EDITORIAL

NEGATIVE STUDIES: WHY SHOULD BE THEY METHODOLOGICALLY STRONG?

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Negative studies are the studies in which author has failed to disprove the null hypothesis. Occasionally, these type of studies are also referred as inconclusive studies. It is observed that strong publication bias exist regarding the publication of negative studies. Few studies published so far reveal that negative studies are not published as frequently as positive studies. It is observed that the trend of publication of negative studies is declining.[1,2] Various efforts are done to increase the awareness and publication of negative studies. New journals are launched which publishes exclusively negative studies, new section of negative studies are included in the existing journals and complete or partial waiver of publication fee for the negative studies is granted.[3] Even after these efforts it is observed that negative studies are in rarity. Prevalence of negative studies is below two digits in prominent Indian Medical Journals even after these vigorous efforts.

Ideally the published negative study should be methodologically strong, as weak negative study may have long term negative impact on research and patient care. If the published studies report negative result, the researcher working for the same objective may get discouraged to work again on the same line. For example, consider that researcher is planning to do a study of antidiabetic property of a herb. But if the published study reveal that the herb has no antidiabetic effect, he may feel to discontinue the study thinking this to be the conclusive finding. Here it is very important to know that the negative results may be witnessed in a study because of true negative effect or underpowered study (less sample size) or may be because of chance (type 2 error). On the basis of Indian Council of Medical Research (ICMR) funded project "Critical evaluation of negative studies published in Indian Medical Journals" and few pilot studies, it can be concluded that majority of negative studies published in Indian Medical Journals are not powered sufficiently to find the actual difference.[4] Similar findings were also observed for clinical trials and other negative studies published in some high impact medical journals.[5,6] We also found that not only majority of studies were underpowered but in many of them inappropriate statistics was used.[7] It will really be a setback to the process of evidence based medicine if conclusion of these underpowered negative studies are accepted and considered as a reason for discontinuation of the research. Hence publication of methodologically strong negative studies should be encouraged.

I also request the researcher not to consider results and conclusion of published negative studies as true, without critically analysing the published negative studies. Our previous work and recent project by ICMR clearly revealed that parameters reported in the published research article regarding methodology and statistics were not adequate and there was under reporting of various parameters which were needed for critical analysis of published negative studies.[8] Similar results were also seen for negative studies published in high impact western journals.[9] It is the duty of editor and reviewer to ascertain that all parameters which are important for critical appraisal of published negative studies should be included in the manuscript before acceptance.

I strongly believe that publication of negative studies should be encouraged but at the same time importance of their methodological and statistical strength should also be highlighted. A methodologically weak negative study may harm the science more as compared to the methodologically weak positive study.

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