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International Framework for Examination of the Cervical Region for potential of vascular pathologies of the neck prior to Orthopaedic Manual Therapy (OMT) Intervention:



International IFOMPT Cervical Framework

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Background

The IFOMPT Cervical Framework Document, a resource for clinicians, was first published in 2012 and scheduled for revision from 2017. The document was a result of IFOMPT Member Organisations' appeals (with its <u>vision and mission</u> for excellence and standards) for consistency and guidance regarding the teaching and practice of assessment and management of individuals with neck and head pain and dysfunction. In this revision, the International Classification for Patient Safety terminology has been adopted to recognise the wider context of patient safety events (<u>Runciman et al</u>, 2009; <u>Sherman et al</u>, 2009; <u>WHO</u>, 2009). The rationale for the existence of a Framework Document was explained in the 2012 document. However, for clarity and to foreground this revised framework, this rationale is summarised herewith.

There are a range of potential vascular pathologies of the neck relating to the arterial system which supplies blood to the brain. The relevance of this for physical therapists who treat musculoskeletal conditions is two-fold. First, there is a clinical and empirical history stemming from the early days of manual therapy that neurovascular patient safety incidents have been associated with therapeutic interventions. Second, in more recent years, it has become more evident through scientific and clinical case studies that there are a range of arterial pathologies which have the potential to present as musculoskeletal pain and dysfunction – vascular

masqueraders; with patients presenting to the physical therapist with a vascular pathology of the neck complaining of, for example, neck pain and headache. The priority for the physical therapist is, therefore, to first do no harm, and second, to excel in clinical reasoning and differential diagnosis. These two dimensions overlap in so much that it is likely that many safety incidents follow treatment of people with vascular pathologies or occur in those with a predisposition to vascular pathologies. There are of course rare exceptions to this where the incident might seem unpredictable, e.g. some spontaneous dissections. The goal of the International IFOMPT Cervical Framework is to increase the physical therapists' understanding of risk and pathology, thereby promoting patient safety. To avoid confusion owing to multiple uses of the acronym CAD, the previously used terminology of Cervical Artery Dysfunction has been replaced with 'vascular pathologies of the neck'.

Risk and context: one mission of the Framework authors is to ensure that educators and physical therapists understand risk in both its epidemiological and individual contexts. Epidemiologically, without doubt, the risk of patient safety incidents related to any form of therapeutic intervention is small. This does not mean, however, that utmost attention should not be given to assessing, mitigating, and limiting risk at an individual level. Individuals will differ widely with regards to their own risk and hazard profile (predisposition to arterial pathology) or existence of vascular pathology (masquerading as a musculoskeletal dysfunction). The Framework aims to provide the necessary information to allow both educators and physical therapists to teach and practice with the sound reasoning and knowledge required to make the best clinical decisions, with the result that they are capable of minimising this risk.

Is there a need for a Framework document? In the context of a clinician deciding whether or not to refer a patient onwards for further investigation, there is no difference between vascular pathologies of the neck and any other serious pathologies which presents with features of a musculoskeletal disorder (so called masqueraders). However, the Framework is published in response to several decades of uncertainty leading to professional anxiety, and inconsistency of knowledge and practice, as well as the call for guidance from professional bodies. This present revision continues to summarise and reflect the best of contemporary evidence and expert thought in the area. Feedback from the original 2012 framework has been extremely positive and it is anticipated that this revision will have similar impact on clinical practice and education. Future iterations will be produced in response to any key changes in the evidence base for this area.

A key development is the removal of positional testing from the Framework since the 2012 version. Provocative positional testing is frequently used in practice with the intention to provide a challenge to the vascular supply to the brain, and the presence of signs or symptoms of cerebrovascular ischaemia during or immediately post testing indicates a positive test. However, the predictive ability of these provocative positional tests to identify at risk individuals is lacking, and there is some evidence against its use (<u>Hutting et al</u>, 2018; <u>Hutting et al</u>, 2020). Provocative positioning testing is therefore not recommended.

The framework is freely available through <u>www.ifompt.org</u>, is based on best available evidence at the time of writing and is designed to be used alongside the <u>IFOMPT Standards Document (2016)</u>. The Framework is a consensus document developed through rigorous methods. Central to this Framework are sound clinical reasoning and evidence-based practice. It is not intended that the Framework be a series of systematic reviews of the key issues which aim to answer specific questions. Rather, because of the breadth and complexity of the Framework, gathering of literature was based on extensive searches, reviews, and collation of relevant literature in line with methodological frameworks for scoping reviews (<u>Arksey and O'Malley, 2005</u>). Each section

author team identified discrete substantive areas; searched relevant electronic databases; reference lists; hand-searched key journals, existing networks, and relevant organisations and conferences. Study selection and charting of data and information was undertaken within each section author team, in-line with the focus of each particular section.

Consensus method

Stage 1: A survey to evaluate the 2012 Framework was distributed to all Member Organisations and Registered Interest Groups of IFOMPT in 2016. The survey explored the perceived value of the Framework, its strengths, its limitations, and examples of its use.

Stage 2: The key issues identified in the survey were initially explored at the IFOMPT Conference in 2016 in Glasgow. Findings from the evaluation survey were presented to facilitate discussion and debate. This stage supported the need for an updated version of the Framework. The session generated considerable discussion to inform the first revisions of the Framework. Guidelines and systematic reviews were used to inform the draft and when no evidence was available, expert consensus was used.

Stage 3: Through an iterative consultative process, drafts of the Framework were developed and circulated for review and feedback to: Member Organisations and Registered Interest Groups of IFOMPT, International experts / authors, nominated experts with IFOMPT countries, and professional organisations across physical therapy, osteopathy and chiropractic. The final version was reviewed and appraised by a medical practitioner specialising in stroke and interventional neurology.

Structure of the Framework

The Framework is divided into the following sections, and is designed to be used in conjunction with key literature sources identified in the context section:

- 1. <u>Summary infographic</u>
- 2. <u>Aim and scope of the Framework</u>
- 3. Framework underpinned by clinical reasoning
- 4. <u>Patient history</u>
- 5. <u>Planning the physical examination</u>
- 6. <u>Physical examination</u>
- 7. <u>Risk and benefit</u>
- 8. Shared decision-making, informed consent and medico-legal framework
- 9. <u>Safe OMT practice</u>
- 10. <u>Teaching OMT for the cervical region</u>
- 11. <u>References</u>



SECTION 2: AIM AND SCOPE OF THE FRAMEWORK



The Framework is designed to provide guidance for the assessment of the cervical spine region for potential of vascular pathologies of the neck in advance of planned OMT interventions; within the broad context of the <u>IFOMPT definition of OMT</u>. OMT interventions for the cervical spine addressed through this Framework include mobilisation¹, manipulation ² and exercise.

Within the cervical spine, events and presentations of vascular pathologies of the neck are rare (<u>Kranenburg et al, 2017</u>), but are an important consideration as part of an OMT assessment. Vascular pathologies (<u>Table 1</u>) may be recognisable if the appropriate questions are asked during the patient history, if interpretation of elicited data enables recognition of this potential, and if the physical examination can be adapted to explore any potential vasculogenic hypothesis further. The Framework is therefore reflective of best practice and aims to place risk in an appropriate context informed by the evidence. In this context, the Framework considers ischaemic and non-ischaemic presentations to identify risk in a patient presenting for cervical examination and management.

