Knowledge, Attitude and Practice of Indian Oncology Residents on Clinical Trials: An Observational Study

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Abstract

Background and objectives: A limiting factor in cancer treatment and prevention has been an inadequate accrual of patients onto clinical trials this more so in India and developing countries may be because of majority of trials will be done as dissertation of an oncology fellow. Many oncology training institutions are not having training curriculum regarding clinical trial design and basic statistical training which are barriers for accrual of patient in trials. Therefore, we aimed to assess the knowledge, attitude and practice of oncology residents on clinical trials across the country to improve the curriculum methodology so that we can produce better data on clinical trials.

Methods: A total 50 students were recruited across the country; students were interviewed either directly or through telephonic conversation. Minimum criteria to enroll in the study was to have at least 1 year of working knowledge in oncology institute (only senior residents were included). Verbal informed consent was obtained from all the study participants.

Results: All residents participated in the study know that clinical research is imperative, however only 30 (60%) of them showed interest towards cancer clinical trials. Thirty (60%) of the participants depending on western data for their patient management. 36 (73%) participants felt that they were not able to interpret the data given in clinical trials. Only 6 (11%) of the participants had access to all cancer related journals. Though 35 (70%) of the participants discuss published clinical trials every week, only 25 (50%) of the residents are changing their decision based on clinical trial data during their patient management.

Conclusions: In our study it was found that the resident doctors felt that clinical research is imperative in delivering appropriate management in malignant diseases. However, they had displeasing knowledge on health research. They have positive attitude towards cancer research, but they are failing to implement due to lack of training curriculum.

Keywords: Oncology • Clinical trials • Cancer

Introduction

Clinical trials and translational research have produced advances in finding out disease causation, prevention, treatment and rehabilitation for many diseases, including the cancer management. The quality of medical research in India is limited and number of research articles published in the field of medicine at undergraduate and post-graduate level was very few. As per the data available till 2008, India holds the twelfth rank among the productive countries in medicine research consisting of 65,745 articles with a global publication share of 1.59% [1]. There is urgent need to improve the existing medical education system to improve the research culture. The medical education system in India does not incorporate research methodology as a part of the curriculum. Clinical cancer research has undergone progressive globalization over the past decade. In the year 2002 the percentage of submitted studies done exclusively in USA decreased from a high of 80% to a recent level of 24% [2]. A limiting factor in cancer treatment and prevention has been inadequate accrual of patients onto clinical trials this more so in India and developing countries may be because of majority of trials will be done as dissertation of an oncology fellow. Many oncology institutions are not having training curriculum regarding clinical trial design and basic statistical training which are very important for understanding of their impact in the outcomes of a study.

In this study we aimed to assess the knowledge and attitude of oncology residents across the country thus we can improve the curriculum methodology so that we can produce better data on clinical trials.

Materials and Methods

Study design

We conducted a cross-sectional survey by department of medical oncology, JIPMER, during the period between September and October 2015.

Study participants

Total 50 students were recruited across the country; students were interviewed either directly or through telephonic conversation. Minimum criteria to enroll in the study was to have at least 1 year of working knowledge in oncology institute (only senior residents were included), from all participant informed verbal consent was obtained.

Data collection

We developed a structured questionnaire based on our study objectives, taking directions from the previous literature [3-5]. It was subjected to a thorough peer review by five senior teachers from the college. The
questionnaire was also administered to 10 resident doctors to validate its content. It was subsequently modified as per the suggestions of the teachers and resident doctors and the final questionnaire consisted of 25 questions. The questionnaire was validated with institute professors and it was approved by IEC.

The questionnaire consisted of several parts. The first part addresses the attitude of resident towards clinical trials. The questions in the second part of the questionnaire assessed the residents’ knowledge about research methodology and statistics. The third part of the questionnaire addressed questions related to their practices in the clinical trials.

Statistics
The data was expressed in percentage and was analyzed using descriptive statistics.

Results
50 senior residents were recruited in this survey across the country, doing either DM (Doctor of Medicine)/Mch (Magister Chirurgiae)/Senior residency in oncology department. All residents participated were in between 30-35 years old, males were predominate (n=45), all residents had passed out for MBBS and MD (Internal medicine or Pediatrics or Radion oncology) degree and doing super specialty training, among 50 residents 25 were in their final year of super specialty training, 15 were second year and 10 were first year of training (Table 1).

