Barriers to Clinical Trial Accrual

25TH ANNUAL SAN ANTONIO BREAST CANCER SYMPOSIUM 4

The accrual rates to breast cancer clinical trials are disappointingly low. Barriers to clinical trial recruitment may be both physician- and patient-related. A number of studies have evaluated the reasons physicians do not enroll patients as well as the reasons patients refuse to participate. Hopefully, the identification and subsequent elimination of these obstacles will lead to improvements in patient recruitment. No formal mechanisms have been established to inform clinical trial participants of study results. Ann Partridge, from the Dana-Farber Cancer Institute, assessed the preferences and attitudes of breast cancer patients about being informed of clinical trial results. The impact of learning about clinical trial results upon the participants is another area that will require future evaluation.

CANCER PATIENTS' ATTITUDES TO RANDOMIZED TRIALS: SUMMARY OF RESPONDENTS' KNOWLEDGE OF THE RANDOMIZED TRIAL PROCESS (N=58)

Statement	Agree	Don't know	Disagree
Clinical trials are only offered when the doctor thinks the situation is hopeless	10 (18%)	6 (10%)	42 (72%)
Clinical trials test treatments that nobody knows anything about	11 (19%)	12 (21%)	35 (60%)
In a randomized trial the treatment you get is decided by chance	25 (43%)	15 (26%)	18 (31%)
In a clinical trial the doctor would make sure I got the best of the treatments	43 (74%)	8 (14%)	7 (12%)
Clinical trials are more helpful for the doctor or the drug company than for the patients	11 (19%)	19 (34%)	27 (47%)
Randomized trials are the best way of finding out whether one treatment is better than another	30 (51%)	23 (40%)	5 (9%)
The doctor really knows that one of the treatments in the trial is better than the other	14 (24%)	23 (40%)	21 (36%)

Ellis PM et al. **Attitudes to randomized clinical trials amongst out-patients attending a medical oncology clinic.** *Health Expect* 1999;2(1):33-43.

REASONS WHY WOMEN MIGHT OR MIGHT NOT CONSIDER PARTICIPATING IN A BREAST CANCER CLINICAL TRIAL

Reasons to Participate	No. of Respondents*
I may have a greater chance of being cured	193
To further medical research	198
Others will benefit from the trial results	215
I may benefit personally from the trial	139
It may be the only way to receive a new treatment	72

Reasons Not to Participate	No. of Respondents*
The treatment might be too severe for me	136
The treatment might be worse on a clinical trial	125
The doctor may not know as much about the treatment	94
A clinical trial feels like a gamble	83
A clinical trial may involve extra inconvenience	99

*545 respondents at a breast clinic.

DERIVED FROM: Ellis PM et al. *J Clin Oncol* 2001;19:3554-3561.

METASTATIC BREAST CANCER PATIENTS' (N=25) PREFERENCES AND ATTITUDES ABOUT BEING INFORMED OF RESULTS FROM CLINICAL TRIALS IN WHICH THEY PARTICIPATED

Preferences	Percent of Patients
Want to be informed when results available	96%
Believe they have a "right" to be informed	96%
Believe their desire to be informed might be influenced by their own response to treatment	56%
Want family/significant other to be informed if they are unable to be informed	84%
Would allow study results to be provided by their physician	84%
Would allow study results to be provided by their nurse	76%
Would allow study results to be provided by a member of the research team	48%
Willing to be informed by mail	76%

DERIVED FROM: Partridge AH et al. *Breast Cancer Res Treat* 2001; Abstract 543.

SELECT PUBLICATIONS

Ellis PM. **Attitudes toward and participation in randomised clinical trials in oncology: A review of the literature.** *Ann Oncol* 2000;11:939-945.

Ellis PM et al. **Randomized clinical trials in oncology: Understanding and attitudes predict willingness to participate.** *J Clin Oncol* 2001;19:3554-3561.

Goodare H, Lockwood S. **The rights of patients in research.** *Br Med J* 1995;310:1277-1298.

Goodare H, Smith R. **Involving patients in clinical research.** *Br Med J* 1999;319:724-725.

Lara PN et al. **Prospective evaluation of cancer clinical trial accrual patterns: Identifying potential barriers to enrollment.** *J Clin Oncol* 2001;19:1728-1733.

Partridge AH, Winer EP. **Informing clinical trial participants about study results.** *JAMA* 2002;288:363-365.

Partridge AH et al. **Preferences and attitudes of patients with metastatic breast cancer regarding receiving results information following participation in a clinical trial.** *Breast Cancer Res Treat* 2001;Abstract 543.

Siminoff LA et al. **Factors that predict the referral of breast cancer patients onto clinical trials by their surgeons and medical oncologists.** *J Clin Oncol* 2000;18:1203-1211.

BARRIERS TO CLINICAL TRIAL RECRUITMENT

"In truth, despite the clamor by the public to more quickly develop new and better drugs, the first stumbling block to the timely accrual to and completion of clinical trials is the reluctance of physicians to offer patients a chance to participate in a trial. The second major barrier is the low acceptance rate of patients when a trial is offered."

—Siminoff LA et al. JCO 2000;18:1203-1211.

"Barriers can be summarized into four broad groups: (i) physician barriers, (ii) protocol or eligibility barriers, (iii) patient barriers, and (iv) funding barriers. These are all potentially modifiable in that efforts can be made by study investigators to reduce the influence of these barriers on accrual. The most common reason that physicians cited for excluding a patient outright was their perception of 'no available protocol' appropriate for that particular patient's tumor site and stage. This perception is clearly not the actual case for many patients because most cancer centers (including ours) offer a variety of trials, including Phase I trials that allow any type of advanced malignancy. Physicians are, therefore, encouraged to regularly check the protocol lists before assuming protocol unavailability."

—Lara PN et al. JCO 2001;19:1728-1733.

FACTORS INFLUENCING CLINICAL TRIAL PARTICIPATION

"Women who would consider participating in a randomized trial were more knowledgeable about procedural aspects of randomized trials, younger, better educated, more likely to be in professional occupations, and more likely to want an active role in treatment decision-making. Women who had a better understanding of issues about clinical trials had more favorable attitudes toward randomized trials and were more willing to consider participation in a clinical trial."

—Ellis PM et al. JCO 2001;19:3554-3561.

INFORMING PARTICIPANTS ABOUT TRIAL RESULTS

"Following completion of a clinical trial, participants are not routinely informed about the aggregate study results unless this information would influence their future care. However, anecdotal experience suggests that many patients who participate in clinical trials are interested in the experience of other patients enrolled in the study and in learning about the aggregate results. A recent consensus conference recommended that the results of clinical trials should be made available to participants and suggested that providing participants with results, both positive and negative, should be considered the 'ethical norm.'"

—Partridge AH, Winer EP. JAMA 2002;288;363-365.

BARRIERS TO CLINICAL TRIAL ACCRUAL

Ann Partridge's study is fascinating and very provocative. It really challenges the clinical research community to think about ways to communicate with patients about what has been learned in clinical trials. However, this is a complicated message, particularly when some patients do better than others. Sharing that information in a respectful and appropriate manner is going to be a challenge.

—Harold Burstein, MD