An important underlying principle of the Framework is that physical therapists cannot rely on the results of only one test to draw conclusions, and therefore development of an understanding of the patient's presentation following an informed, planned and individualised assessment is

¹ A passive articulatory movement applied to a single joint or joints in close proximity to each other with the intent to restore optimal motion, function, and/or to reduce pain

² 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.

essential. There are multiple sources of information available from the process of patient assessment to improve the confidence of estimating the probability of vascular pathologies of the neck. Data available to inform clinical reasoning will improve and change with ongoing research. Current data does not allow for a prescriptive or protocol-based guideline. This Framework therefore provides a starting decision-making framework whilst encouraging physical therapists to keep abreast of the current literature to enable support for their clinical decisions.

The Framework is intended to be informative and not prescriptive, aiming to enhance the physical therapist's clinical reasoning as part of the process of patient assessment and treatment. The current focus on effective clinical reasoning in the musculoskeletal research literature is supportive of this aim (Rushton and Lindsay, 2010; Petty, 2015; Taylor and Kerry, 2017; Hutting et al, 2018). The Framework is intended to be simple and flexible. The physical therapist should be able to apply it to their individual patients thereby facilitating patient-centered practice.

Structure/site	Pathology	Symptoms/Presentation
Carotid artery	Atherosclerosis Stenotic Thrombotic Aneurysmal	Carotidynia ³ , neck pain, facial pain, headache, cranial nerve dysfunction, Horner's Syndrome, transient ischaemic attack (TIA), stroke
Carotid artery	Hypoplasia	Commonly silent, rare cerebral ischaemia
Carotid artery	Dissection	Neck pain, facial pain, headache, TIA, cranial nerve palsies, Horner's syndrome
Vertebral artery	Atherosclerosis	Neck pain, occipital headache, possible transient ischaemic attack (TIA), stroke
Vertebral artery	Hypoplasia	Commonly silent, rare cerebral ischaemia
Vertebral artery	Dissection	Neck pain, occipital headache, TIA, cranial nerve palsy
Temporal/ Vertebral/ Occipital/Carotid arteries	Giant cell arteritis	Temporal pain (headache), scalp tenderness, jaw and tongue claudication, visual symptoms (diplopia or vision loss – may be permanent)
Cerebral vessels	Reversible cerebral vasoconstriction syndrome (RCVS)	Severe 'thunderclap' headaches
Subarachnoid	Heamorrhage	Sudden severe headache, stiff neck, visual disturbance, photophobia, slurred speech, sickness, unilateral weakness,
Jugular vein	Thrombosis	Neck pain, headaches, fever, swelling around neck/angle of jaw
Any other cervico-cranial vessel	Vascular anomaly or malformation	Possible headache/neck pain i.e. un-ruptured carotid aneurysm

Table 1: Range of vascular pathologies of the neck

³ Pain and tenderness along the carotid arteries

SECTION 3: FRAMEWORK UNDERPINNED BY CLINICAL REASONING

Clinical reasoning is employed to underpin the Framework detailed in this document (Figure 1). The cognitive and metacognitive processes of reasoning, using evidence-informed knowledge within OMT are the central components to expertise of practice in OMT (Rushton and Lindsay, 2010; Petty, 2015). The IFOMPT Standards Document (IFOMPT, 2016) states that:

Advanced clinical reasoning skills are central to the practice of OMT Physical Therapists, ultimately leading to decisions formulated to provide the best patient care. Clinical decisions are established following consideration of the patient's clinical and physical circumstances to establish a clinical physical diagnosis and treatment options. The decisions are informed by research evidence concerning the efficacy, risks, effectiveness and efficiency of the options (<u>Haynes, 2002</u>). Given the likely consequences associated with each option, decisions are made using a model that views the patient's role within decision-making as central to practice (<u>Hiags and Jones, 2000</u>), thus describing a patient centered model of practice. Therefore, practice in OMT is informed by a complex integration of research evidence, the patient's preferences and the patient's individual clinical presentation.

The application of OMT is based on a comprehensive assessment of the patient's neuromusculoskeletal system and of the patient's functional abilities. This examination serves to define the presenting dysfunction(s) in the articular, muscular, nervous and other relevant systems; and how these relate to any disability or functional limitation as described by the WHO's International Classification of Functioning, Disability and Health (ICF). Equally, the examination aims to distinguish those conditions that are indications or contraindications to OMT Physical Therapy and/or demand special precautions, as well as those where anatomical anomalies or pathological processes limit or direct the use of OMT procedures.

OMT includes a large range of therapeutic procedures such as passive movements (mobilisation and/or manipulation), rehabilitative exercises, patient information/education as well as other interventions and modalities. The main aims of OMT are to relieve pain and to optimise the patient's functional ability.

Dimension 6 of the IFOMPT Standards Document requires demonstration of critical and an advanced level of clinical reasoning skills enabling effective assessment and management of patients with NMS disorders. Specifically, that OMT Physical Therapists are able to:

- Use advanced clinical reasoning to integrate scientific evidence, clinical data and biopsychosocial factors related to the clinical context.
- Critically apply the hypothetico-deductive and pattern recognition clinical reasoning processes using the various categories of hypotheses used in OMT, related to diagnosis, treatment, prognosis.
- Critically evaluate and effectively prioritise clinical data collection to ensure reliability and validity of data and quality of clinical reasoning processes.
- Integrate evidence informed practice, reflective practice, and metacognition into a collaborative reasoning/clinical decision-making process with the patient, carers and other health professionals to determine management goals, interventions, and measurable outcomes.

The Framework requires effectiveness in clinical reasoning to enable effective, efficient, and safe assessment and management of the cervical spine region. It is clear that some recorded safety incidents (e.g. following cervical manipulation) could have been avoided if more thorough clinical reasoning had been exercised by the clinician (<u>Rivett, 2004</u>). The Framework is therefore designed to be an aid to patient-centered clinical reasoning.

Data obtained from patient history

Planning the physical examination

Possible vasculogenic hypothesis? Quality of data obtained? Gaps in data? Contraindications or precautions? Physical tests to use & priority for testing?

Evaluation of patient's presentation

Data obtained from the physical examination

Quality of data obtained? Gaps in data? Risk versus benefit analysis? Decision regarding action?



Best decision regarding management

Shared decision making with the patient

Fundamental to interpretation of data at each stage



SECTION 4: PATIENT HISTORY

Patient History Head and/or neck pain can be a symptom of an underlying vascular pathology or dysfunction							
Sub Risk fact DIS Recent tra	Is the tle signs and Is there tors indicatin SECTING	CON re presence of frank symptoms of the sus predisposition to va g the potential for ne STROKE sent an important	S va: pe scu	IDER scular patholog cted pathologies Jar pathologies o-vascular path NON-E Cardiovascul	ies of neck? s should be r of the neck? ology should DISSECTIN ar risk factors a	ecognised be recognised IG STROKE re more common in	
RISK FACTORS	SYMPTOMS	SIGNS		RISK FACTORS	SYMPTOMS	SIGNS	
 Recent trauma Vascular anomaly Current or past smoker Etc 	 Headache Neck pain Visual disturbance Paresthesia (upper limb, face, lower limb) Dizziness Etc 	 Unsteadiness Ptosis Weakness (upper limb,lower limb) Facial palsy Speech difficulties Swallowing difficulties Nausea/vomiting Dizziness Drowsiness Loss of consciousness Confusion Etc 		 Current or past smoker Hypertension High cholesterol Etc 	 Headache Paresthesia (upper limb, lower limb, face) Visual disturbance Neck pain Dizziness Etc 	 Weakness (upper limb,lower limb) Speech difficulties Ptosis Facial palsy Unsteadiness Confusion Vomiting Swallowing difficul Loss of consciousnes Etc 	ties ess

4.1 Clinical reasoning processes

The patient history is used to establish, and test hypotheses related to either the predisposition of vascular pathologies of the neck, or the presence of frank vascular pathologies of the neck.

