyahu DJ. Magnetic resonance imaging and clinical follow-up: study of 27 patients receiving chiropractic care for cervical and lumbar disc herniations. J Manipulative Physiol Ther 1996;19:55-64.
22. Kuo PP, Loh ZC. Treatment of lumbar intervertebral disc protrusions by manipulation. Clin Orthop 1987;215:47-55.
23. Bergman TF, Jongward BV. Manipulative therapy in lower back pain with leg pain and neurological deficit. J Manipulative Physiol Ther 1998;21:288-94.
24. Morris C. Chiropractic rehabilitation of a patient with S1 radiculopathy associated with a large lumbar disc herniation. J Manipulative Physiol Ther 1999;22:38-44.
25. Kazemi M. Adolescent lumbar disc herniation in a Tae Kwon Do martial artist: a case report. J Can Chiropr Assoc 1999;43: 236-42.
26. Cramer GD, Tuck NR, Knudsen JT, Fonda SD, Schlieser JS, Fournier JT, et al. Effects of side-posture adjusting on the lumbar zygapophyseal joints as evaluated by MRI: a before and after study with randomization. J Manipulative Physiol Ther 2000;23:380-94.
27. Tibbles A, Cassidy JD. Cervical disc herniation missed at operation: a case report. J Can Chiropr Assoc 1992;36:17-21.
28. Rivett D, Milburn P. Complications arising from spinal manipulative therapy in New Zealand. Physio 1997;83:626-32.
29. Rydell N, Raf L. Spinal manipulation–treatment associated with a high risk of complications. Lakartidningen 1999;96: 3536-40.
30. Assendelft WJ, Bouter LM, Knipschild PG. Complications of spinal manipulation: a comprehensive review of the literature. J Fam Pract 1996;42:475-80.
31. Powell F, Hanigan W, Olivero W. A risk/benefit analysis of spinal manipulation therapy for relief of lumbar or cervical pain. Neurosurgery 1993;3:73-79.
32. Jagbandhansingh MP. Most common causes of chiropractic malpractice lawsuits. J Manipulative Physiol Ther 1997;20: 60-4.
33. Haldeman S, Rubinstein SM. Cauda equina syndrome in patients undergoing manipulation of the lumbar spine. Spine 1992;17:1469-73.
34. Shekelle PG, Adams AH, Chassin MR, Hurwtiz EL, Brook RH. Spinal manipulation for low back pain. Ann Intern Med 1992;117:590-8.
35. Kostiuk JP, Harrington I, Alexander D, Rand W, Evans D. Cauda equina syndrome and lumbar disc herniation. J Bone Joint Surg 1986;68A:386-91.
36. Koes BW, Assendelft WJ, van der Heijden GJ, Bouter LM, Knipschild PG. Spinal manipulation and mobilisation for back and neck pain: a blinded review. BMJ 1991;303:1298-1303.
37. Ladermann JP. Accidents of spinal manipulations. Ann Swiss Chiropr Assoc 1981;7:161-208.
38. Terrett AG, Kleynhans AM. Complications from manipulation of the low back. Chiropr J Aust 1992;27:129-40.
39. Haupt BJ, The nations' use of health resources. 2nd ed. Rockville (MD): US Department of Health, Education, and Welfare, Public Health Service, Office of Health Research, Statistics, and Technology, National Centre for Health Statistics, Division of Health Resources Utilization Statistics. DHEW publication (PHS) 1979. p. 80-1240.
40. Patijn J. Complications in manual medicine: a review of the literature. Man Med 1991;6:89-92.
41. Burton AK, Tillotson KM, Cleary J. Single-blind randomised controlled trial of chemonucleolysis and manipulation in the treatment of symptomatic lumbar disc herniation. Eur Spine J 2000;9:202-207.
42. Kirkaldy-Willis WH, Cassidy JD. Spinal manipulation in the treatment of low back pain. Can Fam Physician 1985;31: 535-40.
43. Hadler NM, Curtis P, Gillings DB, Stinnett S. A benefit of spinal manipulation as adjunctive therapy for acute low-back pain: a stratified controlled trial. Spine 1987;12:703-6.
44. Evans DP, Burke MS, Lloyd KN, Roberts EE, Roberts GM. Lumbar spinal manipulation on trial: part 1 - clinical assessment. Rheumatol Rehabil 1978;17:46-53.
45. Senstad O, LeBoeuf-Yde C, Borchgrevink C. Frequency and characteristics of side effects of spinal manipulative therapy. Spine 1997;22:435-40.
46. Michaeli A. Reported occurrence and nature of complications following manipulative physiotherapy in South Africa. Aust Phys 1993;39:309-15.
47. Nyiendo J, Haldeman S. A prospective study of 2000 patients attending a chiropractic teaching clinic. Med Care 1987;25: 516-27.
48. Barrett AJ, Breen AC. Adverse effects of spinal manipulation. J R Soc Med 2000;93:258-9.
49. Ernst E. Prospective investigations into the safety of spinal manipulation. J Pain Symptom Manage 2001;21:238-42.
50. Vernon H, McDermaid CS, Hagino C. Systematic review of randomized clinical trials of complementary/alternative therapies in the treatment of tension-type and cervicogenic headache. Complement Ther Med 1999;7:142-55.
51. Hurwitz EL, Coulter ID, Adams AH, Genovese BJ, Shekelle PG. Use of chiropractic services from 1985 through 1991 in the United States and Canada. Am J Pub Health 1998;88:771-6.
52. Schwartzer AC, Aprill CN, Derby R, Fortin J, Kline G, Bogduk N. The prevalence and clinical features of internal disc disruption in patients with chronic low back pain. Spine 1995;20:1878-83.
53. Ohnmeiss D, Vanharanta H, Ekholm J. Degree of disc disruption and lower extremity pain. Spine 1997;22:1600-5.
54. Floman Y, Liram N, Gilai AN. Spinal manipulation results in immediate H-reflex changes in patients with unilateral disc herniation. Eur Spine J 1997;6:398-401.
55. Bjorkman DJ. Current status of nonsteroidal anti-inflammatory drug (NSAID) use in the United States: risk factors and frequency of complications. Am J Med 1999;107:3S-8S.
56. Rainsford KD. Profile and mechanisms of gastrointestinal and other side effects of non-steroidal anti-inflammatory drugs (NSAIDs). Am J Med 1999;107:27S-34S.
57. Graumlich JF. Preventing gastrointestinal complications of NSAIDs. Risk factors, recent advances and latest strategies. Postgrad Med 2001;109:117-20.

