Critical Appraisal of an Article about Harm: Chiropractic Adjustment and Stroke


Abstract — Observational research suggests that there may exist an association between neck manipulation and stroke. Although the issue of harm is best studied using randomized trials, the rarity of such accidents often make the use of that design impossible. As a result, whether an association exists between an intervention and harmful side-effects is often assessed with controlled observational studies (cohort and case-control studies). This article aims to provide a guide for practicing chiropractors on how to assess the validity of case-control studies concerning harm. Furthermore, this article provides a guide on how to assess the extent to which causal inferences can be made from such studies. The example used is the possible relationship between chiropractic adjustments and stroke. This article is structured through the use of two critical appraisal guidelines, the likes of which are widely promoted and used by the proponents of Evidence-based Medicine. The guidelines propose a series of questions and criteria that allow the different research designs used in studies reporting an association between neck manipulation and vertebrobasilar accidents (VBA’s) to be critically appraised. The critical appraisal of a study concerning harm is best achieved using a structured guideline that facilitates assessment of the validity of individual papers and consideration of the extent to which causal inferences can be made. There is no human experimental evidence that chiropractic adjustments, or neck manipulations, are causally related to VBA’s. The strength of the inferences that can be made from observational studies carried out to date are severely limited by design issues. Although there may exist a weak association between neck manipulation and VBA’s we know very little about the nature of that relationship. The recent publication of a case-control study by Rothwell et al. provides little insight into whether a causal relationship exists between chiropractic adjustments and VBA’s.

Key Words: Chiropractic, Adjustment, Neck manipulation, Stroke, Vertebrobasilar accident, Critical appraisal, Evidence-based Health care, Case-control studies, Case series, Case report.

Introduction

Although the issues of harm and cause-effect are widely believed to be best studied using randomized clinical trials (RCTs), that design is often impossible in the case of rare events, and unethical when adverse outcomes are being investigated. Instead, case-control studies have come to form the cornerstone of epidemiological research. Case-control studies have become popular amongst epidemiologists because they are easier, quicker, and much less expensive than experimental and cohort studies. As a result, from headlines in the popular press, to recommendations made by the Center for Disease Control (CDC) and World Health Organization (WHO), the public along with health care practitioners are bombarded by statements and claims based largely on case-control studies. However, case-control studies pay a price for their savings in time and dollars. A multitude of systematic distortions (biases) may effect the results and conclusions drawn from case-control studies. The present article aims to provide examples of the kind of structured critical appraisal guides that allow readers to better assess the validity of a case-control study and the extent to which it is affected.
by potential biases. Furthermore, through the use of a causal inference guideline this article attempts to help readers to better assess the extent to which causal inferences might be drawn from such a study.

Three kinds of studies make use of controls in epidemiological research: RCT’s, cohort studies and case–control studies. Of those three designs, case–control studies are the easiest, cheapest and quickest to perform because they — like case reports and case series — are carried out retrospectively. This means that investigators begin by observing an outcome of interest and then work backwards to the possible cause. The investigator starts with 2 groups of subjects. One in which cases already have the outcome of interest, the other in which they do not, and compares the occurrence of exposure in the 2 groups. In doing so the investigators are measuring the association between the exposure, or intervention, and outcome of interest in order to test a null hypothesis. The measure of association is called the Odds Ratio (OR) and provides an estimate of the relative risk (RR). Because an association, no matter how strong, does not prove causation, other criteria must be used to determine whether an association is actually causative.

At this point in time, due to the rarity with which VBA’s occur, experimental evidence in humans and prospective cohort studies examining the hypothesis that chiropractic adjustments cause stroke do not exist. If such studies were to be carried out they would take a number of years to reach completion and given the infrequency of VBA’s would require thousands of subjects. In fact, until recently all the studies related to this topic were either case series, case reports or surveys. Although such studies do have a limited initial role in identifying harm associated with an intervention, they are susceptible to many biases and confounders so that they do not allow us to make definitive causal inferences.

