

**Safety of Chiropractic Manipulation of the Cervical Spine  
A Prospective National Survey**

**Spine**

**Volume 32(21), October 2007, pp 2375-2378**

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FROM ABSTRACT

Study Design.  
Prospective national survey.

Objective.  
To estimate the risk of serious and relatively minor adverse events following chiropractic manipulation of the cervical spine by a sample of U.K. chiropractors.

Summary of Background Data.  
The risk of a serious adverse event following chiropractic manipulation of the cervical spine is largely unknown.

Estimates range from 1 in 200,000 to 1 in several million cervical spine manipulations.

Methods.  
We studied treatment outcomes obtained from 19,722 patients.

Manipulation was defined as the application of a high-velocity/low-amplitude or mechanically assisted thrust to the cervical spine.

Serious adverse events, defined as referred to hospital and/or severe onset/worsening of symptoms immediately after treatment and/or resulted in persistent or significant disability/incapacity, and minor adverse events reported by patients as a worsening of presenting symptoms or onset of new symptoms, were recorded immediately, and up to 7 days, after treatment.

Results.  
Data were obtained from 28,807 treatment consultations and 50,276 cervical spine manipulations.

There were no reports of serious adverse events.

This translates to an estimated risk of a serious adverse event of, at worst  $\approx 1$  per 10,000 treatment consultations immediately after cervical spine manipulation,  $\approx 2$

per 10,000 treatment consultations up to 7 days after treatment and  $\approx 6$  per 100,000 cervical spine manipulations.

Minor side effects with a possible neurologic involvement were more common.

The highest risk immediately after treatment was fainting/dizziness/light-headedness in, at worst  $\approx 16$  per 1000 treatment consultations.

Up to 7 days after treatment, these risks were headache in, at worst  $\approx 4$  per 100, numbness/tingling in upper limbs in, at worst  $\approx 15$  per 1000 and fainting/dizziness/light-headedness in, at worst  $\approx 13$  per 1000 treatment consultations.

Conclusion.

Although minor side effects following cervical spine manipulation were relatively common, the risk of a serious adverse event, immediately or up to 7 days after treatment, was low to very low.

THESE AUTHORS ALSO NOTE:

It is generally assumed that serious complications following spinal manipulative therapy of the cervical spine, including neurologic deficit and stroke, are relatively uncommon.

Estimates of serious complications following spinal manipulative therapy of the cervical spine "vary between 1 serious adverse event in 200,000 manipulative neck treatments to 1 in several million."

"Relatively minor side effects of cervical spinal manipulation, such as neck pain, stiffness and soreness, headache, and tiredness are common in clinical practice."

This study is the first, large-scale prospective study designed to record serious and minor adverse events following chiropractic manipulation of the neck.

This study involved 377 chiropractors, 19,722 patients and 50,276 cervical manipulations.

"To estimate risk in cases where no occurrence of an adverse event occurs, Hanley's rule of three was used. This states that if none of  $n$  patients show the event, then it can be assumed with 95% confidence that the chance of this event is, at worst, 3 in  $n$  (i.e.,  $3/n$ ). It is generally accepted that treatment associated events occurring at a rate of 1 in 10,000 to 100,000 can be categorized as very low risk. Therefore, a sample size of 50,000 cervical spine manipulative interventions was sought to give a frequency of 1 serious adverse event in approximately 17,000 interventions." **[This appears completely bizarre to me]**

## RESULTS

"No significant adverse event was reported by the chiropractors using the definition criteria."

The most common of complaint reported by patients was fainting/dizziness/light-headedness, which occurred in 1.5% of cases.

During the following 7 days, discomfort in the area of the manipulation (neck pain) occurred in 7.3%, symptoms of shoulder/arm pain occurred in 4.8%, and reduced movement in the neck and upper limb occurred in 3.9%.

Also, during the following 7 days, headache occurred in 3.9%, numbness/tingling in upper limbs occurred in 1.3%, and fainting/dizziness/light-headedness occurred in 1.1% of cases.

## DISCUSSION

"Safety of treatment interventions is best established with prospective surveys, and this study is unique in that it is the only prospective survey on such a large scale specifically estimating serious adverse events following cervical spine manipulation."

"The risk rates described in this study compare favorably to those linked to drugs routinely prescribed for musculoskeletal conditions in general practice."

"The risks reported here are also lower than those reported for acupuncture, which were described as a very safe intervention in the hands of a competent practitioner."

"Although minor side effects were found to be relatively common, the risk of a serious adverse event, immediately and up to 7 days after treatment, was estimated to be low to very low in these consultations."

