

EVIDENCE APPRAISAL OF A SINGLE STUDY
– TREATMENT / THERAPY: CASE–CONTROL STUDY –

Project / Topic of your Clinical Question: _____

Reviewer: _____ **Today's Date (mm/dd/yy):** _____ **Final Evidence Level:** _____

Article Title: _____

Year: _____ **First Author:** _____ **Journal:** _____

Do the study purpose/objectives and inclusion/exclusion criteria assist in answering the clinical question?

Yes No Unknown

Comments:

A. What is the study purpose/objective? _____

B. What are the Inclusion Criteria? _____

C. What are the Exclusion Criteria? _____

* **Bolded** questions represent the key criteria for each section.

* *Lettered questions (A., B., ...) provide additional information to better answer the bolded questions.*

VALIDITY: ARE THE STUDY RESULTS VALID OR CREDIBLE?

1. Is the study purpose clearly stated? (e.g., aim, hypothesis, or objective) Yes No Unknown

Comments:

2. Are the study methods clearly described and appropriate for the question? Yes No Unknown

Comments:

A. Is the setting clearly described and appropriate? Yes No Unknown

Comments:

B. Is the sample population clearly described and sufficient? Yes No Unknown

Comments:

C. Are cases and controls matched appropriately for confounders/comorbidities? Yes No Unknown

Comments:

D. Are appropriate numbers of control participants matched to the case participants? Yes No Unknown

Comments:

3. Were instruments used to measure the outcomes tested to be valid and reliable? Yes No Unknown

Comments:

A. Are the variables and interventions clearly described and appropriate? Yes No Unknown

Comments:

B. Are the outcome measures clearly described and appropriate? Yes No Unknown

Comments:

4. Was the follow up process described and complete? Yes No Unknown

Comments:

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- A. Were all patients who entered the study accounted for at its conclusion? Yes No Unknown
Comments:
- B. Was the follow up described and complete with a low rate of attrition? Yes No Unknown
Comments:
- C. Was the follow up long enough to fully study the effects of the intervention? Yes No Unknown
Comments:
- 5. Was there freedom from conflict of interest?** Yes No Unknown
Comments:
- A. Was there freedom from conflict of interest in the sponsor/funding agency? Yes No Unknown
Comments:
- B. Was there freedom from conflict of interest in the investigators? Yes No Unknown
Comments:

RELIABILITY: ARE THESE VALID STUDY RESULTS IMPORTANT?

6. Were the statistical analysis methods clearly described and appropriate? Yes No Unknown
Comments:
7. Did the study have a sufficiently large sample size? Yes No Unknown
Comments:
8. What are the main results of the study?
(Enter or calculate results in the appropriate fields in the tables below. Point estimates? Effect Size? How large was the treatment effect?)
* A table is also available for calculation or presentation of study results on the last page of this form.
- A. What are the main tables or graphs of results in the article? *(Page #, Table #, Figures, Graphs)*
- B. How precise were the results? *(Were the results presented with Confidence Intervals?)*
9. Were any adverse events clearly described? Yes No Unknown
Comments:

APPLICABILITY: CAN I APPLY THESE VALID, IMPORTANT STUDY RESULTS TO TREATING MY PATIENTS?

10. Can the results be applied to my population of interest? Yes No Unknown
Comments:
- A. Is the treatment feasible in my care setting? Yes No Unknown
Comments:
- B. Were all patient important outcomes considered? *(Are substitute endpoints valid?)* Yes No Unknown
Comments:

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C. Are the likely benefits worth the potential harm and costs? Yes No Unknown

Comments:

D. Were the patients in this study similar to my population of interest? Yes No Unknown

Comments:

11. Are your patient's values and preferences satisfied by the treatment and its consequences? Yes No Unknown

Comments:

12. Would you include this study/article in development of a recommendation? Yes No Unknown

Comments:

Additional Comments or Notes: _____

* Consider each "No" answer and the degree to which this limitation is a threat to the validity of the results, then check the appropriate box to assign the level of quality for this study/article.

