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How Rapidly Do Oncologists Respond to Clinical Trial Data?

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ABSTRACT

In the era of evidence-based medicine, convincing clinical trial data should influence clinical practice if disseminated in an appropriate manner. Here we discuss the influence of clinical trial results from the Arimidex, Tamoxifen Alone or in Combination trial on the usage of tamoxifen and anastrozole in the treatment of postmenopausal women with hormone receptor-positive early breast cancer. Data were derived from structured interviews with practicing medical oncologists over a period of 28 months. The overall use of hormonal therapy was high and increasing over the period studied. Significant increases in the use of anastrozole as adjuvant hormonal therapy were accompanied by significant decreases in the use of tamoxifen. This culminated in the use of anastrozole surpassing tamoxifen use by the end of the study period, accounting for over 50% of hormonal therapy use for postmenopausal early breast cancer. This study suggests that the dissemination of key clinical data, accompanied by professional commentary and regulatory actions, can rapidly influence the clinical practice of medical oncologists.

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INTRODUCTION

There are many factors that may influence clinical practice. Scientific and clinical trial data, information awareness among community physicians and influential opinion leaders, marketing, public knowledge, and product features are among these factors [1]. In this era of evidence-based medicine, large clinical trials can and should have a profound impact upon clinical practice. The influence of positive data on the use of lipid-lowering agents was clearly seen in the 3.6-fold increase in monthly statin use after publication [2]. Conversely, the use of α-blockers in hypertension decreased by 54% between...
The present study examines the impact of presentation and publication of the results from this very large EBC clinical trial on the practice of oncologists.

**RESEARCH METHODS**

**Participants**

A nationally representative stratified quota sampling of 150 medical oncologists was recruited per study period (see below). All physicians were board certified and had been in practice for at least 2 years but not more than 30 years. The physicians had at least 50% office or private practice and had managed or treated at least 10 breast cancer patients within the past 30 days.

Using Intercontinental Marketing Services data, medical oncologists who wrote 100 or more hormonal therapy prescriptions for breast cancer in the past 6 months qualified for each time period. Oncologists were stratified by use of hormonal therapy for breast cancer in the 6 months preceding the interview as follows: group 1: 100–571 prescriptions, group 2: 572–870 prescriptions, and group 3: >870 prescriptions. The sample was randomly selected from each stratum to include: 75 group 1 (50%), 45 group 2 (30%), and 30 group 3 (20%) (except for July 2001, which contained 67%, 21%, and 12% of the three groups, respectively). To allow for a comparison of trend between the July 2001 sample and the other time points, the responses of the July 2001 sample were adjusted to reflect the mix at 50% group 1, 30% group 2, and 20% group 3.

**Data Collection**

Data were collected via structured computer-assisted telephone interviews of 45-60 minutes duration. Predefined questions were used (Table 1). Interviews were conducted over 3–4 weeks. Eight study periods were used for analysis: July 2001, March 2002, July 2002, November 2002, February 2003, June 2003, August 2003, and November 2003.

Oncologists were asked to report their first hormonal therapy choices for their last five postmenopausal patients with estrogen receptor (ER)-positive EBC (stage I and II).

**Statistical Analysis**

A t-test at the 95% confidence level ($p < 0.05$) was conducted to determine significant differences ($p < 0.05$) in

| Table 1. The predefined questions used to interview oncologists participating in the study |
| Questions |
| 1. Thinking of the last five postmenopausal patients with ER-positive early- or adjuvant-stage breast cancer who you have treated in the past 3 months, what products, alone or in combination with other treatment modalities such as hormonal, chemotherapy, radiation, surgical, etc. did you use as first therapy? |
| 2. Please indicate the therapy you prescribed for your last five postmenopausal patients with early- or adjuvant-stage breast cancer. |
| 3. If you used hormonal therapy, please specify the brand or product. Let’s start with patient #1… (Please use the number code[s] for each product used alone or in combination.) The total must equal five patients. |
hormonal therapy choices between and among different time periods.