It is important to understand that there are very limited diagnostic utility data for the proposed physical examination tests recommended below, and therefore, the physical therapist's aim is to use the patient history to make the best judgment on the *probability* of either contraindications to treatment or serious pathology that is present.

4.2 General considerations

Of primary importance is the fact that vascular pathologies of the neck have the potential to mimic musculoskeletal dysfunction i.e. head/neck pain in the early stages of their pathological progression (<u>Murphy, 2010</u>; <u>Taylor and Kerry, 2010</u>). A patient experiencing a vascular pathology of the neck may seek OMT for the relief of this associated pain.

Subtle signs and symptoms of the suspected pathologies should be recognised in the patient history. It is also important to recognise risk factors indicating the *potential* for neuro-vascular pathology. Information is given below to highlight the key components of the patient history in this context.

4.3 Specific vascular pathology of the neck considerations

4.3.1 Risk Factors

First and foremost, it is reiterated that the aetiology of a vascular pathology of the neck event is complex and multi-factorial. Rarely is an event associated with a single causal factor. However, there are several factors which are known to be associated with an increased risk of arterial pathologies related to either internal carotid or vertebrobasilar vessels. These should be thoroughly considered during the patient history. Recent data analysis allows some degree of understanding as to the degree of risk of certain factors. The following tables are presented in-line with retrospective and prospective study data from Thomas et al (2011, 2012, 2014, 2015), complemented and supported by other available reviews (Rubinstein et al, 2005), including the most contemporary reviews (Selwaness et al, 2013; Chauhan and Debette, 2016; Isabel et al, 2016; Selwaness et al, 2016):

Tables 2 and **3**: Risk factors for dissection and non-dissection vascular events (combining vertebrobasilar and internal carotid artery pathologies)

The percentage figures refer to the proportion of all observed patients (from the quoted studies, above) with the specified condition (e.g. 'Dissection event') who exhibit the specific risk factor stated in the first column.

As no meaningful reference class data exist with regards to these specific factors, these data are not intended to be used to judge relative risk. Rather, they indicate the known proportionality of observed features in each condition, thereby giving the clinician a developing idea of clinical patterns.

The key message from these data is the general difference between the characteristics of dissection and non-dissection events.

Risk Factor - in order of most-to-least common	Dissection event (%)
Recent trauma	40 - 64
Vascular anomaly	39
Current or past smoker	30
Migraine	23
High total cholesterol	23
Recent infection	22
Hypertension	19
Oral contraception	11
Family history of stroke	9

Table 2: Risk factors for dissection vascular events

Risk factor - in order of most-to-least common	Non-dissection event (%)
Current or past smoker	65 - 74
Hypertension	53 - 74
High total cholesterol	53
Migraine	19
Vascular anomaly	16
Family history of stroke	14
Oral contraception	9
Recent infection	9
Recent trauma (mild-moderate, which may include recent OMT)	7

Table 3: Risk factors for non-dissection vascular events

It is equally important to note that spontaneous dissection events are not associated with these historical risk factors detailed in <u>Table 3</u>. As such, clinical reasoning must recognise that an absence of risk factors does not necessarily rule out the risk of serious neuro-vascular event.

4.3.2 Presenting features of vascular pathologies of the neck

It is important for the clinician to recognise elements of a clinical pattern which may further support or refute a vascular hypothesis. Again, due to the extremely low prevalence, range of pathologies, and high variation of the presenting features of vascular pathologies of the neck, a definite clinical pattern is not possible to identify. However, certain consistent features of clinical presentation do emerge from historical case reports which are supported by observations from systematic reviews.

These features are presented in the tables below and allow the clinician to begin to understand the way in which different vascular pathologies of the neck are most likely to present. These estimates of degree are again split between dissection and non-dissection events. For the list of clinical signs, data are presented also by separating vertebrobasilar (VBA) dissection from internal carotid (ICA) dissection as there is a wide variation in clinical signs between these two pathologies.

Tables 4 and 5: Reported symptoms for dissection and non-dissection vascular events in the neck (Thomas et al, 2011; Kranenburg et al, 2017)

The percentage figures refer to *the proportion of all observed patients with the specified condition (e.g. 'Dissection vascular event') who exhibit the specific symptoms stated in the first column.* Again, these data are not intended to inform any judgement on relative risk, rather contribute to the clinician's reasoning regarding the developing clinical pattern.

Table 4: Reported symptoms for dissection events

Symptoms - in order of most-to-least common	Dissection vascular event %
Headache	81
Neck pain	57 - 80
Visual disturbance	34
Paraesthesia (Upper Limb)	34
Dizziness	32
Paraesthesia (face)	30
Paraesthesia (Lower Limb)	19

Table 5: Reported symptoms for non-dissection events

Symptoms - in order of most-to-least common	Non-dissection vascular event %
Headache	51
Paraesthesia (Upper Limb)	47
Paraesthesia (Lower Limb)	33
Visual disturbance	28
Paraesthesia (face)	19
Neck pain	14
Dizziness	7

Tables 6, 7 and 8: Reported clinical signs in the dissection and non-dissection subjects

(UL = upper limb, LL = lower limb) VBA = vertebrobasilar artery ICA = internal carotid artery (<u>Thomas et al, 2011</u>). The percentage figures refer to *the proportion of all observed patients (from the quoted studies, above) with the specified condition (e.g. 'ICA Dissection') who exhibit the specific sign stated in the first column.* The same caveat regarding relative risk applies as above. These data allow the clinician to further develop their understanding of the clinical pattern.

Table 6: Signs of VBA dissection

Signs - in order of most-to-least common	VBA Dissection %
Unsteadiness/ataxia	67
Dysphasia/dysarthria/aphasia	44
Weakness (Lower Limb)	41
Weakness (Upper Limb)	33
Dysphagia	26
Nausea/vomiting	26
Facial palsy	22
Dizziness / disequilibrium	20
Ptosis	19
Loss of consciousness	15
Confusion	7
Drowsiness	4

Table 7: Signs of ICA Dissection

Signs - in order of most-to-least common	ICA Dissection %
Ptosis	60 - 80
Weakness (Upper Limb)	65
Facial palsy	60
Weakness (Lower Limb)	50
Dysphasia/dysarthria/aphasia	45
Unsteadiness/ataxia	40
Nausea/vomiting	30
Drowsiness	20
Loss of consciousness	20
Confusion	15
Dysphagia	0.5

Table 8: Signs of non-dissection event (VBA or ICA)

Signs - in order of most-to-least common	Non-dissection vascular event %
Weakness (Upper Limb)	74
Dysphasia/dysarthria/aphasia	70
Weakness (Lower Limb)	60
Ptosis	5 - 50
Facial palsy	47
Unsteadiness/ataxia	35
Confusion	14
Nausea/vomiting	14
Dysphagia	5
Loss of consciousness	5
Drowsiness	2

Importance of observation throughout history

Signs and symptoms of serious pathology and contraindications / precautions to treatment may manifest during the patient history. This is an opportunity to observe and recognise possible red flag indicators such as gait disturbances, subtle signs of disequilibrium, upper motor neuron signs, cranial nerve dysfunction, and behaviour suggestive of upper cervical instability (e.g. anxiety, supporting head/neck) early in the clinical encounter.