58. Page J, Henry D. Consumption of NSAIDs and the development of congestive heart failure in elderly patients: an unrecognized public health problem. Arch Intern Med 2000;160: 777-84.
59. Henriques T, Olerud C, Petrin-Mallmin M, Ahl T. Cauda equina syndrome as a post-operative complication in patients operated for lumbar disc herniation. Spine 2001;26:293-97.
60. McLaren AC, Bailey SI. Cauda equina syndrome: a complication of lumbar discectomy. Clin Orthop 1986;204:143-9.
61. Kardaun JW, White LR, Schaffer WO. Acute complications in patients with surgical treatment of lumbar herniated disc. J Spinal Disord 1990;3:30-8.
62. Elias WJ, Simmons NE, Kaptain GJ, Chadduck JB, Whitehill R. Complications of posterior lumbar interbody fusion when using a titanium threaded cage device. J Neurosurg 2000;93: 45-52.
63. Rhyne AL, Smith SE, Wood KE, Darden BV. Outcome of unoperated discogram-positive low back pain. Spine 1995; 20:1997-2001.
64. Bessette L, Liang MH, Lew RA, Weinstein JN. Surgery literature revisited. Spine 1996;21:259-263.
65. Mooney V. Point of view. Spine 2001;26:2532-33.
66. Terrett AGJ. Misuse of the literature in discussing spinal manipulative therapy injury. J Manipulative Physiol Ther 1995; 18:203-10.
67. Adams MA, Dolan P, Hutton WC. The stages of disc degeneration as revealed by discograms. J Bone Joint Surg 1986; 68:36-41.
68. Gordon SJ, Yang KH, Mayer PJ, Mace AH, Kish VL, Radin EL. Mechanism of disc rupture: a preliminary report. Spine 1996;16:450-6.
69. Hindle RJ, Pearcy MJ. Rotational mobility of the human back in forward flexion. J Biomed Eng 1989;11:219-223.
70. Adams MA, Hutton WC. Gradual disk prolapse. Spine 1985; 10:524-31.
71. Krismer M, Haid C, Rabl W. The contribution of annular fibres to torque resistance. Spine 1996;21:2551-7.
72. Bogduk N. Pathology of lumbar disc pain. Man Med 1990; 5:72-9.
73. Brinckman P, Porter RW. A laboratory model of lumbar disc protrusion: fissure and fragment. Spine 1994;19:228-35.

