

Research Paper Review

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Serious adverse events and spinal manipulative therapy of the low back region: A systematic review of cases

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ABSTRACT

OBJECTIVE:

The purpose of this study was to systematically search the literature for studies reporting serious adverse events following lumbopelvic spinal manipulative therapy (SMT) and to describe the case details.

METHODS:

A systematic search was conducted in PubMed including MEDLINE, EMBASE, CINAHL, and The Cochrane Library up to January 12, 2012, by an experienced reference librarian. Study selection was performed by 2 independent reviewers using predefined criteria. We included cases involving individuals 18 years or older who experienced a serious adverse event following SMT applied to the lumbar spine or pelvis by any type of provider (eg, chiropractic, medical, physical therapy, osteopathic, layperson). A serious adverse event was defined as an untoward occurrence that results in death or is life threatening, requires hospital admission, or results in significant or permanent disability. We included studies published in English, German, Dutch, and Swedish.

RESULTS:

A total of 2046 studies were screened, and 41 studies reporting on 77 cases were included. Important case details were frequently unreported, such as descriptions of SMT technique, the pre-SMT presentation of the patient, the specific details of the adverse event, time from SMT to the adverse event, factors contributing to the adverse event, and clinical outcome. Adverse events consisted of cauda equina syndrome (29 cases, 38% of total); lumbar disk herniation (23 cases, 30%); fracture (7 cases, 9%); hematoma or hemorrhagic cyst (6 cases, 8%); or other serious adverse events (12 cases, 16%) such as neurologic or vascular compromise, soft tissue trauma, muscle abscess formation, disrupted fracture healing, and esophageal rupture.

CONCLUSIONS:

This systematic review describes case details from published articles that describe serious adverse events that have been reported to occur following SMT of the lumbopelvic region. The anecdotal nature of these cases does not allow for causal inferences between SMT and the events identified in this review. Recommendations regarding future case reporting and research aimed at furthering the understanding of the safety profile of SMT are discussed.

ANALYSIS

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Background Information:

Previous reports of harm following lumbopelvic spinal manipulative therapy (SMT) have suggested that benign and self-limiting events, such as muscle soreness and local discomfort, are fairly common. Serious adverse events, however, have not been observed in prospective studies, and systematic reviews of randomized controlled trials (RCTs) have not identified a single serious adverse event following lumbopelvic SMT. In fact, the only reports of serious adverse events following lumbopelvic SMT have been in case reports – a lower level of evidence subject to numerous potential biases.

Considering what has been reported on the subject to date, the incidence of serious adverse events following lumbopelvic SMT is thought to be extremely low. Nonetheless, better knowledge about the risk associated with SMT in this region would be of benefit in clinical decision making.

Therefore, the purposes of this study were to:

- 1. Systematically search the literature for cases reporting serious adverse events following lumbopelvic SMT,
- 2. describe the case details, and
- 3. offer recommendations regarding future case reporting.

Pertinent Results:

A total of 2512 citations were identified during the searches; 29 additional references were found in the reference sections of the selected articles. After duplicate references were removed, 2046 records remained. Screening the titles and abstracts of those papers left 117 articles to be obtained for full-text review. Ultimately, 41 studies involving 77 patient cases were included.

The reported serious adverse events (in descending order) were as follows:

- Cauda equina syndrome (29 cases, 38% of total)
- Lumbar disc herniation (23 cases, 30% of total)
- Fracture (7 cases, 9%)
- Hematoma or hemorrhagic cyst (6 cases, 8%)
- Other serious adverse events (12 cases, 16%)

When the information was available, the type of clinician that provided the care was reported to be a doctor of chiropractic in 80% of the cases – this is logical, as chiropractors deliver the majority of SMT treatments. Other provider types included an osteopath (6%), a medical doctor or physician (4%), or another type of healthcare provider or nonprofessional (10%!!).

Information about the time to onset of the adverse event following SMT was available in about half of the cases. It was reported that 76% of serious adverse events occurred within 24 hours of SMT.

Information on the type of treatment that was rendered in conjunction with the adverse event was available in 82% of the cases, which showed that some type of surgical intervention was done 84% of the time. Patient outcome was only reported 69% of the time, but in those that did include that information, the patient's clinical outcome was favorable following treatment in 64% of the reported cases.

Clinical Application & Conclusions:

The only way this review was able to report on serious adverse events following lumbopelvic SMT was by including case studies, though this type of low-level evidence is typically eliminated from a systematic review. Moreover, estimates of the incidence of serious adverse events following SMT that are based on case studies are not likely to provide valid depictions of the true rate and therefore should be interpreted with caution.

Prospective studies that have attempted to estimate the incidence of serious adverse events following SMT have not been successful thus far because only mild to moderate adverse events have been identified. Consequently, the rate of serious adverse events following SMT is still thought to be extremely low.