"On this basis, this survey provides evidence that cervical spine manipulation is a relatively safe procedure when administered by registered U.K. chiropractors."

## KEY POINT FROM AUTHORS:

"Based on treatment outcomes obtained from 19,722 patients, the risk of a serious adverse event following cervical spine manipulation was estimated to be low to very low; risks of minor side effects, on the other hand, were relatively common."

## KEY POINTS FROM DAN MURPHY

- 1) This study is the first, large-scale prospective study designed to record serious and minor adverse events following chiropractic manipulation of the neck.
- 2) This study involved 377 chiropractors, 19,722 patients and 50,276 cervical manipulations. "There were no reports of serious adverse events."
- 3) "No significant adverse event was reported by the chiropractors using the definition criteria."
- 4) "The risk of a serious adverse event, immediately or up to 7 days after treatment, was low to very low." **[The incidence in this study was zero]**
- 5) Prior estimates of serious complications following spinal manipulative therapy of the cervical spine "vary between 1 serious adverse event in 200,000 manipulative neck treatments to 1 in several million."
- 6) "Relatively minor side effects of cervical spinal manipulation, such as neck pain, stiffness and soreness, headache, and tiredness are common in clinical practice."
- 7) The most common immediate complaint reported by patients was fainting/dizziness/light-headedness, which occurred in 1.5% of cases.
- 8) During the following 7 days, discomfort in the area of the manipulation (neck pain) occurred in 7.3%, symptoms of shoulder/arm pain occurred in 4.8%, and reduced movement in the neck and upper limb occurred in 3.9%.
- 9) Also, during the following 7 days, headache occurred in 3.9%, numbness/tingling in upper limbs occurred in 1.3%, and fainting/dizziness/light-headedness occurred in 1.1% of cases.
- 10) "The risk rates described in this study compare favorably to those linked to drugs routinely prescribed for musculoskeletal conditions in general practice."
- 11) "The risks reported here are also lower than those reported for acupuncture, which were described as a very safe intervention in the hands of a competent practitioner."
- 12) "Although minor side effects were found to be relatively common, the risk of a serious adverse event, immediately and up to 7 days after treatment, was estimated to be low to very low in these consultations."
- 13) "On this basis, this survey provides evidence that cervical spine manipulation is a relatively safe procedure when administered by registered U.K. chiropractors."

## COMMENTS FROM DAN MURPHY

Although there were no serious events associated in this study involving 50,276 cervical spine adjustments, the authors applied something called "Hanley's rule of three" noting:

"To estimate risk in cases where no occurrence of an adverse event occurs, Hanley's rule of three was used. This states that if none of  $n$  patients show the event, then it can be assumed with 95% confidence that the chance of this event is, at worst, 3 in  $n$  (i.e.,  $3/n$ ). It is generally accepted that treatment associated events occurring at a rate of 1 in 10,000 to 100,000 can be categorized as very low risk. Therefore, a sample size of 50,000 cervical spine manipulative interventions was sought to give a frequency of 1 serious adverse event in approximately 17,000 interventions."

Based upon this Hanley's rule of three, these authors compute:

"This translates to an estimated risk of a serious adverse event of, at worst  $\approx 1$  per 10,000 treatment consultations immediately after cervical spine manipulation,  $\approx 2$  per 10,000 treatment consultations up to 7 days after treatment and  $\approx 6$  per 100,000 cervical spine manipulations.

The highest risk immediately after treatment was fainting/dizziness/light-headedness in, at worst  $\approx 16$  per 1000 treatment consultations.

Up to 7 days after treatment, these risks were headache in, at worst  $\approx 4$  per 100, numbness/tingling in upper limbs in, at worst  $\approx 15$  per 1000 and fainting/dizziness/light-headedness in, at worst  $\approx 13$  per 1000 treatment consultations."

Again, this seems very bizarre to me because the 3 does not change, yet the number of adjustments could change. Using this study of 50,000 adjustments, the risk is  $50,000/3 = 16,666$ , meaning one serious adverse event per 16,666 adjustments.

If only 10,000 adjustments were given with no serious adverse events, the risk would be  $10,000/3 = 3,333$ , meaning one serious adverse event per 3,333 adjustments.

If only 100 adjustments were given with no serious adverse events, the risk would be  $100/3 = 33$ , meaning one serious adverse event per 33 adjustments.

This seems crazy to me. I am certainly glad this study had at least 50,000 adjustments.

Additionally, using Hanley's rule of three, the number of serious adverse events per 50,000 adjustments was  $1 / 16,666$ ; yet the authors interpreted it as  $1 / 10,000$  adjustments. Again, this seems crazy.