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Adverse events following cervical manual physical therapy techniques

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GENERAL INTRODUCTION

1

INTRODUCTION

Manual physical therapy is considered an effective intervention for non-specific neck pain and neck-related headache. However, there is a debate in literature and amongst clinicians about the use of these therapeutic interventions in relation to the risk of complications following manual physical therapy. Within the process of clinical reasoning, manual physical therapists (and other professionals who apply manual therapy intervention to the cervical spine) should weigh the expected benefit of the interventions in an individual patient against the risk of adverse events, the so-called risk-benefit ratio. Considerations of the risk-benefit ratio should be based on the knowledge of the effectiveness of these interventions, and on the risk and frequency of occurrence, also known as the incidence, of adverse events following these interventions. Until now, there has been a lack of information about the incidence and characteristics of adverse events following manual physical therapy (and comparable interventions) applied to the cervical spine.

This introduction to the thesis will focus on the determinants of the risk-benefit ratio related to manual physical therapy interventions applied to the cervical and upper cervical spine. An oversight of literature concerning the characteristics of non-specific neck pain (and related headache), the epidemiology of non-specific neck pain (and related headache), and the effects of manual physical therapy will be described. Thereby, current knowledge of the characteristics and frequency of occurrence of adverse events (which knowledge is scarce) will be given. As manual physical therapy interventions are described in relation to adverse events, characteristics of these interventions are described too.

CHARACTERISTICS AND CLASSIFICATION OF NON-SPECIFIC NECK PAIN

Neck pain is a common and multimodal health problem that includes physical, affective, cognitive, and social aspects.(Blanpied et al., 2017; Hoy et al., 2014) Usually the cause of the neck pain is benign (99%).(Rubinstein et al., 2008) The patho-anatomical basis for neck pain is unknown in most patients and therefore characterized as nonspecific or mechanical.(de Vries et al., 2016) The most common used categories for neck pain are: 1] neck pain with mobility deficits; 2] with impaired movement coordination; 3] neck pain with headache; 4] neck pain with radiating pain; and 5] neck pain and migraine.(Blanpied et al., 2017; Gross et al., 2015; Hogg-Johnson et al., 2008; Jull and Hall, 2018) The exact relationship between neck pain and headache is unknown. However, the prevalence of neck pain is significantly higher in patients with migraine (76.2%) and tension type headache (88.4%) than in the general population (57.8%).(Ashina et al., 2015; Moore et al., 2017) The most

used classifications for neck pain are by time, severity, symptoms or anatomical structures.(Bier et al., 2018; Blanpied et al., 2017; Guzman et al., 2009)

EPIDEMIOLOGY OF NON-SPECIFIC NECK PAIN

The incidence of neck pain is estimated varying from 14%-21%, a point prevalence of 4.9%, and a 1 year prevalence ranging of 37.5%.(Blanpied et al., 2017; Fejer et al., 2006; Hoy et al., 2014) With a 4th place for disability on the musculoskeletal burden of disease, the influence on daily life can be considered as severe.(Smith et al., 2014) In the Netherlands, It is the third musculoskeletal location for complaints and 40% of the total costs of spinal pain are thought to be due to neck pain.(Bier et al., 2018; Picavet and Schouten, 2003)

CHARACTERISTICS OF MANUAL PHYSICAL THERAPY INTERVENTIONS

Both neck pain and headache patients frequently seek help in primary care for a diagnosis and to relieve symptoms.(Blanpied et al., 2017; Gross et al., 2015; Moore et al., 2017) Treatments are often multimodal during which both hands-on and hands-off techniques are advised and used.(Bier et al., 2018; Blanpied et al., 2017) Hands-off techniques may consist of specific or general exercises, advice, postural corrections, cognitive behavioural therapy, and workplace interventions. Hands-on therapy may consist of cervical mobilizations, manipulations, neurodynamics, taping and massage therapy. Most of the advised techniques are based on low quality evidence. However, the combination of cervical mobilizations or manipulations and exercise therapy for neck pain patients Grade I or II is based on high quality evidence.(Bier et al., 2018; Blanpied et al., 2017)

