

SURVEY OF THE KNOWLEDGE AND ATTITUDES OF MEDICAL DOCTORS AND PATIENTS FOR PARTICIPATION IN POST-MARKETING CLINICAL TRIALS

V. Atanasov, I. Getov

Department „Social pharmacy and pharmacoconomics“, Faculty of Pharmacy, Medical University – Sofia

Summary. The aim of this study was to examine the attitudes and to assess the willingness of patients and medical doctors to participate in post-marketing clinical trials. The purposes were realized by completing the following tasks: review of the literature with an emphasis on patients and medical professionals' participation in interventional and non-interventional post-marketing clinical trials. Following in-site nested survey was designed to assess the patients' knowledge about their disease and treatment, attitudes to adhere to ongoing therapy and willingness to participate in clinical trials of investigational medicinal products for coronary heart disease. The willingness of medical doctors to be involved in post-marketing study of medicines in ischemic heart disease was also examined.

Key Words: clinical trials, post-marketing, Investigational medicinal product, willingness

Introduction

The formulation and assessment of a new drug is a complex and multi-stage process in which human clinical trials are an essential tool.[1]The studies and analyses that were carried out led to key findings and conclusions on the potential and the willingness of patients and medical doctors to participate in monitoring the safety of investigational medicines.[2]Conducted field researches among patients with coronary heart disease found absolute refusal to terminate bad habits such as smoking and alcohol consumption.The respondents – medical doctors and patients expressed willingness to participate in clinical trials in coronary heart disease.

The results and conclusions could be used for discussions on the role and place of pharmacists in the fight against bad habits, deteriorating quality of life, the prognosis of therapeutic success and outcomes. [3]They can also debate about reconsidering the place and importance of observational studies in the field of pharmaceuticals and monitoring of different social diseases.[4]

Materials and methods

Methodology of the survey:

The study was conducted by the method of direct anonymous questionnaire.

Characteristics and structure of the survey:

The questionnaire begins with a brief address to the respondents stating the object and purpose of the study, who and how will use the obtained data.

The initial part of the survey provides demographic data: age, sex, education. The respondents - physicians were asked additional questions about the degree of postgraduate qualification and practical experience as a medical doctor.

The questionnaire was structured as a tunnel design starting from general questions and proceeding to issues tightly related to the purposes of the study. Surveys were divided into two groups – conducted among medical experts and polls among patients.

The aim of the study was also to assess patients' awareness and opinion about their health status and their general attitude towards potential participation in clinical trials

Results and Discussion

Study of the willingness of medical doctors to participate in post-marketing studies

Results of a survey conducted among medical practitioners

Demographic data

Within this survey were analysed valid ques-

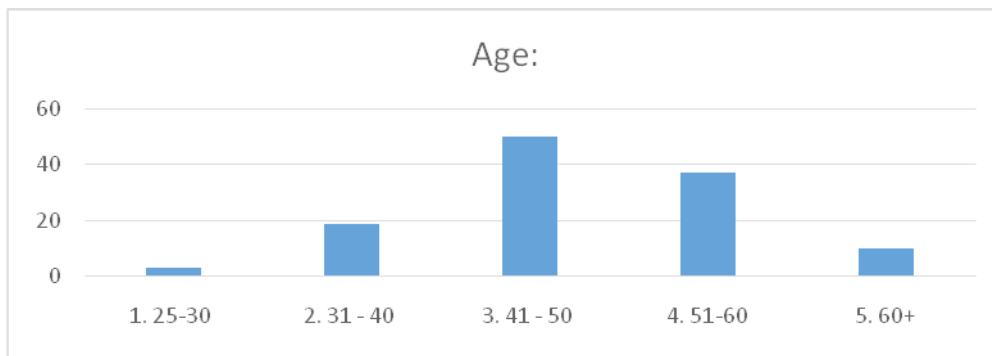


Figure 1. Age distribution of the doctors involved in the study

tionnaires received from a total of 119 medical doctors practicing in Bulgaria. The gender distribution of physicians is 49% men and 51% women. Predominant age groups of 41-50 and 51-60 year olds. (Figure 1).

The chart may lead to conclusion that doctors who participated in the poll are professionals with years of experience. Established practice in researchers is associated with better accuracy of the provided data. The average length of work experience of doctors participated in the survey was 19 years. This experience allows researchers to have an extensive overview of the diagnosis, treatment approaches and evaluation of therapy. This increases their willingness to participate in clinical trials, allowing to ameliorate the effectiveness of drug therapy.

