WHEREAS, the House of Delegates referred H-333-A/2014 OSTEOPATHIC MANIPULATIVE TREATMENT (OMT) OF THE CERVICAL SPINE to the Bureau of Osteopathic Clinical Education and Research (BOCER) to review and update as some of the information provided in support of the position statement was out of date and needed citations; and

WHEREAS, the BOCER reviewed referred resolution H-333 - A/2014 and developed an updated position statement; now, therefore be it

RESOLVED, that the Bureau of Osteopathic Clinical Education and Research recommend that the following policy be REAFFIRMED as AMENDED:

H333-A/14 OSTEOPATHIC MANIPULATIVE TREATMENT (OMT) OF THE CERVICAL SPINE

The American Osteopathic Association, in the hopes of advancing the science of osteopathic medicine adopts the following position (2004; reaffirmed 2009 [Editor’s note: This policy has been referred to as some of the information is out of date and needs citations - 2014]).

(These recommendations are provided for osteopathic educators and physicians making decisions regarding the instruction of cervical spinal manipulation and the care of patients. As such, they cannot substitute for the individual judgment brought to each clinical situation by a patient's physician. Like all reference resources, they reflect the best understanding of the science of medicine at the time of publication, but they should be used with the understanding that continued research is needed.)

AMERICAN OSTEOPATHIC ASSOCIATION OSTEOPATHIC MANIPULATIVE TREATMENT OF THE CERVICAL SPINE

Background and Statement of Issue

There has recently been an increasing concern about the safety of cervical spine manipulation. Specifically, this concern has centered on devastating negative outcomes such as stroke. This paper will present the evidence behind the benefit of cervical spine manipulation, explore the potential harm and make a recommendation about its use.

Benefit

Spinal manipulation has been reviewed in meta-analysis published as early as 1992, showing a clear benefit for low back pain. There is less available information in the literature about manipulation in regards to neck pain and headache, but the evidence does show benefit. There have been at least 12 randomized controlled trials of manipulative treatment of neck pain.
Some of the benefits shown include relief of acute neck pain, reduction in neck pain as measured by validated instruments in sub-acute and chronic neck pain compared with muscle relaxants or usual medical care. There is also short term relief from tension-type headaches. Manipulation relieves cervicogenic headache and is comparable to commonly used first line prophylactic prescription medications for tension-type headache and migraine. Meta-analysis of 5 randomized controlled trials showed that there was a statistically significant reduction in neck pain using a visual analogue scale.

Harm

Since 1925, there have been approximately 275 cases of adverse events reported with cervical spine manipulation. It has been suggested by some that there is an under-reporting of adverse events. A conservative estimate of the number of cervical spine manipulations per year is approximately 33 million and may be as high as 193 million in the US and Canada. The estimated risk of adverse outcome following cervical spine manipulation ranges from 1 in 400,000 to 1 in 3.85 million manipulations. The estimated risk of major impairment following cervical spine manipulation is 6.39 per 10 million manipulations.

Most of the reported cases of adverse outcome have involved “Thrust” or “High Velocity/Low Amplitude” types of manipulative treatment. Many of the reported cases do not distinguish the type of manipulative treatment provided. However, the risk of a vertebrobasilar accident (VBA) occurring spontaneously, is nearly twice the risk of a VBA resulting from cervical spine manipulation. This includes cases of ischemic stroke and vertebral artery dissection.

A concern has been raised by a recent report that VBA following cervical spine manipulation is unpredictable. This report is biased because all of the cases were involved in litigation. The nature of litigation can lead to inaccurate reporting by patient or provider. However, it did conclude that VBA following cervical spine manipulation is “idiosyncratic and rare”. Further review of this data showed that 25% of the cases presented with sudden onset of new and unusual headache and neck pain often associated with other neurologic symptoms that may have represented a dissection in progress.