<table>
<thead>
<tr>
<th>S.NO</th>
<th>Question</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Do you consider it is necessary for physicians to conduct clinical research? Y/N</td>
<td>100%/0%</td>
</tr>
<tr>
<td>2</td>
<td>What is your level of interest in cancer treatment clinical trials? a) Very interested b) Somewhat interested c) Not at all interested</td>
<td>60% 40% 0%</td>
</tr>
<tr>
<td>3</td>
<td>Do you feel that you are well informed about available cancer treatment clinical trials? a) Very well informed b) Somewhat informed c) Not at all informed</td>
<td>26.90% 53.30% 19.20%</td>
</tr>
<tr>
<td>4</td>
<td>Do you feel data available on clinical trial reliable Y/N</td>
<td>76.9% Vs. 23.07%</td>
</tr>
<tr>
<td>5</td>
<td>Do you depend on Indian data or western data for your patient management?Indian/ Western</td>
<td>34% Vs. 65.38%</td>
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Table 1. Results related to attitude domain are depicted.

In the attitude domain all (100%) resident doctors felt clinical research is necessary, however only 60% (n=30) interested in clinical trials and in about 19.2% resident doctors were felt that they are not at all informed about cancer clinical trials. About 23% felt that data available in the clinical trials not reliable and 2/3rd dependent on western data for the patient management (Table 2).
Results

About 76% of residents felt that they don’t have any training program or curriculum designated for trial designing and interpretation of results in a clinical trials and about 26% able to interpret the results given in a clinical trials at reasonable extent, about 53% given awrong response for CTRI (Clinical Trials Registry-India) and 57% given wrong response for DCGI (Drugs Controller General of India). The regulatory body responsible for adverse drug reactions will be carried out by CDSCO (Central Drugs Standard Control Organization), only 50% of residents only knows about the existence of such regulatory body. According to ICMR guidelines minimum number of faculty required for formation of IEC quorum would be four, only 4% of residents knows about this information. The Indian Statistical institute is located in Kolkata but 80% of resident doctors lack the knowledge about its existence (Table 3).

Discussion

Medical research carried out by undergraduate and postgraduate students in India is disappointing compared to developed countries [6]. Postgraduate students are introduced to the concept of designing and conducting research during residency, but reality is clinical subject is interested to learn statistics, good clinical practices, medical ethics, clinical research, followed by lack of time. Postgraduate students were too much of paperwork was the most frequently cited obstacle in conducting research during residency, such as inadequate training facility. Similar educational institutes to facilitate the development to the local literature. There is an immediate need to improve research training in the undergraduate students were involved in research projects [8]. We carried out this study to assess the awareness of residents toward research and to find out whether the current methods of training and facilities are adequate to foster a research culture in postgraduate students.

Our survey revealed that resident having attitude towards participating in good clinical trials as indicated by all resident (100%) knew that clinical research is essential for physicians, about 60% residents stated that they are very interested in clinical trials but their knowledge concerned having lacunae despite majority of institutions are participating in trials (80%), the reason might be majority of residents (76%) not having training program regarding designing and interpretation of trials, this might be the most important that we have to consider in teaching institution because majority residents (50%-54%) would like to work either in teaching institute or trial setting after their course, unless they trained reasonably they may not participate good clinical practice (GCP) and this become a vicious cycles for their students also.

Bhatt et al., all published in a paper on quality of clinical trials mentioned regarding quality system requirement for clinical trials includes personnel role and responsibilities, training, policies and procedures, quality assurance and auditing, document management, record keeping and reporting, corrective and preventive action [9], same author also mentioned errors likely to be occur in clinical trials in designing, procedural, recording and analytical areas. Hence during training period residents has to learn proper trial design, basic analytical details how to analyze the data and to find out whether the current methods of training and facilities are adequate to foster a research culture in postgraduate students.

In the present study, residents reported significant barriers impeding research during residency, such as inadequate training facility. Similar obstacles for research among residents have been reported in a study done by Khan et al. [11] Another study done by Sumi et al., [3] also reported that too much of paperwork was the most frequently cited obstacle in conducting clinical research, followed by lack of time. Postgraduate students were interested to learn statistics, good clinical practices, medical ethics, and protocol writing. Hence, a research curriculum should be designed
considering these aspects.

Conclusion

In our study it was found that the residents felt that clinical research is imperative in delivering appropriate management in malignant diseases. However, they had displeasing knowledge of health research. They have a positive attitude towards cancer research, but they are failing to implement due to lack of training curriculum. There is need to encourage residents to carry out research through provision of technical assistance and essential infrastructure during their postgraduate training program.

Limitations of Study

Our study was a pilot study with small sample size and we may have to do much bigger study for better results and it should be conducted across the countries so that we can have better and uniform curriculum to improve the clinical trial understanding.

References


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