A spot check on quality of reporting issues in acne trials

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Clinical dermatology • **Review article**

CED
Clinical and Experimental Dermatology

Management of acne vulgaris: an evidence-based update

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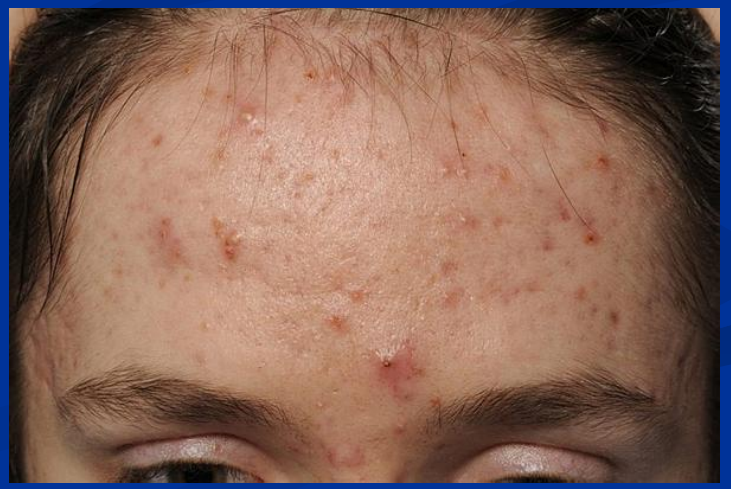
- 2007-2009 evidence update
- Only one new systematic review



Ingram *et al. Trials* 2010, **11**:77
http://www.trialsjournal.com/content/11/1/77

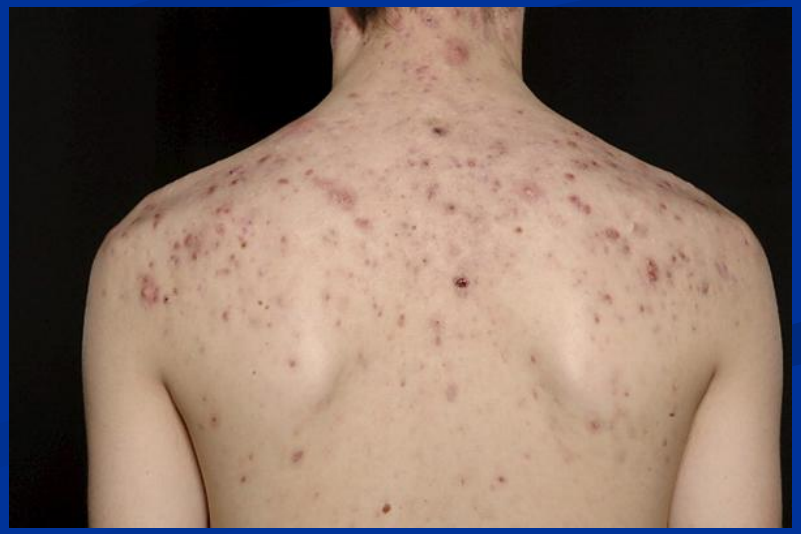
TRIALS

COMMENTARY Open Access

Problems in the reporting of acne clinical trials: a spot check from the 2009 Annual Evidence Update on Acne Vulgaris

