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Original article

Decision-making from multidisciplinary team meetings to the bedside: Factors influencing the recruitment of breast cancer patients into clinical trials

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ABSTRACT

Aim of the study: Our aim was to determine factors influencing physicians and breast cancer patients to respectively propose or accept participation in a clinical trial following proposals made during a multidisciplinary team meeting (MTM) in a Comprehensive Cancer Centre.
Patients and methods: Consecutive patients considered eligible for a clinical trial by a breast cancer-specific MTM were included. A detailed analysis of factors predictive of the physician proposing the trial and the patient's acceptance and final inclusion was conducted.
Results: MTM proposed 547 inclusions in 25 clinical trials for 397 patients between March and September 2011. The physician proposed the scheduled clinical trial in only 39% of the cases. The patients accepted the proposal in 74% of the cases, and finally 29% were included. The main reason for non-inclusion was the physician's failure to propose the trial in 45–81%, depending on the type of study. The only factor predictive of both the physician proposing the trial and final inclusion was the type of study (both $p < 0.001$). Diagnostic/prognostic studies were the most frequently proposed trials. The professional status (of the subject) was predictive of acceptance ($p = 0.03$) with higher rates among retired patients and executives (84 and 76% respectively).
Conclusion: The major reason for non-inclusion in clinical trials was the physician's failure to propose the trial, while the patient's professional status and the type of study influenced both physicians and patients. Educative measures mostly directed at physicians could be implemented to overcome such poor compliance.

Introduction

In the molecular oncology and personalized medicine era, decision making for breast cancer (BC) patients at any stage of the disease relies on decisions emanating from multidisciplinary team meetings [1,2]. Besides the standard surgical, medical and radiation therapies, there is considerable leeway for clinical trials in this setting in all areas of uncertainty. Clinical trials may currently enable patients to benefit from treatment de-escalation (surgery, radiation therapy, chemotherapy) or from specific personalized targeted therapies in the localized and advanced setting.

However, the rate of patients included in clinical trials in western countries has been reported to be less than 10% in most countries. This rate varies according to the type of clinical trial and the disease stage [3,4]. Previous meta-analyses evaluated obstacles to patient recruitment as well as the possibility of improving patient compliance with medical research [5,6]. The arguments for non-inclusion concerned both physicians and patients, and were multifactorial including social, racial, educational and demographic reasons [6]. However, those reports mostly concerned medical research in general or oncology but there is a lack of studies specifically devoted to the BC setting. Moreover, research in BC encompasses several fields including medical and surgical oncology as well as radiology and radiotherapy where compliance may not be documented to the same extent.

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To determine the factors that might influence the recruitment of patients into clinical trials of all-stage breast cancer, we retrospectively analysed the incidence of accruals and reasons for non-inclusion among patients identified as potentially eligible for any type of clinical trial by a dedicated BC multidisciplinary team.

Patients and methods

Patient population

Patients whose clinical file had been examined at the multidisciplinary BC meeting of a single institution, the Institut Gustave Roussy (IGR) Cancer Centre, in Villejuif, France, between March and September 2011 and who had been considered potentially eligible for a breast cancer-specific clinical trial were selected. Eligibility criteria included: 1) subjects with a primary BC, 2) on-going follow-up of patients at the IGR, 3) patients had been screened and found eligible for one of the available clinical trials.

Survey and data collection

The medical records of the patients were retrospectively reviewed and complete data were retrieved regarding: 1) patient demographics (age, marital status, professional category, and living location), 2) information on the disease and health status, and 3) clinical trial pre-screening details (date of screening, proposal and inclusion, type of study).

A questionnaire was given to physicians for the purposes of this study, inquiring about and grading the importance of the reasons behind failure to propose a clinical trial to patients in general. Items included i) frequency: how often trials were proposed once the patient had been identified by the MTM (never, rarely, sometimes, and often) and ii) reasons for failure to propose the trial (13 items). Replies were given anonymously.

