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Perceptions and Attitudes of Cancer Patients and Caregivers Towards Enrollment in Clinical Trials in Lebanon

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Abstract

The rates of participation in oncology clinical trials (CTs) are relatively lower in the Middle East compared to other areas in the world. Many social and cultural factors underlie the patients' reluctance to participate. To probe the knowledge, attitudes, and perceptions of patients with cancer and their caregivers regarding participation in CTs at our tertiary referral center in Lebanon, we interviewed 210 patients and caregivers visiting the outpatient clinics in the Naef Basile Cancer Institute at the American University of Beirut. A questionnaire was derived from literature and administered in Arabic. The study was approved by the Institutional Review Board (IRB). Two hundred individuals agreed to answer the questionnaire. The majority of participants (90.5%) were Lebanese with the remaining being non-Lebanese Arabs. Eighty-nine participants (45%) were aware of the concepts of CTs. Eighty-two respondents (41%) would participate in phase I CTs. Twenty-nine individuals (14.5%) agree to be enrolled in CTs with the approval of their family members only. One hundred twenty-nine subjects (64.5%) stated that they would refuse enrollment in a CT where they might receive placebo. Eighty-eight (44%) of participants considered that medical records could be reviewed for research without consent while 54% agreed that samples collected during clinical workup could be used for research without the consent of the patient. There are several social and demographic correlates for participation in CTs. Raising awareness and overcoming barriers of misconception are keys to promote participation in CTs in Lebanon.

Keywords Clinical trials · Perceptions · Cancer · Lebanon · Attitudes

Abbreviations

CT	Clinical trial

Introduction

Clinical trials (CTs) are essential for answering scientific questions and refining treatment paradigms. From a patient perspective, CTs also offer an opportunity to try novel therapeutic approaches when available standards of care lack efficacy or have low therapeutic index. Careful design, rigorous methodology, and oversight by scientific and regulatory committees are pillars for success of any CT. Positive receptivity by patients remains another critical element for success but also a major limiting factor. In fact, more than two thirds of published trials do not achieve their recruitment targets, leading in some cases to premature closing of the trial [1]. The appeal might vary widely between individuals. Apart from inter-individual variance in appeal to trials, there are other social and cultural factors that can affect individual attitudes towards enrolling in CTs [2].

In the Middle East and especially in Lebanon, the numbers of CTs are much lower when compared to international figures. Based on clinic trial registration (www.clinicaltrials.gov), 82 trials are registered and 25 trials are being conducted in Lebanon with the title "open study" that indicates active recruitment or planning in recruiting participants (Table 1).

In Lebanon, the law did not regulate CTs until 2014, when the Ministry of Public Health issued a decree setting a legal

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Table 1 Clinical trial in Lebanon and the world (source: https:// clinicaltrials.gov/ct2/results/map?cond=cancer&map=)

Region	Population 2016 × 10^3	Number of cancer studies	Number of cancer studies per 100,000 capita	Number of cancer open studies	Number of cancer open studies per 100,000 capita
Africa	1,216,130	834	0.068	191	0.015
Asia	4,174,462	10,578	0.253	3405	0.081
Middle East	261,762	1925	0.735	487	0.186
Europe	738,848	15,742	2.130	4442	0.601
Canada and Central America	259,618	5904	2.274	1334	0.513
USA	319,406	31,668	9.914	7350	2.301
South America	425,131	1466	0.344	314	0.073
Australia	39,901	2015	5.049	474	1.187
Lebanon	5988.15	82	1.36	25	0.417

framework for a safe conduction of CTs on subjects. While some patients have been enrolled in phase III and IV CTs, Lebanese academic centers still lack early phase CT units and the general population is not familiar with the concept of patients receiving experimental medications at earlier phases of development. On another note, there has been very little research about uptake of clinical trials in the region, and our study is the first of its kind in Lebanon to look at uptake of clinical trials.

Several studies have investigated the reasons why individuals are wary of participating in trials. Many factors were identified to be the contributors: the patient awareness and willingness to take part of CTs, the physicians conducting the study, and the type of intervention used in the CTs [3]. Very little research of this kind has been carried out in the Middle East and none in Lebanon. In this study, we aimed at exploring the perception, awareness, and willingness of Lebanese patients to participate in CTs.

