Polish Annals of Medicine

Journal homepage: https://www.paom.pl

Research paper

Assessment of knowledge and awareness about clinical trials of patients participating in cancer trials

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ARTICLE INFO

Article history
Received 26 October 2020
Accepted 3 December 2020
Available online 1 March 2021

Keywords
Cancer
Oncology
Awareness
Clinical trial
Phase of clinical trials
Informed conset

Doi
https://doi.org/10.29089/2020.20.00145

ABSTRACT

Introduction: Clinical research in the field of oncology is necessary to check the safety and effectiveness of potential treatment methods and translate innovative knowledge into measurable benefits for patients as well as to introduce innovative therapies for cancer treatment. In 2019, 18.1 million new cancer cases were diagnosed worldwide.

Aim: The purpose of this study is to assess patients knowledge and awareness of the clinical trials they participate in, as well as the quality of treatment in the clinical trial compared to standard treatment.

Material and methods: The authors anonymous questionnaire was used to assess the state of knowledge of patients. Seventy patients in clinical trials participated in the study, 87% of whom were women, and 13% were men. The patient's knowledge was compared with the actual state of research in the chemotherapy department, and general questions about clinical trials were asked.

Results and discussion: Most often, patients gained knowledge about clinical trials from the attending physician (37%). As many as 79% of study participants were satisfied with the informed consent procedure. The factor that most determined the participation in the clinical trial (36%) was access to innovative therapy not available in the national healthcare system. Every fourth participant in the study was unable to determine the phase of participation in clinical trials.

Conclusions: Based on anonymous survey results, patients who participate in clinical trials know the clinical trials essential parts. The vast majority are satisfied with the informed consent process, the availability of innovative therapies, and a clinical trial phase.

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1. INTRODUCION

Clinical trials are a scientific process that aims to improve knowledge of a substance and, consequently, to introduce it into the pharmaceutical market. The complex clinical trial process is divided into phases – from the first to the fourth phase, in which the clinical experiment is conducted.[1] It would not be possible to conduct a clinical trial without the participation of patients who take part in the informed consent process. Clinical trials in oncology are essential to test the safety and efficacy of potential treatments and to translate innovative knowledge into measurable benefits for patients, as well as to introduce innovative cancer therapies.[2] The increase in the incidence of cancer focuses even greater efforts of scientists in the development of new therapeutic substances.

Cancer is the second cause of death after cardiovascular diseases. In Poland, cancer is responsible for 20% of deaths among citizens.[3] In 2018, 18.1 million new cancer cases were diagnosed worldwide, and 9.6 million people died from cancer. The number of people with cancer diagnosed, whose survival rate is over 5 years, is 43.8 million, which is more than the number of all Polish citizens.[4,5] There are approximately 72 000 clinical trials conducted worldwide (active research and recruitment), and 1663 clinical experiments are being conducted in Poland. Polish patients take part in 768 clinical trials in oncology. Oncology is the field of medicine in which the largest number of clinical trials are conducted in Poland and abroad.[6,7] Over 20 000 clinical trials are currently registered in 16 national and regional registers every year, and healthcare professionals, researchers, patients, and sponsors are increasingly taking advantage of the advantages offered by the registration of clinical trials.[8]

Patients who decide to take part in a clinical experiment must take into account several obligations in relation to the clinical trial protocol, which imposes guidelines on both the research team and patients to conduct the trial. Therefore, it is important to provide patients with reliable information on any implications of the clinical trial and an overview, most often conducted by pharmaceutical companies. This lack of understanding may contribute to a general reluctance to clinical trials.[9]

2. AIM

This study aims to assess the patients knowledge and awareness of the clinical trials in which they participate, as well as the quality of treatment in a clinical trial compared to standard treatment. It also aims to present the factors that contribute to participation in a clinical trial.

3. MATERIAL AND METHODS

The authors anonymous questionnaire was used to assess the state of patients knowledge.

Seventy questionnaires of patients already participating in the clinical trial were collected. The survey were conducted on February 4, 2019 to June 30, 2020.

The questionnaire was divided into three parts. In the first part of this survey, demographic data were collected. In the second part, the patients could individually assess their knowledge and indicate the sources from which they gained knowledge of clinical trials. In the third part, the patients knowledge was compared with the actual state of affairs in the chemotherapy ward, and general questions about clinical trials were addressed.

Inclusion patients

The criterion for inclusion in the survey was participation in a clinical trial.