In a recent issue of the journal Stroke, Rothwell et al.², (from here forward referred to as the Rothwell study) present data from the first population-based, nested, case-control study to examine the relationship between visiting a chiropractor and VBA’s. A nested case-control study is a case-control study within a cohort. The authors of that study contend that their study is a significant step forward in researching this topic because it is the first controlled study to have been conducted. Rothwell et al report that their results suggest that those aged <45 years who had a VBA were 5 times more likely than controls to have visited a chiropractor within 1 week of having the VBA (95% confidence interval, CI, 1.32 to 43.87). Additionally, they report that in the younger age group, cases were 5 times as likely to have had ≥3 visits with a cervical diagnosis in the month before the case’s VBA date (95% confidence interval, CI, 1.34 to 18.57).

Do these results suggest that chiropractic adjustments cause VBA’s? In answering that question, which deals with the issue of harm, and therefore also causation, this paper proceeds by attempting to assess at least the following two questions:

1. Are the results of the Rothwell study valid?

We will proceed in this article by critically appraising the case–control study by Rothwell et al by using the guidelines outlined in Table 1.

2. Is there evidence of a cause-effect relationship?

It is not enough to just assess the validity of an individual study when looking at the issue of harm. The extent to which causal inferences can be made from that study must also be assessed. Epidemiologists acknowledge that the answer to questions concerning causation do not lie purely in statistics but instead also require applied logic and common sense. The author of this article proceeds in differentiating between association and causation with the help of structured lists of inductively oriented causal criteria. The most widely recognized list of criteria useful for making causal inferences are those outlined by Hill (Table 2).³ Because no individual study is definitive it can be misleading to assess a study dealing with the issues of harm and causation in isolation from the existing body of literature to which that individual study pertains. Furthermore, some of the 9 causal criteria outlined by Hill are more powerful than others in suggesting causation. Therefore, after assessing the validity of Rothwell’s study, we apply Hill’s list of 9 criteria (Table 2) in this paper, in order to focus on assessing whether the case–control study in question, along with other relevant literature, suggest that chiropractic adjustments cause stroke.

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**Table 1. Guidelines for evaluating the validity of a case-control study about harm**

- Were there clearly identified comparison groups that were similar with respect to important determinants of outcome other than the one of interest?
- Were the exposures and outcomes measured in the same way in the groups being compared?
- Were case subjects found and identified accurately and completely?
- Was the diagnosis of harm made without any knowledge of the exposure?
- Was exposure state investigated blindly or objectively?
- How strong was the association between exposure and outcome?
- Were confounding factors considered and handled appropriately?
- If an association was found, were reasons other than a cause-effect relationship considered?
- Was a confidence interval around the estimate of risk presented and, if so, how precise was the estimate of risk?

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**Table 2. Hill’s list of causal criteria**

1. experimental evidence
2. strength of association,
3. consistency,
4. temporality (Appropriate time relationship)
5. biologic gradient,
6. coherence of evidence
7. biological plausibility,
8. specificity,
9. analogy.
Are the Results of the Rothwell Study Valid?

Were there clearly identified comparison groups that were similar with respect to important determinants of outcome other than the one of interest?

The extent to which we can be sure that harm is associated with a specific intervention is in large part dependent upon the degree to which cases and controls are comparable. We can have more confidence in the results of case-control studies when controls have been appropriately matched to cases on important determinants of outcome and when subjects in each group are representative of all possible subjects in a defined population. In the ideal situation all the cases should come from a defined population and the controls should also be drawn from that same population. In the Rothwell study cases were identified by searching acute care facility hospitalization records in Ontario, Canada. Controls were randomly selected from the Ontario Registered Persons Database (RPDB). Furthermore for both cases and controls to be included in the study they had to be eligible for Ontario’s universal publicly financed insurance program (OHIP) and to not be living in a chronic care facility. Thus controls are representative of the population from which the cases came from so that this study provides a very good example of a case-control study design in terms of case and control selection.

Was the exposure measured in the same way in the groups being compared?