**STUDY RESULTS**

**Physician Demographics**

At all time points, gender and geographic distributions of the participating medical oncologists were similar. The vast majority (81%–83%) of oncologists participating in the study were male. They were consistently divided across four geographic regions in the United States (northeast [26%–33%], north central [19%–25%], south [26%–33%], and west [17%–23%]).

Overall, there was minimal variation in the total number of breast cancer patients managed or treated across the time points. The mean number of breast cancer patients managed or treated per physician in the past 6 months ranged from 112–150 in group 1, 142-176 in group 2, and 192–284 in group 3. Across all time periods the medical oncologists consistently indicated that approximately 60% of their EBC patients were postmenopausal (59%–61%).

**Trends in Overall Use of Adjuvant Systemic Therapy**

The results obtained reflect the hormonal therapy choices of 150 oncologists for up to 750 total patients at each time period assessed. The overall reported use of hormonal therapy in postmenopausal ER-positive EBC patients was very high across all time periods, starting at 81% and rising to 98% of eligible patients receiving hormonal therapy (Fig. 1). A significant increase occurred from 81% in July 2001 to 91% in March 2002 \( (p < 0.05) \). Further significant increases occurred between March 2002 and July 2002 \( (p < 0.05) \) and again between July 2002 and November 2002 \( (p < 0.05) \). The use of hormonal therapy then remained stable at approximately 98% until the end of the study time period in November 2003.

The use of chemotherapy remained relatively stable over the time period studied, varying from 36% to 50% of breast cancer products and therapies prescribed (Fig. 1).

**Trends in the Use of Specific Adjuvant Hormonal Therapies**

The influence of the presentation and publication of the ATAC trial results and professional commentary and discussion, as well as the reported use of specific adjuvant hormonal therapies, are shown in Figure 2. Clinically relevant data publications and professional commentaries are presented along the time axis.

Over the time period assessed there were significant changes in the reported use of tamoxifen and anastrozole, but little change in the use of other hormonal agents. The significant increases in the trend in anastrozole prescribing was substantiated across the three strata of oncologists.

The first results of the ATAC trial were presented in December 2001 at the San Antonio Breast Cancer Symposium [18]. The trial data showed increased disease-free survival

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**Figure 1.** Overall trends in use of adjuvant chemotherapy and hormonal therapy for postmenopausal patients with estrogen receptor-positive early breast cancer.

**Figure 2.** Impact of presentation and publication of ATAC results, professional discussions, and regulatory actions on use of adjuvant hormonal therapy for postmenopausal estrogen receptor-positive EBC. Abbreviation: SABC, San Antonio Breast Cancer Symposium. *NCCN guidelines were first modified in December 2001 to allow consideration of anastrozole as an option.
in November 2002 to 41% in February 2003 (report. Anastrozole use for adjuvant therapy rose from 27% confirmed the safety and tolerability picture from the earlier of anastrozole over tamoxifen in efficacy end points and 2002 [24, 25]. These data continued to show the superiority at the San Antonio Breast Cancer Symposium in December a median therapy duration of 36.9 months, were presented low-up of 47 months, and updated safety analysis, based on anastrozole for adjuvant therapy of EBC in September was contraindicated for a patient. recommended that anastrozole could be used if tamoxifen use in EBC are only available for anastrozole, the committee acknowledge that treatment approaches can change over time. As both efficacy and toxicity data for primary adjuvant treatments to address their changes in clinical practice, the study did probe each physician’s sense of overall efficacy and safety measurements.

The observations presented here, based on structured interviews of samples of medical oncologists, appear robust. There are some limitations associated with the study methodology. A different sample of oncologists was interviewed at each time point and the data included in the study were self-reported; thus potential bias might be introduced and accuracy could be affected by personal recall. Despite these limitations, the consistency of answers between samples at each time period is supportive of the reliability of the
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