4.4 Typical case histories of vascular dysfunction

Case: Typical vertebral artery dissection with ischaemic changes

A 46-year-old female supermarket worker presented for physical therapy with left-sided head (occipital) and neck pain described as "unusual". She reported a 6-day history of the symptoms following a road traffic accident. The symptoms were progressively worsening. The pain was eased by rest. She reported a history of previous road traffic accidents. Past medical history included hypertension, high cholesterol, and a maternal family history of heart disease and stroke. Cranial nerve tests for VIII, IX, and X were positive and resting blood pressure was 170/110. Two days after assessment, the patient reported an onset of new symptoms including "feels like might be sick", "throaty" and "feels faint" – especially after performing prescribed neck exercises. Two days after this, she reported a stronger feeling of nausea, loss of balance, swallowing difficulties, speech difficulties and acute loss of memory. Magnetic resonance arteriography revealed an acute vertebrobasilar stroke related to a left vertebral (extra-cranial) artery dissection.

Synopsis:

A typical background of vascular risk factors and trauma, together with a classic pain distribution for vertebral arterial somatic pain which was worsening. Positive signs (blood pressure and cranial

nerve dysfunction) were suggestive of cervical vascular pathology. Signs of vertebrobasilar ischaemia developed in a typical time period post-trauma.

Case: Vertebral artery with pain as the only clinical feature (non-ischaemic)

A friend presents to a physical therapist with a sore neck and unremitting headache. The individual complains that they "think" their "neck is out". They ask if they can have their neck manipulated to "put it back in". The headache has been present for 3-4 days and is getting worse. They note that the pain has been unrelieved by medication (paracetamol) and it appears to be of a mechanical presentation. Without taking a full history and carrying out a physical examination, the physical therapist goes ahead and manipulates the neck. The result was the individual experiencing numbness and paralysis to their left arm and hand.

Synopsis:

Investigation post incident identified an intimal tear of the vertebral artery. The key issue in this case is that the presentation was not fully assessed through a detailed history and physical examination. The warning feature from the history of worsening pain, unrelieved by medication, combined with an inadequate physical examination and limited clinical reasoning, all contributed to an unfortunate and potentially avoidable outcome.

Case: Internal carotid artery dissection

A 42-year-old accountant presents to physical therapy with a 5-day history of unilateral neck and jaw pain, as well as temporal headache, following a rear-end motor vehicle collision. There is a movement restriction of the neck and the physical therapist begins to treat with gentle passive joint mobilisations and advises range of movement exercises. The following day, the patient's pain is worse, and he has developed an ipsilateral ptosis. The patient's blood pressure is unusually high.

Synopsis:

On medical investigation, an extra-cranial dissection of the internal carotid artery was found. The patient had underlying risk factors for arterial disease, and the presentation was typical of internal carotid artery dissection, with a key differentiator being the ptosis. A dramatic systemic blood pressure response was a result of this vascular insult.

SECTION 5: PLANNING THE PHYSICAL EXAMINATION

5.1 Necessity for planning

A process of interpreting the data from the patient history and defining the main hypotheses is essential to an effective physical examination (<u>Maitland et al, 2005</u>; <u>Rushton and Lindsay, 2010</u>; <u>Petty, 2011</u>). Hypothesis generation from the history and refining, re-ranking and rejecting of these hypotheses in the physical examination is necessary to facilitate optimal clinical reasoning in OMT (<u>Jones and Rivett, 2004</u>). Therefore, careful planning of the physical examination is required.

In particular, for this Framework the possible vasculogenic (cervical arterial) contribution to the patient's presentation needs to be clearly evaluated from the patient history data.

5.2 Is any further patient history data required?

An important component of planning is the identification of any further patient history data that may be required. That is, are there any gaps in the information obtained? Is the quality of the information obtained sufficient?

5.3 Decision-making regarding the physical examination

Based upon the evaluation and interpretation of the data from the patient history, the physical therapist needs to decide:

- Are there any precautions to OMT?
- Are there any contraindications to OMT?
- What physical tests need to be included or excluded in the physical examination, with consideration of any risks associated with performing the tests?
- What is the priority for these physical tests for this specific patient? This is to inform decisions regarding the order of testing and to determine which tests should be completed at the first visit.
- Do the physical tests need to be adapted for this specific patient?

SECTION 6: PHYSICAL EXAMINATION



The purpose of the physical examination is to continue to test the vascular hypothesis generated during the history. The results of the history and physical examination serve to determine whether or not a medical referral for further investigation is warranted. Following the evaluation of the history and physical examination, a specific diagnosis is not rendered, rather the decision to refer for further vascular workup or proceed with physical therapy management is made. Due to both the rare and varied nature of the range of vascular pathologies (as per <u>Table 1</u>), data regarding the diagnostic utility of many of the recommended tests are often lacking. However, existing data support the use of conventional vascular examination (<u>Elder et al</u>, 2016) whereby the below recommended tests have moderate to good utility in supporting further investigation. The totality of the existing data evaluating *functional positional tests* for the identification of vertebral artery pathology does not support the continued recommendation of these tests (<u>Hutting et al</u>, 2018).

6.1 Blood pressure

Examination of blood pressure is an important physical measurement to inform clinical reasoning for two distinct reasons:

- 1. To assess for risk of stroke, particularly from carotid origin (<u>Selwaness et al, 2013</u>; <u>Chauhan</u> <u>and Debette, 2016</u>; <u>Isabel et al, 2016</u>; <u>Selwaness et al, 2016</u>)
- To assess for acute arterial trauma *in situ*. An increase in blood pressure may be related to acute arterial trauma, including of the internal carotid and vertebral arteries (<u>Arnold et al</u>, <u>2006</u>).

Blood pressure measurement is reliable and valid if done well (<u>Kallioinen et al, 2017</u>), and with the right equipment (<u>Myers, 2014</u>). The recently updated guidelines from the National Institute for Clinical Excellence (<u>NICE, 2016</u>) provide a useful and comprehensive resource.

Although hypertension is a strong predictor of cardiovascular disease (<u>Saiz et al, 2017</u>), interpretation of readings must be in the context of other findings, and sound clinical reasoning. Vascular disease is an interplay between many factors, of which high blood pressure is just one (albeit a consistently important one). Blood pressure is a graduated, continuous measure and as such cannot have a discreet threshold. The physical therapist should keep these points in mind during clinical decision-making. Hypertension and neck pain are only two of the many factors which influence the decision on probability of vascular pathology.

Data regarding scaled risk is clinically useful. There is a positive correlation between increased systolic and diastolic pressure and risk of stroke, which is the higher the pressure, the greater the risk. This would mean that a patient with say 190mmHg / 100mmHg is at greater risk than a patient with 160mmHg / 95mmHg. Thus, the risk is different even though they are both hypertensive. However, to reiterate, the actual utility of these data in isolation is limited as the true clinical risk is dependent on additional co-existing factors (<u>Nash, 2007</u>; <u>NICE, 2016</u>).