Statistic

The Statistica v. 13.3 program was used for statistical evaluation. The χ^2 test was used to assess statistical significance, assuming that $P < 0.005$.

Study population

The study population was 87% ($n = 61$) women, and 13% ($n = 9$) men. The respondents most often, i.e., as much as 60% ($n = 42$), represented the group of 51–69 years of age. The questionnaire was then represented by people aged 31–50 years (27%; $n = 19$), 70–74 years (7%; $n = 5$), and 75 and more years old (6%; $n = 4$). No person represented the 18–30 age group. The mean age was 52.01 years. The largest group consisted of people from cities with more than 250 000 inhabitants (32%; $n = 23$). The next group included people from cities from 100 000 to 250 000 (21%; $n = 15$). Cities up to 50 000 were indicated by 17% ($n = 12$) of respondents, 15% ($n = 15$) each were groups from villages and cities from 50 000 to 100 000.

. As regards the level of education and professional situation, it can be noted that among the respondents the most often they were people with secondary education (50%; $n = 35$) and professional situation of retired people (65%; $n = 46$). In the analysis of medical history, patients were asked to indicate the cases of cancer in the family. Respondents in 63% ($n = 44$) indicated that such cases occurred. In the chemotherapy ward, clinical trials in breast and colorectal cancer diseases were conducted during the analyzed period. Respondents participated in 76% ($n = 53$) of breast cancer clinical trials and 24% ($n = 17$) of colorectal cancer clinical trials, respectively. In these patients, the most common duration of treatment at the time of the survey was 1–2 years (50%; $n = 35$). The next groups of 17% ($n = 12$) were 2–5 years, and less than a year. In 16% ($n = 11$) of patients, this process lasted more than 5 years.

4. RESULTS

Each respondent could individually assess their knowledge of clinical trials at the very beginning of the questionnaire.

As many as 40% ($n = 14$) of the respondents assessed their knowledge as 'average' and 35% ($n = 24$) as 'good' ($\chi^2 = 15.20$; $P < 0.05$). Most often, patients obtained their knowledge on clinical trials from the attending physician (37%; $n = 26$), i.e., from the person who presented them with a proposal to take part in the trial. The next group gained knowledge or supplemented it with the use of the Internet (31%; $n = 22$). Another group was medical personnel participating in the clinical trial – nurses and clinical coordinator (20%; $n = 14$) indicated this group as a source of knowledge ($\chi^2 = 93.77$; $P < 0.05$).

In the third question, 67% ($n = 48$) of respondents answered that they did not know anything about clinical trials prior to their participation ($\chi^2 = 22.85$; $P < 0.05$). Next questions concerned participation in a clinical trial, clarification of the informed consent process, and family support in this decision. The vast majority of patients (75%; $n = 53$) answered that the attending physician explained exactly what the clinical trial would consist of and had time to answer any questions. As many as 79% ($n = 56$) of the respondents were satisfied with the process of signing the informed consent and had enough time to think about their decision ($\chi^2 = 31.85$; $P < 0.05$). As many as 75% ($n = 53$) of the respondents received family support in making decisions ($\chi^2 = 39.80$; $P < 0.05$).

Patients (36%; $n = 25$) rated the highest 'access to innovative therapy with the tested medicine' as the main motive for taking part in the clinical trial. Another highly rated reason was 'access to more imaging tests, e.g., CT/MRI' (30%; $n = 20$). Next questions aimed to refine previous question on the factor encouraging participation in a clinical trial such as the lack of queues and the increased number of imaging examinations. Patients indicated the answer 'absolutely' in 48% ($n = 33$) and 'a little bit' in 40% ($n = 28$), which clearly shows that such reasons most often encourage patients to take part in a clinical trial.

Another part of the survey concerned the side effects of unregistered medicines and their possible impact on current health status. A vast majority of the respondents (75%; $n = 53$) are afraid of adverse reactions ($\chi^2 = 9.02$; $P < 0.05$), but half of them (50%; $n = 35$) would have taken part in the clinical trial if the chance of selecting a tested drug over a placebo had been ($\chi^2 = 6.35$; $P < 0.042$).

Patients in both questions that are presented in Figure 1 answered what, in their opinion, was the most burdensome in standard treatment and what in clinical trials. According to the respondents, the most burdensome standard treatment was the long waiting time for imaging tests (48%; $n = 64$), and the long waiting time to the clinic (26%; $n = 35$). The most burdensome in the clinical trial for patients were more frequent hospital visits (36%; $n = 44$), followed by additional medical procedures (25%; $n = 27$).