In cohort studies and RCT’s ascertainment of outcome is a key issue, whereas in case-control studies, ascertainment of the exposure is a key issue. In the study by Rothwell et al., the authors state, “We sought to examine whether cervical manipulation, as practiced in Ontario, Canada, was associated with an increased risk of VBA...” Therefore the exposure of interest was cervical manipulation by a chiropractor and the outcome of interest was VBA.

The reason why case-control studies are so susceptible to biases is that the measurement of exposure to an intervention takes place retrospectively. Information about an exposure may come from a number of different sources: patient interviews, medical records, or insurance records. Despite where researchers get their information about exposure, there exist a number of potential biases that may detract from the accuracy with which exposure is measured. For example, if exposure measurement was dependent upon asking people about their prior exposure to a particular intervention, it has been shown that people who suffer an injury as a result of that intervention are more likely to remember having received the intervention than would a person who had not suffered such an injury. At least two types of biases may contribute to such a scenario: recall bias, wherein a patient has a greater motivation to remember information, and interviewer bias, where an interviewer searches more vigilantly for evidence of exposure amongst cases. Both these biases, if not guarded against, tend to increase the strength of association. Researchers can reduce the likelihood of such biases effecting case-control studies by ensuring that both interviewers and subjects are blinded to the study hypothesis. Alternatively, recall and interviewer biases can be eliminated by using a source of exposure other than patient interviews, i.e. medical records, billing or insurance records. However, the use of such records can present another set of potential biases. One of the disadvantages, beyond the data being collected retrospectively, is that such data very possibly contains a number of inaccuracies and this certainly may have been the case in the Rothwell study.

In the Rothwell study chiropractic service billing data was obtained for the 6 year period 1992-98 from Ontario’s universal publicly financed insurance program (OHIP). Billing data, which was classified according to whether a cervical diagnosis was made, were extracted for both cases and controls for the year preceding the reference date. Therefore, in the Rothwell study, data about the intervention of interest was collected in the same way for both cases and controls. However, the authors acknowledge a number of limitations to the chiropractic billing diagnostic code which they used for assuming if a cervical adjustment had, or had not, been given. In actual fact, the authors were unable to tell from the billing data if manipulation was or was not performed during a visit to a chiropractor. This significantly weakens their study when their stated objective was, “...to examine whether cervical manipulation, as practiced in Ontario, Canada, was associated with an increased risk of VBA...” Importantly the billing data did not actually provide information on whether cervical manipulation was or was not part of the care provided. If, as a result, individuals who suffered a VBA were incorrectly assumed to have received cervical manipulation, this bias will have lead to an overestimation of the odds ratio (OR). In discussing their results Rothwell et al. concede that their application of the chiropractic billing diagnostic code across chiropractic offices was not standardized and that it is likely that some visits would have been categorized as receiving cervical adjustments when no adjustment was performed and vice versa.

Another problem was encountered in the measurement of exposure to intervention. It is possible, even though most patients reported having had less than 20 visits, that not all visits to chiropractors were accounted for. This is because OHIP only pays for and therefore only documents the first 20 visits of each year. If the number of visits to chiropractors in the population was higher than revealed by the OHIP data, then the odds ratio (OR) would be lower and the association between visiting a chiropractor and having a stroke would have been weaker.

Were case subjects found and identified accurately and completely?

It is important that the definition of a case is specific and clearly delineated so that individuals with a different type of stroke, or other disease, are not misclassified as cases. Furthermore, ascertainment of cases should be complete so that as many cases as possible are detected from the study population. There is a possibility that the ICD-9 codes used to identify participants with VBA may have led to an overinclusion of subjects in the Rothwell study. According to the diagnostic criteria used by Rothwell et al., 0.42% of all hospital admissions, with stroke in Ontario during the course of the study had a VBA. Since VBA’s occur at half to one third the frequency of Carotid Artery Dissections (CAD’s); and considering that one cohort study has suggested that cervical dissections make up...
only 0.13% of strokes, the figure from Rothwell's study exceeds the expected percentage by more than 7 fold. Furthermore, the average age of cases in the Rothwell study was 60, while the average age in a recent review of published case reports was 39. Together these 2 unexpected findings might suggest a problem existed with the case definition used by Rothwell et al.

