

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

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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 residents 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).

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

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).

S.NO	Question	Results
1	Is your institution involved in clinical trials? Y/N	80%/20%
2	Do you have teaching program regarding designing and interpretation of data: Y/N	24%/76%
3	Are you able to interpret the data given in a clinical trials	
	a) Very confusing	3.80%
	b) Partly understand	69.20%
	c) Well able to interpret	26.90%
4	Which one you feel best clinical trial	
	a) Observational study	0%
	b) Pilot study	0%
	c) Cohort study	0%
	d) RCT	38.40%
	e) Meta-analysis	61.50%
5	Which type of clinical trial you feel it will help more towards patient care	
	a) Sponsored clinical trials	7.60%
	b) Institution based trials	92.30%
6	Which survival factor do you feel best for early approval of a drug in clinical trials	
	a) Progression free survival (PFS)	57.60%
	b) Overall survival (OS)	42.30%
7	How many phases of clinical trials are there:	
	a) 1	0%
	b) 2	0%
	c) 3	0%
	d) 4	100%
8	In which phase of clinical trial, post marketing surveillance is done? a) 1	
	b) 2	0%
	c) 3	0%
	d) 4	100%
9	What CTRI stands for : correct/wrong response a) 1	46.2%/53.8%
	What does DCGI stands for: correct/wrong response	42.3%/57.6%
10	Do you know existence of Pharmaco-vigilance program in India? Y/N	77% Vs. 23%
11	In India which regulatory body is responsible for monitoring ADRs?	
	a) MCI	11.40%
	b) ICMR	23%
	c) ICRI	11.53%
	d) CDSCO	53.80%
12	Where is the Indian statistical institute located? Correct/Wrong response	19.2% Vs. 80.7%

13	Minimum how many persons are required to form the quorum in IEC?	
	a) 4	3.80%
	b) 5	23%
	c) 6	11.53%
	d) 8	61.40%

Table 2. Results related to knowledge domain are depicted.

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 trails and about 26% able to interpret the results given in a clinical trials at reasonable extent, about 53% given awrong response for CTRL(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).

S.No	Question	Results
1	Gathers information on cancer trials from which sources? Tumor boards (TB)/Grand rounds(GR)/ Conferences(C)/Journals(J)/Internet(I)/One-hour meetings(1Hr)	J>I>C>TB>GR>1hr
2	Do you have accessibility for published clinical trials	
	a) For all	11.50%
	b) Only few	73.07%
	c) no accessibility	15.30%
3	How often you discuss published clinical trials in your institution	
	a) Weekly once	69.20%
	b) Monthly once	19.20%
	c) Quarterly	3.80%
	d) No such discussion	7.60%
4	Have discussed clinical trials with patients: Y/N If so how often:	
	a) Every patient	61.60%
	b) Every week	38.40%
	c) Occasionally	0%
5	Have you changed your decision based on clinical trials in patient management If yes how often :	
	a) Frequently	53%
	b) Occasionally	26.90%
	c) not so far	38.40%

6	Where do you like to practice after your traininglf yes how often :	
	a) Teaching institution	50%
	b) Private institution	26.90%
	c) Clinical trial setting	3.80%

Table 3. Results related to practice of clinical trials domain are depicted.

The majority of residents are dependent on journals for their information gathering and about 70% of resident are discussing published clinical trials on a weekly basis.

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 residents will spend 90% of their daily time with their patient in ward or operation theater.To date research has not become a mandatory part of the curriculum of undergraduate medical education in India. In Germany, where research is an integral part of undergraduate medical curriculum; medical students were involved in 28% of the publications in a particular institution [7]. A study reported that in a European country, Croatia, 23% of 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 importantthat we have to consider in teaching institution because majorityresidents (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 basic statistical methodologies and proper record keeping. Aslamet al., reported in their paper theattitude of residents towardsresearchwerepo sitive,but residents weredeficientpractically in terms of reading and writing literature. There is an immediate need to improve researchtraining in the educational institutes to facilitate the development to the local literature both in terms of research utilization and production [10].

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.

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