In direct contrast to this concern of unpredictability, another recent report states that cervical spine manipulation may worsen preexisting cervical disc herniation or even cause cervical disc herniation. This report describes complications such as radiculopathy, myelopathy, and vertebral artery compression by a lateral cervical disc herniation. The authors concluded that the incidence of these types of complications could be lessened by rigorous adherence to published exclusion criteria for cervical spine manipulation. The current literature does not clearly distinguish the type of provider (i.e. MD, DO, DC or PT) or manipulative treatment (manipulation vs. mobilization) provided in cases associated with VBA. This information may help to understand the mechanism of injury leading to VBA, as there are differences in education and practice among the various professions that utilize this type of treatment.

Comparison of Alternative Treatments

NSAIDs are the most commonly prescribed medications for neck pain. Approximately 13 million Americans use NSAIDs regularly. 81% of GI bleeds related to NSAID use occur without prior symptoms. Research in the United Kingdom has shown NSAIDs will cause 12,000 emergency admissions and 2,500 deaths per year due to GI tract complications. The annual cost of GI tract complications in the US is estimated at $3.9 billion, with up to 103,000 hospitalizations and at least 16,500 deaths per year. This makes GI toxicity from NSAIDs the 15th most common cause of death in the United States.
Epidural steroid injection is a popular treatment for neck pain. Common risks include subdural injection, intrathecal injection and intravascular injection. Subdural injection occurs in ~1% of procedures. Intrathecal injection occurs in ~ 0.6-10.9% of procedures. Intravascular injection is the most significant risk and occurs in ~2% of procedures and ~8% of procedures in pregnant patients. Cervical epidural abscess is rare, but has been reported in the literature.

Provocative Tests

Provocative tests such as the DeKline test have been studied in animals and humans. This test and others like it were found to be unreliable for demonstrating reproducibility of ischemia or risk of injuring the vertebral artery.

Risk Factors

VBA accounts for 1.3 in 1000 cases of stroke, making this a rare event. Approximately 5% of patients with VBA die as a result, while 75% have a good functional recovery. The most common risk factors for VBA are migraine, hypertension, oral contraceptive use and smoking. Elevated homocysteine levels, which have been implicated in cardiovascular disease, may be a risk factor for VBA.

A study done in 1999 reviewing 367 cases of VBA reported from 1966-1993 showed 115 cases related to cervical spine manipulation; 167 were spontaneous, 58 from trivial trauma and 37 from major trauma.

Complications from cervical spine manipulation most often occur in patients who have had prior manipulation uneventfully and without obvious risk factors for VBA. “Most vertebrobasilar artery dissections occur in the absence of cervical manipulation, either spontaneously or after trivial trauma or common daily movements of the neck, such as backing out of the driveway, painting the ceiling, playing tennis, sneezing, or engaging in yoga exercises.” In some cases manipulation may not be the primary insult causing the dissection, but an aggravating factor or coincidental event.

It has been proposed that thrust techniques that use a combination of hyperextension, rotation and traction of the upper cervical spine will place the patient at greatest risk of injuring the vertebral artery. In a retrospective review of 64 medical legal cases, information on the type of manipulation was available in 39 (61%) of the cases. 51% involved rotation, with the remaining 49% representing a variety of positions including lateral flexion, traction and isolated cases of non-force or neutral position thrusts. Only 15% reported any form of extension.

Conclusion

Osteopathic manipulative treatment of the cervical spine, including but not limited to High Velocity/Low Amplitude treatment, is effective for neck pain and is safe, especially in comparison to other common treatments. Because of the very small risk of adverse outcomes, trainees should be provided with sufficient information so they are advised of the potential risks. There is a need for research to distinguish the risk of VBA associated with manipulation done by provider type and to determine the nature of the relationship between different types of manipulative treatment and VBA.

