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Original Research Article

Evaluation of knowledge, attitude and practices of postgraduate medical students towards clinical research in a tertiary care teaching hospital

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ABSTRACT

Background: Clinical research is a component of medical and health research that facilitates valuable knowledge regarding diagnosis, prevention as well as treatment of a disease. Nowadays, the practise of medicine is evidence-based and combining medical education with clinical research provides a channel for translating scientifically advanced knowledge into better public health. The aim of the study was to assess knowledge (K), attitude (A), and practices (P) about clinical research among post graduate medical students.

Methods: After obtaining institutional ethics committee approval, a cross-sectional and questionnaire-based study was conducted. A pre-structured and validated KAP questionnaire comprising of 25 questions (knowledge-15, attitude-5 and practices-5) was shared online through google forms with post graduate students. The responses to the questions were later marked correct or incorrect. The data was collected and compiled using Microsoft excel and expressed in percentage (%). Data analysis was performed using SPSS version 25.0.

Results: 102 students responded to the questionnaire completely. Out of which males (55.9%) pre-dominated and majority of the PG students belonged to I year accounting for 40.2%. About 61.76% PG students were aware about a clinical research unit in the college. Majority of the students acknowledged the necessity of conducting clinical research and exhibited good knowledge about key concepts of clinical trials. Even responses to questions pertaining to attitude towards clinical research were also majorly positive. On the contrary, more than 90% students had neither attended any workshop on ICH-GCP guidelines nor registered their academic study under clinical trial registry of India. However, 73.5% of them expressed their willingness to participate in a clinical trial in future.

Conclusions: Although, assessment of knowledge and attitudes about clinical research among post graduate students showed positive results but discrepancies were observed in its practise. As such, this necessitates incorporation of clinical research activities into existing medical education system.

Keywords: Clinical research, Knowledge, Attitude, Practices, Questionnaire, Post graduate students

INTRODUCTION

Clinical research is a component of medical and health research that helps to determine safety and efficacy of medications, therapeutic regimes, devices and diagnostic products meant for human use. As such, it facilitates valuable knowledge regarding diagnosis, prevention as well as treatment of a disease.^{1,2} Indian clinical trial

industry has experienced an expeditious growth in the recent years.³ Economic globalization, outsourcing of clinical trials to India by numerous multinational companies and availability of suitable infrastructure contributes to this flourishing industry in India.³ Moreover, our country has English as primary and medical language which provides an additional benefit for the conduct of clinical trials.⁴

Nowadays, the practise of medicine is evidence-based and combining medical education with clinical research provides a channel for translating scientifically advanced knowledge into better public health.⁵ However, it has been observed that research programs in medical colleges are not prioritised due to insufficient funds and manpower resources which finally leads to degradation of research oriented medical education.⁶ Although undergraduate medical students are taught briefly about drug discovery and drug development process (phases of clinical trial) in pharmacology curriculum but it lacks practical exposure. On the other hand, postgraduate (PG) students are mandated to undertake a dissertation project as a part of their MD/MS curriculum through which they get exposed to the concept of design and conduct of research.⁷ However, as compared to pharmacology PG students, the level of awareness regarding basic concepts of clinical research is quite adequate among other medical students.⁵ In a study by Deo MG, it was observed that among 1,00,000 Indian medical students, only 0.9% exhibited keen interest in research.⁸ In conduct of clinical research, investigators, who are generally experts in the condition being studied, have numerous responsibilities. They should make sure that a clinical trial is conducted in an ethical manner and complies to regulatory requirements as well as International conference on Harmonisation Good Clinical practise (ICH-GCP) guidelines.⁹ But many studies in the past suggest that our country produces highly skilled clinicians but lacks skilled investigators.¹⁰

Numerous clinical trials are being conducted in various departments of MGM Medical college and Hospital, Aurangabad. PG students assist clinical trial investigators in documentation and subject related activities. As the situation of clinical research is improving in India, today's medical students might become investigators in clinical trials or pursue career in clinical research in future. The aim of the study was to assess the three quotients-knowledge (K), attitude (A), and practices (P) about clinical research among PG students.