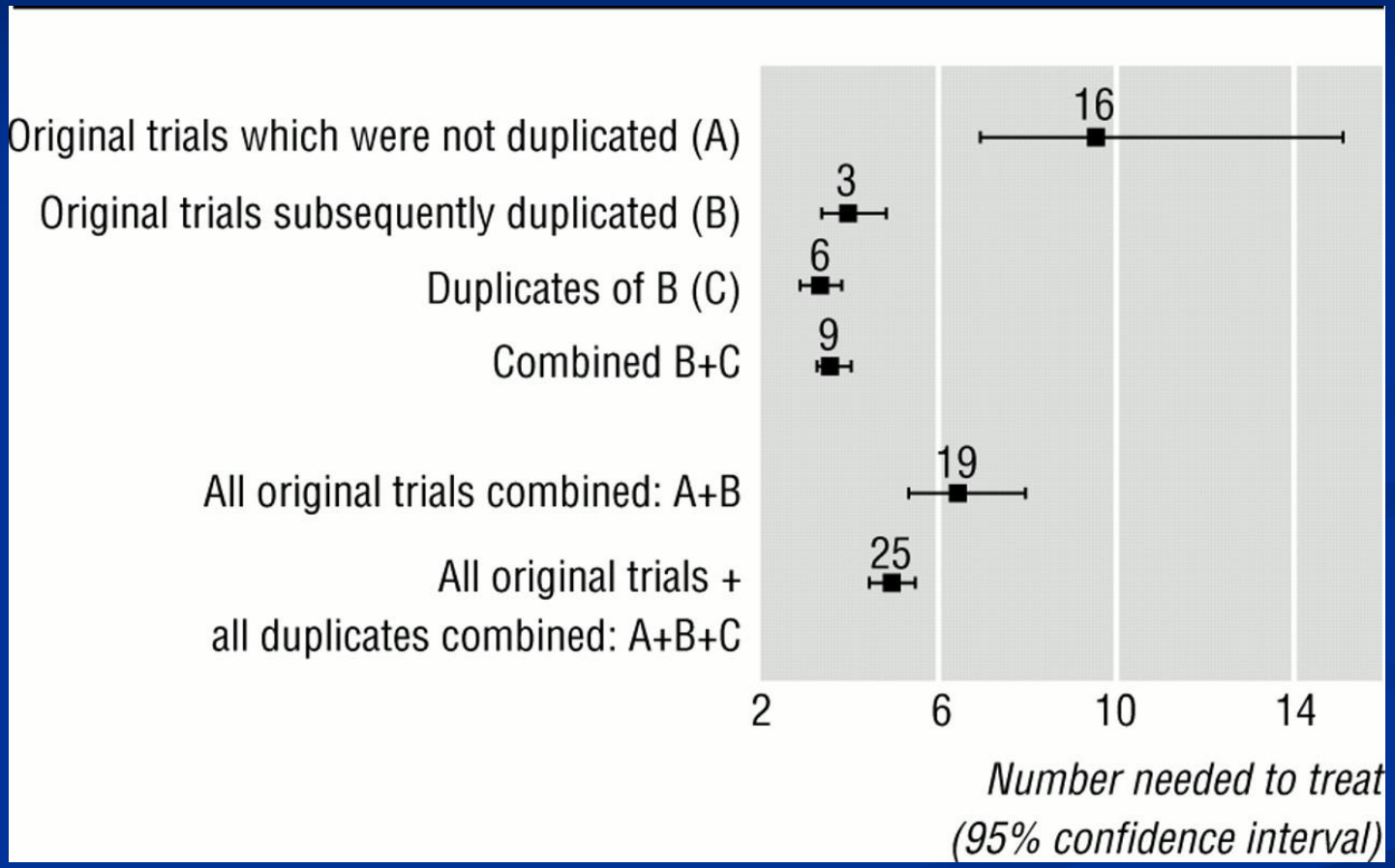
John R Ingram[1], Douglas JC Grindlay[2] and Hywel C Williams*[2]