Therefore, it is the position of the American Osteopathic Association that all modalities of osteopathic manipulative treatment of the cervical spine, including High Velocity/Low Amplitude, should continue to be taught at all levels of education, and that osteopathic physicians should continue to offer this form of treatment to their patients.
Background and Statement of Issue

Treating chronic pain continues to be an important health issue for osteopathic physicians. Chronic pain affects over 100 million Americans over the age of 18 and negatively impacts their quality of life. In addition, it costs $600 billion a year in healthcare costs and loss of productivity. Back and neck pain are two leading causes of chronic pain and they are amongst the leading causes of people living with disabilities in the United States (U.S.) as well as worldwide. More specifically, back and neck pain are ranked in the top 8 diseases and injuries in the U.S. regarding years lived with disability (YLDs) and in the top 6 globally. Cervical spine manipulation is one option for treating back and neck pain.

Concerns continue to arise regarding the safety of cervical spine manipulation. Specifically, concerns center on the potential development of serious adverse events such as stroke and cervical artery dissection after spinal manipulation. Since spinal manipulation is an option available to osteopathic physicians to incorporate into the care of their patients, it is important to examine these concerns and develop a position on the issue. This paper will present the evidence behind the benefit of cervical spine manipulation, explore the potential harms and make a recommendation about its use.

Benefit

Spinal manipulation has been reviewed in various systematic reviews and meta-analyses over the past three decades. The majority of the studies conducted on spinal manipulation focus on low back pain for which the evidence has shown spinal manipulation has clear benefits. For neck pain, however, there are fewer studies and the findings vary, but there is some evidence that conclude spinal manipulation benefits patients presenting with neck pain. This evidence indicates that the benefits of spinal manipulation include relief of acute neck pain, and reduction in neck pain as measured by validated instruments in sub-acute and chronic neck pain compared with muscle relaxants or usual medical care. Bronfort et al. specifically concluded that for patients with chronic neck pain, there is moderate evidence that (1) manipulation and mobilization are superior to general practitioner management in the short term, (2) high-technology exercise results in more pain improvement than manipulation in the long term for a mix of patients with acute and chronic pain, and (3) mobilization is superior to physical therapy and general medical care and similar to manipulation in both the short and long term.

Benefits of spinal manipulation for areas beyond the low back and neck include short-term relief from tension-type headaches. Manipulation relieves cervicogenic headache and is comparable to commonly used first line prophylactic prescription medications for tension-type headache and migraine.

Harm

Overall

The literature presents varying conclusions on the harms of spinal manipulative treatment (SMT). In a 2017 review of risks associated with spinal manipulation, 46% percent of the studies reviewed found spinal manipulation to be safe, 42% percent were neutral (did not find harm/benefit); and the remaining 12% percent concluded that spinal manipulation was unsafe because of the possibility of serious adverse events. Nevertheless, the existence of any adverse effect should not be trivialized.

Studies have noted that there are two types of adverse effects as a result of SMT. The first type is considered to be mild adverse events that are short-term and non-serious such as dizziness, fatigue, and muscle soreness/discomfort. These side effects occur in 23-83% of patients.
The second type of adverse events is more serious and includes cervical artery dissection, stroke, spinal cord injuries, and other serious conditions outcomes related to vertebrobasilar accidents (VBAs). Currently, much of the literature discusses vertebrobasilar insufficiency or vertebralbasilar ischemia (VBI) which is a type of VBA and is often determined to be the link to the more serious adverse events. Nonetheless, serious adverse events are seen as a rarity, and it is estimated that they occur in the range of every 20,000 to 250,000,000 manipulation performed.\textsuperscript{18,27}

Most of the reported cases of adverse outcomes have involved thrust or High Velocity/Low Amplitude (HVLA) types of manipulative treatment.\textsuperscript{18,25} Unfortunately, many of the reported cases do not distinguish the type of manipulative treatment provided.