METHODS

A cross-sectional and questionnaire-based study was conducted in MGM Medical college and Hospital, Aurangabad from 20 January 2020 to 20 February 2020. The study commenced following approval from institutional Ethics committee (MGM-ECRHS). An online structured questionnaire with an annexed informed consent form was developed using Google forms and the link for the same was shared through WhatsApp. Only those who gave consent could access the questionnaire. All the PG students from various clinical and non-clinical departments in MGM Medical college, Aurangabad were included in the study. The participation was voluntary. Incompletely filled questionnaires were excluded from the study. The questionnaire was divided into two sections with several questions pertaining to: (1) socio-demographic details; and (2) KAP towards clinical research. The socio-demographic details included age,

gender, department and year of residency. The KAP consisted of 15 questions relevant to knowledge regarding clinical research, 5 questions probed attitude towards clinical research and 5 questions were related to practices towards clinical research. These questions were designed based upon earlier studies for assessing KAP about clinical research.^{5,7,11-13} Finally, the designed questionnaire was analysed and validated by experts involved in clinical research. All these questions were either multiple choice or dichotomous (yes/no; agree/ disagree). The responses for the same were later marked as correct or incorrect. The data was collected and compiled using Microsoft excel and expressed by using percentage. Data analysis was performed using SPSS version 25.0.

RESULTS

During the study, 104 PG students from various clinical and non-clinical departments responded to the questionnaire. Two questionnaires were incompletely filled; hence they were excluded from the study. The demographic details of all the participants are represented in Table 1. Out of 102 participants, 57 (55.9%) were males and 45 (44.1%) were females. Majority of the PG students belonged to I year accounting for 40.2%, followed by III year (32.35%) and II year (27.45%). Also, respondents from department of medicine predominated.

Table 1: Demographic profile of postgraduate students.

Variables	Values
Age (mean±SD) (years)	25.86±1.463
Gender	
Male	57 (55.9)
Female	45 (44.1)
Year of residency	
I year	41 (40.2)
II year	28 (27.45)
III year	33 (32.35)

Table 2: Department wise distribution of participants.

Department	Number of students
Anaesthesia	9
Dermatology	6
ENT	1
General surgery	14
Medicine	16
OBGY	9
Ophthalmology	7
Orthopaedics	7
Paediatrics	8
Pathology	4
Pharmacology	2
Psychiatry	5
Radiology	9
Respiratory medicine	5
Total	102

Responses of PG students to questions related to knowledge of clinical research are summarised in Table 3. As far as awareness of a clinical research unit in MGM Medical College, Aurangabad is concerned, 61.76% PG students were aware about it (K1). Also, 85.3% students acknowledged the necessity of conducting clinical research by medical professionals (K2). Moreover, majority of the PG students exhibited good knowledge about role of regulatory body i.e., DCGI in India (K3), importance of Informed consent form (K4), phases of

clinical trial (K6, K7), ICH- GCP guidelines (K8, K9, K12) and some important concepts related to clinical trials such as randomization (K10), placebo (K11), reimbursement for clinical trial participation and Adverse drug reaction (ADR) reporting (K15). However, positive response to question regarding importance of Assent form in paediatric population was given by only 36.27% students (K5). Similarly, very few students (35.3%) responded correctly regarding the term ‘non-inferiority trial’ (K13).

Table 3: Knowledge of postgraduate students about clinical research.