Further, prospective data from <u>Thomas et al, 2011</u> suggests that in a sub-population of dissection events in patients younger than 38 years, cardiovascular markers such as hypertension were not associated with the pathological event.

Patients with hypertension that have not been previously identified should be advised to discuss its implications with their primary care provider.

6.2 Neurological examination

Examination of the peripheral nerves and cranial nerves in assessing for an upper motor neuron lesion will assist in evaluating the potential for neuro-vascular conditions. Knowledge of a wide range of testing procedures is required owing to the diversity of possible clinical presentations associated with vascular pathologies of the neck. There are many useful comprehensive texts which help with developing neurological examination skills, for example <u>Fuller, 2013</u>. It is also recommended that clinicians access useful online resources for detailed descriptions of testing procedures, for example: <u>http://www.neuroexam.com/neuroexam/</u>.

Cranial nerve examination is particularly important when examining for the potential of arterial pathology within the cervical region (<u>Redekop, 2008</u>; <u>Patel et al 2012</u>). There is an increasing body of literature that details clinical cases of arterial pathology with cranial nerve involvement to inform pattern recognition. Examples include <u>Peltz & Köhrmann, 2011</u>, <u>Fujii et al, 2014</u>) and <u>Hennings et al, 2014</u>).

Although there are no specific data to support reliability and validity of examination of a complete cranial nerve examination, psychometrics from elements of cranial nerve examination and other components of neurological examination, support at least moderate reliability and validity of cranial nerve examination (for example, <u>Damodaran et al</u>, 2014; <u>Koch et al</u>, 2017; <u>Schmid et al</u>, 2009). Importantly, the absence of clinical findings in these examinations does not rule out an underlying pathology or impending dissection, and should therefore, be viewed with caution.

6.3 Examination of the carotid artery

Palpation and auscultation of the common and internal carotid arteries is possible due to the size of these vessels and their relatively superficial anatomy (<u>Pickett et al, 2011</u>). Such examination of the vertebral arteries is not able to provide meaningful information due to the small diameter of the vessel and its relatively inaccessible anatomy. There is some evidence to support that an alteration of pulse has been identified as a feature of internal carotid disease (<u>Patel et al, 2012</u>). Asymmetry between left and right vessels is considered significant. A pulsatile, expandable mass is indicative of arterial aneurysm (<u>Elder et al, 2016</u>). A bruit on auscultation (controlling for normal turbulence) is indicative of a significant finding and should be considered in the context of other clinical findings. It is possible for dissections and steno-occlusive disease of the carotid arteries to exist in the absence of aneurysm formation; therefore, a negative finding should not be used to rule out the hypothesis of arterial dysfunction. In isolation, pulse palpation is neither sensitive nor specific, but it can offer important data leading to specific diagnoses and treatment (<u>Atallah et al</u>, <u>2010</u>; <u>Pickett et al</u>, 2011).

As pulse palpation and auscultation are relatively simple psychomotor skills, training in these areas should be focused on anatomical landmarks and vessel palpation (<u>Rich, 2015</u>). Ideally, the physical therapist would aim to understand and experience both normal and pathological pulse quality. However, palpation of the internal carotid artery may induce vagal reactions (especially when palpating bilaterally) and so auscultation is advocated. Again, it is important to note that in most cases, the sensitivity or specificity of pulse examination is unknown, but in the correct clinical context it may offer important evidence leading to specific diagnoses and treatment (<u>Picket et al, 2011</u>).

6.4 Differentiation during the physical examination

Differentiation of a patient's symptoms originating from a vasculogenic cause with complete certainty is not currently possible from the physical examination. Thus, it is important for the physical therapist to understand that headache / neck pain may be the early presentation of an underlying vascular pathology, albeit on rare occasions (<u>Rivett, 2004</u>; <u>Taylor & Kerry, 2010</u>). The task for the physical therapist is to differentiate the symptoms by:

- 1. Having a high index of suspicion
- 2. Testing the vascular hypothesis.

This process of differentiation should take place from an early point in the assessment process i.e. early in the patient history. The symptomatology and history of a patient experiencing vascular pathology is what may alert the physical therapist to such an underlying problem (Rivett, 2004; <u>Taylor & Kerry, 2010</u>). A high index of suspicion of cervical vascular involvement is required in cases of acute onset neck/head pain described as "unlike any other" (<u>Taylor & Kerry, 2010</u>). It should be noted that headache and/or neck are features of a range of vascular pathologies of the neck, including dissection and non-dissection events (<u>Carolei and Sacco, 2010</u>; <u>Pollak et al, 2017</u>; <u>Lebedeva et al, 2018</u>; <u>Arca et al, 2019</u>; <u>Diamanti et al, 2019</u>).

Physical therapists may be exposed to patients presenting with the early signs of potential stroke (for example, neck pain / headache) and as such need both knowledge and awareness of the mechanisms involved. A basic understanding of vascular anatomy, haemodynamics and the pathogenesis of arterial dysfunction may help the physical therapist differentiate vascular head and neck pain from a musculoskeletal cause (<u>Rivett, 2004</u>; <u>Taylor & Kerry, 2010</u>) through interpretation of the patient history and physical examination data.

6.5 Refer on for further investigation

There are no clinical guidelines for medical diagnostic work-up in respect of vascular pathology. It is recommended that the physical therapist follows local policy in referring for further investigation. Conventionally, duplex ultrasound, magnetic resonance imaging/arteriography, and computed tomography are used in the work-up. It is recommended that physical therapists refer for immediate medical investigation when their clinical suspicion is supported by the reasoned patient history and physical examination findings suggest vascular pathology.

6.6 Additional training

It is acknowledged that some physical tests included in this section may not be in the domain of current OMT practice in some countries. It is recommended that in those countries where these tests are not within the domain of current practice that their use is considered. Any additional training required in physical examination techniques could be achieved within a physical therapist's local environment. For example, seeking local training in palpation of the common and internal carotid arteries.

SECTION 7: RISK AND BENEFIT



This section relates to those patients NOT presenting with a discrete vascular pathology, but rather with neuromusculoskeletal cranio-cervical dysfunction suitable for OMT mobilisation, manipulation and exercise intervention. Therefore, this assessment of risk and benefit relates to the risk associated with treatment, not misdiagnosis.

7.1 Framework for evaluating risk

Given that serious adverse events are (extremely) rare, it is difficult to express the association between risk and benefit as this would require a large, prospective database including (potentially) hundreds of thousands of subjects. This should be taken into consideration within this Framework.

The risks of a serious adverse event are extremely low, and in comparison to other conservative treatments, vary depending on the patient's individual clinical presentation, and in particular in the presence of known risk factors (see Sections 4.3.1 and 4.3.2). It is, therefore, the responsibility of the physical therapist to recognise and consider whether a given patient poses an increased risk and to minimise this. In the context of this Framework, there are two substantive, but related, risks:

- 1. The risk of misdiagnosis of an existing vascular pathology
- 2. The risk of serious adverse event following OMT.

Based upon empirical data, we know that misdiagnosis occurs, although difficult to assess quantitatively. The current hypothesis is, that patients presenting with neck pain and headache

who go on to develop a serious adverse event, such as a dissection, have an underlying pathology which is subsequently aggravated by treatment. These patients present with a clinical condition which appears to be musculoskeletal-related but underlying is a different pathology. It is, therefore, incumbent upon the physical therapist to mitigate such risk by considering known risk factors, signs and symptoms outlined in this Framework in as much as this is possible (Section 4). The vast majority of existing literature focuses on spontaneous dissection, of which OMT represents a small proportion. We attempt to summarise these risks and provide balance against known benefits.

