



Unethical Conduct of Underpowered Clinical Trials

I read with interest the article on the effect of antiseptics on the colonization rate of central venous catheters, published in the recent issue of your Journal.¹ Although the topic is very important, the study suffers from many shortcomings, the most important of which is low study power. Assuming expected prevalence rates of 22% and 17% in the control and treatment groups (an effect size of 5%) and type I error of 0.05, the power of this study is merely 0.17, far less than the minimum acceptable value of 0.80 for clinical trials. Considering the study design, the authors should have recruited almost 2000 patients to detect any difference between the two treatment arms. Conduction of underpowered clinical trials is unethical and discouraged.

Conflicts of Interest: I have no conflicts of interest to be declared.

Reference

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Unethical Conduct of Underpowered Clinical Trials: Reply

Thank you for your comments on our study, which is a newly noticed, yet common, concern regarding clinical

trials. However, there are some issues with respect to your comments.

The fact that our study was a trial carried out for the first time means that the existing literature contained no precedents.

As regards ethical concerns, we obtained approval from the Ethics Committee of Tehran University of Medical Sciences.

In regard to the power of the study, we took into consideration the last local colonization rate of central venous lines (infection control surveillance) and consulted experts so as to determine an appropriate and reliable sample size. We found that 50% of the samples were positive. Accordingly, based on this figure and considering the effect size of 20% reduction after intervention, probability of type I error of 0.05, and power of 95%, we decided to allocate 125 individuals to each group. Unfortunately, the power achieved was low and also no clinically important difference was observed. Nevertheless, the results are based on a prospective calculation of the sample size and the observed difference is not of clinical importance.

Power analysis can be performed before (an a-priori or prospective power analysis) or after (post-hoc or retrospective power analysis) data collection. Furthermore, although the utility of an a-priori or prospective power analysis in experimental study designs is universally accepted, the usefulness of retrospective methods remains controversial.¹ Yielding to a temptation to apply the statistical analysis of the collected data of the study to estimate the power invariably results in uninformative and misleading values, not least when taking into account that post-hoc power is the one-to-one function of the p-value attained.²

Our title asks; "Can a new antiseptic agent reduce the bacterial colonization rate of central venous lines in post-cardiac surgery patients?" We answer ever so conscientiously; "Consequently, we were unable to demonstrate that adding Sanosil to the routine preparation procedure (Chlorhexidine bath one day before and scrub with Povidone-Iodine at the time of CV line insertion) would be effective in reducing catheter bacterial colonization." (Page 74, last sentence of Conclusion).³ This tentative conclusion surely restricts the results to our specific trial conditions.

In addition, we present some probable reasons as to why there was no meaningful difference between the groups of study: "There are some probable reasons why we did not achieve meaningful differences between our two groups: ..." (Page 74, first sentence of second paragraph).³



References

1. Thomas L. Retrospective power analysis. *Conservation Biology* 1997;11:276-280.
2. Hoening JM, Heisey DM. The Abuse of Power: The Pervasive Fallacy of Power Calculations for Data Analysis. *Am Stat* 2001;55:19-24.
3. Yousefshahi F, Azimpour K, Boroumand MA, Najafi M, Barkhordari K, Vaezi M, Rouhipour N. Can a new antiseptic agent reduce the bacterial colonization rate of central venous lines in post-cardiac surgery patients? *J Teh Univ Heart Ctr* 2013;8:70-75.

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