

# An audit of medical postgraduate theses registered in the Clinical Trials Registry of India in 2019

## INTRODUCTION

An important avenue of academic clinical research in India is the medical postgraduate (PG) thesis. The Clinical Trials Registry of India (CTRI) encourages registration of all types of PG theses. The inclusion of medical PG theses into the CTRI is useful to increase the availability of information and to ensure adherence to the quality standards in research.<sup>[1,2]</sup> An audit of PG theses registered in the CTRI was undertaken to analyze the number and nature of medical PG theses, their specialty, and state-wise distribution.

## METHODS

Using the keyword “CTRI/2019,” entries from January 1 to December 31, 2019, were searched on [www.ctri.nic.in](http://www.ctri.nic.in). Studies mentioning “yes” under the heading “Postgraduate thesis” were filtered. All theses in PG allopathic medical disciplines were included. Data were gathered on state, specialty, degree-wise distribution of PG theses, prospective or retrospective registration, and nature of the study (interventional or observational). Type of study intervention, phase-wise distribution, randomization, and off-label drug trials were observed. Data were analyzed using descriptive statistics (Microsoft Excel-2019). The study was exempted from review by the Institutional Ethics Committee.

## RESULTS

Of 5769 registrations in the CTRI in 2019, 1693 (29.3%) studies were medical PG theses. Majority were from anesthesia (727, 42.9%), making up 27.5% of the 2644 PG seats in anesthesia in 2019.<sup>[3]</sup> There were less registrations in pharmacology (1.93%, 17 registered/877 seats) and community medicine (1.5%, 15 registered/993 seats).<sup>[3]</sup> Six states and two union territories accounted for more than 3/4<sup>th</sup> (1291/1693, 76.3%) of the total registrations, with maximum number from Delhi (19.8%), Karnataka (16.1%), and Puducherry (8.0%). The proportion of theses registered out of the total PG seats was Chandigarh (21.8%), Puducherry (19.8%), and Delhi (13.2%). In Maharashtra, the registration rate was only 2.9%, with 119 theses registered out of 4146

total PG seats.<sup>[4]</sup> Further, 57 studies (3.4% of 1693) were retrospectively registered. A number of interventional studies were 1177/1693 (69.5%), while 512/1693 (30.2%) were observational studies. In addition, four studies (0.2%) were erroneously categorized as postmarketing surveillance. For some observational studies (45/512), phase of trial stated was incorrect. Of 1177, 643 (54.6%) interventional studies were randomized clinical trials (RCT), 48 were non-RCT, 131 were single-arm trials, and 355 studies were mentioned as “other.” Of 1693 studies, 270, i.e., 15.9%, studied the off-label use of drugs. These studies constituted almost 50% (270/545) of the total drug trials which were registered, and 61.5% of off-label drug trials (166/270) were from the field of anesthesia.

## DISCUSSION

There were 34,926 combined PG specialty and superspecialization seats in India in 2019.<sup>[3]</sup> and only 1693 theses were registered in the CTRI. The highest number of registrations from anesthesia. However, these made up only 27.4% of the total 2644 PGs in anesthesia. Surprisingly, low registrations were observed in pharmacology and community medicine, which are expected to be more research-oriented branches from the perspective of drug development, drug utilization, and public health policy.<sup>[3]</sup> Thesis registrations were disproportionate to the number of seats across all the states.<sup>[4]</sup> The states such as Delhi, Puducherry, and Chandigarh, having the apex medical institutions, showed the highest registration rate. By contrast, Maharashtra state with the highest number of PG seats saw a registration rate of only 2.9%.<sup>[4]</sup>

Almost half of the drug trials were conducted on off-label drug use, and the highest contribution was from anesthesia. This is an encouraging finding which will be useful to provide impetus to larger clinical trials for generating higher levels of evidence. Trials having a randomized study design offer a higher level of clinical evidence. More than half of the interventional studies were RCT. However, the persistence of retrospective registration and errors in the documentation of PG theses indicate room for improvement in reporting. Emphasis on methodological

soundness should be emphasized by guides and institutions at the PG level for building research competency.

Previous study from a single medical institution found a PG thesis-to-publication conversion rate of about 30%.<sup>[5]</sup> It is worthwhile to assess the scientific merit and publication rate of thesis studies to assess their translational potential, especially of the interventional clinical trials.

Our study demonstrates the utility of the CTRI in observing trends in medical PG students' research in India. Overall, low rate of voluntary CTRI registrations and errors in documentation were observed. More RCTs were registered. There is a need to increase transparency and accountability, and it may be advantageous to make CTRI registration mandatory for PGs by the National Medical Council, India.

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### Conflicts of interest

There are no conflicts of interest.

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