- Nearly half of the 25 RCTs examined had problems of trial reporting



One trial = One paper

Duplicate publication

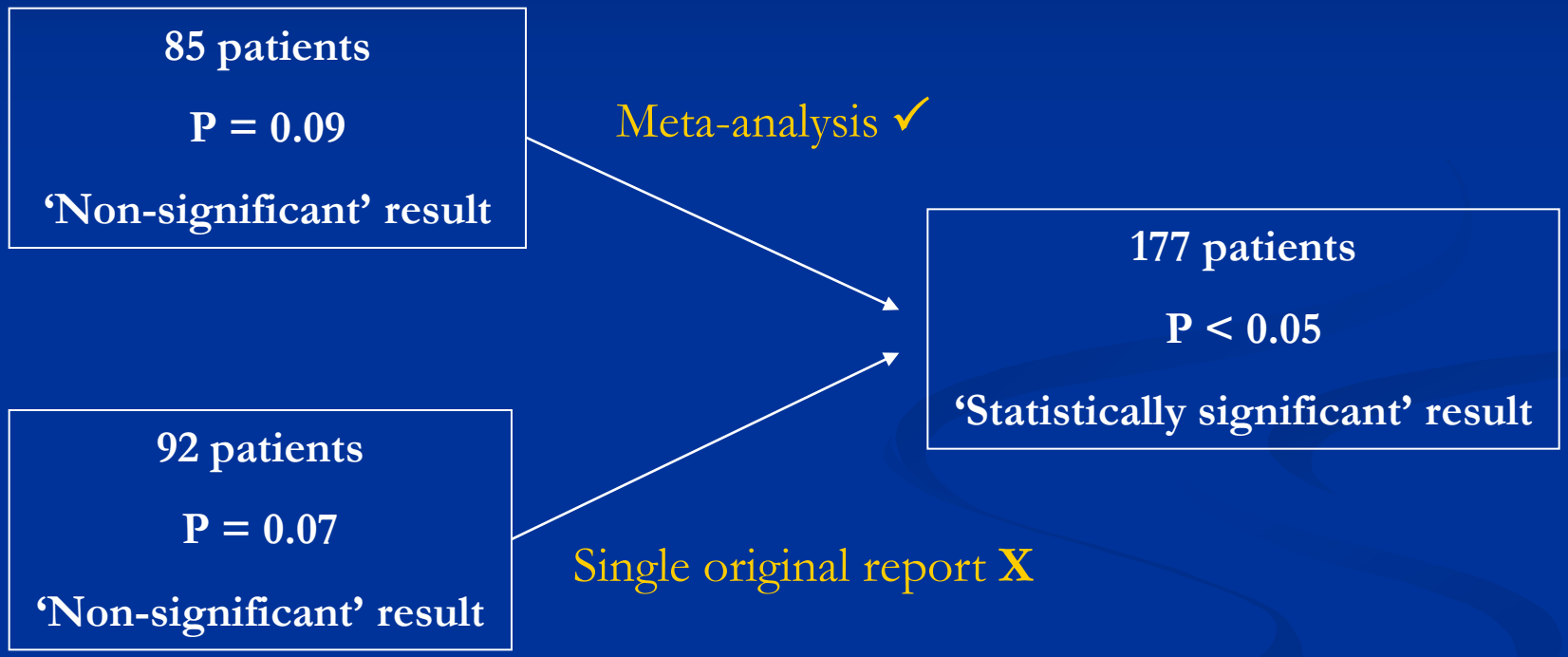


Tramer MR et al. Impact of covert duplicate publication on meta-analysis. BMJ 1997;315:635.

‘Salami’ publication

- 3 arm parallel group study – 2 arms compared with 3rd arm and published separately; neither referenced the other

