EXPERT EVALUATION AND CRITICAL ANALYSIS OF THE CERVICAL SPINE MANIPULATIONS

David Darfeuille, DO ; Pascal Javerliat, DO ; Didier Prat, DO ; Edouard O. Renard, DO, PhD; Jean P. Saby DO *

1. Study design: Principles and practice of cervical spine manipulation were analysed in a review of the literature from 1960 to 2003.

2. Objectives: To evaluate the indications and the danger of such manipulations and to determine guidelines of good practice.

3. Summary of the background data: Although recent research has demonstrated the potential risks of cervical spine manipulations, little is known about the relationship between the patient, the technique used, the kind of practitioner and the type of accident.

4. Methods: the French Register of osteopaths (ROF) initiated an expert evaluation and a critical analysis of the cervical spine manipulations.

In order to do this study, the ROF relied on:

- Edict n° 96-345 of the 24th of April 1996 relative to the control of health care expenditure, recommendations of good practice and opposable medical references.
- Present state of scientific knowledge
- Expert's reports done between 1988 and 2003

The working group created in April 2003 followed argumentation and methodology developed by the Accreditation and Evaluation in Health National Agency (ANAES) during a meeting with Professor Yves Matillon the 29th of June 2002.

A structured research of computerized bibliographic data bases (Medeline, Pascal...) and of other references was performed to find literature on the risks of spinal manipulations and guidelines of good practice.

A working group was established, including osteopaths, chiropractors, medical doctors, professors of University, research workers, barrister at-law, insurance experts and patients' representative (see appendix 1). A first draft was established, amended by a validation committee. The latter one being composed of different persons presenting the same qualifications as the working group members (see appendix 2).

5. Conclusion: The critical analysis of the collected data demonstrates that complications due to cervical spine manipulations are a very controversial question.
Nevertheless, it is possible to establish the following facts. One of the major complications of post cervical spine manipulative accident remains the cervical artery dissection. However, in the majority of cases, dissection is not associated with manipulative treatment. Dissection is a random and unforeseeable risk of any cervical movements, including manipulation. It is mentioned in the consensus conferences literature that dissections are produced during conditions in which the physiopathological process follows a common non-manipulative rotation or extension of the cervical spine. No vascular complication can be avoided by performing X-ray.

The vascular risk is not linked with the radiological state of the cervical spine. However, manipulations to the cervical spine must be considered only after a complete examination of the patient in order to evaluate the benefit / risk impact.
Some criteria enable the osteopath to define a population which must not be manipulated, a population for which manipulation during the first treatment is not recommended, and a population for which manipulation offers a benefit.

The strict application of procedures such as: case history taking, clinical examination including osteopathic assessment, examination of complementary investigations when necessary and osteopathic techniques, combined with clear and appropriate information to the patient, and respect to ethical rules must grant the patient safety during cervical spine manipulation.

Guidelines of good practice are recommended to osteopath registered with the ROF. (see appendix 3). These recommendations will be regularly updated according to new available data, in order to maintain a high secure level for patients.

Appendix 1:

Dr Jean Paul AMAT : MD, David DARFEUILLE : DO, Marcel DUBOURDEAU : insurance expert, Claude DURAND : councel, Pr Vincent DUVERGER : vascular surgeon, Geneviève FAVARIO : patient's representative, Philippe FLEURIAU : DC, Elisabeth GERBAULT : insurance expert, Pr Emmanuel HOUDARD : neuro-radiologist, Pascal JAVERLIAT: DO, Laurent LE SOLLEU : DO, Vincent LONGUEVILLE : insurance expert, Gilles Jean PORTEJOIE : barrister at law, Didier PRAT DO, Edouard Olivier RENARD DO, PhD, Dr Michel de ROUGEMONT : MD, expert in juridical compensation of the body damage, Jean Paul SABY DO, Philippe STERLINGOT DO, Pr Christian VALLEE Radiologist, Dr Alain VENET : research director.

Appendix 2 :

Pr Didier PAYEN de la GARANCIERE Anaesthetist, Michel ROBINE DO, Dr Pierre LEPORC MD, Véronique DANANCHE DO, Rafael ZEGARRA PARODI DO, Jean Pierre BARRAL DO, Pr Patrick MAMOUDY Orthopedist, Jean-Pierre AMIGUES DO Pr Jean Pierre RELIER, pédiatrician, Dr Anne Marie SCHOOT : MD, méthodologist , Pr Gilbert VERSIER Orthopédist Begin, Dr Michèle KHAYAT : MD.

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* Drafting committee of the multi-professional Council for framing the risk due to osteopathy and chiropractic – France. April 2004. Members of the French Register of Osteopath – Registre des Ostéopathes de France (ROF), 6 rue Joule, 33692 MERIGNAC, FRANCE: www.osteopathie.org

6. Analysis

6.1) Determination of the risks related to cervical spine manipulation:

Age: The older the patient is, the more his/her cervical spine is unstable and degenerated.