VBAs
VBAs account for 1.3 in 1000 cases of stroke, making them a rare event. Approximately 5% of patients with a VBA die as a result, while 75% have a good functional recovery.\textsuperscript{28} The most common risk factors for VBAs are migraine, hypertension, oral contraceptive use and smoking.\textsuperscript{26} Elevated homocysteine levels, which have been implicated in cardiovascular disease, may be a risk factor for a VBA.\textsuperscript{30}

The risk of a VBA occurring spontaneously, is nearly twice the risk of a VBA resulting from cervical spine manipulation.\textsuperscript{14} A study done in 1999 reviewing 367 cases of VBA reported from 1966-1993 showed 115 cases related to cervical spine manipulation; 167 were spontaneous, 58 from trivial trauma and 37 from major trauma.\textsuperscript{31}

A study in 2002 conducted by Haldeman et al., reported that a VBA following cervical spine manipulation was unpredictable.\textsuperscript{14} The authors, however, concluded that a VBA following cervical spine manipulation was “idiosyncratic and rare”. Further review of the data showed that 25% of the cases presented with sudden onset of new and unusual headache and neck pain often associated with other neurologic symptoms that may have represented a dissection in progress.\textsuperscript{32}

Complications from cervical spine manipulation most often occur in patients who have had prior manipulation uneventfully and without obvious risk factors for a VBA.\textsuperscript{14} “Most vertebrobasilar artery dissections occur in the absence of cervical manipulation, either spontaneously or after trivial trauma or common daily movements of the neck, such as backing out of the driveway, painting the ceiling, playing tennis, sneezing, or engaging in yoga exercises.”\textsuperscript{21} In some cases manipulation may not be the primary culprit for causing the dissection, but an aggravating factor or coincidental event.\textsuperscript{32}

It has been proposed that thrust techniques that use a combination of hyperextension, rotation and traction of the upper cervical spine will place the patient at greatest risk of injuring the vertebral artery. In a retrospective review of 64 medical legal cases, information on the type of manipulation was available in 39 (61\%) of the cases. Fifty-one percent (51\%) involved rotation, with the remaining 49\% representing a variety of positions including lateral flexion, traction and isolated cases of non-force or neutral position thrusts. Only 15\% reported any form of extension.\textsuperscript{32}

Cervical Artery Dissection (CAD)
CAD occurs at a rate of 2.9 per 100,000 individuals every year in the general population, and a large majority (89\%) of the individuals diagnosed with CAD have no symptoms or no significant disability that prohibits them from being productive within the following three months of the event.\textsuperscript{33} Among those with symptoms, headaches and neck pain are the
predominant symptoms for CAD. This creates a dilemma for physicians because cervical spine
manipulation is often sought to treat these medical issues. Thus, it is difficult to determine if
manipulation causes CAD or if CAD existed at the time of treatment.

Limitations of Studies and Concerns with Pre-manipulation Screening
Due to the design of studies (case reports or retrospective surveys), infrequent reporting of
adverse events, and the rare occurrence of many of the more serious complications, it is
difficult to determine a causal relationship between SMT and the serious adverse effect.7,33 Thus
the lingering question of whether or not pre-existing pathologies may have existed prior to the
patient receiving SMT remains.18,26,34

In Malone et al., the authors reported that cervical spine manipulation may worsen preexisting
cervical disc herniation or even cause cervical disc herniation.26 This report describes
complications such as radiculopathy, myelopathy, and vertebral artery compression by a lateral
cervical disc herniation. The incidence of these types of complications could be lessened by
rigorous adherence to published exclusion criteria for cervical spine manipulation.26,35

Another noteworthy point to highlight is that the literature does not clearly distinguish the type
of provider (i.e. M.D., D.O., D.C. or P.T.) or manipulative treatment (manipulation vs.
mobilization) provided in cases associated with serious adverse effects. This information may
help to understand the mechanism of injury leading to serious adverse effects, as there are
differences in education and practice among the various professions that utilize this type of
treatment. It is duly noted that the osteopathic approach strictly limits the “thrust”, which is
more commonly referred to as “impulse” in osteopathic practicums, to the physiologic barrier
as opposed to the chiropractic approach may extend to the paraphysiologic space.