Statistical analyses

Descriptive methods were used to summarize demographic characteristics. The Chi-square test was used to compare the distribution of baseline characteristics among groups for categorical factors, whereas the Student's *t* test was used for continuous variables.

A 5% significance level was used and all *p* values were two sided. All analyses were performed in R, an open source statistical package (http://www.r-project.org/) [7].

Results

Patient and study characteristics

Five hundred and forty-seven patients with BC initially eligible for a clinical trial were identified by the MTM at the Institut Gustave Roussy (IGR) between March and September 2011. Within the same period, 1650 files were discussed within the MTM. For the patients selected and finally not eligible, the reasons traced by physicians were standard and multiple, therefore we did not consider interesting to report them: In 8%, it was related to abnormal biologic tests, in 16% to outlier delays, in 3%, to previous medical history, in 2% to metastatic work-up, in 20% to geographical reasons, in 8% to a trial closed between screening and visit, in 44%, to other various or not defined causes.

Patient characteristics are shown in Table 1. The median age of the entire cohort was 55 years (range 21–88 years). Five hundred and thirteen patients (93.8%) had early-stage disease, and 34 (6.2%) had advanced disease. The two diagnoses investigated were: invasive BC ($n = 499$ [91.2%]) and 48 intraductal carcinoma [8.8%].

Table 1
Study population characteristics.

	$N = 547$
Age, median (min–max)	55 (21–88)
≤50 years	203
>50 years	344
Marital status	
Married	363 (66.4)
Single	179 (32.7)
Not assessable	5 (0.9)
Professional category	
Farmers	1 (0.2)
Chief executives, managers, professionals and self-employed	17 (3.1)
Executives and intellectual professions	53 (9.7)
Intermediate non-manual workers	92 (16.8)
Lower non-manual workers	153 (27.9)
Manual workers	6 (1.1)
Retired	142 (26)
Unemployed	66 (12.1)
Not assessable	17 (3.1)
BC diagnosis	
Invasive	499 (91.2)
Intraductal	48 (8.8)
Stage	
Early	513 (93.8)
Advanced	34 (6.2)
Type of study	
Cognitive	211 (38.6)
Studies on interventional innovative therapeutics	115 (21)
Diagnostic/prognostic biology	136 (24.9)
Imaging	13 (2.4)
Radiotherapy	72 (13.1)

A total of 252 patients had been considered eligible for a trial: 101 for 2 trials, 24 for 3, 4 for 4 and 1 for 5 trials. The classification of the different types of clinical trials and patients proposed for each type were as follows: 211 (38.6%) patients for cognitive studies, 136 (24.9%) for diagnostic/prognostic biology, 116 (21.2%) for interventional therapeutic studies, 71 (13%) for radiation therapy and 13 (2.4%) for imaging.

Clinical trials proposed and reasons for non-inclusion

A clinical trial was proposed to 215 (39.3%) patients. Among them, 159 patients accepted, which represents 74% of the patients proposed a trial but only 29% of those initially identified during the MTM.

The main reasons for non-inclusion in clinical trials were: the clinician's failure to propose the trial in 65.7% ($n = 255$), ineligibility in 12.1% ($n = 47$), patient refusal in 4.9% ($n = 19$), a study problem in 1.3% ($n = 5$) and other reasons in 16% ($n = 62$).

The analysis of patient characteristics which could have motivated the physicians' decision to propose the clinical trial is shown in Table 2. The patient's professional status was not a predictive factor ($p = 0.11$). In the univariate analysis, none of the patient characteristics were found to have a statistically significant influence on physician triage decision making. Patient age was of borderline significance, since patients in the "proposed-group" were younger than in the "non-proposed" group (53.9 years *vs* 55.7 years, respectively; $p = 0.06$). No difference was observed among the primary cancer care providers ($p = 0.58$).

The type of clinical trial significantly influenced the physician's decision to propose the MTM-earmarked trials ($p < 0.001$). Thus studies on cognitive and interventional innovative therapeutics were more represented in the "non-proposed" group.