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Meaning of p-value in Medical Research

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Abstract

Any researcher begins the research with null hypothesis and alternative hypothesis. Null will be for supporting the old fact and alternative will be for the new fact invented/ doubted by the researcher/ scientist. Next step is to select one of this scientifically by using the science of statistics. For that the researcher should calculate the likelihood or probability that the difference observed in the study, however big or small, could have arisen purely by chance. This probability is known as p-value and it is sufficiently small, you can conclude that you have obtained a statistically significant difference. Confidence intervals and p-values take as their starting point the results observed in a study. Crucially, we must check first that this is an unbiased study.

Introduction

"Medicine is a science of uncertainty and an art of probability", mused William Osler. Medical journals are a confluence of medicine, science and journalism—and are expected to have the values of all three. Medical journals differ fundamentally from scientific journals in that the former is read mainly by practising doctors and not by scientists. Medical journals will continue to be the main vehicle of scientific information for years to come, particularly where access to computer and internet facilities are relatively limited. Nowadays the output—and rewards— of research are based almost entirely on published papers in scientific journals. Scientists in low-income and middle income settings want an opportunity to analyze data for their populations according to their own concerns. They want to be in the frontlines of national and global communications about their country's experiences. The basic assumption of inferential statistics is that we're observing a sample of finite size drawn from a population that is effectively infinite. By making observations about the sample, we are trying to make generalizations about the population. The Neyman-Pearson theory of hypothesis testing addresses the problem of choosing between two statistical hypotheses, H_0 and H_1. The solution involves selecting, before the data are observed, a set of potential observations (the critical region), then choosing H_1 if the actual observations fall in the critical region, and choosing H_0 if they do not. More clearly in large sample test, we will check the calculated value of the test formula is greater than the tabular value from the Z- table. Value is 1.96 for 95% and 2.58 for 99% Confidence Interval. The other method is so called software adopted method or widely used method p-value. It is described by Cox and Hinkley. Several people described p-value in several manners but finally it is the supporting probability of Null Hypothesis [1-30].

A p-value is a measure of how much evidence we have against the null hypothesis. The null hypothesis H_0, represents the hypothesis of no change or no effect, population mean and sample mean equal, population proportion or sample proportion equal. It is also known as producer's hypothesis, if customer is doing research. The smaller the p-value, the more evidence we have against H_0. It is also a measure of how likely we are to get a certain sample result or a result more extreme, assuming H_0 is true. **Medical research involves making a hypothesis and then collecting data to test that hypothesis. The p-value measures consistency by calculating the probability of observing the results from your sample of data or a sample with results more extreme, assuming the null hypothesis is true.** We will reject H_0 when p-value is less than 0.05. Sometimes, though, researchers will use a stricter cut-off (e.g., 0.01) or a more liberal cut-off (e.g., 0.10). The general rule is that **a small p-value is evidence against the null hypothesis while a large p-value means little or no evidence against the null hypothesis.**

Suppose that a Viagra medicine company alleges that **only 40% of all patients who take it have a side effect of headache.** If, you prescribed Viagra for effective treatment for Erectile Dysfunction and believe that the adverse event rate is much higher in patients. **In a sample of 100 patients, all hundred have a headache. The data supports your belief because it is inconsistent with the assumption of a 40% headache rate.** It would be like tossing a coin 100 times and getting heads each time. The p-value, the probability of getting a sample result of 100 **headache** events in all 100 patients assuming that the **headache** event rate is 40%, is a measure of this inconsistency. **The** p-value, 0.00000001**, is small enough that we would** reject the hypothesis that the **headache** event

rate was only 40%. **Researcher see a large p- value, he will decide null hypothesis is wrong. But if the sample size is not adequate and the sample is not the proper representative part then automatically p value will be high even though null hypothesis clinically right. So, the researcher** should also look for one of two things: First one is the power of the test which confirms that the sample size in that study was adequate for detecting a clinically relevant difference. Second one is **confidence interval** that lies entirely within the range of clinical indifference. Researcher should also be cautious about a small p-value, but for different reasons. **In some situations, the sample size is so large than required then the researcher can prove the medically insignificant result statistically significant** [1-30].

Consultant is reading a research paper for finding a better drug for a particular disease. In a good research paper author of the research paper should inform you what size difference is clinically relevant and what sized difference is trivial. But all the manuscripts are not good. So, the reader has to find out **how much of a difference would be large enough.** Then compare this to the confidence interval in the research paper. **If both limits of the confidence interval are smaller than a clinically relevant difference, then consultant should not change the drug, no matter what the p-value tells.**

Conclusion(s)

P-value is a very important concept for any medical researcher for understanding the research articles published and for making correct statistical and medical inferences in his own paper. Researcher should not interpret the p-value as the probability that the null hypothesis is true. Such an interpretation is problematic because a hypothesis is not a random event that can have a probability.

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