

Tremayne-Lloyd T, Srebrolow G. Research ethics approval for human and animal experimentation: Consequences of failing to obtain approval – including legal and professional liability JCCA 2007; 51(1):56–60.

To the Editor:

We read with interest the article coauthored by Ms. Tracey Tremayne-Lloyd and Dr. Gary Srebrolow, *Research ethics approval for human and animal experimentation: Consequences of failing to obtain approval – including legal and professional liability* 2007; 51(1):56–60.

The article contained many valid points, and highlighted the importance of practitioners obtaining free and informed consent in health research.

We wish to draw attention to several points made in the article.

The authors state “REB reviews are generally only conducted where the test will be funded by an organization that requires ethics review.” They then suggest that “If an investigator is able to fund research by alternative means, it is possible to avoid a REB review altogether.”

The first statement is misleading. While ethics review may be required by some funding agencies and not others, such reviews are a mandatory component of the research process at most public institutions (e.g., universities, medical institutions) where the research will be carried out. It is the nature of the research, and not the source of funding, that mandates ethics review. Indeed, research not requiring funding may still need to undergo ethics review. Consistent with the Tri-Council Policy Statement, such institutions require that all research protocols involving humans undergo review and approval by an REB before they are initiated. Furthermore, privacy legislation in many provinces requires that researchers who want to use clinical information for research purposes obtain the consent of their patients or request a waiver of consent from an appropriately constituted REB.

The second statement in this paragraph suggesting that researchers can take steps to avoid REB review altogether is very worrisome. REBs exist to ensure scientific research is held to a high ethical standard and respect for human dignity is maintained. Peer review of the ethical integrity of research protocols is a safeguard that serves to protect dignity and rights of research subjects and should not be viewed as a burden or impediment to the

conduct of research. Chiropractic researchers have a fiduciary relationship to their clients as research subjects and, as members of the scholarly community, have a responsibility to foster integrity in research. These obligations demand a commitment to ethical research practice that should encourage REB review.

REBs operate to protect the interests of institutions that support the research, in addition to protecting the interests of human research subjects. Although, as described by the authors, the disciplinary power of REBs is typically limited to financial recourse, allegations of ethical misconduct, or failure to obtain ethics approval, may be referred for management under an institution’s provisions for academic or professional misconduct. Individuals may face direct sanctions ranging from reprimand through to termination of employment.

Finally, the authors outline numerous avenues that researchers may face liability. Submission of research protocols to an REB for review provides a means of catching potential ethical transgressions before they become a liability.

Respectfully submitted,

Stacey Page, PhD
Member, Conjoint Health Research Ethics Board, University of Calgary

Glenys Godlovitch, LLB, PhD
Chair, Conjoint Health Research Ethics Board, University of Calgary

To the Editor in reply:

I am writing in response to the letter received from Stacey Page, PhD and Glenys Godlovitch, LLB, PhD, regarding the article I authored with Tracey Tremayne-Lloyd entitled: *Research ethics approval for human and animal experimentation: Consequences of failing to obtain approval – including legal and professional liability*. I would like to thank them for their comments and interest, but wish to provide clarification on some of the points they raise.

The purpose of our article was to provide information about legal liability which ensues “if” experiments are able to avoid being subject to a Research Ethics Board

(REB). We are not suggesting, condoning or counselling the avoidance of REB's, but pointing out that if an experimenter is able to bypass the involvement of a REB, they remain accountable for their actions and could face consequences by way of professional, civil or criminal liability.

We agree that REBs play an important role in safeguarding experiments and research, but wish to point out that REBs are only required at most (and not all) public institutions. Therefore, it is important for all researchers to be aware of the legal liability they face, even if they are not subject to a REB.

Whether an experiment should or should not be subject to a REB is an issue for another article.

Gary Srebrolow, LLB, DDS, BSc

Hart J. Structural problems of the spine do not necessarily require intervention. JCCA 2007; 51(1):8-13 (Commentary).

To the Editor:

In response to the Commentary by Dr. John Hart in the March 2007 issue I must quickly state that I am amazed by the lack of respect for proper function and health and the development of symptoms and disease. Any disease is a process that takes time. So Dr. Hart, what would you do if your medical doctor told you you had high blood pressure and elevated cholesterol in the absence of symptoms?