7.2 Risk

The rate of vertebral artery dissections in the general population is estimated to be 0.75 – 2.9 per 100,000 (Rothwell et al, 2001; Lee et al, 2006; Boyle et al, 2008; Cassidy et al, 2008; Bejot et al, 2014; Vaughan et al, 2016; Kranenburg et al, 2017). Internal carotid artery (ICA) dissections occur 3-5 times more frequently than vertebral artery (VA) dissections in a general population (Debette et al, 2009; Debette et al, 2015). In contrast, the vast majority of serious adverse events associated with OMT involve the vertebral artery rather than the ICA.

The best data available regarding prevalence of VA dissections associated with OMT suggest the rate is approximately 0.4:100,000 to 5:100,000 patients (converted for comparison from <u>Nielsen et al, 2017</u>). The relative risk of stroke following OMT is thought to vary between 0.14 and 6.66. These estimates are so broad, they suggest both a reduced or much greater risk of stroke, which indicates a fundamental problem with definitions and identification of cases. <u>Table 9</u> shows known risk of management options for headache and neck pain. This table presents meaningfully comparable adverse events with regards to quality of life, morbidity and mortality, and uses the baseline prevalence of these events to calculate absolute risk given the intervention. Recognise that due to the very low baseline prevalence of vascular pathologies of the neck, the absolute risk of OMT is much less than that of comparable therapies.

Intervention	Adverse Event	Baseline prevalence (events occurring without any intervention) per 100,000 ^a	Absolute Risk (absolute percentage increase if intervention is given)
NSAIDS (non-	Myocardial infarct ¹	2,400	5.95% - 6.6%
specific)	Gastrointestinal bleed ²	8/	0.46%
NSAIDS	Myocardial infarct ¹	2,400	6.19% - 8.67%
(Cox-2)	Gastrointestinal bleed ²	87	0.34%
Aspirin	Bleed ^b	87	0.21% - 0.35%
Paracetamol ³	Cardiovascular events ^c	2,400 (e.g. of MI)	5.26% - 6.43%
	Gastrointestinal bleed ^d	87	0.18% - 0.27%
	Renal	1,350	3.24% - 4.30%
Cervical OMT ^e	Stroke (VBA)	0.79	0.006%

Table 9: Comparative risks of commonly used therapeutic interventions for head and neck pain

¹: Bally et al, 2018; ²: Masclee et al, 2014; ³:Zeng and Roddick, 2019 and Roberts et al, 2016

^a: based on UK government data ^b:intra- and extracranial, and gastrointestinal; ^c Including MI; cerebrovascular accidents and hypertension ^d Specifically reductions in estimated glomerular filtration rate, increases in serum creatinine concentration and the need for renal replacement therapy ^eusing a 'worse-case' scenario of lowest baseline (0.79/100,000) and highest OMT-prevalence (5/100,000) While those exposed to OMT have a potentially increased risk, data suggest that OMT in those presenting with neck pain and headache-related diagnoses does not result in an increased risk compared to a visit to the general practitioner. The underlying hypothesis is that patients present with existing or impending vascular pathology, which is subsequently aggravated by treatment (<u>Cassidy et al</u>, 2008). This might suggest that OMT, as part of treatment, does not result in vascular pathology in those who are otherwise 'healthy'. Additionally, biomechanical studies in healthy individuals suggest that OMT itself – especially if undertaken in a combination of mid-range positions - is not able to generate sufficient vessel stress or haemodynamic changes to singularly explain the onset of a dissection event (<u>Symons and Herzog</u>, 2013).

The majority of these data refer to dissection events. There is less data regarding non-dissecting events following OMT, primarily due to a lack of proper reporting. Although this is likely to be higher than dissection events (due to non-dissection pathology being generally more prevalent), it is likely that the overall absolute risk is extremely low (Swait and Finch, 2017).

7.3 Benefit

The benefits of OMT are reported in high-quality systematic reviews and meta-analyses (summarised below). OMT and exercise interventions are also included in the most recent Clinical Practice Guidelines linked to the International Classification of Functioning, Disability and Health (<u>Blanpied et al, 2017</u>). The known effectiveness of OMT and exercise for neck pain and associated disorders (headache, radiculopathy) are presented below.

ΟΜΤ

The Cochrane Review on manipulation and mobilisation for neck pain (<u>Gross et al, 2015</u>) suggests that pain, disability, and functional outcomes, provide moderate to large clinically-beneficial effects compared to inactive or active interventions. These benefits of OMT were independent of follow-up (short-, intermediate- or long-term) and duration of the neck pain (acute, sub-acute, or chronic).

<u>Lozano Lopez et al, 2016</u> reviewed trials for tension-type headache, concluding more favourable outcomes from OMT. However, data were clinically quite heterogeneous, and the methodological quality varied greatly across the trials, thus precluding any strong recommendations. Nevertheless, this conclusion is supported by the updated Bone and Joint Decade Task Force on neck pain and associated disorders (<u>Varatharajan et al, 2016</u>).

<u>Zhu et al, 2016</u> reviewed three moderate quality trials concluding cervical manipulation had an immediate effect with moderate to large effects on cervical radiculopathy compared to no treatment, placebo, or traction interventions.

Adding exercise to OMT

<u>Hidalgo et al, 2017</u> report moderate to strong quality evidence which suggests that combining different forms of OMT with exercise is better than exercise alone for people with sub-acute and chronic non-specific neck pain for the outcomes of pain, functional status, patient satisfaction and quality-of-life. About half the included trials demonstrated moderate to large clinically beneficial effects when OMT was added to the treatment at short- and medium-term follow-up. These findings were, however, not supported by Fredin and Loras, 2017 who report moderate quality evidence that the addition of OMT to exercise therapy does not provide additional benefit on pain, disability, or quality-of-life in adults with low-grade neck pain. The evidence is therefore conflicting at present.

In summary, the risks of serious adverse events following OMT are very small and related to some known risk factors. As such, risk can be somewhat mitigated via a thorough history taking and physical examination. No specific data exists for risk following exercise. The benefits of both OMT and exercise are largely positive, with many interventions resulting in moderate to large effects sizes for meaningful outcomes, with some moderate quality evidence suggesting effects are long-term.

7.4 Person-centred decision-making (refer also to Section 8: Shared Decision Making)

From an individual level, based on the background literature which highlights various risk factors for specific pathologies in specific people, the epidemiological data must be contextualised in the specific patient encounter. This is also the case for decision-making regarding choice of intervention and its predicted benefit. Again, accurate data to inform precise level of risk at an individual level is lacking, so it is not possible to develop valid clinical prediction rules for risk nor benefit.

It is again reiterated that an absolute risk judgement cannot be made by the physical therapist. The physical therapist must accept that the clinical decision is made in the absence of certainty and a decision based on a *balance of probabilities* is the aim of analysis.-When in doubt, the physical therapist should consider not intervening, and assess the chance of recovery of pain and dysfunction (assuming a musculoskeletal dysfunction).

<u>Figure 2</u> summarises the decision-making process. It is the responsibility of the physical therapist to make the best decision regarding treatment in these situations using their clinical reasoning skills (Jones and Rivett, 2004; Kerry and Taylor, 2006; Hutting et al, 2018).