Two independent trials reported as one

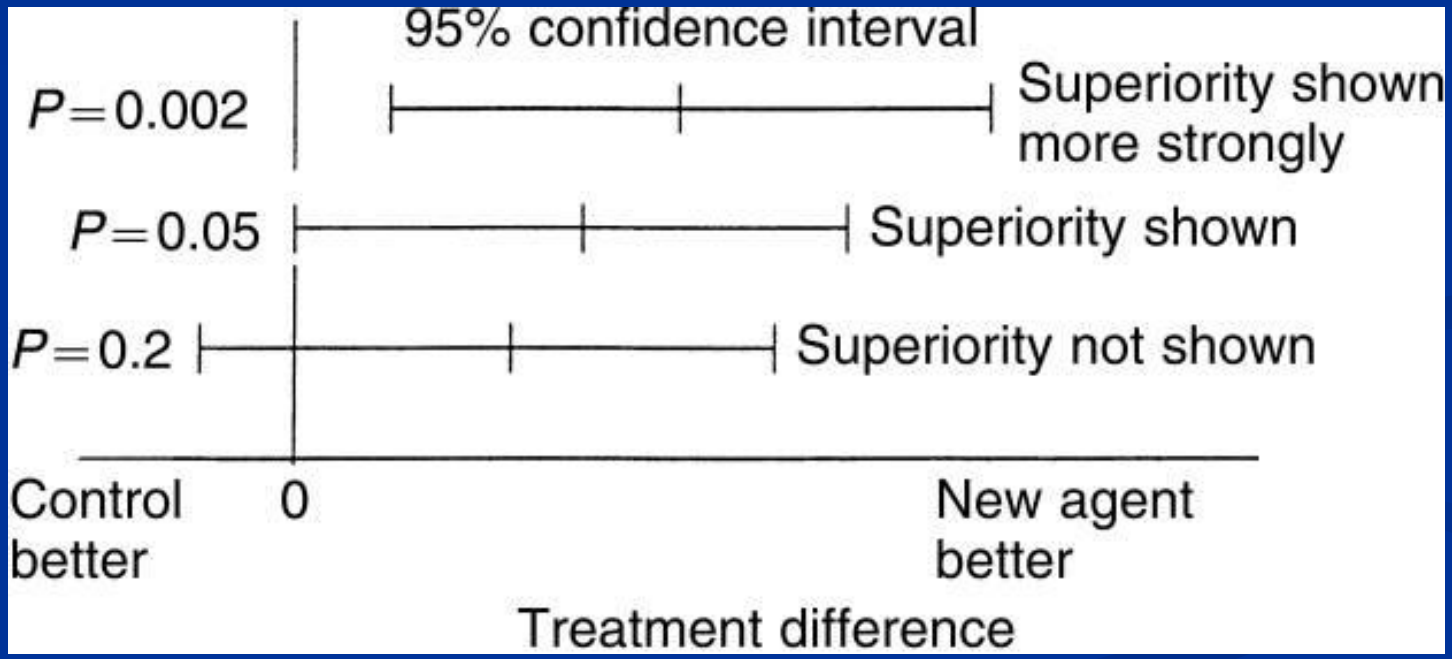


Hypothetical example. See also Katz KA et al. Reporting clinical trials: why one plus one does not equal two. J Am Acad Dermatol 2009; 61: 1082-3.

Were they really double-blind?

