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Original Research Article

Enhancing ethical standards: a quantitative analysis of knowledge improvement a through structured good clinical practice workshop

Narasimha Murthy K. Muthahanumaiah, Manjunath G. Narasimahaiah, Swamy R. Mallikarjuna, Pesala Pavan Kumar Reddy*

Department of Pharmacology, Sri Siddhartha Medical College, Tumkur, Karnataka, India

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***Correspondence:**
Dr. Pesala Pavan Kumar Reddy,
Email: pavankumarreddy@ssmctumkur.org

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ABSTRACT

Background: Good clinical practice (GCP) is an internationally recognized ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. In India, postgraduate medical students are mandated to take part in research projects as part of their academic curriculum, but a lack of training leads to considerable disparity in their understanding of GCP principles. A structured educational intervention like the GCP workshop helps in filling these disparities and promotes the conduction of ethical research.
Methods: An educational interventional study was conducted to assess the impact of a GCP workshop on knowledge among postgraduate medical students during a one-day GCP workshop at a tertiary care teaching hospital. A total of 163 students participated in the study. A self-developed, pre-validated questionnaire was used to assess the impact of knowledge before and after the workshop. Data was collected using Google forms and analysed by using Microsoft Excel and Jeffreys's Amazing Statistics Program (JASP) software.
Results: Out of 163 participants, 158 postgraduate students completed both pre- and post-tests. The mean pre-test score was 22.3±3.5, which increased to 24.5±0.9 in the post-test. To assess the normality of data distribution, the Shapiro-Wilk test was performed and resulted in $p<0.001$, indicating the use of a nonparametric test. Then the Wilcoxon signed-rank test was performed, and results indicated statistically significant improvement ($Z=7.48$, $p<0.001$). Question-wise analysis revealed an increase in accuracy from 87.06% to 98.36%, indicating improvement in knowledge across the questionnaires.
Conclusions: The overall findings suggest that a structured good clinical practice (GCP) workshop plays a significant, important role in enhancing knowledge among postgraduate medical students.

Keywords: Ethical principles, Good clinical practice, Postgraduate, Research

INTRODUCTION

The history of clinical research is marked by numerous incidents of unethical practices, such as the Tuskegee Syphilis study and Nazi experiments, these violations lead to formation of essential ethical codes like Nuremberg Code, Belmont Report and Declaration of Helsinki.[1] All the codes paved a foundation for good clinical practice (GCP), an international recognized ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects.[2] These guidelines have two important fundamental principles ensuring the rights, safety, and well-being of trial participants, and maintaining the credibility and accuracy of the data generated.[3]

In the Indian context, the need for structured research ethics training is particularly important, given the increasing volume of clinical trials conducted in the country and the ethical concerns surrounding them.[4] India

offers a favourable environment for conduction of clinical trials due to its large and diverse patient population, availability of skilled professionals and cost-effective infrastructure.[5] However, there were significant gaps in the knowledge and practices among the researchers due to the absence of formal GCP training among physicians and postgraduate students.[6]

In India, postgraduate medical students are mandated to undertake research projects as part of their academic curriculum, which includes dissertation work and participation in institutional research with this growing research involvement, many students lack formal training in research ethics and regulatory standards, leading to substantial gaps in their understanding of GCP principles and their attitude towards ethical research conduct.[7] Medicine is an evidence-based profession, and combining medical education with clinical research acts as a critical aspect for converting scientific knowledge into better public health outcomes.[8] Many students often begin research activities without understanding the essential concepts like ethical considerations, patient safety and data integrity.[9]

This lack of awareness about GCP guidelines leads to compromise of both ethical and scientific standards in postgraduate medical research.[10] Studies suggest that targeted educational interventions like GCP workshops, helps in increasing awareness among the researchers.[11] Therefore, the present study aimed to assess the impact of the GCP workshop in enhancing the knowledge of postgraduate medical students.