Manipulations and mobilizations are both hands-on techniques. Although the terms might seem alike, they are interchanged in literature and are often deployed for the same indications or outcomes, they are significantly different.(Mintken et al., 2008; Rushton et al., 2016, p. 31) In their educational standards document, the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) has defined a manipulation as: *"A passive, high velocity, low amplitude thrust applied to a joint complex within its anatomical limit with the intent to restore optimal motion, function, and/or to reduce pain."* Following the same document a mobilization is defined as: *"A manual therapy technique comprising a continuum of skilled passive movements that are applied at varying speeds and amplitudes to joints, muscles or nerves with the intent to restore optimal motion, function, and/or to reduce pain."*(Rushton et al., 2016, pp. 31–32) The key difference between those two techniques is the high velocity impulse with which a manipulation is applied. Furthermore, a manipulation is applied towards the end

of the anatomical limit of a joint, whereas a mobilization can be applied in an end range position as well as in the range before that anatomical limit.

BENEFITS OF MANUAL PHYSICAL THERAPY

The possible benefits of treatment modalities which are weighed against the possible risks are an essential component of the complex and multimodal clinical reasoning process of a manual physical therapist.(Rushton et al., 2016) Cervical manipulations seem more effective for neck pain than thoracic manipulations and demonstrated fewer side effects.(Puentedura et al., 2011) The effectiveness of cervical techniques, including manipulations and mobilizations, has been described in a Cochrane review.(Gross et al., 2015) This review, including 51 trials with 2920 participants, showed that manipulations seemed not to be more effective than mobilizations at an immediate, short term and intermediate follow-up. However, multiple sessions with cervical manipulations led to more pain relief and functional improvement than pain medication at immediate, short, intermediate and long follow-up. Effect sizes described in Standard Mean Differences (SMD) were reported for pain between -0.19 and -0.34 favoring multiple cervical manipulations versus medication. When comparing cervical manipulations versus cervical mobilizations the pooled SMD for pain was -0.07 favoring manipulation and the SMD for function and disability scored between 0.10 and -1.71. Differences in execution of manual techniques could also lead to differences in effectiveness.(Gross et al., 2015) A combination of manual techniques and exercise is recommended.(Bier et al., 2018)

RISKS OF MANUAL PHYSICAL THERAPY

The World Health Organization considers cervical manipulations or mobilizations performed by chiropractors as safe and effective treatment which carries the risk of few mild and transient adverse events.(World Health Organization, 2015) Most of those risks concern minor or moderate adverse events.(Cagnie et al., 2004; Chaibi and Russell, 2019; Sweeney and Doody, 2010) Although it can be hard to classify adverse events, they can be classified as not adverse, minor, moderate and major adverse. (Carnes et al., 2010) 'Major' adverse events are defined as medium to long term, moderate to severe and unacceptable, they normally require further treatment and are serious and distressing; 'Moderate' adverse events are as 'major' adverse events but only moderate in severity; and 'Mild' and 'not adverse' adverse events are short term and mild, non-serious, the patient's function remains intact, and they are transient/reversible; no treatment alterations are required because the consequences are short term and contained.(Carnes et al., 2010) Classification can be difficult without a context or details and there is a possible overlap between

categories in the classification as described by Carnes.(Carnes et al., 2010) In particular, the category 'moderate' is difficult to work with in clinical practice and in research. The overlap between the minor and major categories is probably too large. (Carlesso et al., 2011) Furthermore, if the definitions used to categorize were linked to the international classification of diseases and Related Health Problems (ICD-10) and the international classification of functioning, disability and health (ICF), that would enhance clarity and simplify usage. (World Health Organisation, 2012, 2001)