Sr. No.	Questions	Correct response- N	Incorrect response- N
K1	Is there a clinical research unit in MGM medical college, Aurangabad? Yes*/No	63 (61.76)	39 (38.24)
K2	Do you consider it is necessary for medical professionals to conduct clinical research? Yes*/No	87 (85.3)	15 (14.7)
K3	From whom to seek approval for conducting clinical research using new drugs in India? a. DCGI* b. ICMR c. DTAB d. Both a and b	86 (84.3)	16 (15.7)
K4	Which document is mandatory to enrol a subject in a clinical research study? a. Study protocol b. Case record form c. Informed consent form* d. Investigator’s brochure	73 (71.57)	29 (28.43)
K5	When doing research in paediatric population, which of the following need(s) to be obtained? a. Informed consent from parent or guardian b. Informed consent from the child c. Assent from the child of 7 years and above d. Both a and c*	37 (36.27)	65 (63.73)
K6	Phase I clinical trial is done in a. Healthy volunteers b. Patients with malignancy or HIV c. Both a and b* d. None	77 (75.5)	25 (24.5)
K7	In which phase of a clinical trial is post-marketing surveillance done? a. I b. II c. III d. IV*	55 (53.9)	47 (46.1)
K8	What is ICH-GCP? a. International conference on Harmonisation- Good Clinical Practise* b. International council on Harmonisation- Good Clinical Practise c. Intermittent conference of Harmonisation- Good Clinical Practise d. Either a or b	89 (87.25)	13 (12.75)
K9	A subject’s participation in a clinical trial is a. Voluntary and may withdraw consent at any time* b. Voluntary but may not withdraw consent c. Mandatory d. Both a and b	98 (96.1)	4 (3.9)
K10	In a clinical trial, when allocation of subjects to treatment groups is by chance, it is known as a. Allocation concealment	79 (77.45)	23 (22.55)

Continued.

Sr. No.	Questions	Correct response- N	Incorrect response- N
	b. Randomization* c. Blinding d. None		
K11	Which of the following is true regarding placebo? a. It is a pharmaceutically inert substance b. It is also known as the sugar pill. c. It is unethical to use a placebo for the control arm in a clinical trial when a standard treatment already exists. d. All of the above*	100 (98.04)	2 (1.96)
K12	ICH-GCP guidelines are followed in all of the following except a. Phase I trial b. Pre-clinical trial* c. Phase IV trial d. Phase II trial	80 (78.43)	22 (21.57)
K13	Which would be the most suitable form of trial, if the test product is as effective as the comparator but may be a little better? a. Non-inferiority trial* b. Superiority trail c. Equivalence trial d. Either a or b	36 (35.3)	66 (64.7)
K14	Clinical trial subjects should be reimbursed for trial participation in all the following cases except a. Time spent in coming to trial site and loss of daily wages due to trial participation b. Travel cost incurred in coming to the site c. Payment offered to encourage trial participation* d. Both a and b	81 (79.4)	21 (20.6)
K15	Which of the following should be reported by investigator when an adverse event occurs in a clinical trial? a. Institutional Ethics committee b. Regulatory Authority c. Sponsor d. All of the above*	88 (86.3)	14 (13.7)

*correct response. Figures in parentheses indicate percentage

Table 4: Attitude of postgraduate students about clinical research.

Sr. No.	Questions	Agree	Disagree
A1	Do you think the potential benefit of clinical research is to deliver basic need for betterment of mankind and health status?	68 (66.67)	34 (33.34)
A2	Do you think by participation in clinical trials, doctors obtain a better understanding of the disease and contributes to medical progress?	80 (78.43)	22 (21.57)
A3	Do you think conducting clinical trials is just a waste of time, manpower and money?	17 (16.67)	85 (83.34)
A4	Do you think undertaking clinical research increases burden on already overworked post graduate students?	91 (89.2)	11 (10.8)
A5	Do you think training in ICH-GCP guidelines should be incorporated in PG curriculum?	67 (65.7)	35 (34.3)

Figures in parentheses indicate percentage

Table 5: Practices of postgraduate students about clinical research.