Sex: Women aged of less than 50 years old and women with hormone replacement therapy (HRT) present predispositions to cerebro-vascular accidents.

***Well known medical risks*:** Many diseases are considered to be contra-indications to cervical spine manipulations. This is well demonstrated in the literature. Therefore many red flags justify complementary investigations. Two of them are less well known and are directly linked with osteopathic principles and cervical manipulations:

- A multidirectional neck stiffness.
- A decreased neck pain following manipulation with progressive increasing of neck pain a few hours later.

***Vascular risks*:** Although the links between cervical spine manipulation and vertebral artery dissection are often mentioned, the majority of cases are not associated with high velocity – low amplitude techniques (HVLAT). Vertebral artery dissections are mainly spontaneous and are preceded by minor trauma or strenuous activities.

Risks due to manipulation v/s other proposed treatments in the case of neck pain: The French national agency of medicine (Agence Nationale du médicament) drafted a report in 2002. It explains that in 2001, 8000 deaths were due to non steroid anti inflammatory medication (all diseases considered). In 2001 no complaint was reported to the French register of osteopath (ROF).
NB: French population: 62 M. Number of people practising manipulations: about 4000. ROF members: about 1000.

What is the maximal delay between a manipulation and the appearance of clinical sign to consider the manipulation as the cause of the problem?: Clinical signs may appear immediately and up to 72 hours after manipulation. Recent studies have demonstrated that vertebral artery dissection is random and unforeseeable of any cervical motion and particularly of manipulation.

Percentage of death due to different kinds of treatments:

- ***30 %:*** *Incidence of adverse drug event in hospitalized patients. (Anderson, 1992).*
- ***10 %:*** *Incidence of psychosis due to corticosteroid therapy. (Havey,1984)*
- ***1-2 %:*** *Incidence of paralysis due to neurosurgery of the cervical spine. (Rocha vs. Harris, 1987)*
- ***0.7 %:*** *Incidence of oesophageal perforation during anterior approach cervical spine surgery. (Van Berge Henegouwan et al., 1991)*
- ***0.3-0.9 %:*** *Incidence of death due to cervical spine surgery.(Graham, 1989)*
- ***0.00002-0.00008 %:*** *Incidence of death due to lightning in the U.S.A. (Eriksson & Ornehult,1988)*
- ***0.00001-0.00003 %:*** *Incidence of serious neural complications due to cervical manipulation. (Cyriax, 1978, and Gutman, 1983, respectively)*

Mobility of the cervical spine and strains on the vertebral artery: There are wide variations in cervical spine mobility between individuals depending on age and sex. Differences appear at about 30 years of age. Women are more mobile than men, especially in rotation and rotation with full flexion. After the age of 50, men are more mobile than women in side bending and rotation with full extension. After 60 years old, there is no difference between sexes. The range of motion decreases with age except in rotation with full flexion which remains the same. The population which presents the most mobile cervical spine is the female population between the age of 20 to 30. Influence of cervical motion to vertebral artery flow is well known and supported by clinical investigations. Blood flow is diminished during rotation and extension. This diminution is more important when both movements occur simultaneously. The forces applied to the vertebral artery during high velocity and low amplitude techniques are less than the force required to rupture it. Therefore HVLAT present very low risk of arterial rupture.

6.2) What is a practitioner?

What is an osteopathic technique (HVLAT)?*:*
It is a manual response without force to the osteopathic diagnosis. It is a specific and monitored procedure which:

- restores the mobility of the disturbed movement(s), within the limits of physiological range of motion.
- Restores the functional qualities of the connective soft tissues.

The osteopathic diagnosis is based on theoretical and palpatory knowledge of the normal range of mobility. Normal range of mobility means: variations depending on age, patient background and postural strains. The assessment is always comparative with the opposite side of the body. It is always compared to the clinical examination findings. It is important to note that the osteopathic diagnosis leads to treat the cause (somatic dysfunction) which can be at a distance from the symptom(s).

The expected physiological response is to restore the loss of mobility. This can be obtained by different techniques.
The choice of technique is guided by the diagnosis, the knowledge of contraindications, the patient state of health and the practitioner's experience.

Absolute contraindications are:

- Weak bone due to pathological process.
- Clinical signs of nerve root entrapment or medullar compression.

- Circulatory troubles due to reflex arterial spasm or direct pressure.
- Uncertain diagnosis due to the absence of concordant signs.
- Pain preventing the precise positioning, in order to apply a technique, whatever the cause.

***What is the level of competence of the pratitioners involved in complaints following complications allegedly arising from cervical spine manipulation?*:** Two studies made in collaboration with the GAMM, the GROUPAMA and AXA (NB: the three main French insurance companies of health practitioners), were carried out by Docteur de Rougemont (MD, expert in juridical compensation of the body damage, court expert), in order to determine complications following spinal manipulations in France.