The incidence of major adverse events following manual therapy is of considerable interest and has only been described anecdotally. However, incidences have been estimated ranging from 1:3.000 to 1:6.000.000.(Assendelft et al., 1996; Magarey et al., 2004; Nielsen et al., 2017) However, due to the severity of the consequences cases are repeatedly published and are abundantly covered by media. In most published cases a cervical manipulation was involved during the treatment session.(Ernst, 2007; Nielsen et al., 2017) The Health and Youth Care Inspectorate in The Netherlands receives approximately two cases with major AE following manual physical therapy per year.(Pool, 2019) However, the frequency with which manipulations and mobilizations are applied is unknown in The Netherlands. The absence of representable incidence rates makes it difficult to place those adverse events in perspective. Particularly since causality has not been established, discussions remain intense on whether or not to use these techniques and which precautions should be considered.(Cassidy et al., 2012; Church et al., 2016; Wand et al., 2012) To assist the clinician in this clinical reasoning process and physical assessment the IFOMPT has developed a framework which has also generated discussion.(Kerry et al., 2014; Rushton et al., 2014; Scholten-Peeters et al., 2014) Since most of the adverse events following cervical manipulations seem of a neurovascular origin the framework focusses on cervical artery dysfunctions.(Biller et al., 2014)

CERVICAL ARTERIAL DISSECTION

Cervical arterial dissections arise when the inner wall of an artery (tunica intima) of the outer adventitia layer ruptures and creating a false lumen.(Blum and Yaghi, 2015) This may narrow or even close the lumen of the artery. Also, it can create a secondary blood flow in the false lumen, resulting in a thrombus which can cause a stroke. Cervical arterial dissections can occur in the internal carotid arteries and in the vertebral arteries. (Figure 1) The internal carotid arteries are also known as the anterior circulation because they supply the anterior part of the brain with blood. The vertebral arteries are often referred to as the posterior circulation because they supply the posterior part of the brain with blood. Fortunately, mortality rates of

cervical dissections are low (4%) and functional outcomes are usually good.(Debette, 2014) The pathophysiology of cervical dissection is multifaceted and not yet fully understood.(Debette, 2014; Hutting et al., 2018; Thomas, 2016) The incidence rate for a spontaneous carotid artery dissection is 2.3-3.0 per 100.000 people and for the vertebral artery 1.0-1.3 per 100.000 people and should be taken into account when calculating an increased risk after cervical techniques.(Debette et al., 2009; Dziewas et al., 2003; Schievink et al., 1994) Although no causal relationship between cervical manipulations and cervical dissections has been established, an association has been suggested.(Cassidy et al., 2017, 2008) A cervical artery dissection can be caused by intrinsic and extrinsic factors.(Debette, 2014; Thomas, 2016) Intrinsic factors may be an underlying arterial pathology, anomaly or a genetic predisposition. (Debette et al., 2009; Thomas, 2016) Infections or cervical traumata such as motor vehicle accidents are considered extrinsic factors. It is unlikely that a cervical manipulation will damage a healthy arterial wall. However, in extremely rare cases, when a cervical arterial dissection is already present, it cannot be disregarded that cervical manipulation is such an extrinsic factor.(Eriksen et al., 2011) It has also been suggested that the manipulation may trigger an embolus or a vasospasm or that