METHODS

An educational interventional study was conducted to assess the impact of a good clinical practice (GCP) workshop on knowledge among postgraduate medical students at Sri Siddhartha Medical College and Hospital. Ethical approval was obtained from the institutional ethics committee prior to the study, which was carried out during a one-day GCP workshop in January 2025. The study population consisted of postgraduate medical students enrolled in various departments. The inclusion criteria were postgraduate medical students currently enrolled in any specialty who attended the full duration of the GCP workshop and completed both the pre-test and post-test questionnaires. Students who did not attend the entire workshop, failed to complete either the pre-test or post-test forms, or submitted incomplete responses were excluded from the study. A convenience sampling method was used. Data collected by using Google forms through a self-developed, pre-validated questionnaire consisting of both open-ended and close-ended items was used to assess participants' knowledge towards GCP. The questionnaire was subjected to content validation by subject experts and reliability analysis of the 25-item questionnaire was performed using Cronbach's alpha (α=0.882). The pre-test questionnaire was circulated to all participants before the commencement of the workshop and post-test questionnaire was circulated immediately after the completion of the workshop. The collected data was compiled by using Microsoft excel and statistical analysis was performed by using Jeffreys's amazing statistics program (JASP) software.

RESULTS

A total of 163 postgraduate medical students from a tertiary care teaching hospital participated in the GCP workshop. In these 158 participants are completed both pre-test and post-test questionnaires and 5 participants were excluded due to incomplete responses. Most of the participants were between 25 and 30 years old (n=149, 94.3%), while the remaining 9 participants were aged above 30 years (5.7%). Among them, 92 (58.2%) were second-year postgraduate students and 66 (41.8%) were third-year postgraduate students (Table 1).

Table 1: Demographic distributions of postgraduate medical students.

Variables	Category	N	Percentage
Gender	Male	68	43
	female	90	57
Age group (in years)	25-30	149	94.3
	>30	9	5.7
PG year	2nd	92	58.2
	3rd	66	41.8

The mean pre-test score was 22.3±3.5 and post-test score was 24.5±0.9. By comparing the mean of pre-test and post-test, the difference shows there is a significant impact of GCP workshop. To assess the normality of data distribution Shapiro-wilk test was employed and resulted in p value was <0.001 indicating that the data was not normally distributed, and therefore it is required to perform a non-parametric statistical method (Wilcoxon signed-rank test) for further analysis.

To determine the effectiveness of the GCP workshop Wilcoxon signed rank test was employed which compares the pre-test and post -test scores. The results demonstrated that there was a statistically significant increase on post-test scores compared to pre-test scores (Z=7.48, p<0.001, n=158) demonstrating the effectiveness of the educational intervention (Table 2).

Based on the question-wise analysis of pre-test and post-test score percentages. The participants showed significant improvement in knowledge in understanding of key concepts related to good clinical practice. The accuracy of the mean percentage increased from 87.06% to 98.36%, indicating a strong impact on the knowledge of participants following the workshop (Table 3).

Table 2: Summary of descriptive statistics, normality assessment, and Wilcoxon signed-rank test results comparing pre-test and post-test scores.

Variables	N	Range		Mean	Std. deviation	Shapiro-Wilk	
		Min	Max			W	P value
Pre-test	158	6	25	22.37	3.474	0.756	<0.001
Post-test	158	20	25	24.54	0.886	0.576	<0.001
Wilcoxon signed rank test							
Total n					158		
Test statistic (W)					6004.000		
Standardized test statistic (Z)					7.484		
Asymptotic Sig. (p value)					<0.001		

Table 3: Question wise comparison of participants knowledge before and after attending the GCP workshop.