**Was the diagnosis of disease, or in this case harm, made without any knowledge of the exposure?**

If either the patient, or the physician making the diagnosis, suspect that some association exists between the harmful outcome and a particular intervention which the patient underwent, then the harmful outcome is more likely to be diagnosed in that patient. For example, if the treating physician at an intensive care unit (ICU) has a pre-existing suspicion about a possible cause-effect relationship between cervical manipulation and VBA's, there is more chance that a VBA would be inappropriately diagnosed if a patient presents to the ICU with vague neurological signs/symptoms and a history of having recently attended a chiropractor's office. In the Rothwell study, hospitalization records were used to retrospectively identify VBA's in Ontario, Canada, which occurred between 1993 and 1998. In the data collected for that study it is likely that the physicians who made the diagnosis of VBA had access to the patient's history and were therefore not blinded as to whether patients had or had not received chiropractic care.

We are told that, "Positive validation of the type of stroke would require diagnostic imaging and invasive testing well beyond the scope of the present study." This suggests that positive validation of the type of stroke did not take place thus increasing the possibility that VBA was incorrectly diagnosed.

Based on the information provided by Rothwell et al. it is impossible to tell if the diagnosis of VBA was made by the treating medical physician with or without knowledge of exposure to chiropractic care. Therefore, it is possible that the patient and/or the treating physician suspected that some association exists between VBA and cervical manipulation, and that the harmful outcome (VBA) was inappropriately diagnosed in patients who had received chiropractic care. This bias will have lead to an overestimation of the odds ratio (OR).

**Was exposure state investigated blindly or objectively?**

Chiropractic service billing data were obtained for the period 1992-98 from Ontario’s universal publicly financed insurance program (OHIP). Billing data, which was classified according to whether patients had attended a chiropractor’s office and the diagnosis made, were extracted for both cases and controls for the year preceding the reference date. Using the billing data helps to eliminate both recall and interviewer biases. Moreover, the use of such administrative data increases the likelihood that data on exposure was obtained objectively. We are not told whether those who investigated the billing data were or were not blinded to the study hypothesis.

**How strong was the association between exposure and outcome?**

The word strong when used in this context means there was a high risk or odds of harm arising with, compared to without, the intervention in question. Three main factors influence our interpretation of whether the calculated risk or odds figures are strong or weak:

1.) Size of the RR or RO — The calculated RR or RO needs to be greater than 1 for it to signify that more harm has occurred with than without the intervention in question.

2.) Type of study from which RR or RO was calculated — If the RR was calculated from figures derived from a RCT and was greater than 1 the association could be considered strong. If the RR was based on figures from a cohort study, because they are more susceptible to biases, the RR would need to exceed 3. Because a case-control study is highly susceptible to systematic distortions the OR would need to be 4 or more before taken seriously. One group of authors summarize as follows, “...readers can place considerable confidence in estimates of strength from a randomized clinical trial, fair confidence in an estimate of strength from a cohort study, and only a little confidence in an estimate of strength when it comes from a case-control study.”

3.) RR or RO confidence interval width — The confidence interval (CI) is a measure of the precision of the odds ratio. Basically, the wider the CI the less certain one can be about the applicability of the study’s findings to all such patients in a population. In the Rothwell study the Confidence Intervals were exceedingly wide so that we can not be confident in the precision of the OR’s that were calculated.

Given that the Rothwell study was a case-control study, had a number of methodological shortcomings, was susceptible to a number of biases, and that the calculated OR’s had extremely wide confidence intervals, the OR’s of 5 do not provide strong evidence of an association.

**Were confounding factors considered and handled appropriately?**

A confounder is a risk factor or determinant of the harmful outcome and is associated with the intervention of interest. Furthermore a confounder is predictive of the outcome but is not necessarily causal, it is predictive of the outcome independent of the intervention, and the confounder should not be an intermediate step in the possible causal pathway. Potential bias due to confounding can be minimized provided it is suspected before the study. If a confounder is suspected, a number of different methods can be used in case-control studies to control or adjust confounding. For example, the randomized recruitment of controls from a community-based sample can help to minimize the effect of unknown confounders compared to hospital-based or neighborhood controls. Other available methods for controlling confounding include: Restriction — wherein the study is limited to a group of subjects, Matching — where controls are selected that are almost identical to cases in respect to one or more potential confounders, Stratification — in which the effect of an intervention is measured within a strata.