Patients could compare and assess the quality of treatment in a clinical trial and standard treatment (Figure 2). In the clinical trial, the majority of patients (55%; $n = 39$) rated the quality of treatment at 6 points out of 7. In a standard treatment, the largest group (44%; $n = 31$) assessed the quality of treatment at 5 points (in a 7-points, where 1 is very bad, 7 is excellent).

The actual data concerning the clinical trials at the ward in a given period of analysis were also compiled. Another questions concerns the definition of the stage of a clinical trial in which the patient is involved. The data are as follows: 50% ($n = 35$) of the respondents indicated that they participate in the observational study, and 20% ($n = 14$) are unable to

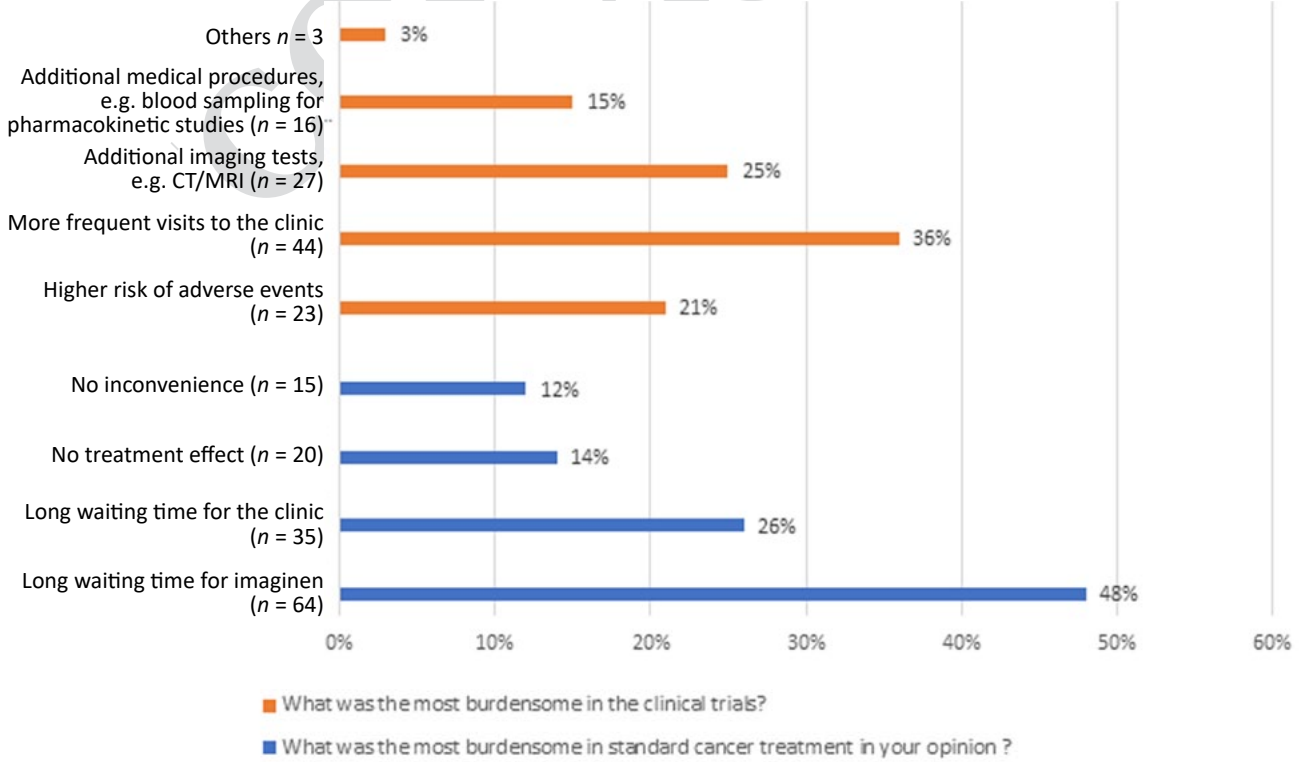

Table 1. The most burdensome in standard cancer treatment and in the clinical trial.