Q. No.	Questions	Pre-test score %	Post-test score %
1	What is the primary purpose of good clinical practice (GCP)?	94.79	100
2	Who is primarily responsible for the safety and rights of trial participants during a clinical study?	81.25	95.74
3	Which international guideline governs good clinical practice?	66.67	97.87
4	What is the role of an institutional review board (IRB) or ethics committee (EC)?	94.79	100
5	Informed consent in clinical trials must be	97.92	100
6	What is the Declaration of Helsinki primarily concerned with?	90.62	100
7	When can a clinical trial protocol be amended?	94.79	100
8	Which of the following is NOT a fundamental principle of GCP?	85.42	97.87
9	Which document is critical for documenting that a participant voluntarily agreed to participate in a clinical trial?	93.75	100
10	What is the Belmont Report known for?	75	100
11	What does ICH stand for in the context of clinical trials?	72.92	96.81
12	Which of the following is a key ethical principle outlined in the Nuremberg code?	82.29	97.87
13	According to GCP, how long must essential documents be retained after the trial?	72.92	88.3
14	Which type of clinical trial participant is considered “vulnerable”?	95.83	98.94
15	What should happen if a serious adverse event (SAE) occurs during a clinical trial?	90.62	98.94
16	In GCP, what is a “case report form” (CRF)?	84.38	97.87
17	What is the meaning of “beneficence” in research ethics?	84.38	100
18	Which of the following is NOT included in informed consent?	92.71	98.94
19	What is the primary focus of the GCP guideline on “monitoring”?	93.75	100
20	What does "justice" mean in research ethics?	76.04	94.68
21	What is the purpose of a clinical trial protocol?	88.54	96.81
22	What should an investigator do if they deviate from the trial protocol?	89.58	100
23	Which of the following is an example of “vulnerable populations” in research?	94.79	100
24	Which GCP principle is violated if a trial participant's identity is disclosed without authorization?	94.79	97.87
25	What is required before enrolling participants in a clinical trial?	93.75	98.94

DISCUSSION

Over the last few decades, India has emerged as a prime centre for clinical trials by the international pharmaceutical industry. India does not have a shortage of skilled physicians but their deficiency of skilled investigators who are trained in ICH-GCP guidelines. Effective training in clinical research is important in ensuring the integrity of the trials conducted in India.[12]

This present aimed to evaluate the effectiveness of a structured GCP workshop in enhancing the knowledge of postgraduate medical students in the conduct of ethical research. The demographic distributions of 158 participants revealed a dominance of younger students aged between 25 and 30 years (94.3%). Of these, 58.2% were in their second year and 41.8% were in their third year of postgraduation. These findings suggest that students were actively engaging in research activities at their early academic stages. These findings align with a study

conducted by Sukriti et al, who also found that postgraduate medical students, particularly in their second year, demonstrated the highest levels of research participation and interest.[13]

Comparison of pre-test score (mean =22.37±3.474) with post-test score (mean =24.54±0.886), revealed a significant improvement which is consistent with findings from a study by Vora et al, demonstrated an importance of structured GCP training in improving knowledge among participants.[14]

To assess the normality of data distribution Shapiro-wilk test was employed and resulted in p value was <0.001 indicating that the data was not normally distributed, and therefore it is required to perform a non-parametric statistical method. Wilcoxon signed-rank test was employed to compare pre-test and post-test scores to assess effectiveness of the GCP workshop after educational intervention and the results revealed a statistically significant improvement in post-test scores ($Z=7.48$, $p<0.001$, $n=158$). This finding aligns with the study by Patel et al, and Kumar et al.[15,16]

A question-wise analysis was conducted across the 25-items of pre-test and post-test scores to determine the knowledge shift on key aspects of GCP workshop. The mean accuracy increased from 87.06% to 98.36% and consistent across all 25 items, suggesting that the workshop was well-structured, comprehensive, and successful in delivering its intended outcomes after educational intervention. These findings align with pervious researches conducted by Awatagiri et al, and Sureshbabu et al.[17,18]

One of the vital findings in the present study was the high internal consistency of the questionnaires (Cronbach's alpha =0.882) indicating excellent reliability. This tool reinforces the credibility of questionnaires and helped in assessing pre- and post-test knowledge shifts. The findings align with the study conducted by Biswas et al, who assessed the reliability of a pre-test and post-test questionnaires.[19]

This study also has some limitations. The study assessed the impact of educational intervention on knowledge improvement immediately after the workshop, but the sustainability of knowledge gains over time is still unknown.

CONCLUSION

This study underscores the impact of a well-structured good clinical practice (GCP) workshop among postgraduate medical students. At the end of the workshop, the students showed a significant gain in knowledge across all 25 questionnaire items when compared with their pre-test scores. Overall results highlight the effectiveness of educational interventions through workshop in enhancing ethical research competence.