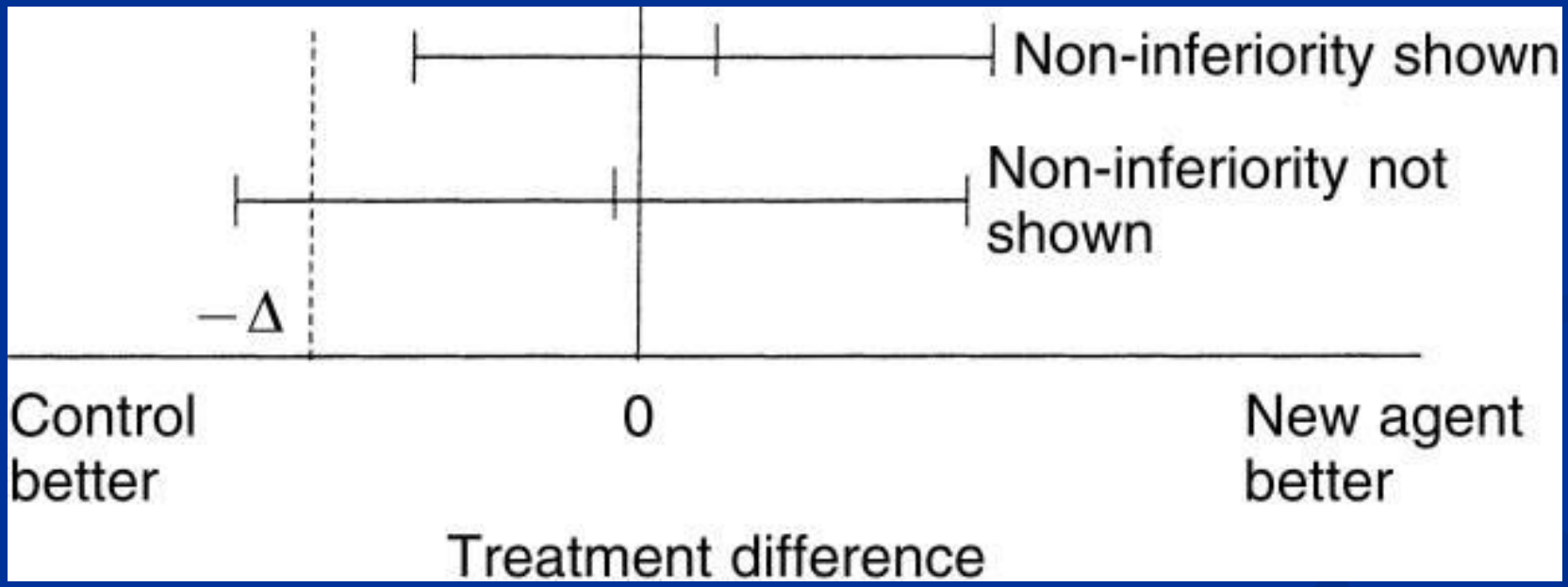
Superiority vs non-inferiority trial

Analysis of superiority trial



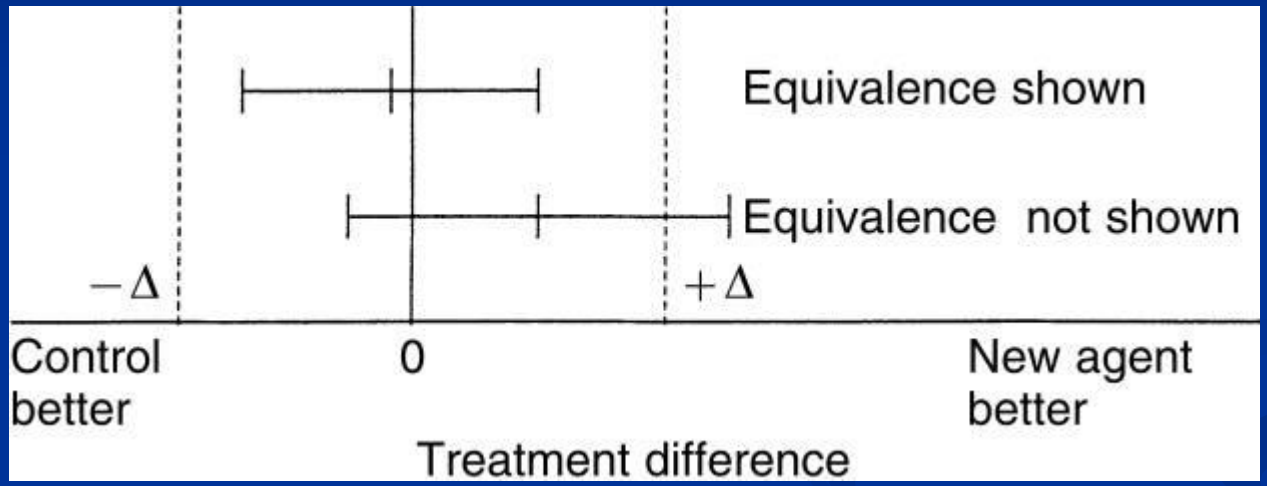
The European Agency for the Evaluation of Medicinal Products Committee for Proprietary Medicinal Products (2000). Points to consider on switching between superiority and non-inferiority.

Non-inferiority trial: failure to pre-specify non-inferiority margin



The European Agency for the Evaluation of Medicinal Products Committee for Proprietary Medicinal Products (2000). Points to consider on switching between superiority and non-inferiority.

