

da qualidade

Avaliação dos ensaios clínicos

randomizados



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Objetivos da aula

- Formulação da pergunta
- Identificação e seleção do estudo
- Modelo de avaliação crítica
- Sintetizando informações de vários ensaios clínicos
- Qualidade de ensaios clínicos

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Formulação da Pergunta

Situação clínica
Intervenção
Tipo de estudo

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Questões Clínicas

Qual a melhor opção terapêutica?
Qual a melhor opção para a reabilitação?
Qual a melhor opção educacional?
Qual a melhor opção para prevenir a doença?
Qual a melhor intervenção?

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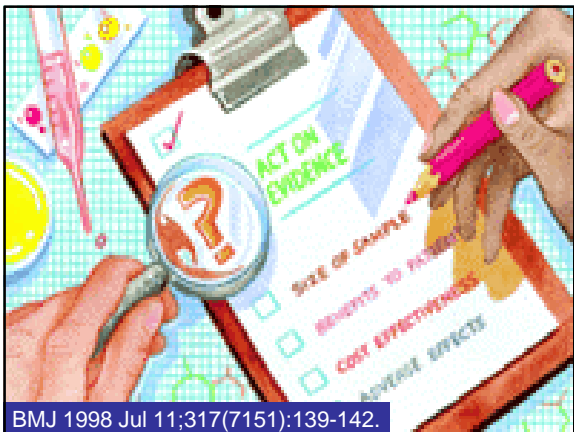
Identificação de Estudos

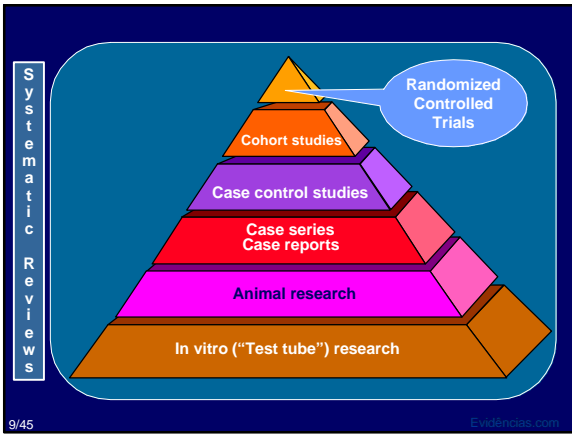
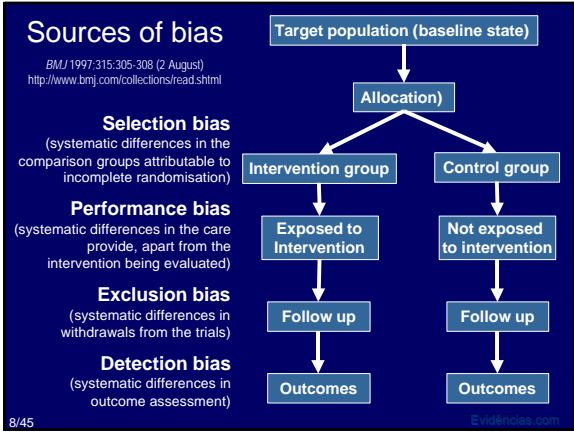
Best single terms	Sensitivity	Specificity	Database
clinical trial (pt)	93%	92%	1990 - present
random:	82%	95%	<1990

Cochrane search strategy for RCTs

ACP Journal Club 1994;121(1):A-10.
http://www.cche.net/principles/howto_therapy.asp

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Levels of Evidence

1a) Systematic Review (with homogeneity) of RCTs
 1b) Individual RCT (with narrow CI)
 1c) All or none

<http://cebmr2.ox.ac.uk/docs/levels.html>

Levels of Evidence

2a) Systematic Review (with homogeneity*) of cohort studies
 2b) Cohort study (including low quality RCT)
 2c) "Outcomes" Research

<http://cebmr2.ox.ac.uk/docs/levels.html>

Levels of Evidence

3a) Systematic Review (with homogeneity*) of case-control studies
 3b) Individual Case-Control Study

<http://cebmr2.ox.ac.uk/docs/levels.html>

Levels of Evidence

- 4) Case-series (and poor quality cohort and case-control studies)
- 5) Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

<http://cebim.jr2.ox.ac.uk/docs/levels.html>

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Princípios

Validade
Importância
Aplicabilidade

JAMA 1993;270(17):2093-2095.

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Modelo de avaliação

- **Validade**
 - Eu posso confiar nos resultados?
- **Importância**
 - A informação, se verdadeira, é clinicamente importante?
- **Aplicabilidade**
 - Eu posso aplicar aos meus doentes?

JAMA 1993;270(17):2093-2095.