The data collected by survey is presented in Table 1 and shows that 72% of physicians have two post-graduate specializations—internal medicine and cardiology. This shows that the majority of doctors - researchers are highly competent professionals, which is partly the reason for satisfying results of the treatment of cardiac diseases.

The medical doctors were asked about the age distribution of the patients in their practice the data

is presented in Table 2. It shows that the largest age group is of patients over 50 years. This fact is medically justified and confirmed by the practice of the majority of respondents.

Survey among medical doctors revealed three main groups of morbidity among the total number of patients. From the results thus obtained was concluded that patients suffering from ischemic heart disease represent between 30-50% of all patients with cardiac problems. Our data support the claim that ischemic disease is a socially significant disease. Inappropriate treatment of this problem led to a continued deterioration in the quality of life and disability of the majority of patients with cardiac problems. As a solution to this serious social problem in our society, doctors search different approaches to the prevention of disease, as well as approval of new methodologies and guidelines for the treatment of coronary diseases and/or putting into practice new medicinal products.

From the results obtained from the survey among cardiologists, the question about their experience in the field of clinical trials showed that the majority of respondents have solid experience in this area. According to the results 67% of respondents have more than 5 years of experience in clinical researches field,

Table 1. Distribution of respondents according to the acquired post-graduate specialty

Specialty	Number of physicians
Internal medicine	28
Internal medicine and Cardiology	86
Internal medicine, Cardiology, Invasive cardiology	2
Medical intern	2
Emergency Medicine – specializing in cardiology	1

Table 2. Age distribution of patients suffering from coronary ischaemic disease.

Age distribution of patients in the practice	%
1. Until 40 years	n/a
2. Between 41-50 years	1.7
3. Between 51-60 years	28.5
4. Between 61-70 years	39.5
5. Over 70 years	30.3

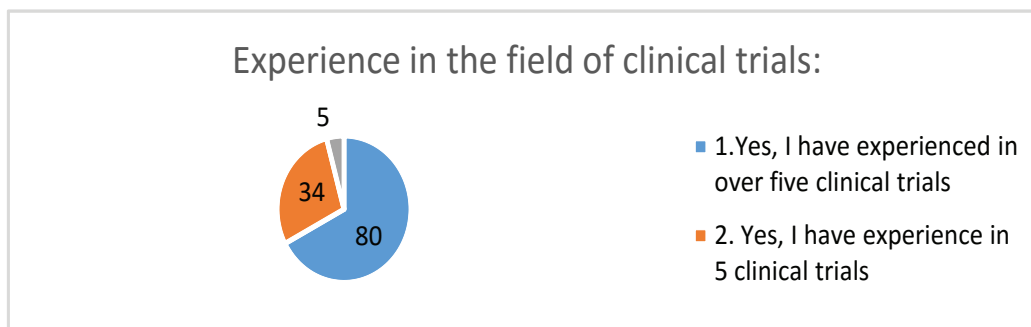


Figure 2. Experience in conducting clinical trials of medical doctors involved in the study

while 29% reported less experience in this regard. Only 4% of respondents are not familiar with the nature and have no experience in conducting clinical trials. These results could give us the impression that the majority of cardiologists in Bulgaria are familiar with the basic procedures in the conduct of clinical trials. This shows that many researchers have adopted clinical trials as accessible and innovative approach in the treatment of their patients. (Figure 2).

From a global perspective, through the conduct of clinical trials on innovative therapeutic approaches, researchers participate in the development of medicine and pharmacy and modern society. The collected data on the effectiveness and safety of investigational therapeutic approaches can be used as a complementary database of information about the medicinal products. The analysis of these data and the decision of withdrawal from the market of drugs with a proven safety profile can jeopardize the safety and treatment of thousands of patients. On the other hand the collection of sufficient data on the system of risk management updates and helps improvement of therapeutic guidelines for the treatment of diseases.

Separate question in the questionnaire studies the

medical doctors' attitude to the treatment outcome of their patients. The following results were obtained (Figure 3).