Materials and Methods

Study Design

We conducted our study at the American University of Beirut Medical Center (AUBMC), in Beirut, Lebanon. The Institutional Review Board (IRB) approved the study protocol. Patients were interviewed in the period ranging between February and March 2017. Study investigators identified subjects meeting inclusion criteria and asked them to participate. Those participants who agree to participate gave written consent.

Study Population

Participants were adult patients or their companions visiting outpatient oncology clinics at AUBMC. They were more than 18 years of age, could read Arabic or English, and were willing to participate in the study. The participants were selected randomly. Subjects were either attending the clinic for the first time or coming for follow-up. Patients whose age is less than 18 years, those who were not yet informed about their diagnosis or those with documented psychiatric disorders, were all excluded.

Recruitment

We approached and invited 210 adult patients and their companions from the outpatient oncology clinics at AUBMC over a 1-month period to reach our sample size requirement of 200 participants.

Data Collection

All eligible participants were interviewed by trained medical doctors and signed informed consent. The duration of each interview lasted between 20 and 30 min. The questionnaire assessed several elements influencing subjects' participation into CTs and was based on a questionnaire used in a similar study in Saudi Arabia [4, 5]. It consisted of 40 questions and was divided into 4 sections including demographic information, general awareness of CTs, awareness of its availability in Lebanon and in the Arab countries, and willingness to participate in CTs. The surveyor provided a brief explanation of terms such as phase I, II, III, and IV trials to all participants before starting the questionnaire. Questions in the second, third, and fourth portion of the survey included yes or no answers.

The questionnaire was written in Arabic language, the native language of the subjects, and was also translated to English for submission and revision by the ethics committee with the Arabic version. Each patient was allocated a unique study code, which was written on the completed questionnaires.

Statistical Analysis

A total of 200 subjects were planned for enrollment. The sample size was set empirically and based on several similar publications conducted in the Middle East [4, 6–9]. Data analysis was performed using the Statistical Package for the Social Sciences software version 17.0 (SPSS, Chicago, IL, USA). Statistical analysis included frequencies for categorical data and means and standard deviation for continuous data. Descriptive and chi-square analyses were used to assess the statistical association between different demographic variables and outcomes of interest for the study.

Results

Demographics

Two hundreds subjects were interviewed, of whom 114 (57%) were patients and 123 (61.5%) were women. The median age of participants was 51 years (range 19–86 years), and only 14 (7%) of the patients were presenting for the first visit. More than half (58%) of the respondents had achieved university level of education. The majority (73%) lived in an urban area (Table 2).

Awareness and Perception of CTs

Only 89 participants (45%) were aware of the concept of CTs, and 7 (3.5%) had already participated in the latter. Patients who were older than 45 years, had a higher level of education, or coming for a follow-up visit tended to be more familiar with the concept of CTs with *p* value of < 0.0001 for each subject category (Table 3).

Fifty-two participants (26%) believe that CTs are conducted to test new drugs only, and 114 participants (57%) believe that the studied drugs are not safe enough to be tried in humans. We identified a lack of information and lack of trust regarding clinical trials being conducted in the Middle East. Ninety-three (46.5%) knew that CTs are being conducted in the Arabic countries but only 56 (28%) stated that they would trust the results. 94.5% believed that CT would result in novel therapies that would be effective against cancer.

Willingness to Participate in CTs

Eighty-two (41%) participants would participate in phase I CTs, 102 (51%) who stated that they would participate in a study where treatment would be randomly chosen randomly chosen, while 129 (64.5%) would not be happy to take part in a CT where they might get a placebo treatment.

Table 2 Demographic characteristics

Participant demographics	
Patients	114 (57%)
Family members	86 (43%)
Median age	51 (19–86 years)
Gender	
Females	123 (61.5%)
Males	77 (38.5%)
Nationality	
Lebanese	181 (90.5%)
Arab—non-Lebanese	19 (9.5%)
Primary cancer site (114 patients)	
Breast	40 (35%)
Central nervous system	1 (1%)
Gastrointestinal	22 (19%)
Genitourinary	11 (10%)
Head and neck	2 (2%)
Hematologic malignancies (leukemia/lymphoma/multiple myeloma/bone marrow failure syndromes/myeloproliferative diseases)	32 (28%)
Thoracic	6 (5%)
Education level	
Less than high school	48 (24%)
High school graduate	36 (18%)
More than high school (university degree)	116 (58%)
Current hometown	
Urban area	146 (73%)
Rural area	54 (27%)
Clinic visit (114 patients)	
First visit	8 (7%)
Follow-up	106 (93%)