Additionally, pre-manipulation screening tools, that might be used to identify a patient’s risk for
VBA and cervical artery dissection have been widely criticized because they have been found to
be unreliable and difficult to validate.26,29,36-43 These studies have examined the DeKleyn’s test
and others like it and determined the tests are unreliable for demonstrating reproducibility of
ischemia or risk of injuring the vertebral artery.36-43 For this reason, researchers and groups such
as the Bone and Joint Decade Task Force on Neck Pain and Its Associated Disorders
recommend that all health care providers conduct a thorough patient history, physical
examination and patient self-assessment to rule out certain pre-existing conditions.43,44

Alternative Treatments
Non-steroidal anti-inflammatory drugs (NSAIDs)
NSAIDS such as ibuprofen and aspirin are the most commonly prescribed medications for
neck pain. More than 30 million people worldwide use NSAIDs regularly.45 In fact, 5% of all
medical visit outcomes in the U.S. include a prescription for NSAIDS.46 NSAIDs offer
temporary relief, but long-term use, gender, age, strength of dose as well as consumption of
multiple medications simultaneously may be associated with serious risks affecting the
gastrointestinal (GI), renal and cardiovascular systems.47,48 Eighty-one percent (81%) of GI
bleeds related to NSAID use occur without prior symptoms.49 Research in the United Kingdom
has shown NSAIDs will cause 12,000 emergency admissions and 2,500 deaths per year due to
GI tract complications.30 The annual cost of GI tract complications in the U.S. is estimated at
$3.9 billion, with up to 103,000 hospitalizations and at least 16,500 deaths per year therein
making GI toxicity from NSAIDs the 15th most common cause of death in the United States.49

Epidural steroid injections
Epidural steroid injections (ESIs) are a popular treatment for neck pain.\textsuperscript{50} Complications to ESIs generally occur because of needle placement or drug administration. Common risks associated with needle placement include subdural injection, intrathecal injection and intravascular injection.\textsuperscript{51} Subdural injection occurs in ~ 1% of procedures, intrathecal injection occurs in ~ 0.6-10.9\% of procedures, and intravascular injection, the most significant risk, occurs in ~ 2% of procedures.\textsuperscript{51} Other risks include cervical epidural abscess, dural puncture, spinal cord trauma, infection, hemotoma, nerve damage, vascular injury and cerebral vascular or pulmonary embolus.\textsuperscript{52,53} Complications that may arise from drug administration include osteoporosis, Cushing’s syndrome, avascular necrosis of bone, and steroid myopathy. While complications due to needle placement or administration of steroids are rare, they have been reported in the literature.\textsuperscript{52,53}

Conclusion

Osteopathic manipulative treatment of the cervical spine, including but not limited to HVLA treatment, is effective for low back and neck pain and is safe. Because of the rarity of serious adverse events, trainees and practicing physicians should be provided with sufficient information so they are advised of the potential risks and able to communicate the potential risks to their patients. Prior to recommending cervical spine manipulations, physicians should conduct a thorough patient exam and medical history review to try to identify any preexisting conditions that may indicate the patient is at risk for a serious adverse event. Additionally, it is recognized that there is a need for research to distinguish the risk of VBA and CAD associated with manipulation done by specific provider types as well as research to determine the nature of the relationship between the different types of manipulative treatment and VBA and CAD.

It is the position of the American Osteopathic Association that all modalities of osteopathic manipulative treatment of the cervical spine, including HVLA, should continue to be taught at all levels of education, and that osteopathic physicians should continue to offer this form of treatment to their patients. Physicians should use a combination of medical history reviews and physical exams, diagnostic studies, and best judgment to determine if a patient has any preexisting conditions that place the patient at risk of suffering a serious adverse event.

Special Acknowledgements

In crafting the updated Position Statement, the Bureau of Osteopathic Clinical Education and Research (BOCER) would like to thank the Osteopathic Manipulation Medicine and Osteopathic Manipulative Treatment (OMM/OMT) Research Task Force for its input, and a special thank you to Hollis King, DO, PhD, who served as an outside contributor.

References


Explanatory Statement:

ACTION TAKEN _____________________

DATE ______________________________