

SERIOUS ADVERSE EVENTS AND SPINAL MANIPULATIVE THERAPY OF THE LOW BACK REGION: A SYSTEMATIC REVIEW OF CASES

Jeffrey J. Hebert, DC, PhD,^a Norman J. Stomski, PhD,^b Simon D. French, PhD, MPH, BAppSc(Chiropractic),^{c,d} and Sidney M. Rubinstein, DC, PhD^e

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. (*J Manipulative Physiol Ther* 2015;38:677-691)

Key Indexing Terms: *Risk; Manipulation, Spinal; Lumbosacral Region; Intervertebral Disc Displacement; Cauda Equina Syndrome; Injury*

^a Senior Lecturer, School of Psychology and Exercise Science, Murdoch University, Perth, Western Australia, Australia.

^b Postdoctoral Researcher, School of Health Professions, Murdoch University, Perth, Western Australia, Australia.

^c Adjunct Senior Lecturer, School of Health Professions, Murdoch University, Perth, Western Australia, Australia.

^d Senior Research Fellow, Melbourne School of Health Sciences, The University of Melbourne, Carlton, Victoria, Australia.

^e Senior Researcher, Department of Epidemiology and Biostatistics, EMGO+ Institute for Health and Care Research, VU University Medical Center, Amsterdam, the Netherlands.

Submit requests for reprints to: Jeffrey J. Hebert, DC, PhD, Murdoch University, 90 South St, ECL 4.008, Murdoch, Western Australia 6160, Australia (e-mail: j.hebert@murdoch.edu.au).

Paper submitted July 28, 2012; in revised form December 5, 2012; accepted December 6, 2012.

0161-4754

Copyright © 2015 by National University of Health Sciences.

<http://dx.doi.org/10.1016/j.jmpt.2013.05.009>

Spinal manipulative therapy (SMT) is a form of manual therapy commonly used to provide care for people with low back pain and other disorders of the lumbar spine and pelvis.¹ The frequency of SMT use by health care providers has increased over the past several decades.² Spinal manipulative therapy is generally recommended by treatment guidelines³⁻⁵ and appears to be a cost-effective therapeutic option for patients with spinal pain.⁶

Previous prospective analyses of harm following lumbopelvic SMT have primarily reported benign and self-limiting events, such as muscle soreness and local discomfort, but have not observed and, hence, reported the occurrence of serious adverse events. Senstad et al⁷ investigated the outcomes of a large cohort of chiropractic patients (n = 1058) and reported that when SMT was included in the course of care, an adverse reaction was associated with 25% of SMT treatments and 55% of patients reported at least 1 adverse

event. Reactions primarily consisted of short-term local discomfort, headache, and tiredness or radiating discomfort and were classified as mild to moderate in most patients. There were no reports of serious adverse events. In another analysis, Leboeuf-Yde et al⁸ surveyed 66 chiropractors who reported on 625 patients who received 1858 chiropractic treatments, of which 99% included spinal manipulation. Adverse events were found to be common, benign, and usually self-limiting within 24 hours. In addition, the authors reported that adverse reactions with chiropractic treatment were associated with female sex, treatment at first consultation, and longer pain duration. Neither study, however, reported a serious adverse event associated with SMT.

Recent systematic reviews of randomized controlled trials, cohort studies, and a patient survey have failed to identify a single serious adverse event following lumbopelvic SMT.⁹⁻¹³ However, the reporting of harms in the primary literature is generally poor,¹⁴ and case reports of serious adverse events following lumbopelvic SMT have been described. Examples of serious adverse events following lumbopelvic SMT include cauda equina syndrome,¹⁵ lumbar disk herniation,¹⁶ fracture,¹⁷ and spinal hematoma.¹⁸ Gouveia et al¹⁹ undertook a systematic review of articles reporting adverse events following chiropractic treatment. Although the authors identified several reports of serious adverse events following lumbopelvic SMT, they implemented a limited search strategy and excluded adverse events following therapy performed by other types of healthcare providers.

Although the incidence of serious adverse events following lumbopelvic SMT is thought to be extremely low,²⁰ such events represent a potentially important source of morbidity. Improved knowledge of SMT risk with respect to serious adverse events has potential to inform clinical decision making, and understanding the circumstances surrounding such events would serve as a first step in this process. Therefore, the purposes of this study were to systematically search the literature for cases reporting serious adverse events following lumbopelvic SMT, to describe the case details, and to offer recommendations regarding future case reporting.

METHODS

Types of Studies and Participants

Case reports, case series, and studies using other designs to report original, individual case details were included. Identified cases involved individuals 18 years or older who experienced a serious adverse event following SMT applied to the lumbar spine or pelvis. We included studies published in English, German, Dutch, and Swedish.

Types of Interventions

The intervention of interest was SMT applied to the lumbar spine or pelvis. The terminology reported in the

literature to describe SMT and other manual therapy procedures has been described as problematic,²¹ with some calling for a clear distinction between spinal mobilization and spinal manipulation.^{22,23} Consequently, we considered SMT to include both spinal manipulation and spinal mobilization, although we attempted to distinguish between these 2 approaches when extracting data. We operationally defined spinal manipulation as a therapeutic procedure involving the use of a high-velocity, low-amplitude thrust, whereas *spinal mobilization* was defined as a nonthrust therapeutic procedure involving low-velocity passive joint movements. Cases involving SMT applied while the patient was under anesthesia were excluded.

Types of Outcome Measures

The outcomes of interest in this systematic review were serious adverse events. No widely adopted definition of serious adverse event exists in the rehabilitation literature. We defined a serious adverse event as an untoward occurrence that results in death or is life threatening, requires hospital admission, or results in significant or permanent disability.²⁴ Examples of serious adverse events resulting from lumbopelvic SMT could include disk herniation, cauda equina syndrome, fracture, dislocation, or hematoma/hemorrhagic cyst.

Search Methods for Identification of Studies

A comprehensive search was conducted by an experienced reference librarian in the following databases from inception to January 12, 2012: PubMed including MEDLINE, EMBASE, CINAHL (via EBSCO), and The Cochrane Library (via Wiley). Search terms included MeSH terms in PubMed, Emtree terms in EMBASE, and CINAHL Headings in CINAHL as well as free text terms. We used free text terms only in The Cochrane Library. The search syntax developed for PubMed is presented in Table 1. No time or language restrictions were applied. The reference lists of included studies were also examined.

Selection of Studies

Two review authors independently examined the title and abstract of studies identified by the search strategy and excluded those studies not meeting the selection criteria. Next, the full text of reports thought to fulfill the selection criteria were retrieved and assessed. Disagreements between the review authors regarding study inclusion were resolved by consensus, and if necessary, a third review author was consulted. All review authors were experienced in conducting systematic reviews.

Data Extraction

We extracted the following information, when available: clinician related (discipline, country of origin, years in

Download English Version:

<https://daneshyari.com/en/article/2620500>

Download Persian Version:

<https://daneshyari.com/article/2620500>

[Daneshyari.com](https://daneshyari.com)