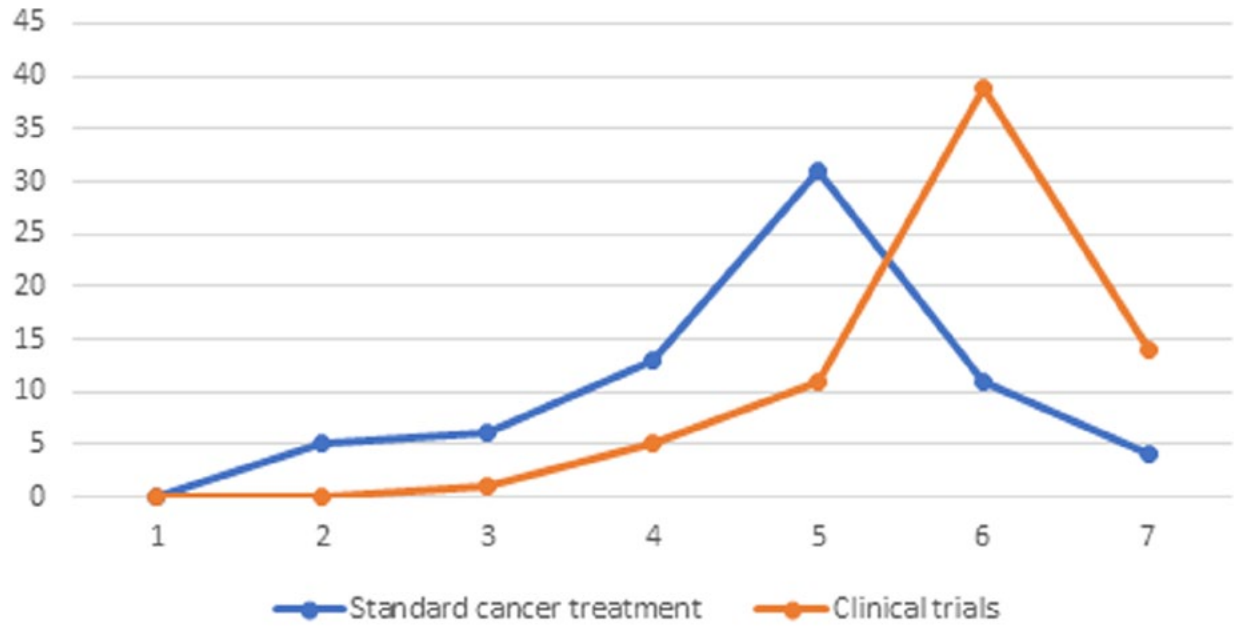

Table 2. Assessment of the quality of cancer treatment.

determine the phase in which they participate. Phase III was determined by 15% (n = 10) of the respondents, phase II by 13% (n = 9), and phase I by 2% (n = 2). The actual stage division with the number of patients participating in the survey is as follows: Phase III – 33% (n = 23), phase IV – 50% (n = 35), phase II – 17% (n = 12). However, there were no tests in phase I. The rest of the survey concerns the specification of the type of test in which the respondent participates. The group of 50% (n = 35) of people declares that it is a test of a medicinal product, 30% (n = 21) is an observational test, 20% (n = 14) is unable to determine. The factual situation is 37% (n = 26) of tests on a medicinal product and 63% (n = 44) of observational tests. Another questions involves the methodology used in a given clinical trial. Here, 48% (n = 33) of the respondents indicate that it is an open-access trial, 27% (n = 19) take part in an observational trial, 20% (n = 14) are unable to determine the methodology used, while 5% (n = 4) indicate a blinded trial (no such trials in the chemotherapy ward).

The last part of the survey concerns the cost of introducing medicine to the pharmaceutical market: 40% (n = 28) of the respondents indicated that it was about 100 million dollars. The actual cost of introducing medicine to the market is about 1–2 billion dollars.[10] The seventeenth question concerning the area in which the most significant number of clinical trials are conducted in Poland, a vast majority, as much as 80% (n = 56), indicated that it is oncology. Final study assessed the number of conducted clinical trials in Poland according to the respondents, 40% (n = 28) assessed that 100–300 trials are conducted in Poland.