THE EVIDENCE LEVEL IS: **Good Quality Case–Control Study** (4a)
 Lesser Quality Case–Control Study (4b)
 Not Valid, Reliable, or Applicable

| TABLE OF EVIDENCE LEVELS | | | | | | | | | |
|-----------------------------|------------------------------|------------------|----------------------|------------------------|----------------|--|-------------------|--------------------------------------|-----------------------------|
| DOMAIN OF CLINICAL QUESTION | TYPE OF STUDY / STUDY DESIGN | | | | | | | | |
| | Systematic Review | RCT ⁺ | Cohort – Prospective | Cohort – Retrospective | Case – Control | Longitudinal (Before/After, Time Series) | Cross – Sectional | Epidemiology Descriptive Case Series | Expert Opinion Case Reports |
| | Meta–Analysis | | | | | | | | |
| Treatment / Therapy | 1a 1b | 2a 2b | 3a 3b | 4a 4b | 4a 4b | 4a 4b | 4a 4b | 4a 4b | 5 |

⁺ RCT = Randomized Controlled Trial

Development for this appraisal form is based on:

1. Guyatt, G.; Rennie, D.; Evidence-Based Medicine Working Group.; and American Medical Association.: Users' guides to the medical literature : a manual for evidence-based clinical practice. *Users' guides to the medical literature : a manual for evidence-based clinical practice*: "JAMA & archives journals." Chicago, IL, 2002
2. Melnyk, B. M. and E. Fineout-Overholt (2005). Evidence-based practice in nursing & healthcare : a guide to best practice. Philadelphia, Lippincott Williams & Wilkins.
3. Lohr, K. N. and T. S. Carey (1999). "Assessing "best evidence": issues in grading the quality of studies for systematic reviews." Joint Commission Journal on Quality Improvement 25(9): 470-9.
4. Fineout-Overholt, E. and L. Johnston (2005). "Teaching EBP: asking searchable, answerable clinical questions." Worldviews Evid Based Nurs 2(3): 157-60.
5. Jerosch-Herold, C. (2005). "An evidence-based approach to choosing outcome measures: a checklist for the critical appraisal of validity, reliability and responsiveness studies." British Journal of Occupational Therapy 68(8): 347-53.
6. Phillips, et al: Oxford Centre for Evidence-based Medicine Levels of Evidence, 2001. Last accessed Nov 14, 2007 from <http://www.cebm.net/index.aspx?o=1025>.
7. Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs*, 2(3): 157-60, 2005.

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2X2 TABLE / STUDY CALCULATIONS / RESULTS TABLE:

| | | | |
|------------------------|--------------------------|----|---|
| | Outcome / Disease | | Control Event Rate – CER = $c / c+d$ |
| | Yes | No | Experimental Event Rate – EER = $a / a+b$ |
| Exposed Group | a | b | Relative Risk – RR = EER / CER RR Reduction – RRR = $(CER - EER) / CER = 1-RR$ |
| Unexposed Group | c | d | Odds Ratio – OR = ad / bc Confidence Interval – CI = $\pm 1.96 \sqrt{CER*(1-CER)+EER*(1-EER)}$ # control pts. # exper. pts. |

| TREATMENT OUTCOMES | Sample Size [N] | Event Rates | Odds Ratio [OR] | Effect Size | Confidence Interval [95% CI] | Other Data Results | p value |
|--------------------|------------------------|-------------|-----------------|-------------|------------------------------|--------------------|---------|
| Outcome 1: | N = | CER = | | | | | |
| | n _{group 1} = | EER = | | | | | |
| | n _{group 2} = | | | | | | |
| Outcome 2: | N = | CER = | | | | | |
| | n _{group 1} = | EER = | | | | | |
| | n _{group 2} = | | | | | | |
| Outcome 3: | N = | CER = | | | | | |
| | n _{group 1} = | EER = | | | | | |
| | n _{group 2} = | | | | | | |
| Outcome 4: | N = | CER = | | | | | |
| | n _{group 1} = | EER = | | | | | |
| | n _{group 2} = | | | | | | |
| Outcome 5: | N = | CER = | | | | | |
| | n _{group 1} = | EER = | | | | | |
| | n _{group 2} = | | | | | | |
| Outcome 6: | N = | CER = | | | | | |
| | n _{group 1} = | EER = | | | | | |
| | n _{group 2} = | | | | | | |