The Rothwell study made use of a number of these strategies. The population-based controls were drawn at random, matching was used to control for age and sex, and since cervical artery dissection is one of the most common causes of stroke in those...
less than 45 years of age, the authors examined the suspected associations by age strata.

If an association was found, were reasons other than a cause-effect relationship considered?

Rothwell et al. did briefly discuss and consider reasons other than a cause-effect relationship, between the intervention and outcome of interest, to explain their results. One very obvious possible explanation for the observed association, mentioned by Rothwell et al., is that the intervention is being sought as a treatment of the early symptoms of the outcome of interest. To state this more explicitly, the observed association between attending a chiropractor’s office and stroke may be explained by the very real possibility that the intervention of interest, chiropractic manipulation of the cervical spine, is seen to be and sought as, an effective treatment of the neck pain and headache which are often the only early symptoms of an evolving spontaneous vertebral artery dissection. Note that in one series it was found that headache and/or neck pain was the prominent feature in 88% of patients and was a warning sign in 53%, preceding onset of stroke by up to 14 days. Furthermore, case reports have documented fatal vertebral artery dissection following motor vehicle accidents (MVA) in which stroke occurred as long as 7–8 weeks after the accident. Such long delays between exposure to the etiological event (MVA) and stroke, increase the chances that a visit to the chiropractor will take place somewhere between the two events.

Another possible explanation, other than cause-effect, is that the intervention uncovers pre-existing disease as opposed to causing it. One author has proposed the following, “It seems unlikely that any form of dissection could occur with enough rapidity to result in immediate stroke or ischemic symptoms (as has been observed on extremely rare occasions). A much more plausible mechanism would be of a pre-existing dissection and clot that following manipulation embolizes to a distal artery to a point too small to pass through and produces ischemia.”

Because the Rothwell paper failed to collect data on whether patients had experienced any prior neurological symptoms or risk factors for stroke we cannot exclude any one of a multitude of non-causal explanations for their observed association between attending a chiropractor’s office and stroke.

Was a confidence interval around the estimate of risk presented and, if so, how precise was the estimate of risk?

After calculating the relevant OR’s, Rothwell et al. calculated the respective confidence intervals (CI). The CI is a measure of the precision or uncertainty of a study’s results for making inferences about the population of all such patients. The wider the CI the less certain one can be about the applicability of the study’s findings to all such patients in a population. Because CI’s are to a large extent affected by the square root of the sample size, and because the study in question had a small sample size, the CI’s for the study by Rothwell et al. were extremely wide. For example, the authors of the study report that those aged <45 years who had a VBA were 5 times more likely than controls to have visited a chiropractor within 1 week of having a VBA (95% confidence interval, CI, 1.32 to 43.87). There is therefore more than a 33 fold difference in the limits of the CI for this association. Additionally, Rothwell et al. report that in the younger age group cases were 5 times as likely to have had ≥3 visits with a cervical diagnosis in the month before the case’s VBA date (95% confidence interval, CI, 1.34 to 18.57). There is more than a 13 fold difference in the limits of the CI in this case. Therefore, these extremely wide CI’s suggest we are very uncertain about the precision of the study’s results. The following statement is also worth keeping in mind when reviewing the results of the Rothwell study: “...when we find that a clinical trial or epidemiological study gives no significant difference overall, but does so in a particular subset of subjects, significant differences in subsets are to be treated with the utmost suspicion.”

2. Is there evidence of a cause-effect relationship?

Epidemiologists have made every effort to avoid confronting the thorny issue of cause. Instead they have made extensive reference to determinants, exposures, risk factors and association. However, a number of individuals have realized the need to attempt to delineate the essential properties of a cause and from there have managed to develop a set of criteria by which to judge the existence of those properties (Table 2). These 9 criteria, although far from perfect, help us in answering the question, “How do we know a cause upon seeing one?” And, “How do we avoid confusing the real thing from an imposter.”