5. DISCUSSION

It is disturbing that 67% of the surveyed population have never heard of clinical trials until they have taken part in them, which shows that patients are not very aware of clinical trials possibilities. According to a study conducted by Leiter A et al., general awareness of clinical trials increased between 2008 and 2012, although there are racial and ethnic differences in awareness of clinical trials. Targeting the education of the society will allow for equal opportunities in the availability and general awareness of clinical trials.[11] Patients in 37% obtained knowledge from their attending physician, but 31% indicated the Internet as a source of knowledge, which may also be a cause for concern about unreliable and unproven information that often appears on the Internet. The study conducted on patients with lung cancer by Du W et al. suggest the potential impact of educational videos to improve awareness and encourage participation in a clinical trial.[12]

However, it is encouraging that 79% of patients were satisfied with the informed consent process, in which they had enough time to think about their decision and talk to their loved ones. Therefore, according to the Alexa-Stratulat et al. survey, despite the patients understanding of the general principles of conducting a clinical trial as described in the informed consent form, the researchers efforts should be focused on the patients to help them better understand consent, in particular the meaning of the trial and protection of their interests.[13] The factor that determined the participation in a clinical trial to the greatest extent (36%) was the greater access to innovative therapy. A higher number of imaging tests encouraged almost half of the respondents (48%) to participate in the trial. An interview study conducted by Agrawal M et al. on a group of cancer patients who decided to participate in phase I of the clinical trial showed that the main factor predisposing to participate in the trial was the chance to maintain hope in the advanced stage of cancer and to engage in an action that would provide cancer treatment at a high organizational level.[14]

A comparison of standard treatment with a clinical trial enabled patients to indicate the most burdensome activities. In a standard treatment, the respondents as the most

burdensome factor considered the excessive waiting time for imaging tests (48%), whereas, in clinical trials, this factor included more frequent hospital visits than the standard treatment (36%). A survey conducted by Anderson A et al. on a group of 12 427 patients who participated in a clinical trial indicated that the most burdensome process in a clinical trial is frequent visits to the clinical center to perform the trial procedures, especially as protocols become increasingly demanding.[15] When assessing the quality of treatment, patients valued the clinical trial's medical services more than in the standard treatment.

The phase of a clinical trial is significantly different from each other, hence appropriate information and explanation to the patient on what a given phase of the trial is about will be crucial for understanding the clinical trial process. Unfortunately, every fourth participant of the survey was unable to determine the phase of participation. Determining the type of trial: experiment with the product being tested or observational study does not seem to be a difficult task. Therefore, most patients should have knowledge regarding this issue, which, at the very beginning, determines the informed consent form. The vast majority of the respondents as well defined their type of trial. The methodology of the clinical trial also at the very beginning is defined by the informed consent form, clinical trials conducted in the chemotherapy ward were conducted as open access trials and observational study. Respondents in the vast majority also well-defined the methodology of their trial. A meta-analysis of studies on understanding informed consent over three decades conducted by Thanh Tam et al. showed that understanding 'randomization' and 'placebo' have not improved over 30 years and are still at a low level.[16] The question about the general knowledge of clinical trials among patients concerned. In the first question, only 10% of respondents indicated the correct answer. The cost of introducing a drug to the pharmaceutical market is estimated at 1-2 billion dollars.[17] In the second question, as much as 80% correctly chose oncology as the field in which most clinical trials are conducted in Poland. The last question was answered well by only 5% – the number of clinical trials in Poland is above 1000 trials.[3]

Improvement of the quality of medical services provided by the research team shows the high demands that the clinical trials sponsors imposes on the center. Patients who decide to take part in a clinical trial make a decision that often involves a higher risk of adverse effects than the standard treatment, hence the need for a team of researchers to work together and with the patient to help identify and report adverse effects. Further efforts are needed to ensure that trial participants fully understand the risks and benefits before signing the informed consent.[18] In addition to compulsory insurance for the study sponsors researcher, there is a regional commission for the medical event in Poland.[19] A higher percentage of patient participation in clinical trials may be achieved by increasing the availability of such trials in public healthcare institutions offering standard treatment, in order to ensure that all qualified patients participate in the clinical trial.[20] Clinical trials relieve the burden on health care systems and guarantee the scientific and economic development of the country.

6. CONCLUSIONS

Based on anonymous survey results, patients who participate in clinical trials know the clinical trials essential parts. The vast majority are satisfied with the informed consent process, the availability of innovative therapies, and a clinical trial phase.

Conflict of interest
None declared.

Funding
None declared.

Ethics
The survey was submitted to the bioethics commission, which ruled that in the case of an anonymous survey, you do not need the opinion of the bioethics commission. Each patient was informed about the voluntary study of the questionnaire survey and expressed verbal consent.

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