Would you really wait for your first heart attack before you take care of it? For the same reason, I do not wait for my patients to come to my office in pain before I correct their dysfunctions that we can now easily measure scientifically. In chiropractic I care for patients. I hope you do to.

Martin Jolicoeur BSc, DC
Rosemere, Quebec

To the Editor in reply:

I would like to thank Dr. Jolicoeur for his response to my article.¹ In reply I would answer that if a medical doctor told me I had high blood pressure and elevated cholesterol (HBP&EC), I would do the same thing I did in my article – search the recent literature – in an effort to determine what, if anything, should be done about it. In particular, I would look to see if there were differences (i.e., in morbidity and mortality rates) between those with HBP&EC versus without. If there were no differences, then I would be hesitant to act on the information. HBP&EC is however linked with heart disease²⁻³ but what outcomes can be related to asymptomatic SPOTS?

My search in the area of structural problems of the spine (SPOTS) suggested to me that there were often little or no differences, in the long run, between patients with SPOTS versus without. Personally I do not adjust SPOTS (vertebral misalignment) unless there is evidence that nerve dysfunction is also present. If SPOTS is accompanied by nerve dysfunction, then this would, by definition, be considered a chiropractic subluxation. I do not wait for symptoms either but I admit that the validity of the approach I use (SPOTS + nerve dysfunction) is not well-supported by health outcomes research. Rather than base what we do on catchy slogans, such as *structure dictates function*, the various approaches we use should be supported by health outcomes research.

John Hart, DC, MHS

Reference

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- 2 Hypertension: hypertensive heart disease. WebMD. 2005 Oct 1 [cited 2007 May 22]. Available from: <http://www.webmd.com/hypertension-high-blood-pressure/guide/hypertensive-heart-disease>
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CCA/CFCRB-CPG Guideline Development Committee. *Chiropractic clinical practice guideline: evidence-based treatment of adult neck pain not due to whiplash. J Can Chiropr Assoc 2005 49(3):158–209.*
<http://www.ccachiro.org/Client/cca/cca.nsf/web/CPG-sep-05?OpenDocument>

To the Editor:

Evidence-based chiropractic professional guidelines are clearly needed, and the article on evidence-based treatment of adult neck pain not due to whiplash provides useful information to the practitioner in most cases.

However, we disagree strongly with your recommendation to the practitioner concerning Doppler velocimetry, which states ... “Do not use Doppler ... to identify impaired vertebral artery flow, the presence of dissection, or patients with greater or lesser risk of symptomatic (ischemia-provoking) dissection subsequent to manipulation.”

We would like to make the following comments:

1. A single reference was used to support the recommendation, which surely fails to constitute “an extensive review of the literature.”
2. The focus of the paper by Margarey and Coll was not even on Doppler velocimetry. It briefly discussed Doppler studies mainly in the context of the validity of the positional VBI provocation tests.¹ The overwhelming evidence indicates that the positional tests lack validity. Their paper omitted any reference to Doppler velocimetry validity and reliability trials that have been published. Hence no reasonable recommendation about Doppler in pre-manipulative screening can be based on their discussion.^{2,3}

A more extensive review of the literature reveals that:

- Doppler velocimetry is a good screening tool (ie it has high sensitivity and specificity) for detecting high grade stenosis of the vertebral artery.⁴
- A high grade vertebral artery stenosis can be a sign of vertebral artery dissection, with or without the presence of signs and symptoms.^{4,5,6,7}
- Doppler velocimetry can detect high-grade arterial stenosis prior to spinal manipulation being administered;⁴

- If the chiropractor detected abnormal vertebral artery Doppler velocimeter signals which were found to be normal in an earlier examination, this would be a strong indicator for dissection.⁴
- Doppler velocimetry can detect agenesis/non – functional vertebral arteries which are generally accepted as being a risk factor or at least of having a high index of suspicion concerning increased risk.^{4,8}
- Doppler velocimetry can detect major changes in vertebral artery blood flow velocities during cervical rotation (rotational stenosis). Since there is compelling evidence that rotational stenosis is an independent risk factor for vertebro-basilar strokes,^{4,5,8,9,10} Doppler velocimetry appears to have its place in reducing the risk of such cerebro-vascular accidents.

Doppler velocimetry may not be the ultimate tool to prevent all vertebral artery accidents following manipulation but it provides valuable information to the practitioner. We suggest that the authors of the guidelines and your readers reconsider the use of Doppler velocimetry as a pre-manipulative screening test in the light of the information provided.