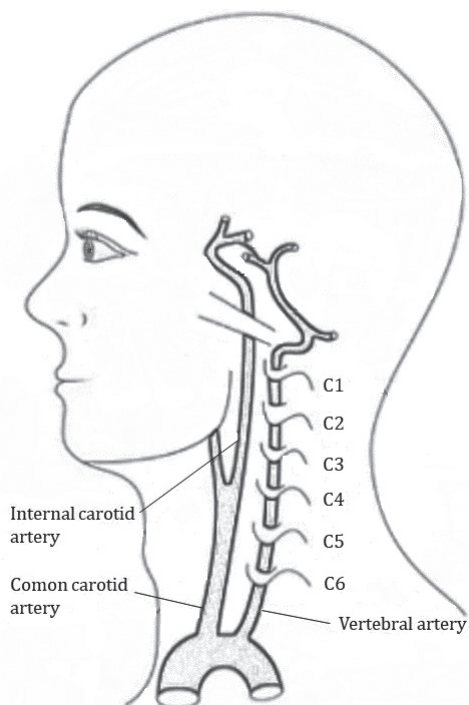


Figure 1. Cervical arteries

the manipulative position might alter blood flow.(Haldeman et al., 1999; Mann and Refshauge, 2001; Mitchell, 2009) However, the latter explanation is challenged by the anatomical disposition via the circle of Willis. Furthermore, it would also mean that the technique itself is secondary to the treatment position which is contrary to the reported cases of major adverse events. Moreover, it would be in contrast to the suggestion that mobilizations are often presented as a safer alternative to manipulations.(Gross et al., 2015) Especially since cervical manipulations are typically performed in a mid-range

position while mobilizations are regularly performed in an end-range position. (Dunning et al., 2016; Reid et al., 2014)

Cervical arterial dissections usually present with local pain, ipsilateral neck pain, ipsilateral headache and a Horner syndrome and this typical pattern is only existent in less than one-third of patients. Diagnosis is regularly overlooked for some time precisely because of the lack of specific signs. (Thanvi et al., 2005) Usually, unilateral neck pain or headache have a musculoskeletal origin and are benign. Unfortunately, these arterial symptoms can mimic the musculoskeletal complaints when other neurological symptoms are absent. Especially, for the carotid artery dissection differentiation can be difficult. (Debette et al., 2009; Thomas, 2016) However, cervical arterial dissection patients frequently label their symptoms as being different to those experienced before or as abnormal. (Debette et al., 2009) Besides an MRI T1 with fat suppression, a comprehensive patient history seems essential to identify patients at risk. (Debette et al., 2009; Puentedura et al., 2012; Rushton et al., 2014; Thomas, 2016) Especially because pre-manipulative arterial tests seem to have a low diagnostic accuracy, a low pretest probability and can even be harmful for the patient. (Hutting et al., 2018, 2013)

AIM OF THIS THESIS

There is a need to gain clarity on patient and treatment characteristics that can predict adverse events following manual physical therapy and data to put the adverse events in perspective. Therefore, the three aims of this thesis are:

1] To identify patients which are more at risk for AE following manual physical therapy by identifying and understanding risk factors within the patient, therapist and the techniques used during treatment.

In **chapter two**, the purpose is to gain a general insight in spinal care in manual physical therapy practices so a perspective can be formed. This will be achieved by quantifying the amount of manipulations per spinal region during treatments in clinic, by determining thoughts of clinicians on safety and efficacy about the application of manipulations and inventory their clinical decision making. The purpose of **chapter four** is to systematically review the literature to identify the characteristics of 1) patients, 2) practitioners, 3) treatment process and 4) adverse events (AE) occurring after cervical manipulation or cervical mobilization. In **chapter five**, the purpose is to explore differences between hospitalized CeAD patients and controls receiving a cervical manipulation in clinical practice by means of a case-control study. The purpose of **chapter six** is to determine, the effects of cranio-

cervical positions and movements on hemodynamic parameters (blood flow velocity and/or volume) of cervical and cranio- cervical arteries.

2] To develop a classification system that is suitable for clinical practice and research by which AE can be reported.

The aim of **chapter three** is to develop a classification system for adverse events that is useful for research and practice, including patients and clinicians' perspectives, has an acceptable number of categories and clear definitions, and is based on the international classification diseases and Related Health Problems (ICD-10) and the international classification of functioning, disability and health (ICF).

3] To collect the frequency with which techniques are used and the frequency with which adverse events are reported to put the AE in perspective.

In **chapter seven**, purpose is to determine the number, type and predictors of AE following cervical treatments performed by Dutch manipulative therapists.

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