

Is the Statistical Significance of $P < 0.05$ Still Relevant?

G.J. Nason¹, M.K. O'Reilly²

1. Division of Urology, Sunnybrook Health Sciences Centre, University of Toronto, ON, Canada

2. Department of Radiology, University of Washington Medical Center, Seattle, WA, USA

Dear Sir,

The medical profession has been criticised for managing patients in a paternalistic manner. The aim of practice is patient centred; presenting patients with evidence based choices to ensure the best care. Many practitioners reference their respective guidelines which are often collated by panels of experts. Level 1 evidence is lacking in many facets of our practices and even when it does exist, these randomised control trials are often focused on can the treatment work, usually in a tightly controlled environment as opposed to does it work, in a more real world setting. As a result many practices have evolved based on lower levels of evidence and often anecdotal "expert" opinion.

To understand the findings of a clinical trial- one needs to be able to analyse and critique results, tables and figures. Without a background in biostatistics or clinical epidemiology- many physicians are lost in the detail and focus on an abstract, conclusion or the Twitter update. Researchers strive to find statistically significant results to ensure their trial is perceived as a positive or a negative trial.

For example, Drug A resulted in improved overall survival compared to Drug B, $p=0.04$ (Positive trial).

Or, there was no difference noted in length of stay between robotic and open surgery, $p=0.06$ (Negative trial).

Without an understanding of the size of the study, the power of the study, the confidence intervals and hazard ratios- a p-value is meaningless. The p-value of 0.05 is an arbitrary value based upon the probability that there is only a 5% chance that the effect observed occurred by chance alone. Statistical significance is not a dichotomy- below 0.05= good, above 0.05= bad. Non-significance does not mean no effect.^{1,2}

We are awash with "evidence", much of it poor. What can we do? It has been suggested to remove the term statistically significant, with a focus on more reliable and interpretable indicators. Should more emphasis be placed on the publishing journal to ensure that the stated interpretation of the results accurately reflect what can be reasonably ascertained from the trial? The most important aspect of any trial, for the physician is the clinical significance and impact on their patient. If results are presented to a patient as binary significant or insignificant- we are feeding them a biased opinion.

An alternative use of the evidence would be to consider presenting patients with an individualised decision model analysis. In this setting the patients options are weighted based upon risk and benefits and what merits importance to that patient.

For example- 67 year old man with prostate cancer (PSA 7, Gleason 3+4 disease). His options include surgery or radiation. The main side effects to consider are urinary incontinence and erectile dysfunction. A decision model analysis would weight his risk of survival, progression and side effect profile based upon what is important to him. One man may weight erectile dysfunction more than the next and be willing to accept a lower overall survival. The binary interpretation of $p < 0.05$ needs to be retired.

Corresponding Author:

Gregory Nason, FRCS Urol, FEBU
Clinical Fellow in Urologic Oncology,
Sunnybrook Health Sciences Centre,
University of Toronto,
Ontario,
Canada
Email: nasong@tcd.ie

References:

1. Amrhein V, Greenland S, McShane B. Scientists rise up against statistical significance. *Nature*. 2019 Mar;567(7748):305-307.
2. Ioannidis JPA. Retiring statistical significance would give bias a free pass. *Nature*. 2019 Mar;567(7749):461.