



Trends in Publication of Negative Studies in Prominent Indian Medical Journals

Arvind Singh Panwar¹, Aseem Saxena², Jaikaran Charan³

¹Associate Professor, Department of Pharmacology, SMIMER, Surat

²Faculty, Management, D college, Indore

³Associate Professor, Department of Pharmacology, AIIMS, Jodhpur

ABSTRACT

Background: Publication of negative studies is as important as positive studies as absence of one may lead to publication bias. Available data based on very few published studies suggests a very strong publication bias for publication of only positive studies and declining trends for publication of negative studies. In spite of a thorough review similar data on trend analysis of publication of negative studies for Indian Medical Journals could not be found. Present study is an attempt to estimate the prevalence and trends in publication of negative studies in selected Indian Medical Journals.

Materials and Methods: Indian clinical practice and clinical specialties journals having an impact factor (Indexed in SCI) with publication history of 12 years or more were included in the analysis. A total of 12 journals were eligible for the inclusion. All the original articles published in these journals were analysed and studies were labeled as negative or positive based on predefined criteria. **Statistics:** Descriptive statistics was reported in the form of frequency, percentage and 95%CI. Fisher exact test was used for comparison of categorical variable and excel was used for linear regression and trend.

Results: Out of total 6341 articles published in amongst these 12 journals between year 2000 to 2011, 284 (4.4%, 95% CI 4.0% to 5.0%) were negative studies. Slight positive trend in the publication of negative studies was observed. It was observed that there were significantly more negative studies were published in the journals having impact factor >1 as compared to journals having impact factor <1 (151/4415 Vs 133/1926, Fisher exact P =0.0000001).

Conclusion: Prevalence and trend of publication of negative studies in prominent Indian Medical Journal shows strong publication bias that needs to be addressed on priority at various levels.

Keywords: Negative Studies, Prevalence, Trends, Indian Medical Journals

INTRODUCTION

Publication of research work in the form of research articles is an important method of sharing the findings of the research conducted by the researcher/s. All important research findings should be published and shared at appropriate forums so that scientific community and other stakeholder's are aware about the recent advances and happening in the scientific world. Publications may assist in application of scientific innovations for appropriate patient care and

clinical outcomes. Outcome of any research can be either positive or negative and both deserve equal importance and hence should share at appropriate forums including publication of findings in academic journals. There must not be any bias in the publication of articles with negative or positive results and scientifically sound research deserve publication irrespective of direction of results.¹

It has been observed that there is a bias favoring the studies with positive results for publication as com-

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Correspondence: Dr. Arvindsingh Panwar (Email: drarvindsingh@yahoo.com)

pared to studies with negative results.² Few studies done to see trends of publication of negative studies revealed that in comparison to positive studies, negative studies are not published frequently and trends of publication of negative studies is also on decline.^{3,4,5,6} Under publication of negative studies may lead to inflated effect size in meta-analysis which can lead to over estimation of difference between interventions and can potentially harm philosophy of evidence based medicine. Non publication of negative studies might also lead to wastage of resources for the exploration of intervention which already proved to be not effective.⁷

It has also been observed that efforts are being under taken by editors of various journals and scientific societies to encourage publication of studies with negative results. Few journals have started publishing exclusively negative studies and new sections of negative studies are also incorporated in established journals. Although to encourage publication of negative studies journals are also offering full or partially waiver of publication fee for negative studies etc, still there is need for continuous monitoring in the trends of publication of negative studies to estimate if these measures are creating substantial impact. Till date very few studies are done to explore the trend analysis of publication of negative studies in medical research more so there is an absence of such data for studies published in the Indian Journals. Present study attempts to see the pattern of publication of negative studies in prominent medical journals related to clinical practice and clinical specialties published in India.

MATERIALS AND METHODS

All the clinical practice or clinical specialty related Indian medical journals having impact factor (i.e Indexed in SCI) with publication history of 12 years or more were included in the analysis. The Journals that met the eligibility criteria included Indian Pediatrics (IP), Annals of Indian Academy of Neurology (AIAN), Indian Journal of Dermatology, Vanereology and Leprology (IJDVL), Indian Journal of Ophthalmology (IJO), Indian Journal of Pharmacology (IJP), Journal of Postgraduate Medicine (JPGM), Neurology India (NI), Indian Journal of Orthopedics (IJO), Indian Journal of Medical Research (IJMR), Indian Journal of Otolaryngology and Head and Neck Surgery (IJOHNS), Indian Journal of Pediatrics (IJP) and International Journal of Diabetes in Developing Countries (IJDD). All the original articles published in these journals between 2000 to 2011 were retrieved either in hard or downloaded from the achieves of the respective web sites and were analyzed to categorize the study as negative studies or positive studies. The criteria decided for labeling any study as negative studies included studies in which:-

1. Difference between primary endpoint was not reported significant

2. In absence of reported primary endpoint, difference in endpoint was considered for sample size calculation and found to be non-significant
3. Sample size was not calculated No primary endpoint reported and difference in first endpoint as reported in abstract was found to be non-significant.