⇨ the first study was related to cerebro-vascular accident allegedly arisen from cervical spine manipulation recorded from 1988 to 2003. Seven complains were recorded:
- 6 were due to MD. Only one ended in financial compensation.
- 1 was due to a French Registered Osteopath. The osteopath was found not guilty.

⇨ the second study was related to all accidents allegedly arising from all spinal manipulations recorded from 1996 to 2003. Twenty complains were recorded:
- 12 were due to MD. Two leading to financial compensation.
- 3 were due to French Registered osteopaths who were not found guilty.
- 5 were due to physiotherapists. Two leading to financial compensation.

NB: this search does not exclude other complains in other companies. Some practitioners are covered by foreign insurance companies.

Was the practitioner involved following the professional guidelines of good practice?: At present, there is no consensus in France relative to manipulations. For this reason, experts looked to see if the practitioners were respecting the guidelines of safety, such as:
- Were X-rays taken to look for malformations or pathological conditions?
- If the patient is older than 50, has the blood pressure been taken?
- Has the practitioner investigated the patient background?
- Did the patient properly answer the questions asked by the practitioner?
- Has clinical assessment of safety been performed?
- Moreover, the outcomes must be recorded in the patient file.

There are no technical guidelines relative to spinal manipulations. In case of accident, practitioners must demonstrate that he/she has performed a normal technique that has been tested or validated by the profession. It must not be a personal technique.

Are X-rays or other complementary examinations compulsory before cervical spine manipulations?: Without specific education, radiologists do not know the principles and techniques of manipulations. His/her point of view must be understood with caution. It can't be opposable. X-rays are unlikely to foresee a VCA due to arterial dissection.
The situation is different when patients present a history of a previous trauma. Unfortunately, X-rays present a lot of "false negatives". CT scans can reveal up to 70% lesions during X-ray examination.
Many authors propose clinical tests before manipulation but it has been demonstrated that these tests present a weak reliability.
In summary, the vascular risk due to cervical manipulation is too small to justify systematic complementary investigations with patient presenting no known medical risks. However, following a trauma, even minor, X-rays are essential and manipulations must be avoided without X-ray examination. The French council of electro radiologists (Conseil des Electro-Radiologistes de France – CERF) recommends to perform additional X-rays 10 days after trauma to rule out a cervical sprain.

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APPENDIX 3:

Guidelines of good practice relative to cervical spine manipulation

1st recommendation

Before performing a cervical spine manipulation, an osteopath must:

- **Look for risks induced by the patient pathology, his medical history, current or previous treatments.**
- **Perform a clinical examination of the cervical spine.**
- **Perform a routine but complete neurological examination.**
- **Take the blood pressure.**
- **Examine the patient's X-rays.**

2Nd recommendation

Systematic X-ray control before a cervical spine manipulation has no particular interest however, X-rays must be taken in case of patients presenting risk factors.

X-rays are necessary:

- **In case of recent or ancient trauma to the cervical spine.**
- **In people aged more than 70.**

3rd recommendation

During case history taking, it is necessary:

- **To ask the patient if she/he has already been manipulated in the cervical spine? And if it is the case ask if:**
- **Undesirable effects such as vertigo or nausea had appear after the manipulation?**

4th recommendation

During the first consultation, manipulation is not advised in:

- **Children and adolescents.**
- **Patients older than 50.**
- **Female between 20 and 30, furthermore if they are under contraceptive pills.**

5th recommendation

Relative or absolute clinical and technical indications and contraindications must be respected.

- **The absence of concordance between clinical signs or the presence of clinical or technical red flags are absolute contra-indications to cervical spine manipulation.**

6th recommendation

To prevent mechanical strains that could modify the blood flow:

- **Manipulation with impulses and high velocity in rotation plus extension and traction of the cervical spine must be forbidden.**
- **Instead, manipulation with minor parameters should be implemented.**

7th recommendation

In order to respect physiological parameters

- **Only joints with somatic dysfunction must be manipulated.**

8th recommendation

Patient must be informed of the potential risks and her/his consent must be enlighten.

- **Patient must give her/his consent to the osteopath before she/he performs the manipulation**.

9th recommendation

Some secondary effects following cervical spine manipulation may occur ie vertigo, headache, nausea, neuro-vegetative reactions:

After a cervical spine manipulation:

- **A current neurological examination must be performed.**
- **Blood pressure must be taken in both arms.**

10th recommendation

In case of neck pain, cervical or upper limb nerve root irritation, myelopathy due to cervical osteoarthritis, cervical spine manipulation is not the final goal in itself. The ratio benefit/risk must be weighed by the osteopath. Therefore:

- **During the first consultation, cervical spine manipulation is not advised.**