

SURG238: PRACTICAL INTRODUCTION TO CLINICAL RESEARCH

Welcome to Week 4!

Agenda

1. Intro to statistics: Dr. Lakshika Tennakoon
2. P values
3. Odds ratios

P values: don't pay attention (too much)

P values and hypothesis testing: watch the language

Our eyes are drawn to “P values”

What is P value?

- Assuming A and B are the same, probability of getting a result=/more extreme than observed

$P \text{ value} \leq \alpha$ = “our results are significant”?

- NO

P values: don't pay attention (too much)

Viewpoint

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The Proposal to Lower *P* Value Thresholds to .005

John P. A. Ioannidis, MD, DSc¹

[□ Author Affiliations](#) | [Article Information](#)

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P values are misinterpreted, overtrusted, and misused. The language of the ASA statement enables the dissection of these 3 problems. Multiple misinterpretations of *P* values exist, but the most common one is that they represent the “probability that the studied hypothesis is true.”³ A *P* value of .02 (2%) is wrongly considered to mean that the null hypothesis (eg, the drug is as effective as placebo) is 2% likely to be true and the alternative (eg, the drug is more effective than placebo) is 98% likely to be correct. Overtrust ensues when it is forgotten that “proper inference requires full reporting and transparency.”³ Better-looking (smaller) *P* values alone do not guarantee full reporting and transparency. In fact, smaller *P* values may hint to selective reporting and nontransparency. The most common misuse of the *P* value is to make “scientific conclusions and business or policy decisions” based on “whether a *P* value passes a specific threshold” even though “a *P* value, or statistical significance, does not measure the size of an effect or the importance of a result,” and “by itself, a *P* value does not provide a good measure of evidence.”³

“ $P < 0.05$ ”

- There is no actual cutoff for being “statistically significant”
- “statistically significant” = failure to reject the null. This is NOT accepting the null
 - No evidence that difference in groups was the same. NOT that groups were different
- Small p value does NOT mean large effect size
 - i.e. “Difference in mean systolic blood pressure (group 1: 140 vs group 2: 142) < 0.001 ”
 - 3 factors affect p value: effect size, sample size, spread of data

P values and testing multiple outcomes

If testing multiple outcomes, need to adjust alpha ***a priori***

- If you look for enough comparisons between two groups, you WILL find a difference...simply by chance
- Bonferroni correction: α/n
- i.e. looking at 5 outcomes. For statistical significance, instead of $p < 0.05$, will be $p < 0.01$. Again, don't rely on threshold itself

P values and Table 1

Not meaningful (personal opinion)

Misleading if populations have large sample sizes: report SMD instead

Odds ratio: what are they?

Odds Ratio (OR)

Contingency (or 2 x 2) Table

	Cases	Controls	Total
Exposed	a	b	a+b
Unexposed	c	d	c+d
Total	a+c	b+d	a+b+c+d

$$\text{OR} = (a/c) / (b/d)$$
$$= (a*d) / (b*c)$$

Relative Risk (RR)

Contingency (or 2 x 2) Table

	Cases	Controls	Total
Exposed	a	b	a+b
Unexposed	c	d	c+d
Total	a+c	b+d	a+b+c+d

$$\text{RR} = I_E / I_U$$
$$= P(D|E) / P(D|U)$$
$$= [a/(a+b)] / [c/(c+d)]$$

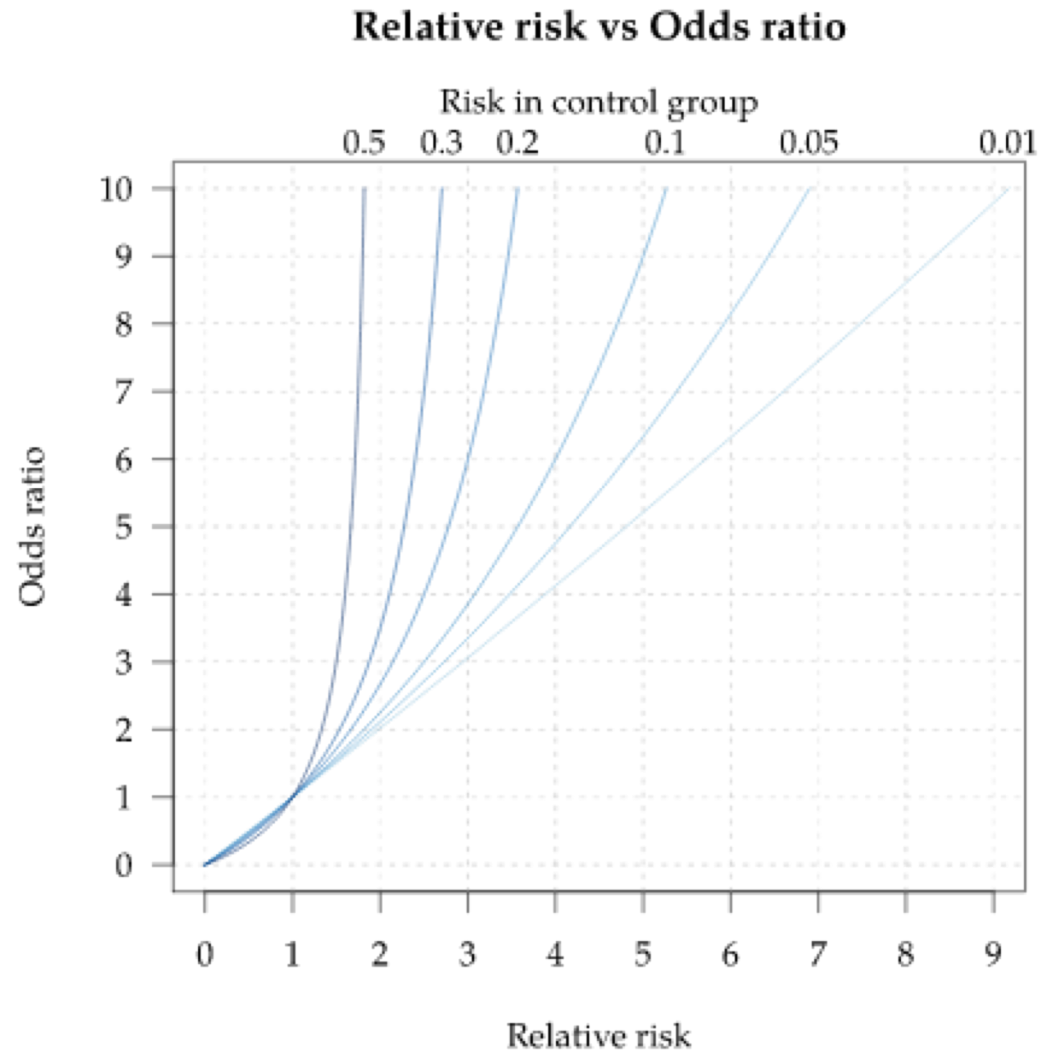
OR are not intuitive

- “your odds of death increase by 5%” is NOT “risk of death”

Why odds ratios?

- Output of logistic regressions (just exponentiate the coefficients)
- Case control studies...no choice

Odds Ratios are dramatic



OR are always farther from the null than RR
- OR paint “more dramatic” picture of differences

Can interpret OR as RR if rare disease assumption is met
(risk in control group <10%)

Look at the confidence intervals!

95% CI is NOT (95% probability true value is in this range),

95% CI is: after hypothetical repeats of experiments using the data, 95% of the time, true value will be within this range