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Avaliação crítica

- **Tratamento:**
 - Randomização adequada?
 - Análise por intenção de tratar?
- **Diagnóstico:**
 - Padrão-ouro presente?
 - Amostra representativa ?

JAMA 1993;270(17):2093-2095.

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Avaliação crítica

- **Prognóstico:**
 - Amostra representativa?
 - Seguimento suficientemente?
- **Revisões de literatura:**
 - Metodologia explícita? Adequada?

JAMA 1993;270(17):2093-2095.

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Aula em um diapositivo

Users' guides to the medical literature
II. How to use an article about therapy
or prevention.

JAMA 1994;271(1):59-63.

JAMA 1993; 270(21):2598-601.

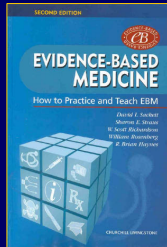
http://www.cche.net/principles/content_all.asp

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Aula em um diapositivo

Users' guides to the medical literature
http://www.cche.net/principles/content_all.asp



www.bmj.com/collections/read.shtml

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Are the Results Valid?

Primary Guides

Treatments randomized?
Follow-up? Intention-to-treat?

Secondary Guides

"Blind" to treatment?
Were the groups similar?
The groups treated equally?

JAMA 1994;271(1):59-63.

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Are the Results Valid?

Was the assignment
of patients to
treatments
randomized?

JAMA 1994;271(1):59-63.

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Are the Results Valid?

Were all patients who
entered the trial properly
accounted for and attributed
at its conclusion?

Follow-up complete?
Intention-to-treat analysis?

JAMA 1994;271(1):59-63.

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Are the Results Valid?

Were patients, health
workers, and study personnel
"blind" to treatment?

JAMA 1994;271(1):59-63.

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Are the Results Valid?

Were the groups
similar at the start of
the trial?

JAMA 1994;271(1):59-63.

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Are the Results Valid?

Aside from the experimental intervention, were the groups treated equally?

JAMA 1994;271(1):59-63.

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What are the Results?

How large was the treatment effect?

JAMA 1993; 270(21):2598-601.

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What are the Results?

How precise was the estimate of the treatment effect?

JAMA 1993; 270(21):2598-601.

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		Desfecho	
		+	-
Grupos	Ex	a	b
	Ct	c	d

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Will the Results Help me in Caring for my Patients?

Can the results be applied to my patient care?

JAMA 1993; 270(21):2598-601.

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Will the Results Help me in Caring for my Patients?

Were all clinically important outcomes considered?

JAMA 1993; 270(21):2598-601.

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Will the Results Help me in Caring for my Patients?

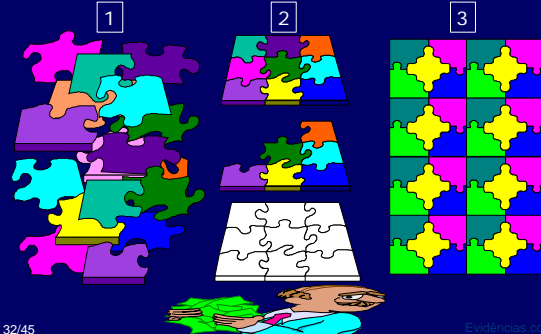
Are the likely treatment benefits worth the potential harms and costs?

JAMA 1993; 270(21):2598-601.

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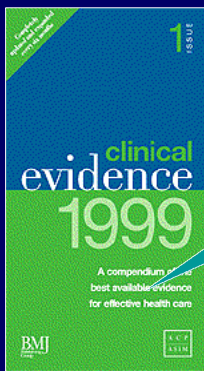
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Sintetizando informações de vários ensaios clínicos



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www.evidence.org

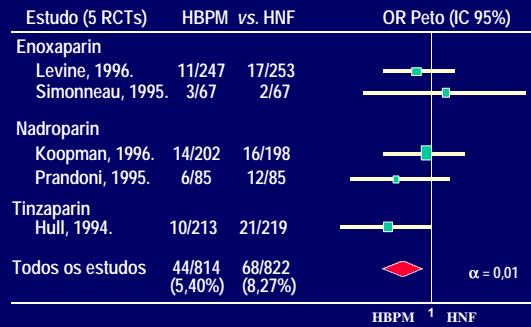
Clinical Evidence is a compendium of the best available evidence for effective health care



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Mortalidade (TVP proximal)