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REFERENCES

1. McNair L. Ethical and regulatory oversight of clinical research: the role of the institutional review board. Exp Biol Med. 2022;247(7):561-6.
2. Vijayananthan A, Nawawi O. The importance of good clinical practice guidelines and its role in clinical trials. Biomed Imag Interv J. 2008;4(1):e5.
3. Mentz RJ, Hernandez AF, Berdan LG, Rorick T, O'Brien EC, Ibarra JC, et al. Good clinical practice guidance and pragmatic clinical trials: balancing the best of both worlds. Circulation. 2016;133(9):872-80.
4. Jadhav M, Bhatt A. Ethics in clinical research in India: a survey of clinical research professionals' perceptions. Perspect Clin Res. 2013;4(1):4-8.
5. Burt T, Sharma P, Dhillon S, Manchanda M, Mittal S, Trehan N. Clinical research environment in India: Challenges and proposed solutions. J Clin Res Bioeth. 2014;5(6):1-8.
6. Harshita H, Panda PK. Study on good clinical practices among researchers in a tertiary healthcare institute in India. World J Methodol. 2023;13(5):466-74.
7. Vimal M, Nishanthi A, Kagne RN. Implementation of research ethics training for postgraduate medical students - A learner-centered approach. Perspect Clin Res. 2023;14(2):102-3.
8. Johar SK, Jaybhaye DL, Chandra S, Mishra PS. Evaluation of knowledge, attitude and practices of postgraduate medical students towards clinical research in a tertiary care teaching hospital. Int J Basic Clin Pharmacol. 2021;10(7):800.
9. Chellaiyan VG, Manoharan A, Jasmine M, Liaquathali F. Medical research: perception and barriers to its practice among medical school students of Chennai. J Educ Health Promot. 2019;8(1):134.
10. Mondal H, Mondal S. A brief review on good clinical practice and its training methods. Indian Dermatol Online J. 2024;15(3):377-82.
11. Dharmendra MY, Bhavsar B, Prajapati VD, Malhotra S. Perception of medical students regarding clinical trials and its impact after educational intervention- a questionnaire-based study. Apollo Med. 2024.
12. Goel D, Walia R, Sharma P, Kaur H, Agnihotri P. Impact of educational intervention on knowledge, attitude and awareness of good clinical practice among

health care providers. Perspect Clin Res. 2017;8(2):90-4.
13. Sukriti SM, Ajay AG, Vinay VB. Perception and attitude of post graduate students towards research and audit of their thesis protocol- a cross sectional study. J Contemp Clin Pract. 2025;11(7):337-46.
14. Vora M, Shah C. Effectiveness of workshop training in basic principles of good clinical practice among the medical teachers- a cross-sectional study. Nat J Physiol Pharm Pharmacol. 2011;2(1):92.
15. Patel A, Padarya SK, Virani A, Singh P. Evaluating the impact of a Good clinical practice workshop on the knowledge and attitude of postgraduate medical students. Cureus. 2025;17(2):e79674.
16. Kumar S, Maity S, Mondal H, Banerjee M, Das A. Impact of GCP workshop in improving knowledge about good clinical practice among participants attending GCP Workshop at Government Medical College, India. J Med Allied Sci. 2025;15(1):20.
17. Awatagiri K, Gadgil D, Kannan S, Rane P, Bandekar B, Sawant N, et al. Effect of a planned training session on good clinical practice knowledge in research professionals: A pilot study. Perspect Clin Res. 2019;10(1):20-5.
18. Goel D, Walia R, Sharma P, Kaur H, Agnihotri P. Impact of educational intervention on knowledge, attitude and awareness of good clinical practice among health care providers. Perspect Clin Res. 2017;8(2):90-4.
19. Biswas A, Sen S, Ray K. Reliability assessment of pre -post-test questionnaire on the impact of a daylong clinical pharmacology workshop among medical professionals. Asian J Med Sci. 2019;10(6):93-7.

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