Table 3 Clinical awareness and affecting factors

Item	Number (%)	Significance (*p* value)
Participant aware of CTs	89 (45%)	$p = 0.0250$
Patient	52	
Family members	37	
Education level		
High school graduate or less	20	$p < 0.0001$
More than high school (university degree)	69	
Age		
Less than 45 years	30	$p < 0.0001$
More than 45 years	59	
Gender		
Female	50	$p = 0.0990$
Male	39	

Respondents' Perceptions Towards Elements of Informed Consent

One hundred eighty-eight participants (94%) agreed that an informed consent is a must before recruiting a patient into a CT, and 15% believe that this approval might be given by the patient families only and not the patient directly.

Eighty-eight (44%) of participants considered that medical records could be reviewed for research without consent (Table 4) while 54% agreed that samples taken for clinical reasons (such as tumor samples taken out during surgery) could be used for research without the consent of the patient (Table 5).

Discussion

CTs are essential for scientific progress and advancement in clinical standards. Low appeal remains one of the leading obstacles facing successful conduction of trials in the Middle East [10, 11]. The results of our survey in Lebanon are consistent with prior reports from Saudi Arabia [4, 6, 12]. We found that 45% of cancer patients are aware of the concepts of CTs with the majority of them (77%) being more than 45 years of age and with higher educational level. These figures highlight the strong correlation between a higher level of education and awareness about CTs [13]. The fact that only 46.5% of the surveyed population is aware about the actual conduction of CTs in Arab countries illustrates the low publicity rates and underscores the need to better inform the public about the ongoing research at national as well as regional levels.

Table 4 Characteristics of patients who agreed on giving free access to medical records for research purpose without consent

Item	Number (%)	Significance (p value)
Total	88 (44%)	$p < 0.0001$
Patient	56	
Family member	32	
Age groups		
Less than 45 years	28	$p < 0.0001$
More than 45 years	60	
Education level		
High school graduate or less	45	$p = 0.7710$
More than high school (university degree)	43	
Gender		
Male	37	$p = 0.0343$
Female	51	
Location		
Urban area	58	$p < 0.0001$
Rural area	30	

Table 5 Characteristics of patients who agreed on giving free access to medical samples for research purpose without consent

Item	Number (%)	Significance (p value)
Total	108 (54%)	
Patient	67	$p = 0.0004$
Family member	41	
Age groups		
Less than 45 years	38	$p < 0.0001$
More than 45 years		
Education level	70	$p = 0.0034$
High school graduate or less	43	
More than high school (university degree)	65	
Gender		
Male	42	$p = 0.0011$
Female	66	
Location		
Urban area	83	$p < 0.0001$
Rural area	25	

Interestingly enough, 65% of participants would refuse to take part in a CT if there is a chance of receiving placebo. This finding has been reported by other investigators and been attributed to the lack of information about placebo in the population [14]. However, in both cases, patients' willingness to participate in whatever type of CT is higher than the one observed among their British counterparts, where only 30.4% of the total 1040 subjects expressed willingness to participate in CTs [15].

On the other hand, low confidence in local and regional scientific bodies was an essential factor impeding participation into CTs [16]. As such, 61% of subjects trusted CTs conducted in Lebanon and only 28% trusted them if they are conducted in another Arab Country and 80% believed that pharmaceutical companies are funding the CTs and manipulating the results for their own interest. In an Indian study, more than 26% of participants expressed distrust regarding the governments' protection of the public from unethical clinical research [5].

As for access to medical records, more than 61% requested an informed consent of the patient to be obtained before granting access to their medical information and charts. Even when informed about the confidentiality and anonymity of collected data, 56% of interviewees insisted on the need of obtaining patient consent before accessing medical charts for research purposes, whereas 54% allowed investigators access to previously collected samples.

The study is limited by the small population size. The patients and companions were all interviewed in a single institution, AUBMC, a large private referral center, where affluent people with higher socio-economic or educational status might be over-represented. Higher education is correlated with more familiarity with CT concept and this fact might have overestimated the actual awareness about CTs compared to the general population. The cross-sectional design prevents the findings from identifying causalities.

The study however provides a glimpse about the patients' perceptions into participation in clinical trials in Lebanon. It sheds the light on their concerns and worries and highlights the misconceptions they have. Our findings invite for putting more efforts in raising awareness about CTs among patients, caregivers, and the general public.

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