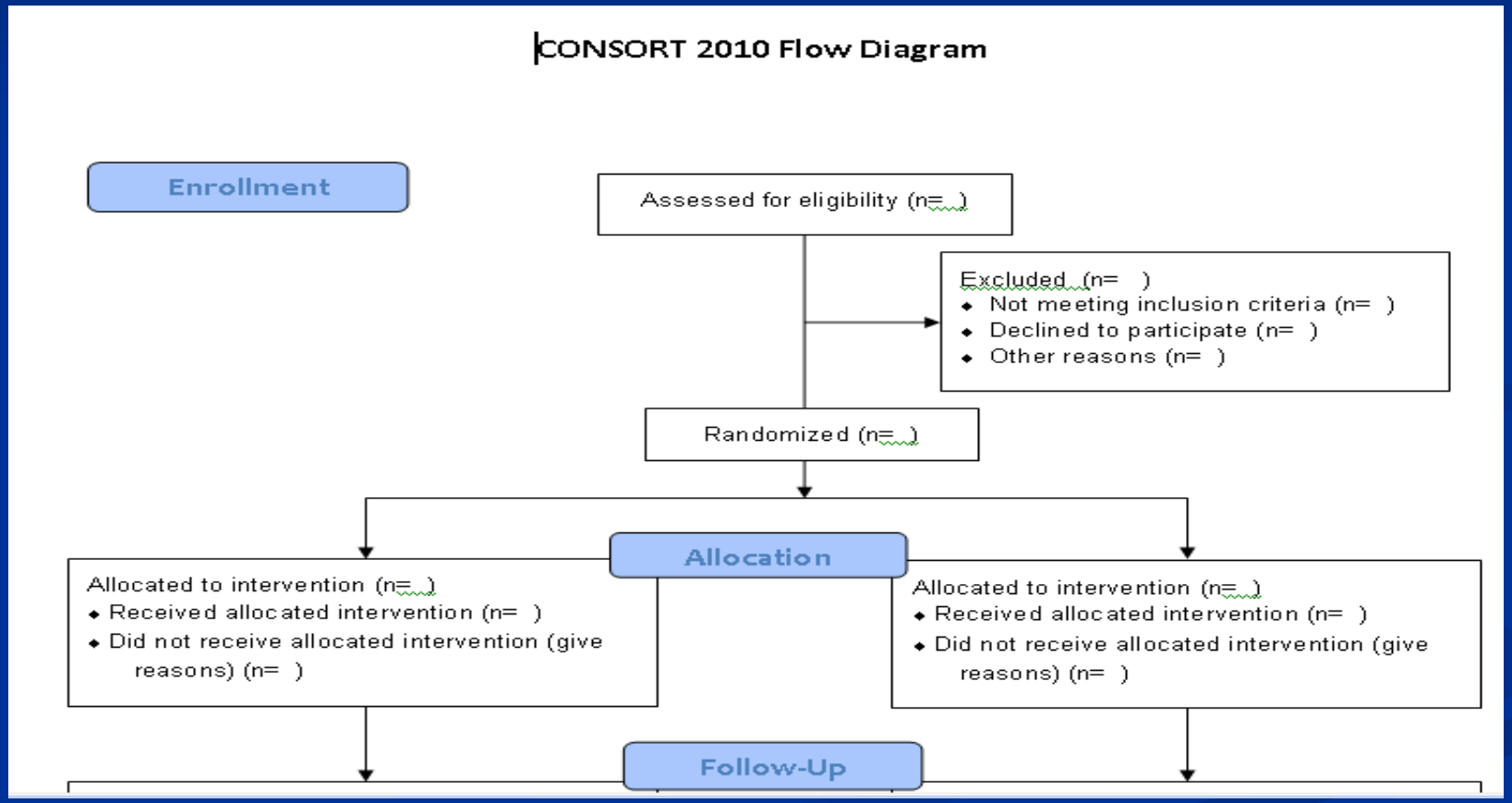
Lack of power to show equivalence



Non-significant result in (underpowered) superiority trial of 2 active comparators ≠ equivalence

The European Agency for the Evaluation of Medicinal Products Committee for Proprietary Medicinal Products (2000). Points to consider on switching between superiority and non-inferiority.

