

EVIDENCE APPRAISAL OF A SINGLE STUDY

– PROGNOSIS: COHORT STUDY (PROSPECTIVE AND RETROSPECTIVE)* –

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. Was there a representative sample of patients at a well-defined point in the course of disease? Yes No Unknown

Comments:

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

Comments:

D. Were the participants recruited prospectively? Yes No Unknown

Comments:

3. Were all potentially important prognostic factors assessed? Yes No Unknown

Comments:

A. Were the patients sufficiently homogeneous with respect to prognostic risk? Yes No Unknown

Comments:

B. Are there subgroups in the sample with very different prognosis compared to other subgroups in the study? Yes No Unknown

Comments:

** May include Pilot Studies or Case Series, if study follows cohort with fair or better sample size (>40 participants)*

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- 4. Were objective and unbiased outcome criteria used?** Yes No Unknown
Comments:
- Were instruments used to measure the outcomes tested to be valid and reliable? Yes No Unknown
Comments:
- 5. Was the follow up process described and complete?** Yes No Unknown
Comments:
- A.** Is there a description of withdrawals and dropouts? Yes No Unknown
Comments:
- B.** Were all patients who entered the study accounted for at its conclusion? Yes No Unknown
Comments:
- C.** Was the follow up described and complete with a low rate of attrition? Yes No Unknown
Comments:
- D.** Was the follow up long enough to fully study the effects of the intervention? Yes No Unknown
Comments:
- 6. 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?

- 7. Were the statistical analysis methods clearly described and appropriate?** Yes No Unknown
Comments:
- 8. Did the studies have a sufficiently large sample size?** Yes No Unknown
Comments:
- 9. Were the endpoints quantifiable and precisely measurable?** Yes No Unknown
Comments:
- Was the assessment of the endpoint made independent of knowledge of prognostic factors? Yes No Unknown
Comments:
- 10. Does the prognosis change as the patient ages?** Yes No Unknown
Comments:

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How likely are the outcomes over time? (*Survival curves?*)

Unknown

Comments:

11. What are the main results of the study?

(Enter or calculate results in the appropriate fields in the tables below. Point estimates? Effect Size?)

* 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 numbers, Table numbers, Figures, Graphs*)

B. How precise were the results? (*Were the results presented with Confidence Intervals?*)

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

12. 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:

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:

13. Are your patient's values and preferences satisfied by the treatment and its consequences?

Yes No Unknown

Comments:

14. 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 Prospective Cohort Study (2a)
 - Lesser Quality Prospective Cohort Study (2b)
 - Good Quality Retrospective Cohort Study (3a)
 - Lesser Quality Retrospective Cohort Study (3b)
 - Not Valid, Reliable, or Applicable

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TABLE OF EVIDENCE LEVELS						
DOMAIN OF CLINICAL QUESTION	TYPE OF STUDY / STUDY DESIGN					
	Systematic Review Meta-Analysis	Cohort – Prospective	Cohort – Retrospective	Case – Control	Epidemiology Case Series	Expert Opinion Case Reports
Prognosis	1a	2a	3a	4a	4a	5
	1b	2b	3b	4b	4b	

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. 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>.
4. Fineout-Overholt and Johnston: Teaching EBP: asking searchable, answerable clinical questions. *Worldviews Evid Based Nurs*, 2(3): 157-60, 2005.

2x2 TABLE / STUDY CALCULATIONS / RESULTS TABLE:

	Outcome / Disease		Unexposed / Control Event Rate CER = $c / c+d$ Exposed / Experimental Event Rate EER = $a / a+b$
	Yes	No	
Exposed / Experimental / Treatment Group	a	b	Relative Risk – RR = EER / CER RR Reduction – RRR = $(CER - EER) / CER = 1-RR$ Odds Ratio – OR = ad / bc
Unexposed / Control Group	c	d	Standard Error – SE = square root of $((p \times (1-p)) / N)$ Confidence Interval <i>proportion</i> CI = ± 1.96 (square root of $((CER*(1-CER) / \# \text{ control pts.}) + ((EER*(1-EER) / \# \text{ exper. pts.}))$)

PROGNOSIS ENDPOINTS	Sample Size [N]	Proportion (n/N)	Standard Error [SE]	Confidence Interval [95% CI]	Relative Risk [RR]	Odds Ratio [OR]	Other Data Results	p value
Prognosis 1:	N =	p = %						
	n prognosis =							
Prognosis 2:	N =	p = %						
	n prognosis =							
Prognosis 3:	N =	p = %						
	n prognosis =							
Prognosis 4:	N =	p = %						
	n prognosis =							
Prognosis 5:	N =	p = %						
	n prognosis =							

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