Appendix 1.

Legend of abbreviations for Table 1

Avg = average
CES = cauda equina syndrome
DC = doctor of chiropractic
Est. = estimate
electro = electrotherapy
Hr = hour
IFC = interferential current
incl = included
LBP = low back pain
LDH = lumbar disk herniation
Mos = months
Mod = moderately
MUA = manipulation under anesthesia
NP = new patient
pts = patients
PTs = physiotherapists
SMT = spinal manipulative therapy
Txs = treatments
US = ultrasound

Appendix 2.

Criteria for assessing the methods of studies of efficacy of spinal manipulation (with respect to adverse reactions)

A. Description of inclusion and exclusion criteria (**1 point**). Restriction to a homogeneous study population (**1 point**).
B. Comparability for duration of complaints, value of outcome measures, age, recurrences, and radiation complaints (**1 point**).
C. Randomization procedure described (**2 points**). Randomization procedure that excludes bias (for example, sealed envelopes)(**2 points**).
D. Information about which group from which patients withdrew and reason for withdrawal (**3 points**).
E. Loss to follow-up: all randomized patients minus the number of patients at main point of measurement of the main outcome measure, divided by all randomized patients, multiplied by 100 (**maximum 4 points**).
F. Smallest group immediately after randomization (> 50 subjects in smallest groups, **6 points**; > 100 subjects in smallest groups, **6 additional points**).
G. Manipulative treatment explicitly described (**5 points**). All reference treatments explicitly described (**5 points**).
H. Comparison with established treatment (5 **points**).
I. Other physical treatments or medical interventions avoided in the design of the study (except analgesics; advice on posture; or use at home of heat, rest, or routine exercise scheme) (**5 points**).
J. Comparison with placebo (**5 points**).
K. Citation of qualified education or experience, or both, of the manipulative therapist (**5 points**).
L. Placebo-controlled study: attempt at blinding (**3 points**), blinding evaluated and fully successful (**2 points**). Pragmatic study: patients fully naive (**3 points**) or time restriction (no manipulative treatment for at least 1 year) (**2 points**);.naiveness evaluated and fully successful (**2 points**).
M. Measured and reported use of pain, global measurement of improvement, functional status (activities of daily living), spinal mobility, use of drugs and medical services (with respect to adverse reactions) (**2 points each**).
N. Each blinding measurement mentioned under point M earns **2 points.**
O. Outcome measures (with respect to adverse reactions) assessed during or just after treatment (**3 points**). Adverse reactions assessed 6 weeks or longer (**2 points**).

P. When loss to follow-up less than 10%: analyses on all randomized patients for main outcome measures and on the most important points of measurement minus missing values, regardless of noncompliance and co-interventions (**5 points**).
When loss to follow-up is greater than 10%: intention-to-treat as well as an alternative analysis that accounts for missing values (**5 points**).

Q. For main outcome measures and at main times of measurement: In the case of (semi-) continuous variable, presentation of the mean or median with standard error or centiles (**5 points**).

Modified from Koes et al[36] with permission from the BMJ Publishing Group.

Appendix 3.

Criteria for assessing the methods of review papers of adverse effects of spinal manipulation (in relation to SMT and LDH or lumbar spine generally)

A. Literature search strategy defined (**5 points**)
-includes search techniques as such as computer search, references of previous review papers, attempt to find new cases from different sources (ie, cases in litigation, court records, etc.), attempt to find foreign language papers (**5 points**)

B. Total number of cases of adverse reactions found in literature is stated (**3 points**)
-this compares with numbers of previous searches (**2 points**)

C. There is an attempt to analyze data on cases / reviews found (**3 points**)
-there is a breakdown of case / review by qualifications of provider, cause / effect relationship, diagnosis of complication, long-term outcome, treatment, explicitly defined (**2 points**)

D. Total number of patients / treatments over the time period is stated / estimated (**5 points**)
-reference / calculation for this number was provided and logical (**2 points**)
-possible under reporting of cases in the literature is accounted for in a reasonable manner (**3 points**)

E. Estimate of incidence / risk from referenced source or calculated from reasonable data is provided (number of complications per number of treatments) (**5 points**)
-discusses risk / benefit ratio (**5 points**)

F. Risk of treatment is compared with risk of other treatment for same condition, to no treatment, to activities of daily living (**5 points**)

G. Recommendations for / against treatment are based on reasonable conclusions (**5 points**)

SMT, Spinal manipulative therapy; *LDH*, lumbar disk herniation.