

Knowledge, attitudes, and perception of 398 cancer patients toward participation in clinical trials: A single-center study from New Delhi, India

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Abstract

Background and Objective: Clinical trials are considered to be the gold standard research methodology for evaluating the efficacy and safety of healthcare interventions.

Materials and Methods: A cross-sectional study was conducted using standardized self-administered questionnaires prepared by the research team and statistician. The questionnaires were offered to cancer patients presented at a tertiary care center.

Results: We surveyed 398 cancer patients, 193 (48.5%) males and 205 (51.5%) females with a mean (\pm standard deviation) 55.39 (\pm 13.59) of age in years. Out of total, only 59 (14.82%) had the prior knowledge of the clinical trial. Forty-three (10.80%) participants were willing to participate in clinical trials.

Conclusion: Cancer patients had preconceived notions and myths that linger in our society that clinical trial participation will harm them. The researchers/oncologists need to explore the rationale, objectives, and benefits of taking part in clinical trials and make it easy to understand by cancer patients.

Keywords: Awareness, cancer patients, clinical trials, oncologists, trial participation, willingness

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INTRODUCTION

Cancer is the second-most important cause of death globally, and liable for 9.6 million deaths in 2018. About portion of the incidence burden occurs in Asia, and about half of this, or 22% worldwide aggregate, arises in China and 7% in India.^[1] Concerning the most recent advancement, the oncologists need to keep updated. All eligible cancer patients with progression, and for whom no standard of care treatment alternatives are available should

be enrolled in a clinical trial.^[2] Clinical trials are considered the gold standard research methodology for evaluating the effectiveness of health-care interventions.^[3] In new drug development, clinical trials offer the latest procedure to detect, diagnose, prevent, or treat a health condition. Clinical trials participants have a choice to contribute to researchers' knowledge regarding cancer and to help in the development of cancer treatments.^[4,5] The success of these clinical trials relies on enlisting the statistically required

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number of participants. Poor enrollment of participants in clinical trials prompts to delay the trial completion and hinder the approval of more efficacious and effective new treatments for patients with all stages of cancer.^[6,7] The participant refers to a number of barriers to participating in the clinical trials.^[8-10] Various factors such as ethnicity, cultural background, socioeconomic status, language, and education pattern affect the patient's knowledge, attitudes, and perception toward clinical trial, which ultimately affect the patient enrollment in clinical trial.^[11,12]

Nowadays, enrollment and individual subject completion rates are the most challenging aspect of a clinical trial.^[8] However, it has been evaluated that fewer than 5% of cancer patients worldwide are taken in clinical trials. Besides, just about 50% of these clinical preliminaries achieve the assigned least collection numbers.^[9] Nearly 45% of the clinical trials were enrolled from Europe, 36% from North America (including the U. S. A and Canada), and 8.4% from Asia (including China and India).^[13] A number of studies have been reported in the USA, Australia, Japan, Denmark, Saudi, and China for the assessment of knowledge and perception of cancer patients toward participation in clinical trials. The findings from these studies vary from country to country due to different language, social culture, socioeconomic background, and knowledge.^[14] In this study, we explore the basic knowledge, understanding, and attitudes of cancer patients toward clinical trials participation in India. This study provides insight to oncology practitioner so that they can decide patient enrollment in cancer clinical trial.

MATERIALS AND METHODS

Study design

The cross-sectional study was conducted at a tertiary care center in the central region of India. The ethical approval was obtained from the institutional ethics committee. The written informed consent has been obtained from cancer patients who meet the inclusion/exclusion criteria were approached to take interest in the study. The study includes Indian patients aged 18 years and above diagnosed with cancer and clinically able to finish the survey.

Questionnaire

The standardized self-administered questionnaires were prepared in English and Hindi both languages by research team based on the previous finding experiences. The questionnaire consist of three parts the first contain the patient's demographics such as age, gender, marital status, habitation, habituation, socioeconomic status, education level, and occupation. The second part contains the

information on the type of cancer, type of therapy they were treated with and family history. The third and main part of the questionnaire consists of 15 questions covering the knowledge, attitude, and perception of cancer patients toward the clinical trial. The participants were marked their answer by ticking the given respective box.