Figure 2: Clinical reasoning flowchart for risk assessment prior to cervical manual therapy (<u>Hutting et al, 2018</u>)



SECTION 8: SHARED DECISION-MAKING, INFORMED CONSENT AND MEDICO-LEGAL FRAMEWORK



When engaging in decision-making with patients, it is recommended that physical therapists use a process that is patient-centered. This is defined as "care that is respectful of and responsive to individual patient preferences, needs, and values" and that ensures "that patient values guide all clinical decisions" (IOM, 2001). The Informed Medical Decision Making Foundation (Coulter and Collins, 2011) states that "Shared decision making is the process by which a health care provider communicates to the patient personalised information about the options, outcomes, probabilities, and scientific uncertainties of available treatment options and the patient communicates his or her values and the relative importance he or she places on benefits and harms. Shared decision making has been widely advocated as an effective means for reaching agreement on the best strategy for treatment." It should be noted that omission of any of the above information may invalidate the consent of the patient.

8.1 Shared decision making

Shared decision-making addresses the professional and ethical obligations of informed consent but goes beyond informed consent by recognising the patients' rights to make decisions about their care, ensuring they are adequately informed about treatment options and their consequences, providing patients with sufficient opportunity to discuss them and by jointly agreeing on a course of action for each individual (Moulton et al, 2013). Patient consent to treatment is a standard of physical therapy practice. The specific requirements of informed consent will vary from country to country according to local laws, regulatory expectations,

customs and norms. This section provides physical therapists with information on this process based on the literature and current generally accepted ethical and legal standards.

The Agency for Healthcare Research and Quality has proposed 5 steps based on the SHARE approach that will help facilitate the process of shared decision making with your patients. https://www.ahrq.gov/professionals/shareddecisionmaking/tools/tool-1/share-tool1.pdf

Step 1: **S**eek your patient's participation. Communicate that a choice exists and invite your patient to be involved in decisions.

Step 2: Help your patient explore and compare treatment options. Discuss the benefits and harms of each option.

- In seeking informed consent, the physical therapist should be confident that the patient has understood the anticipated benefit of the proposed treatment and the potential risks of treatment.
- Ensure the patient is aware of other commonly available treatments and the likely impact of no treatment.

Step 3: Assess your patient's values and preferences. Take into account what matters most to your patient.

• Use verbal communication as part of a dialogue with the patient which will allow for individual patient characteristics to be addressed in the consent process. Accompanying written information may be used to support the process (<u>Dagenais and Haldeman, 2012</u>).

Step 4: **R**each a decision with your patient. Decide together on the best option and arrange for a follow-up appointment.

• It is the responsibility of the physical therapist to ensure that the patient fully understands all of the information that has been provided.

Step 5: Evaluate your patient's decision. Support your patient so the treatment decision has a positive impact on health outcomes.

• It is also the responsibility of the physical therapist to provide further information requested by the patient and to answer all questions asked by the patient in a manner that the patient considers satisfactory (Wear, 1998).

8.2 Application to individual countries

Given the international audience of this document, physical therapists are advised to check local laws and health regulations within their country affecting the informed consent process. Informed consent can be defined as "the voluntary and revocable agreement of a competent individual to participate in a therapeutic or research procedure, based on an adequate understanding of its nature, purpose and implications" (Sim, 1986). The process of informed consent includes the following components: the types of consent, the requirements of disclosure of information by the therapist, how it is obtained, and the requirements of record keeping of the informed consent process. Individual practitioners will need to consider risk associated with each patient and adopt an approach to consent which includes sharing information material to the patient and considering inherent risks associated with the patient's presentation and the interventions that the practitioner is advocating. Given the need for an individualised approach that is material to each patient, a template or standardised form for receiving consent is ill advised.

8.3 Types of consent

Two different processes when considering consent are possible and are introduced here. It is recommended that individuals consult the references for greater detail of each process as well as considering local regulatory expectations.

- 1. Express Consent: Given explicitly either in writing or verbally. This is recommended when initially seeking informed consent for a treatment intervention, as it provides the clearest form of consent and often fulfils legal obligations.
- 2. Implied Consent: Consent is not explicitly given in writing or verbally rather it is taken by the clinician as implied by the patient's actions or lack thereof. Due to its subjective nature it is recommended that this type of consent, if relied upon at all, forms part of the process of care subsequent to express consent (Fenety et al, 2009).

Whatever the form of the consent, it should be given voluntarily and without undue influence from the therapist, and once the patient has given consent they can withdraw their consent at any time during treatment and this should be made clear as part of the consent process.

8.4 Obtaining informed consent

It is recommended that informed consent be obtained after a process of shared decision-making. Informed consent is obtained when a patient explicitly indicates either verbally or in writing, following adequate disclosure of information about the proposed procedure, and their consent to proceed with the treatment. Consent must be obtained before treatment begins. Asking the patient for consent while treatment is in progress may adversely influence the patient's decisionmaking and is not recommended (Jensen, 1990).

For changes in treatment (introducing a different type of intervention or in response to a change in diagnosis), the full process of informed consent must be undertaken, and consent explicitly obtained verbally or in writing.

For continuation of the same treatment, it is recommended that the consent process be revisited in discussion with the patient's wishes and expectations. This does not necessarily entail the full disclosure of information that was required the first time. Agreement by the patient verbally to the ongoing use of an intervention in most cases would be sufficient. If, however, in follow up discussion with the patient, you perceive that there is a lack of understanding of the previously disclosed information, it is recommended that the full process of disclosure of information be revisited.

8.5 Recording of informed consent

It is recommended that the disclosure of information, the obtaining of informed consent and a brief note of what was discussed be recorded in a standardised manner in the patient's clinical record. For each treatment, it is recommended that the obtaining of informed consent be recorded each time. Clinicians should check and align with local regulatory expectations.

SECTION 9: SAFE OMT PRACTICE

9.1 Range of techniques recommended as good practice

OMT practice encompasses a wide range of techniques ranging from patient activated forces to therapist activated forces. OMT is integrated into the overall management strategy of patient multimodal care. Reports of patient harm from OMT in the cervical region have typically been in the practice of cervical manipulation. The following are reasonable considerations for the physical therapist during the selection and application of cervical manipulation (<u>Rivett, 2004</u>; <u>Childs et al, 2006</u>:

- The principle of all techniques is that minimal force should be applied to any structure within the cervical spine i.e. low amplitude, short lever thrusts.
- Patient safety and comfort form the basis of appropriate examination and treatment technique selection. Respect patient autonomy and preference for particular therapeutic approaches.
- Cervical manipulation techniques should be comfortable to the patient.
- Examination and treatment techniques should be used cautiously at the end of range of cervical movement, particularly extension and rotation. Additionally, it is recommended that rotational manipulations be performed in the mid-range of overall cervical rotation by taking advantage of coupled movements of side flexion and slight compression to target the selected level.
- There is flexibility in the choice of the patient's position using the principles that the patient needs to be comfortable, and that the physical therapist needs to be able to receive feedback. The use of the supine lying position with the patient's head supported on a pillow is encouraged. This position allows the physical therapist to monitor facial expressions, eye features, and to communicate with the patient easily.
- Positioning the patient in the pre-manipulative test position prior to a manipulation in order to evaluate patient comfort and any unusual or unexpected response.
- The patient response to all cervical spine movements is continuously monitored.
- The skills of the physical therapist may be a limitation for the selection of manipulation as a treatment technique, even though clinical reasoning may suggest manipulation is the best choice. In this situation, a risk may be introduced due to limited clinical skills and it would therefore be a responsible decision to not use manipulation. The self-evaluative skills of the physical therapist in assessing their ability to perform the desired technique safely and efficiently are therefore important. Referral to a colleague suitably qualified/trained in the desired manipulative technique may be appropriate.

