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Critical Appraisal of a Harm Paper

Goal:
Participants will be able to determine whether a clinical article, which purports to prove (or dismiss) a suspected cause of a disease has drawn conclusions about causation that are valid (true) and, if so, to determine the applicability of the results to one's own clinical practice.

Objectives:
1. Assess the validity of an article about a harm or etiology
2. Explain the magnitude of the effect
3. Explain the precision of the effect, using p values or confidence intervals
4. Determine the applicability of an article on harm or etiology to a particular situation
5. Define and give examples of ecological, case-control, and cohort studies

Reference (Further Reading):
Guyatt GH, Rennie D, Meade M, Cook DJ. Editors. Users' Guides to the Medical Literature: A Manual for Evidence Based Clinical Practice, 3rd Edition, New York, NY: The McGraw-Hill Companies, Inc.

Available here:
http://jamaevidence.mhmedical.com/book.aspx?bookID=847

- Chapter 14: Harm (Observational Studies)
- Chapter 15: Advanced Topics in Harm: Correlation and Regression

Educational Exercise:
1. Read the Users' Guides to the Medical Literature reference chapters (listed above)
2. Read the Clinical Scenario (below)
3. Compose a well-built clinical (PICO) question about the clinical problem
4. Complete a literature search using the headings from your PICO question
5. Complete the critical appraisal form

Clinical Scenario:
Mary is a 55-year-old otherwise healthy woman with a 12-year history of remitting and relapsing uncomplicated neck pain for which she has sought chiropractic care (mainly involving cervical spine manipulation) when symptomatic. This approach has typically resolved her complaint, when present, in 2-3 weeks. However, she has recently come across an article on the internet that suggests there may be a risk of stroke associated with chiropractic care, and she has come to your office asking if she should avoid this form of care in the future. You advise Mary that you will look into this issue further and get back to her at her next visit.

Using PubMed 'clinical queries,' you use the search terms "stroke" AND "chiropractic care" and restrict your search to "etiology." You are aware that case studies cannot be used to establish risk due to the lack of a control group, and you identify the following case-control study which you decide to explore further:

Cassidy JD, et al. Risk of vertebrobasilar stroke and chiropractic care: results of a population-based case-control and case-crossover study. J Manipulative Physiol Ther. 2009. 33:S201-8.

The abstract indicates it is relevant to your patient and you decide to critically appraise this paper using the "Users' Guides" for a harm paper.

After critically appraising this paper, what will you advise Mary?

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CRITICAL REVIEW FORM: HARM/ETIOLOGY

Identify and outline your clinical question in plain language:

Build a PICO:

P	
I	
C	
O	

Databases Searched:	
Resource Acquired:	

Are the results of the study valid?	
Did the investigators demonstrate similarity in all known determinants of outcome?	
Did they adjust for differences in analysis?	

Adapted by John Stites DC and Amy Minkalis DC from: Walsh M, Perkovic V, Manns B, Srinathan S, Meade MO, Devereaux P, Guyatt G. Harm (Observational Studies). In: Guyatt G, Rennie D, Meade MO, Cook DJ. eds. *Users' Guides to the Medical Literature.* New York, NY: McGraw-Hill; 2014.

Were exposed patients equally likely to be identified in the two groups?	
Was follow-up time sufficiently complete?	
What are the results?	
How strong is the association between exposure and outcome? How precise is the estimate of risk?	
What was the magnitude of risk?	
How can I apply the results to patient care?	
Were the patients similar to the patient under consideration in my practice?	
Was the duration of follow-up adequate?	
Should I attempt to stop the exposure?	

Strength of Evidence:

|----------|

Low Quality High Quality

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CRITICAL REVIEW FORM: HARM/ETIOLOGY

Identify and outline your clinical question in plain language:

Is there an increased risk of stroke associated with chiropractic care?

Build a PICO:

P	Stroke
I	Chiropractic care
C	N/A
O	Increased risk

Databases Searched:	PubMed
Resource Acquired:	Risk of vertebrobasilar stroke and chiropractic care: results of a population-based case-control and case-crossover study

Are the results of the study valid?	
Did the investigators demonstrate similarity in all known determinants of outcome?	Yes and no. For the case-control study, subjects were matched by age and gender only, which does not take into account many potential confounders (e.g., connective tissue disorders, migraine, hypertension, infection, level of plasma homocysteine, cervical spine surgery, radiation therapy). Furthermore, cases demonstrated a higher level of comorbidities (see Table 1, p.178). For the case-crossover design ensured that patients acted as their own controls. As the author's note: "This design is most appropriate when a brief exposure (e.g., chiropractic care) causes a transient change in risk (i.e., hazard period) of rare-onset disease (e.g., VBA stroke)."
Did they adjust for differences in analysis?	A case-crossover design was used to account for differences in cases and controls. An important advantage over previous case-control studies was stratification of data not only by age, but by reason for clinical visit (any visit OR headache and cervical visit), and comparison of risks for chiropractic care and primary care provider management.

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Were exposed patients equally likely to be identified in the two groups?	Yes, the system used to identify the exposure of interest (chiropractic care) was a government-maintained healthcare reimbursement database (OHIP) that recorded all government funded healthcare services provided to all individuals in Ontario.
Were the outcomes measured in the same way in the groups being compared?	Yes, the outcome (vertebrobasilar stroke) was captured through codes for all vertebrobasilar occlusion and stenosis strokes (ICD-943.3 and 433.2).
Was follow-up time sufficiently complete?	It was not stated if any patients were lost to follow-up and ICD-9 hospital discharge codes for stroke can show poor positive predictive value when compared to chart reviews. To explore for this bias the authors conducted a sensitivity analysis using different positive predictive values for stroke diagnosis (0.2 to 0.8) and the results did not change.
What are the results?	
How strong is the association between exposure and outcome? How precise is the estimate of risk?	There was a strong association between chiropractic care and vertebrobasilar stroke, particularly for patients under the age of 45 who attended a headache or cervical complaint (OR=2.80; 95% CI=1.43 to 5.48); however, this risk was not greater than for similar patients who sought care from primary care provider (OR=10.64; 95% CI=3.45 to 32.78).
What was the magnitude of risk?	The magnitude of risk for chiropractic care was important, but he did not exceed the risk associated with PCP care, and it therefore appears that there is no additional risk for VBA stroke associated with chiropractic care over PCP care.
How can I apply the results to patient care?	
Were the patients similar to the patient under consideration in my practice?	Study patients were in their early 60's and mostly male (63%), frequently with comorbidities. There are, therefore, some potentially important differences between the study population and your patient.
Was the duration of follow-up adequate?	Yes, VBA stroke is an acute event and a follow-up time of 30 days post exposure should be sufficient.
Should I attempt to stop the exposure?	Mary had advised that, historically, chiropractic care has provided relief from her remitting and relapsing neck pain. The case control and case-crossover study you reviewed suggests that chiropractic care is not associated with additional risk of VBA stroke over PCP care. As such, there appears to be no compelling reason to advise against the exposure (chiropractic care). However, future well-conducted studies should be reviewed to continue to inform this issue.

Strength of Evidence:

|----------X----------|

Low Quality High Quality

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