RESULTS

Between December 04, 2018, and February 23, 2019, 850 cancer patients were asked to fill the questionnaire out of which 402 (47.29%) patients fill the questionnaire. Of 402 participants, 360 (89.5%) participants filled the English questionnaire and 42 (10.5%) participants fill the questionnaire of Hindi language. Of total, four participants were excluded from the study as they already had been participated in clinical trials, leading sample size to 398. The median age in years of the study population was found to be 58 (18–88) with a mean (standard deviation) 55.39 (± 13.59) and mode of 58 years of age. It was found that 336 (84.42%) of cancer patients belong to urban areas of India and 375 (94.22%) with middle class of socioeconomic status. The most of cancer patients were at least graduated 209 (52.51%) followed by 12th grade 96 (24.12%) and postgraduation 63 (15.82%).

The major type of cancer was diagnosed is breast cancer 91 (22.86%) followed by head and neck cancer 65 (16.33%). The majority of patients were treated under chemotherapy 281 (70.60%) followed by radiation therapy. A total of 34 (8.54%) patients reported to have a family history of cancer. Out of the total, only 59 (14.82%) participants had prior knowledge about clinical trials. 377 (94.72%) of the total study population appreciated and agreed that asking about the patient's willingness regarding participation in a clinical trial is important [Table 1]. Over 40 (67.79%) out of 59 patients were having perception about clinical trial as testing of new drug on human being [Table 2]. The majority of participants willing to get latest therapy option available followed by treated under controlled supervision of investigator in clinical trials. The participants wanted to be a part of later phase (of clinical trial due to safety reasons). Very few 43 (15.5%) of participants were willing to participate in clinical trials. The major cause of not willing to participate was fear of possible side effects followed by lack of information about clinical trials [Table 3].

DISCUSSION

Our study is the very first in India to assess knowledge, attitude, and perception of the Indian cancer patients toward clinical trials. We observed that out of 398

Table 1: Knowledge and willingness to participate in a clinical trial (n=398)

Questions	Yes, n (%)	No, n (%)
Do you know about clinical trial?	59 (14.83)	339 (85.17)
Do you know about the informed consent process before participation in clinical trial?	76 (19.09)	322 (80.91)
Do you want to know about clinical trial?	251 (63.06)	147 (36.94)
By knowing about clinical trial would you change your opinion to participate in clinical trial?	91 (22.86)	307 (77.14)
Do you want to participate in clinical trial?	43 (10.81)	355 (89.19)
Would you like to participate in a noninterventional (observational) study?	243 (61.05)	155 (38.95)
Is it important to ask about patient willingness to participate in clinical trial?	377 (94.73)	21 (5.27)

Data are presented as actual n (%)

Table 2: Perception of 59 cancer patients about the clinical trial, who already know about clinical trials

Questions	Response, n (%)
What is the source of information if you already know about clinical trial?*	
Doctor	27 (45.76)
Family/friends	4 (6.78)
News/media	36 (61.02)
Others	3 (5.08)
What do you think about clinical trial?*	
As testing of a new drug on the human being	40 (67.8)
A step to drug development for public health care	28 (47.46)
A tool to make money by doctors/manufacturing company	4 (6.78)
Cannot say anything	5 (8.47)

*Multiple responses by participants. Data are presented as actual n (%)

participants, only 59 (14.82%) had the prior knowledge of the clinical trial whereas in a study by Robert *et al.*, it was 60%.^[3] 254 (63.2%) participants wanted to know more about clinical trial which was reported as 50% by Moorcraft *et al.* in their finding from the survey.^[15] Out of the total patients, 277 (69.59%) wanted to be informed by their treating doctor about clinical trials, which was 80% in a study by Dias *et al.*^[9] Out of the total 377 (94.72%) participants agreed that asking about patients perception regarding clinical trials participation is important. This incidence was reported as 91% by Jenkins *et al.*, in their survey.^[6] Out of the 43, 18 (41.86%) participants wanted to support public, and 14 (32.55%) wanted to get controlled supervision during clinical trials, whereas these incidences were reported as 92.3%, 80.4%, respectively, by Al-Tannir *et al.*^[14] On the basis of the study finding, followings are the key areas of discussion.