Intention to treat analysis



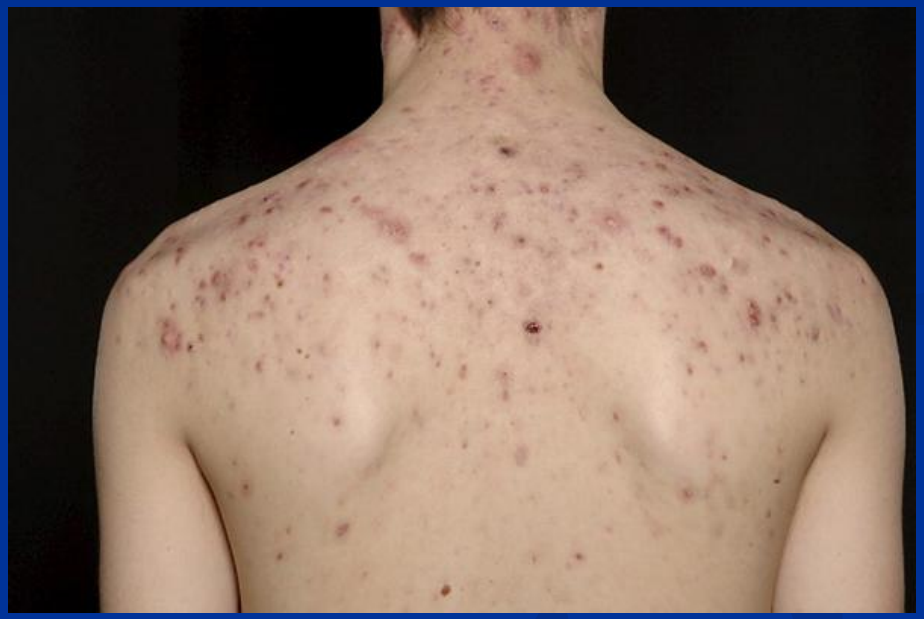
Selective outcome reporting

Outcomes measured	Outcomes in body of manuscript	Outcomes in abstract
Quality of life P = 0.3	% reduction in total acne lesions, P< 0.01	% reduction in total acne lesions, P< 0.01
Patient global assessment P =0.2	% reduction in comedones, P < 0.05	% reduction in comedones, P < 0.05
Physician global assessment, P = 0.07	Physician global assessment, P = 0.07	
% reduction in comedones, P < 0.05		
% reduction in total acne lesions, P< 0.01		