The analysis of the results clearly show that over 50% of doctors believe their patients suffering from ischemic heart disease to be well controlled. 35% of doctors say that the results of ongoing therapy highly dependent on the patient compliance. Only 2% of patients are with "Rather to No" well controlled symptoms. These results again show that the control of a disease is a bilateral process between patient and doctor. Experts are supposed to diagnose in time and accurately the disease and identify effective and precise therapy. Not less important part of the treatment are the clear and precise recommendations and advice to patients during the course of therapy. On the other hand good results depend very much on the level of patient compliance to the prescribed treatment.

Although pharmacists are not subject of our study, they occupy an extremely important part in the treatment of patients having the role of a mediator in the process of prescribing and administration of the therapy. An increase in the results from the prior consent of patients could be expected when these

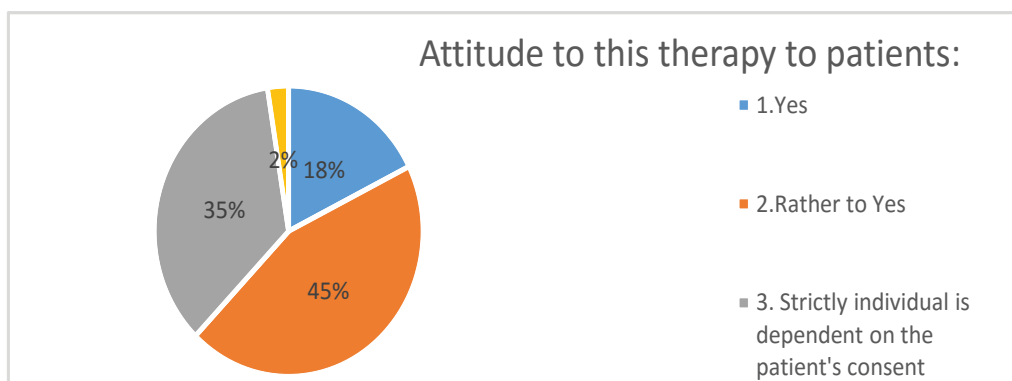


Figure 3. Answer the question: "Do you think ischemic heart disease of your patients is well controlled"

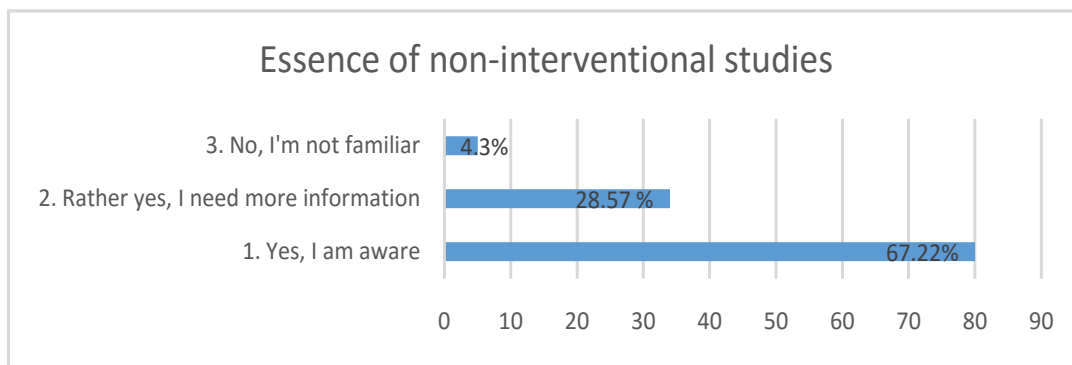


Figure 4. Study of the awareness of medical doctors with the nature of observational studies

health professionals become an indispensable part of the treatment process. Satisfactory effects for patients and society could be achieved as a result of the joined efforts of healthcare professionals. Concerning the awareness of respondents about the nature of observational clinical studies, over 67% responded positively that they consider themselves familiar with it. The purpose of the data collected from such a query is to evaluate awareness of researchers to the nature of observational studies. These results indicate that the majority of physicians are aware of the nature of observational studies.

In relation to this issue next in the survey is the question relating to the distinction between observational and interventional studies. The analysis of the data from Table 3, confirms that half of the surveyed medical doctors clearly distinguish two subtypes of clinical trials. Only one-tenth of respondents express significant fluctuations in differentiation.

These results show that cardiologists and internal medicine specialists are familiar with the nature of clinical trials and can distinguish the two subtypes of clinical trials. In the analysis of the results thus obtained can be assumed that this is a prerequisite for the active participation of experts in the conduct of vari-

ous types and design clinical trials.