Karl Vincent, DC,
President of the SOFEC

References

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About the SOFEC:

The SOFEC is a Franco-European scientific society that stands for “Société Franco-Européenne de Chiropratique.” Its purpose is to study, analyse and conduct research on all aspects of chiropractic art, science and philosophy from a scientific standpoint, and thus contribute to the improvement of chiropractic care in terms of quality delivery and patient safety.

Aims and Objectives

- review current research to see if it supports the technology and validity of chiropractic tools and techniques,
- develop and offer diagnostic, therapeutic and preventive guidelines to the practitioner,
- circulate and/or webcast chiropractic references that are indexed on an international level,
- organise and/or support chiropractic scientific meetings, conference and publications
- develop strong relationships with other agencies or organisations with a similar purpose,
- offer support to students, field practitioners or scientists who want to increase their expertise in the science of chiropractic,
- Strengthen the scientific chiropractic model in the medical community.

To the Editor:

I read with interest the following recommendation of the guidelines¹ under *Section 1.3.3. Noting predispositions during physical examination; impaired vertebral artery flow:*

“Do not use Doppler ... to identify impaired vertebral artery flow, the presence of dissection, or patients with greater or lesser risk of symptomatic (ischemia-provoking) dissection subsequent to manipulation.”

To support this recommendation the guidelines¹ state that: *“The evidence of an extensive review of the literature suggests that a positive (impaired) Doppler “flow test” does not predict impaired vertebral artery blood flow”* {L-5}.¹⁴⁶ <<http://www.ccachiro.org/Client/cca/cca.nsf/web/JCCA-References?OpenDocument>>

The reference number 146 relates to a survey study by Magarey et al.² of Australian physiotherapists about guidelines regarding cervical manipulation. Included in this paper was, as alluded to by the guideline¹ authors, a supposedly extensive review of the literature about Doppler ultrasound of vertebral arteries (VAs). In reality, Doppler was discussed mainly in the context of the provocative tests, rather than as a separate subject, and in insufficient detail to make any legitimate conclusions about its effectiveness.

It seems that, while Magarey et al.² did make a passing mention of some technical difficulties with Doppler, there was an absence of any suggestion that a positive Doppler test is unable to indicate or predict markedly impaired VA blood flow. The discrepancies in the results between the studies of positional stenosis of VAs that are listed in their paper,² are understandable, because most of the Doppler studies had flawed experimental designs, as explained in an analysis of the literature by Haynes.³ Hence, it is inappropriate to use these discrepancies to cast doubt about the usefulness of Doppler. Properly designed validity and reliability trials are required to make decisions about the capabilities of a test, but their review² omitted mentioning any of the relevant trials that have been published. The literature review by Haynes³ included 8 published original studies, which found that vertebral artery Doppler, has high capability.

What scientific justification was there for the authors of the guidelines¹ to choose the Margarey et al.² review, which omitted any reference to validity and reliability studies of VA Doppler, to form a conclusion about the efficacy of Doppler, and then to use this to make a recommendation about Doppler? Was there any scientific rationale for their lack of recognition of the Haynes' liter-

ature review, which did discuss the validity and reliability trials of VA Doppler? Considering that there are at least 8 validity or reliability trials supporting VA Doppler that have been published between 1977 and 2001,³ what evidence is there to support the guidelines' recommendation to refrain from using Doppler in pre-manipulative screening of vertebral arteries?

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References

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- 2 Magarey M, Rebbeck T, Coughlan B, Grimmer K, Rivett DA, Refshauge K. Premanipulative testing of the cervical spine review, revision, and new clinical guidelines. *Man Ther* 2004; 9:95–108.
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To the Editor in reply:

The Guidelines Development Committee (GDC) wishes to thank Drs. Vincent and Haynes for their feedback about the “Chiropractic clinical practice guideline: evidence based treatment of adult neck pain not due to whiplash.” Ongoing expert feedback helps us to keep the guideline current.

The issue of how to best address the theoretical association between manipulation and vertebral artery dissection (VAD) in the clinical setting is of fundamental importance to the GDC as the Guideline's authors. As such, the GDC is planning a formal discussion about the information presented by Vincent and Haynes, and any impact this information may have on the original text. The outcomes of these discussions will be released once final.

Roland Bryans, DC
Chair, Guidelines Development Committee

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