Attitudes toward survey

A lot of patients were upset and already in trouble due to their illness burden that's why they denied to filling the questionnaire and many reported lacks of time. Some of them refused to sign the informed consent form by saying "we don't want to sign any form due to privacy reason" and few of

them denied as they found that the questionnaire was too long and time-consuming and the same has been reported by Moorcroft in their study.^[15] One of the cancer patients said that "I am ready to fill the questionnaire but do not expect any call in future from your side." One patient said that "I am already in trouble due to cancer and you are taking interest in filling the survey questionnaire, it's annoying." One patient said that "let's see I don't want to participate in any study and rest depends on my doctor that what he suggest to do." One patient reported that "Doing the survey like this it is better to do the survey regarding the self-diagnostic, supervision and control over diet pattern to defeat cancer" whereas one patient reported that "It is better to do the survey over whose family member, i.e., husband/wife/sister/brother etc., is/are more supportive of his/her patient." However, lots of patients showed a positive attitude towards filling the questionnaire and wanted to support public health care.

Knowledge about clinical trial

It was found that a very few have prior knowledge about the clinical trial. When participants were asked for knowledge about the clinical trial; a lot of individuals repeated the question back like "what is it?" While some of them re-asked as "Is it testing of the drug on animals?" and one of the participants confirmed that "Is it testing of the drug on a human just like testing of the drug on animals?" Some of them had a fear of randomization, blinding, placebo-controlled trial, and fear of possible side effects of a new intervention. Similar findings have been reported by White *et al.*, in a survey of cancer patient for their view towards randomized controlled trials.^[17] More than 1/3rd of the participants agreed to know about clinical. Similar finding has been reported by Moorcraft *et al.*, in a prospective survey of cancer patients.^[15] By knowing about clinical trial about 1/3rd of the study population change their opinion and reported better understanding of the clinical trial. One subject said that "If participation to clinical trial provides lots of benefit than why cancer patients don't want to participate in clinical trial." However, very few individuals were having good knowledge and understanding about clinical trials and they had thought about it as a step of new drug development.

Attitudes toward clinical trial participation

First, the clinical trial term was new for a lot of patients. They were not aware of new drug testing in human and its approval. One patient said, "Why you are testing a drug on human just like animals?" However, by knowing about the rationale and benefits of clinical trials, a lot of individual shows positive attitudes and they were willing to participate in clinical trials. One patient said that "This is my contact number, contact me if clinical trial option available for me." In a study by Thornton *et al.* one patient reported that "The safety should be considered first and ensure that no harm

Table 3: Attitudes of Cancer patient toward clinical trials and tools to be used for general awareness

Questions	Response, n (%)
What is the reason for participation in a clinical trial?*(n=43)	
Suggested by doctor/family/friends	10 (23.25)
Latest therapy of treatment provided	27 (62.79)
Well-controlled supervision of trial patient	14 (32.56)
Right to withdraw from the trial at any time	11 (25.58)
Free of cost interventions and treatment	6 (13.95)
Want to support public health	7 (16.27)
Compensation	1 (2.32)
If you participate in clinical trial what will be your purpose of participation?*(n=43)	
To support public health	18 (41.86)
To get treated by new intervention/drug	20 (46.51)
To get controlled supervision during treatment	24 (55.82)
To get compensation	0 (0)
Do not know	3 (6.97)
In which phase of clinical trial have you participated/want to participate?*(n=43)	
Phase I (to assess safety and dose range of new drug in healthy volunteer)	Not applicable
Phase II (testing of the drug on a small number of patients to assess efficacy and side effects)	2 (4.65)
Phase III (testing of the drug on a large number of patients to assess efficacy, effectiveness, and safety)	8 (18.61)
Phase IV (Postmarketing surveillance of approved drug use in public)	41 (95.34)
Why you do not want to participate in CT?*(n=355)	
Efficacy and safety of new drug/device not ensured	66 (18.59)
Anyone (doctor/family/friends) suggested to not participating in a study	36 (10.14)
Fear of possible side effect	156 (43.94)
You think that you may or may not get intervention	26 (7.33)
You have no or not much information about clinical trials	145 (40.84)
According to you which is the best tool to encourage/aware the patient participation in clinical trial?*(n=398)	
Counseling by medical staff	277 (69.59)
Poster presented in hospital	59 (14.82)
Public awareness program	185 (46.48)
Media and social media	69 (17.33)
Cannot say anything	5 (1.25)

*Multiple responses by participants. Data are presented as actual n (%). CT=Computed tomography

on human” whereas another patient reported that “I don’t believe the manmade drug.”¹⁸ A well-known language, good communication skill and well education established a better impact on cancer patient to understand the benefits and rationale of taking part in clinical trials.^{3,8,9}

Barriers to participation in a clinical trial

The cancer patients refuse to take interest in clinical trial participation and reported lack of time, a long distance from the hospital and were of old age so that they were unable to participate in a clinical trial. A lot of patients had complete trust in their oncologist; one said that “I am ready to participate in a clinical trial if my doctor suggests.” One of the patients said that “I am not an animal to test new drug.”