Sr. No.	Questions	Yes	No
P1	Have you anytime read any article related to clinical research?	72 (70.6)	30 (29.4)
P2	Have you ever participated in a clinical trial?	4 (3.9)	98 (96.1)
P3	Have you attended a workshop on ICH-GCP guidelines?	10 (9.8)	92 (90.2)
P4	Have you registered your academic study under clinical trial registry of India?	2 (1.96)	100 (98.04)
P5	Are you willing to participate in a clinical trial in future?	75 (73.5)	27 (26.5)

Figures in parentheses indicate percentage

As shown in Table 4, 68%, 80% and 67% PG students agreed that clinical research delivers basic need for the betterment of mankind and health status (A1), participation in clinical trials ensures better understanding of disease and contributes to medical progress (A2) and training in ICH-GCP guidelines should be incorporated in PG curriculum respectively (A3). Also, 83.34% responders disagreed with the statement that conducting clinical trials is just a waste of time, manpower and money (A4). On the contrary, 91% students supported that undertaking clinical research increases burden on already overworked PG students (A4).

As depicted in Table 5, majority of the students (72%) had read any article related to clinical research (P1) but only 3.9% had a chance to participate in any clinical trial in the past (P2). Moreover, more than 90% students had neither attended any workshop on ICH-GCP guidelines (P3) nor registered their academic study under clinical trial registry of India (P4). However, 73.5% students expressed their willingness to participate in a clinical trial in future (P5)

DISCUSSION

In the last few decades, India has emerged as a much-preferred clinical trials hub by global pharmaceutical companies.^{4,14} Although review of clinical research activities in our country advocates the presence of highly skilled physicians but it cannot assure the presence of skilled investigators.^{10,15} For effective conduction of clinical trials, there is a dire necessity of proficient and highly trained personnel who are well-versed with ICH-GCP guidelines. Therefore, proper training in clinical research will definitely ensure integrity of clinical trial conducted in India.¹⁶

The present study was a questionnaire-based study conducted in post graduate students of a tertiary care teaching hospital with the aim to assess their knowledge, attitude and practices about clinical research. In this study, it was observed that the overall knowledge about the needs and pre-requisites of clinical research was fairly good among the post graduate students. In contrast, in studies by Kanna et al, Sharma et al and Vittalrao et al; the overall awareness about clinical trials was found to be less.^{5,17,18} Also, in our study, very few students had an opportunity to participate in clinical trials in the past which complies with a study conducted by Sabzwari et al.¹⁹

Discrepancy between attitude and practices was also observed in this study. Although, majority of the students considered clinical research as an unnecessary burden on already overworked PG students but still most of them wished to get involved in clinical research in future. Their current inhibitions to involve in clinical research can be attributed to time constraints during residency and inadequate guidance from teaching staff. Similar obstacles to research practices were observed in a study by Pawar et al.⁷

Also, in this study, the number of participants who obtained formal education in ICH-GCP guidelines through workshop was very low. Our findings are consistent with a study by Dhodi et al which also showed inadequate knowledge of GCP guidelines among investigators.²⁰

CONCLUSION

We concluded in this study, that that the post graduate students had a relatively good knowledge and attitude but lack in practices towards clinical research. Majority of them acknowledged the importance of clinical trials but only a few had participated in them. Lack of formal training in ICH-GCP guidelines and under sensitization of PG students regarding clinical research is mainly responsible for this. The findings of our study advocates importance of educational interventions, mandatory course in ICH-GCP guidelines and continuous guidance by mentors to increase involvement of PG students in clinical trials. As such, this study provides insight into planning of future programmes that can encourage our clinicians to undertake clinical research in the upcoming years.

Limitations

Since, our study sample was drawn based on convenience sampling technique which included 102 post graduate students that responded to the questionnaire. Thus, its results regarding knowledge, attitude and practices about clinical research may not be generalizable to all post graduate students. Moreover, this was a single centre study which further limits the generalizable of results.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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