With the help of the inductively oriented causal criteria outlined in Table 2, we will now reflect upon whether it is appropriate to infer causation based on the findings of the Rothwell study.

Hill proposed that strong associations are more likely to be causal than weak associations because, if the effect could be explained by another factor, the effect of that factor would have to be stronger than the observed association, and hence would have become evident. In contrast, weak associations are more likely to be explained by undetected biases. When using the term strength in this context we are referring to the odds of the adverse event with, as opposed to without, exposure to the intervention; the higher the odds, the greater the strength. In the Rothwell study the OR for having seen a chiropractor within a week of having a VBA was 5. If an OR of 5 was derived from a RCT, or even from a well performed cohort study, we would consider it indicative of a strong association. However because the Rothwell study is a case-control study which was likely effected by a number of biases, the OR of 5 does not indicate a strong association.

The concept of consistency refers to the repeated observation of an association in different populations, in different countries, and under different circumstances. In the case of neck manipulation and stroke, no other controlled studies exist. The only other studies that have looked at this issue are case reports, case series and surveys. Unfortunately the uncontrolled observational nature of such research designs mean that they are unable to provide data that would satisfy any of the causal criteria outlined by Hill. Furthermore, the reliability of some of those uncontrolled observational studies have been questioned. To strongly fulfill the causal criteria of consistency the body of literature relating to this topic will require prospective observational studies and more basic science research.
**Specificity** requires that a single cause lead to a single effect. This criteria is an ideal requirement but is rarely met. In the case of VBA’s very little is known about the etiology and pathogenesis of this disease. However, the list of possible etiological factors includes many different agents. Specificity is therefore another causal criteria that the Rothwell study, and indeed the body of literature relating to the possible association between chiropractic adjustment and stroke, do not meet.

**Temporality** is an absolute requirement for an effect to be a causative agent. Temporality implies that the causative factor precedes the effect or outcome. When temporality is positive it supports a conclusion of causation whilst should the temporal relationship be negative, causation is ruled out. Importantly, the authors of the Rothwell study did not collect data on whether patients had experienced any prior neurological symptoms or risk factors for stroke. Therefore an appropriate temporal relationship could not be definitively ascertained. This, combined with the retrospective nature of the case-control study mean temporality, the one necessary causal criteria for inferring causation, was not met.

**Biologic gradient** refers to the presence of a unidirectional relationship (dose-response) between the exposure and outcomes of interest. In the case of VBA, a mechanical stress hypothesis has been put forth by a number of authors, while a connective tissue defect may also yet prove to be implicated in a percentage of cases. It has been beyond the scope of all studies carried out to date on this topic to explore a dose-response gradient. The Rothwell study is no exception.

**Biological Plausibility** refers to the plausibility of the hypothesis relative to general biological knowledge. For neck manipulations, it is plausible that excessive mechanical loading leads to tearing of the vertebral artery intima. Whether specific chiropractic adjustments, and neck manipulation for that matter, cause such a tearing of the vertebral artery intima is unknown. However, two recent studies do not support the hypothesis and instead suggest that adjustments delivered by a chiropractor would not damage healthy vertebral arteries. An experimental study which examined vertebral artery blood flow after neck manipulation in pigs concluded, “changes of this magnitude in humans would have very little clinical consequence.” The findings from another recent study have cast serious doubt on whether chiropractic care could cause a stroke. That study revealed that the stretching of the vertebral artery during chiropractic neck adjustments is at most 11% of the stretching observed at the point where an artery tears, and furthermore, the arterial stretching that takes place during chiropractic adjustments are consistently less than that seen during routine range of motion and diagnostic testing.

**Coherence** implies that a cause-effect relationship does not conflict with what is known of the natural history of the harmful outcome. The current understanding of vertebral artery dissection suggests that it is likely a cumulative process born out of some underlying connective tissue disorder or arterial wall defect. Again, two recent studies suggest that such a process is not likely initiated by chiropractic adjustments. Beyond that we can only guess as to whether an adjustment aggravates the existing dissection, or appears temporally related because people with an already evolving VBA are looking for relief from the neck pain and headache that usually proceed dissection by as much as 14 days.