Based only on reports of anecdotal cases, as in this review, it would be unreasonable to recommend that SMT be avoided when there is potential for disc herniation or cauda equina syndrome. Especially given that there is evidence which supports the clinical and cost-effectiveness of SMT in patients with nonspecific low back pain; SMT has also been shown to be of potential benefit to patients with lumbar disc herniation.

NOTE: The use of SMT in lumbar disc patients must be approached with extra caution. There are numerous biological, clinical and medicolegal issues to consider when making this treatment decision. For a more detailed discussion on this topic, see an article co-written by Dr Shawn Thistle DC and Dr. Mark Erwin DC, the latter a world-renowned expert on interverterbral disc pathology. The article is entitled "Spinal Manipulation & Disc Herniation: A Rational Approach" and was published in Back Matters in Spring 2014. It appears in APM's list of research papers.

Cauda equina syndrome (CES) is a serious condition that requires immediate surgical intervention and it is unlikely that SMT would be of benefit in patients with this condition. Clinicians should therefore screen patients for signs and symptoms of CES and immediately refer affected patients for appropriate care. To briefly review, the signs and symptoms of CES include:

- bladder and/or bowel dysfunction,
- reduced sensation in the saddle area, and/or
- sexual dysfunction with possible neurologic deficits of the lower limb.

The authors commented on a meta-analysis of RCTs done by Carnes et al. (1) which investigated the comparative safety between SMT and other treatment options. Yet again, no major adverse events were identified in relation to manual therapy. The relative risk (RR) of mild to moderate adverse events compared with other therapeutic options showed that there was a similar risk of adverse events between manual therapy and exercise (RR 1.04) and a much lower risk when SMT was compared with drug therapy (RR 0.05).

Further research that involves high-quality studies will be needed in order to obtain accurate estimates of the incidence of adverse events associated with lumbopelvic SMT. When estimates are based solely

on case studies, uncertainty will remain.

Study Methods:

An experienced reference librarian conducted a search of the following databases that spanned from inception to January 2012: PubMed including MEDLINE, EMBASE, CINAHL, and The Cochrane Library. The targets of the search were case reports, case series, and other studies that reported original, individual case details. To be included, the cases had to involve persons who were 18 years or older who had experienced a serious adverse event following lumbopelvic SMT.

SMT was considered to include both spinal manipulation and spinal mobilization, although an attempt was made to distinguish between the 2 approaches. Spinal manipulation was defined as a therapeutic procedure involving the use of a high-velocity, low-amplitude thrust, whereas spinal mobilization was defined as a non-thrust therapeutic procedure involving low-velocity passive joint movements. Cases that involved SMT under anaesthesia were excluded.

A serious adverse event was defined as an untoward occurrence that results in death or is life threatening, requires hospital admission, or results in significant or permanent disability. Examples include disc herniation, cauda equina syndrome, fracture, and dislocation.

Articles were selected for inclusion by 2 of the authors who independently examined the title and abstract of studies that were found in the search. Studies that did not meet the selection criteria were excluded. Any disagreements about study inclusion were resolved by consensus, including consultation with a third review author if necessary.

The following information was extracted from the included papers, when available:

- details about the clinician;
- details about the person who was harmed; and

• clinical case details, including the indication for treatment, manual therapy technique, description of adverse event, length of time from SMT to the adverse event, contributing factors, and clinical outcome.

Study Strengths / Weaknesses

This was a systematic review of cases and is therefore subject to the same biases that case studies are. Moreover, case studies are helpful in identifying new and rare findings, as well as providing information about how a condition can be managed clinically, but they do not permit the determination of cause. As a result, the serious adverse events that were identified as being caused by lumbopelvic SMT in this review may actually have been related to other unreported events or natural progression of the condition.

Systematic review methods were utilized, including a comprehensive search process that examined 4 databases; also, the selection of studies was carried out by 2 independent reviewers who used predetermined selection criteria.

The reporting of case details was commonly incomplete, especially concerning the descriptions of SMT technique, the patient's pre-SMT condition, details of the adverse event, time from SMT to the adverse event, other factors contributing to the adverse event, and clinical outcome.

The authors pointed out that the literature on this subject often provides an erroneous representation about which provider type and treatment was involved. This is because any health care worker who provides SMT is frequently labeled as a chiropractor and/or providing chiropractic manipulation, regardless of their clinical training (2).

Additional References:

1. Carnes D, Mars TS, Mullinger B, Froud R, Underwood M. Adverse events and manual therapy: a systematic review. Man Ther 2010; 15: 355-63.

2. Wenban AB. Inappropriate use of the title "chiropractor" and term "chiropractic manipulation" in the peer-reviewed biomedical literature. Chiropr Osteopat 2006; 14:16.

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