At a direct question “Would you participate in the study of a medicinal product for treatment of ischemic heart disease?” 99% of respondents answered positively, with only 1% giving a negative answer about their possible involvement in conducting a clinical trial. (Figure 4)

This data underlines the strong willingness of the majority of medical doctors to conduct clinical researches in cardiology, particularly concerning ischemic heart disease. From this point on we can conclude that cardiologists and specialists in internal medicine are open to innovative approaches to treating this health problem and are willing to take the risk to conduct a clinical trial under their authority or with their participation. By including in the treatment new medicines the researchers take responsibility to protect the rights and health of the patient.

The results strongly confirm the willingness of medical doctors to participate in clinical trials. Many of the doctors that participated in the survey stated that it would be helpful for the treatment and monitoring of their patients.

Conclusion

The results of analysis of the carried out studies can be formulated in the following important conclusions:

1. Establishment and implementation of questionnaires specifically designed to investigate the awareness and willingness of patients and physicians to participate in post-marketing clinical studies are appropriate to conduct in the future with an even wider target group of respondents.

2. Medical doctors are familiar with the essence of clinical trials and distinguish interventional and observational studies, such as design, objectives, and expected results protocol. This is due to the fact that the prevailing practicing physicians have an average

Table 3. Answers to the question „Are you familiar with the differences between interventional and non-interventional clinical trials?“

Are you familiar with the differences between interventional and non-interventional clinical trials?	Doctors who answered the question (%):
Yes	50,42
Rather yes	37,81
Rather no	11,72
No	0,05

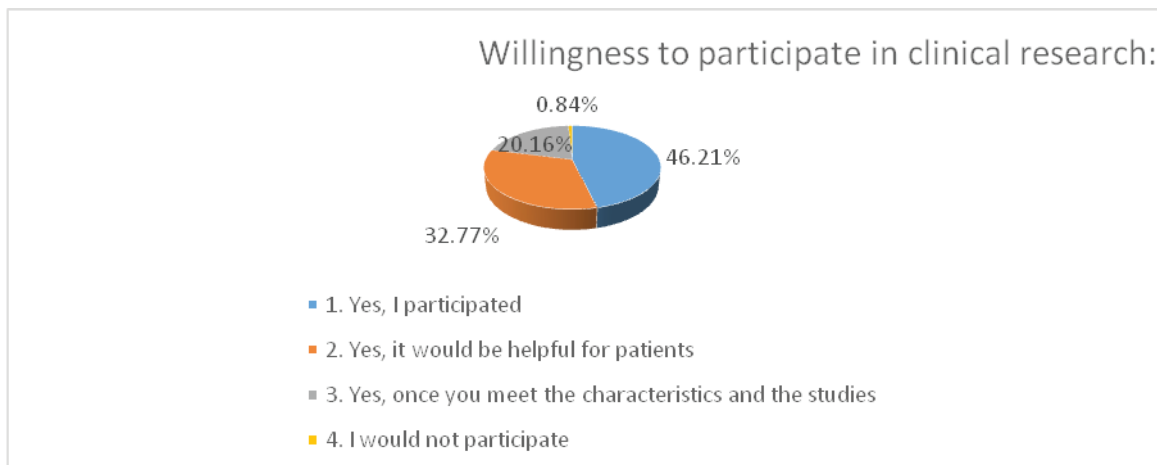


Figure 5. Answer of the question: "Would you surveyed medicine for coronary heart disease?"

of 20 years' experience and skills in clinical trials of pharmaceuticals.

References

1. WHO. The world health report 2013, <http://www.who.org>
2. Bulgarian Drug agency, www.bda.bg [last accessed 01.12.2015]
3. Getov I., Activemonitoring (pharmacovigilance) - essence, components and perspectives (literature review). *Social Medicine*, 10, 1(2002), 36-38.
4. Petrova G., Stoimenova A., Manova M., Draganov G., Legislativeregulation of clinical trials in Bulgaria. *Medical Biology Studies*, 3(2009), 29-33.



Corresponding author:

Prof. Ilko Getov, PhD, MScPharm
 Department of Social Pharmacy
 Faculty of Pharmacy
 Medical University – Sofia, Bulgaria
 office: +359.2.92-36-587
 fax: +359.2.987-98-74
 e-mail: ilko.getov@gmail.com