Statistics: Descriptive statistics reported in the form of frequency, percentages and 95% confidence interval around the percentages. Two tailed Fisher exact test was used for comparison of categorical variable (frequency of negative studies in impact factor > 1 Vs impact factor <1). Linear regression model was used to see trends. Open Epi Version 3.01 software was used for application of Fishers Exact test and Microsoft excel was used to see trends.

RESULTS

Total 6341 original articles were published between years 2000 to year 2011. It was observed that there was an increasing trend of publication of total number of articles in these journals with time. [Figure 1]. Based on the criteria laid, out of 6341 articles which were screened, 284 (4.4%, 95% CI 4.0% to 5.0%) were negative studies.

There was slight increase in the trend in publication of negative studies between years 2000 to 2011. [Figure 2]. It was also observed that even after 10 years (till 2011) negative studies could not contribute to more than 6% of total published articles. [Figure 3] Although negative studies were published more frequently in journals having impact factor > 1 as compared to journals having impact factor <1 (151/4415 Vs 133/1926, Fisher exact P =0.0000001) but it was observed that the trend of publication of negative studies is now declining in journals having impact factor >1 and is on increase in journals having impact factor <1. [Figure 4]. Assuming similar trends of publication of Negative studies, it can be assumed that after year 2014-15, more negative studies will be published in journals having impact factor <1 as compared to journals having impact factor >1. [Figure 5]

Figure 1: Number of original articles published per year between 2000 to 2011

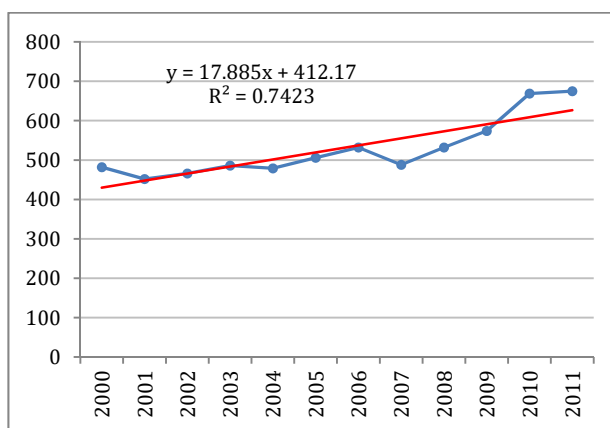


Figure 2: Trend in publication of negative studies in prominent Indian Medical Journals between year 2000 to 2011

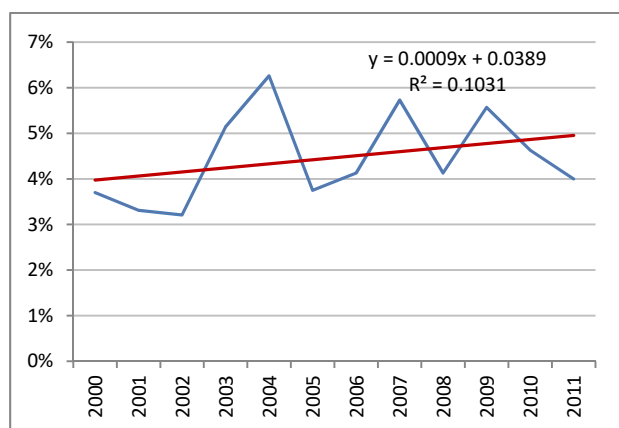


Figure 4: Trend of reporting negative studies in journals having impact factor > 1 as compared to journals having impact factor <1

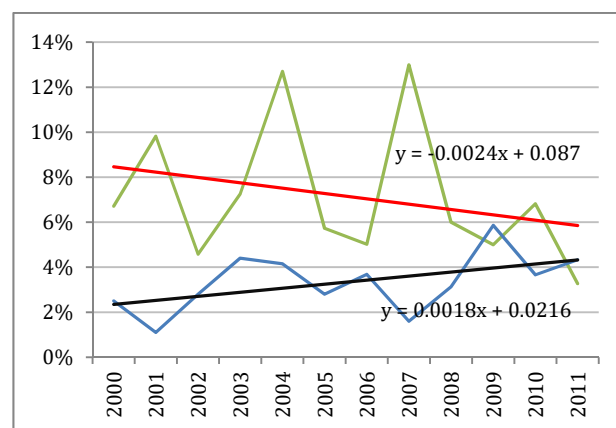


Figure 3: Forecast regarding trend of publication of negative studies in prominent Indian Medical Journals in coming 10 years