**Experimental evidence** refers to evidence from laboratory experiments or data from human experimental trials. Most epidemiologic issues are not readily amenable to investigation by human trials. For instance, to evaluate the role of neck manipulation in VBA’s would require a very large randomized controlled trial where subjects’ exposure to neck manipulation was decided by random allocation. Clearly, this would be unethical and impractical from a feasibility perspective. Extrapolation of evidence from animal experiments to humans has its limitations. Therefore, experimental evidence to support or refute the hypothesis of neck manipulation causing VBA’s is presently not available.

**Analogy** is a very weak criterion for causation. Virtually any hypothesis of causation can be supported by an imaginative analogy without rigorous scientific evidence of likelihood.

**Discussion**

Not all of Hill’s criteria need to be satisfied in order to conclude that a cause-effect relationship exists. The only criterion that could be considered a sine qua non would be that of temporality. Clearly, if the hypothesized cause did not precede the effect or outcome, a causal relationship cannot exist. The findings of the critical appraisal carried out in this article suggest that the design limitations of the Rothwell Study preclude making causal inferences about the relationship between chiropractic care and stroke. Furthermore, the Rothwell study fails to satisfy many of Hill’s 9 criteria that should be considered before inferring causality. In particular the failure of their study, and all others carried out to date, to establish temporality and biologic gradient mean that we do not know whether chiropractic adjustments, or neck manipulation for that matter, are capable of causing vertebral artery dissection.

This article sets out to provide a guide on how to assess an individual article related to the issue of harm. Furthermore, because no single study can be regarded as definitive, the full assessment of the issue of harm requires that the study in question is examined relative to relevant literature that may lend insight to the cause-effect relationship implicit in the question of harm. However, this critical appraisal did not include a systematic review of the relevant literature. Therefore, any statements made during the course of this article which deal with issues beyond the validity of the Rothwell study should be considered tentatively.

The retrospective nature of all epidemiological research carried out to date related to this topic does not discount the possibilities that chiropractic care does, or does not, cause VBA’s. The possibility still exists that chiropractic care has come to be associated with VBA simply because some people with an already culminating stroke present at a chiropractors office seeking relief from the very symptoms that usually precede the full blown neurological consequences of VBA. As already mentioned one study has shown that headache and/or neck pain was the prominent feature in 88% of patients with VBA and was a warning sign in 53%, preceding onset of stroke by up to 14 days.” We already know that many people go to chiropractors with the...
perception that chiropractors treat headache, neck pain and vertigo. The only thing new that the Rothwell Study tells us is that people who have had a VBA, very possibly from causes other than neck manipulation, seek out chiropractic care for their headache, neck pain and vertigo. As do a significant percentage of the population who have the same presenting symptoms, but who are not in the early phases of an evolving VBA.

In general, further research is required to better understand the relationship between all health care interventions and possible harm. More specifically, because issues like force, amplitude, specificity, direction and speed of thrust may differ between what chiropractors call a chiropractic adjustment and what some other health care providers do and call spinal manipulative therapy, this author suggests that further research should be directed towards quantifying and qualifying the difference between those interventions. In light of the widespread recognition of the limitations inherent in all epidemiologic observational studies, researchers should seriously consider whether resources would be better used for basic science research before proceeding with poor quality epidemiological studies with serious design limitations that preclude making causal inferences.

**Conclusion**

Based on the critical appraisal carried out in this article, the validity of the Rothwell study, and the strength of the association between neck manipulation and VBA’s which it set out to study, are far from impressive. Many aspects of the case-control study were fairly well conducted, however a number of methodological shortcomings, for example, attempting to measure exposure with administrative data, render the study susceptible to a number of potential biases. Put very simply, this type of study can not be used for basic science research before proceeding with poor quality epidemiological studies with serious design limitations that preclude making causal inferences.

**References:**