Subjects had safety and efficacy concerns as one of the patients said that “I am taking chemotherapy as treatment which causes hair fall, loss of appetite, darkening of skin and weakness I don’t want to try any other new chemotherapy treatment plan under clinical trial.” Previous finding also suggested that poverty, poor socioeconomic status, poor education, and unemployment affect the knowledge and awareness about clinical trials which leads to poor participation.^{5,7,19} In a meta-analysis by Shah *et al.*, they reported that mistrust of trial organization, concerns about safety and efficacy of trials, dependency issues, loss of confidentiality, trial burden, psychological reason, and language as a major barrier in clinical trial participation.^{8,9}

Aspects which encourage cancer patients towards clinical trial participation

Various aspects such as well-controlled supervision of participants during a clinical trial, latest therapy option available in clinical trials, free of cost intervention and treatment and right to withdraw from clinical trials at any time; play an important role in encouraging cancer patients participation toward clinical trials. Jones *et al.* reported 40% of the population considered very important that they wanted to help future patients by participating in clinical trials.²⁰ When the patients were discussed with rationale and benefits of clinical trials participation, one patient suggested that “There should be a unique toll-free telephone number on which one can contact to gather the information regarding ongoing clinical trials and eligibility criteria as well as general information about clinical trials and benefits of participation.” In a study by Thornton *et al.*, one patient reported that “Doesn’t matter what happen to me If my participation helps other, I will participate.”¹⁹

Our findings and future consideration

Cancer patients had preconceived notions and myths that linger in our society that clinical trial participation will harm them. They were upset and troubled by the issues that occur with diagnosis and treatment and did not want to be part of clinical trials and become “a guinea pig” of medical experiments. There is a very lower ratio of participation in all types of cancer trials reported by Murthy *et al.*, in a meta-analysis.²¹ However, many participants were not aware of clinical trials but they were willing to participate by knowing the benefit and rationale of partaking. Yet, a lot of participants had complete trust in their consulting oncologists and were willing to be informed by them about the rationale and benefits of taking part in clinical trials.¹⁰ We believe that the lack of understanding and faith in clinical trials in India is a serious impede to drug development in a country which is the best suited, i.e., population for the same.⁸ For the purpose, the drug development as a single aspect needs advancement in clinical trials design

and recruitment of a statistically required number of participants. There should be a centralized awareness center for research volunteer to provide generalized and specific information over new health intervention. The center should also provide information over eligibility for specific trials, rationale/benefit of taking part for not only cancer clinical trials but also for other clinical trials at different trial centers in India. For the success of a clinical trial, there is a need for the connivance of all countries throughout the world to overcome the obstacle that we face in the contemporary world of clinical trials. As our study is center specific, there is a need for further research to generate effective evidence over the willingness of cancer patients' participation in clinical trials in India and overcome fence outcomes for the same.

Strengths and limitations of this study

Our study includes limitations such as; this is a single-center study and may not be pertinent to other study population. We included the newly diagnosed patients, thus chances of anxiety are obvious in cancer patients. It is a cross-sectional study; hence, results may be subject to bias.

Strengths include large sample size, questionnaire with English and Hindi (Regional) languages, questionnaire designed after pilot study, and various revisions. The study site is a cancer institute in the central region of India that provides an assortment in the study population.

CONCLUSION

Our findings suggested fear of possible side effect and lack of awareness about clinical trials were the most abundant causes which lessen the willingness of cancer patients to participate in clinical trials. However, parameters such as latest therapy option, well-controlled supervision, and right to withdraw from clinical trials give confidence to cancer patients to participate in clinical trials. Oncologists (because of complete trust in patients' perception) need to aware the cancer patients about the rationale and benefit of partaking in clinical trials in a simple, layperson/regional language. Furthermore, multicentre studies with a huge sample size provide impactful evidence for the same.

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Conflicts of interest

There are no conflicts of interest.

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