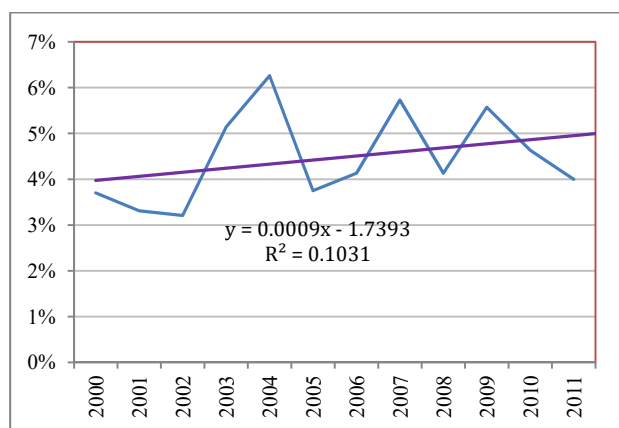
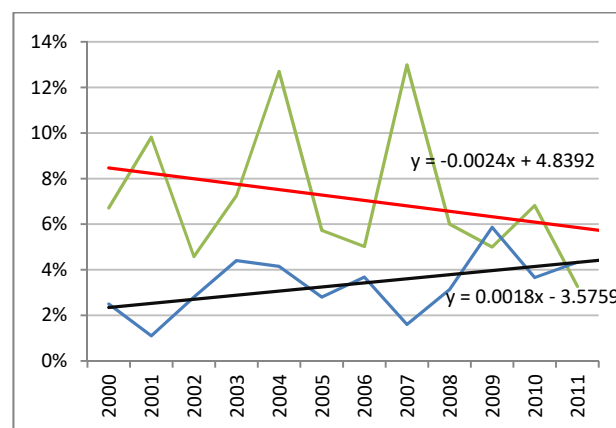


Figure 5: Trend of reporting negative studies in journals having impact factor > 1 as compared to journals having impact factor <1



DISCUSSION

Present study was designed to estimate the trends in publication of negative studies in prominent Indian Medical Journals related to clinical practice and specialties. It was observed that negative studies are not published frequently when compared to positive studies and reflects a possible publication bias. Slight positive trend in publication of negative studies was also observed in journals.

It was also observed that proportion of negative studies published was only 4.4% which is less compared to published studies for other specialties like Social Science, Natural Science and for studies published in western journals.^{3,4} It was observed that publication of negative studies were more in journals having impact factor more than 1 as compared to journals having impact factor less than 1. This observation is just opposite to the study done by Littner Y et al (2005), who reported more negative studies being published in journals having lower impact factor as compared to journals having high impact factor.⁸ Keeping in view of the present trend for publication of Negative studies as reported in present study it

seems that possibly after 2014-15 more negative studies will be published in journals having impact factor less than 1. Present study also reveals a strong publication bias favoring publication of more positive studies as compared to negative studies in prominent Indian Medical Journals which is in line with similar studies published for western medical journals.^{3,4,6}

There might be various compelling reasons for this bias toward publication of positive studies at various levels. The bias might be induced at the level of editor, reviewer or even investigators who might not like to submit studies with negative results as it is presumed that it may not be accepted for publication or even if published may not be cited and hence will not assist the authors in their carrier advancement and possible future funding for research.⁹ It is also observed that there is an association between published studies that are sponsored by pharmaceutical companies with more positive outcomes in results.¹⁰ Possibly, there are chances that pharmaceutical industries selectively publish only those studies which have positive outcomes as compared to the studies

which has negative outcomes.

Present study is possibly a maiden effort to estimate the prevalence and trend analysis of negative studies published in Indian Medical Journals. The study is based on 12 year data of large sample of published original articles (n = 6341) and hence gives more strength to the observed findings. The only limitation to this study is that only journals having indexed in Science Citation Indexed (SCI) were included in the analysis, more meaningful outcome could have been generated by inclusion of sample from journals which were not included in SCI.

CONCLUSION

This study revealed that studies with negative results are not published as frequently as negative studies indicating existence of strong publication bias. The percentage of negatives studies as compared to total original articles published is very less as compared to similar data published for western journals. There is a small positive but unimpressive trend in the publication of negative study observed. There is a need of generation of more awareness regarding publication of negatives studies in authors, guides, editors and reviewers so that this publication bias can be reduced which will ultimately help the evidence based medicine.

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