Clinically insignificant results

P = 0.001

Acne lesion count reduced by 11%



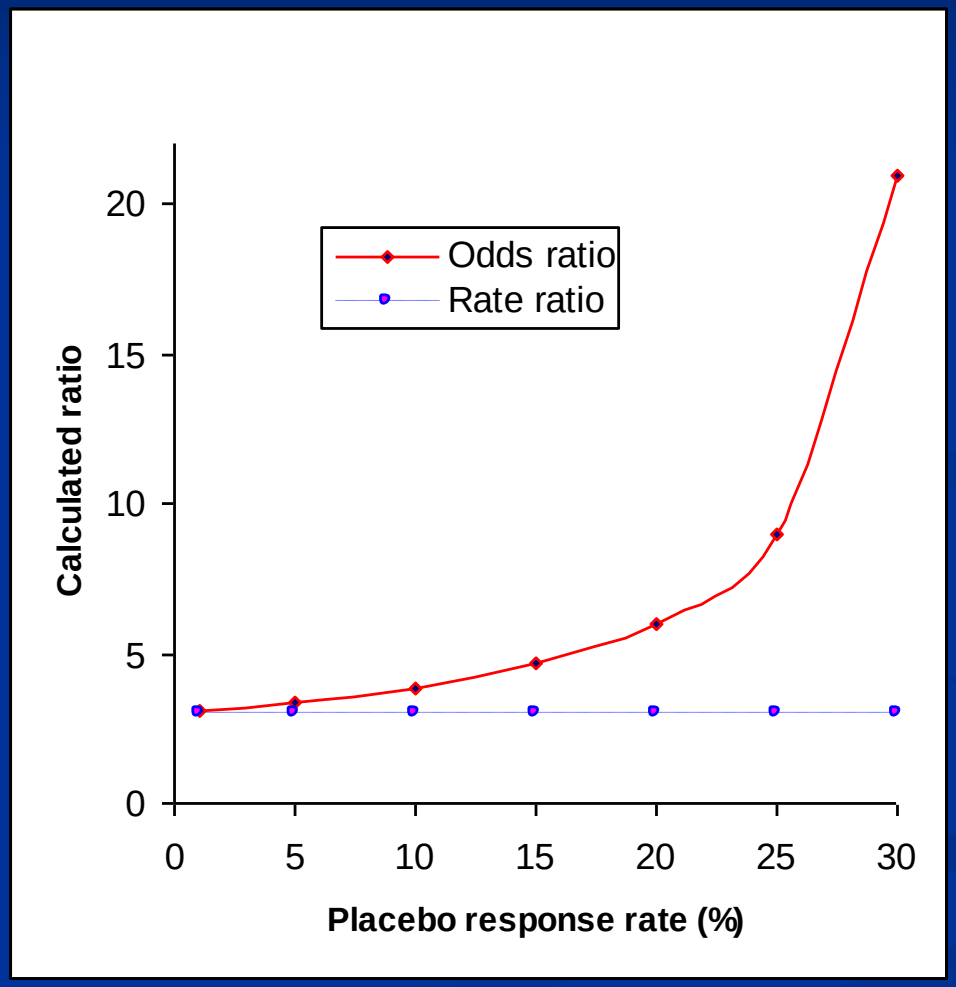
Rate ratio vs odds ratio

- Trial of new acne treatment (Rx)
  - **50%** improve in active group, odds 1:1
  - **10%** improve on placebo, odds 1:9
  - Intuitively response **5x** more likely for active Rx

- Rate ratio = 0.5/0.1 = 5
- Odds ratio = 1/ (1/9) = 9

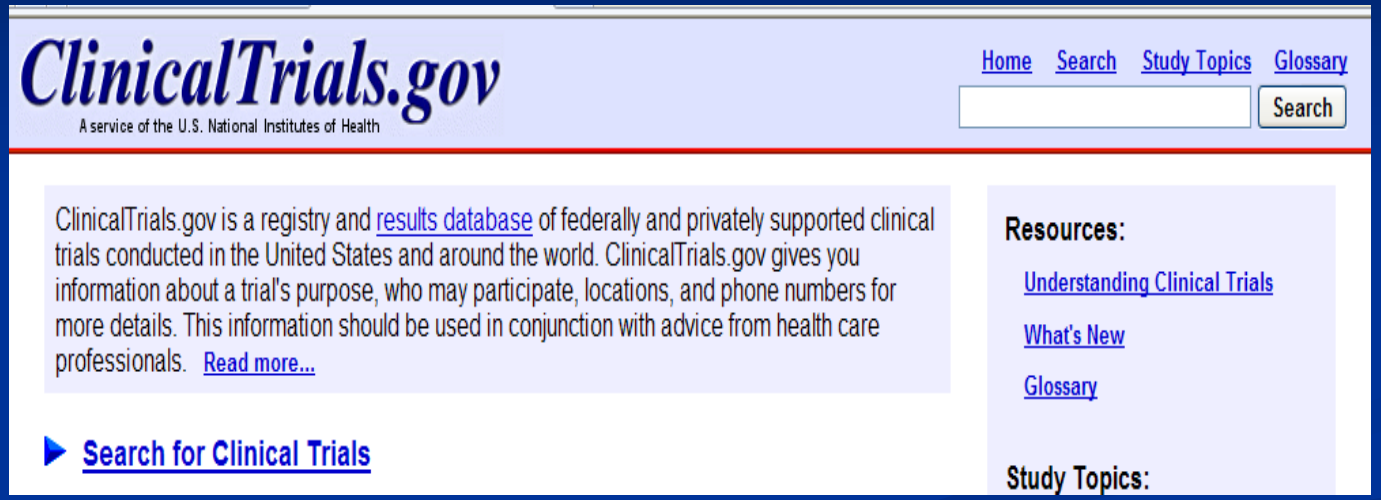
Adapted from Simon SD. Understanding the odds ratio and the relative risk. J Androl 2001; 22: 533-6.

Odds ratio is an overestimate when event rates are frequent



Adapted from Katz KA. The (relative) risks of using odds ratios. Arch Dermatol 2006; 142: 761-4.

Possible solutions



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Rep on pa
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	

Acknowledgements