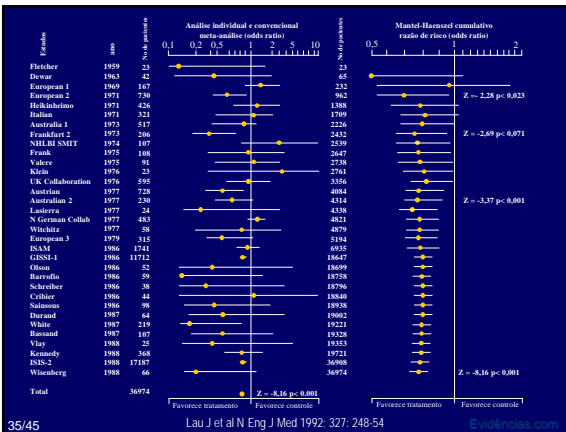


RRR 36% (7% a 57%)

NNT 35 (19 a 235)

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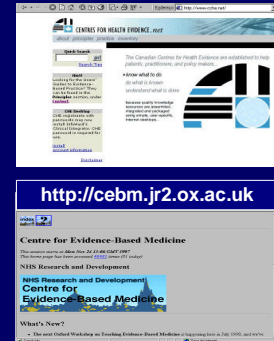
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www.cche.net



<http://cebm.jr2.ox.ac.uk>

Recursos na internet

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Quality

The likelihood of the trials design to generate unbiased results

Jadad *et al.* Control Clin Trials 1996 Feb;17(1):1-12.

Dimensions of Quality

- Internal validity
- External validity
- Statistical analysis

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Escalas de Avaliação da Qualidade

J Clin Epidemiol 1998 Dec;51(12):1235-41.

Sources

Moher 1996.
The doctoral thesis of Jadad (1994)
The Methods group of the Cochrane Collaboration
Medline

Key-words

quality
assessment
methodology
randomised clinical trials
scales
checklist
quality scores
meta-analysis
epidemiology
methods

24 papers

17 papers

17 domain and 206 itens

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Escalas para avaliação da qualidade dos ensaios clínicos

Jadad AR, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 1996 Feb;17(1):1-12.

de Vet HCW, et al. Systematic review on the basis of methodological criteria. Physiotherapy 1997;83:284-9.

Verhagen AP, et al. The Delphi list: a criteria list for quality assesment of randomized clinical trials for conducting systematic reviews developed by Delphi consensus. J Clin Epid 1998 Dec;51(12):1235-41.

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Instrument for Measuring Quality of RCTs

Jadad *et al.* Controlled Clinical Trials 1996;17(1):1-12.

**Was the study described as randomized?
Was the study as double-blind?
Was there a description of withdrawals and dropouts?**

Give 1 point for each "yes"

**Was the randomization described and appropriate?
Was the blinding described and appropriated?**

Give 1 additional point for each "yes"
Deduct 1 additional point for each "not"

**Score range = 0 a 5
Poor quality < 3**

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Delphi list

J Clin Epidemiol 1998;51(12):1235-41.

Domains

1. Study question
2. Population
3. Power calculation
4. Treatment allocation
5. Study design
6. Ethics
7. Intervention
8. Outcomes measures
9. Follow-up / withdrawals
10. Blinding
11. Co-intervention
12. Side-effects
13. Compliance
14. Prognostic comparability
15. Analysis
16. Conclusion
17. Presentation

Delphi-1 & 2

- 2
- 15
- 9
- 12
- 2
- 4
- 19
- 21
- 14
- 28
- 5
- 5
- 6
- 6
- 41
- 10
- 7

Delphi-3

-
- 1
- 1
- 1
-
-
- 1
-
- 1
- 3
- 1
-
- 1
- 1
- 2
-
-

Delphi list

-
- 1
-
- 1
-
-
-
-
-
- 3
-
-
-
- 1
- 2
-
-

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Delphi list

J Clin Epidemiol 1998;51(12):1235-41.

1. Treatment allocation
 - a) Was a method of randomisation performed?
 - b) Was the treatment allocation concealed?
2. Were the groups similar at baseline regarding the most important prognostic indicators?
3. Were the eligibility criteria specified?
4. Was the outcome assessor blinded?
5. Was the care provider blinded?
6. Was the patient blinded?
7. Were point estimates and measures of variability presented for the primary outcome measures?
8. Did the analysis include an intention-to-treat analysis?

Yes / No / Don't know

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Quality

Quality is a set of parameters in the design and conduct of a study related to effect sizes.

Verhagen *et al.* J Clin Epidemiol 1998;51(12):1235-41.

Quality is a set of parameters in the design and conduct of a study that reflects the validity of the outcome, related to the external and internal validity and the statistical model used.

Verhagen *et al.* J Clin Epidemiol 1998;51(12):1235-41.

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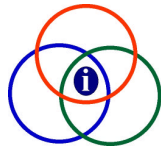
A scientific study ultimately contribute only a piece of an enormous puzzle

Mulrow CD. Rationale for systematic reviews. BMJ 1994 Sep 3;309(6954):597-9.

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