9.2 Alternative approaches to direct cervical treatment

Emerging pain sciences suggests that the effects of manual techniques (such as mobilisation and manipulation) on pain may be largely neurophysiological in nature and not limited to the direct influence of a particular spinal motion segment. Furthermore, clinical trials have reported that thoracic spine manipulation results in short term improvements in perceived levels of cervical pain, ranges of motion, and disability in patients with mechanical neck pain (<u>Cleland et al, 2005</u>; <u>Cleland et al, 2007</u>; <u>Cleland et al, 2007</u>; <u>Krauss et al, 2008</u>; <u>González-Iglesias et al, 2009</u>), although the mechanism by which this occurs is not known.

9.3 Frequency of treatment

Frequency of treatment will vary depending on the individual and injury in question. Current evidence supports a multimodal approach which includes manual therapy, education, advice and exercise when managing a patient's neck pain and headache (<u>Bussieres et al, 2016</u>; <u>Blanpied et al, 2017</u>).

9.4 Minimising end-range cervical interventions

End of range movements are known to stress the cervical arteries and potentially neural structures. Thus, avoidance of these positions is recommended during diagnostic and range of motion testing (<u>Herzog et al, 2012</u>).

9.5 Force minimisation

OMT techniques used to treat the cervical region should be applied in a controlled, comfortable manner in mid ranges of cervical movement in order to reduce the potential stress on vascular and neurological structures. The influence of the head and cervical spine segments not included in the manipulation can be used to direct loads to the targeted segment. Vetebral artery strains measured in cadavers during high velocity, low amplitude cervical spine manipulation are significantly smaller than those obtained with diagnostic and range of motion testing (Herzog et al, 2012).

9.6 Monitor for any patient safety incidents

Monitoring the patient for response to treatment and any harmful incidents is a continual process throughout treatment, at the conclusion of treatment, and prior to a new treatment session. Verbal and physical examination can be carried out while performing a treatment technique through monitoring physical body behaviour, facial expression, muscle tone, and verbal communication / responsiveness. However, the ultimate standard of response should be based on the change in a patient's reported outcome measure (e.g. Neck Disability Index, Global Rating of Change, etc).

9.7 Emergency management of a harmful incident

As a health professional, the physical therapist is expected to act swiftly and judiciously when confronted with an emergency situation. A plan of action should be devised, available, and operational for effective management of a safety incident or adverse reaction. In the unlikely event that a patient becomes unresponsive during any aspect of physical therapy care, the physical therapist should immediately implement an emergency action plan for cardiopulmonary resuscitation. A local accepted procedure for emergency should be initiated, such as calling an ambulance. Training in cardiopulmonary resuscitation should be completed on a regular basis.

SECTION 10: TEACHING OMT FOR THE CERVICAL REGION

10.1 Framework for those teaching cervical assessment and management

A variety of manual techniques are used as part of the examination and management of cervical spine related presentations. The majority of reports of patient harm from OMT in the cervical region have typically been in the practice of cervical manipulation, however, the entire continuum of patient care should be informed by knowledge of the neurovascular structures of the cervical spine. The teaching of OMT for the cervical region requires instructors to have a thorough understanding and proficiency in:

- assessment for pathology that is outside the usual physical therapist's scope of practice
- understanding of the implications of findings from musculoskeletal diagnostic imaging
- the use of tools to determine baseline status, treatment outcomes, and prognostic indicators
- neuromusculoskeletal examination procedures including sensory-motor function, vascular status and ligamentous integrity
- palpatory skills of the cervical region
- differential diagnosis and clinical reasoning.

Practical skills teaching and examination of competency are necessary components of manipulation instruction at all levels of physical therapy education programmes. Based on the available literature, instruction should particularly emphasise the continuum of the amplitude, velocity, patient comfort, and sensitivity and specificity of handling during manipulation tutoring (<u>Flynn et al, 2006</u>; <u>Mintken et al, 2008</u>). This continuum reflects the excellence in manual skills to enable physical therapists to perform manipulation efficiently and effectively.

Practical skills teaching and examination of competency involves students practicing cervical techniques on their peers (<u>Theomes-de Graaf et al, 2017</u>). Instruction should therefore include a process of evaluation and screening of peers to act as models for OMT technique practical sessions.

10.2 Recommended qualifications for instructors

Educational qualifications for first professional (entry-level or undergraduate) and postprofessional (post-licensure or postgraduate) training instructors vary internationally. However, recommended attributes of instructors responsible for teaching the cognitive and psychomotor skills used in cervical manipulation are described below (these are provided to guide educational programmes when planning instructor development processes and resources). Importantly, instructors should:

- Be actively engaged in clinical practice within the area of their expertise and instruction and have an appropriate amount of relevant clinical experience.
- Possess teaching experience that preferably includes mentoring or formal training in adult educational processes and methods.
- Apply evidence-based concepts within both their clinical practice and teaching.
- Have been trained and examined in didactic and psychomotor aspects of manual therapy, including manipulation, or the equivalent.
- Have completed a formally accredited (by an IFOMPT recognised national body or similar professional body) post-professional programme in manual therapy.
- Regularly undertake ongoing professional education and training relevant to cervical manipulation and stay updated on the latest available evidence.

The instructor should be appropriately qualified to ensure that the student can:

- Demonstrate competency in both performing and interpreting examination procedures appropriate for physical therapy management and prevention of musculoskeletal disorders of the cervical spine.
- Demonstrate competency in both the technical application and interpretation of response to manipulative interventions utilised in the management of musculoskeletal disorders of the cervical spine.

Furthermore, specific safety precautions associated with manipulation in general, and particularly manipulation in the cervical spine are a necessary component of instruction. Students should be competent in making decisions regarding when to utilise manipulation, and when to refer to a physician or other practitioner based on safety or other medical concerns.

10.3 Student model's considerations

Development of OMT skills may be associated with some potential risk (<u>Thoomes-de Graaf et al</u>, <u>2017</u>). A clear focus on safe practice should be implemented in laboratory instruction. This may include the following: 1) appropriate screening and open disclosure prior to laboratory activities; 2) presenting the benefits and risk profile for this region; 3) having students practice the hand dexterity skills in an appropriately progressed manner which allows faculty to assess the precision and delivery of each student; 4) provide the opportunity for continuous and ongoing assessment and monitoring i.e. reassessing risk for the student population; and 5) insuring that all student models take on the responsibility to control their degree of practical involvement and engagement i.e. at any point can ask for faculty assistance.

10.4 Educational resources

When teaching manipulation techniques in the cervical region it is essential to present techniques which are easy to understand and implement in the clinical setting. There is a vast array of physical therapy and medical resources that describe the management of cervical spine disorders, including those related to manual and manipulative therapy. Physical therapists should be well versed in current best evidence for managing cervical disorders. This document does not endorse any specific philosophy or approach to manipulation, however, the physical therapist is responsible for choice, application, and monitoring of responses to manipulative techniques following the principles outlined in this document.

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