Impact of Participation in Randomized Clinical Trials on Survival of Women with Early-Stage Breast Cancer - An Analysis of 7985 Patients.

Sub-category: Breast Cancer
Category: Breast Cancer
Meeting: 2000 ASCO Annual Meeting
Abstract No: 287
Citation: Proc Am Soc Clin Oncol 19: 2000 (abstr 287)
Author(s): Michael Gnant

Abstract:

It is generally accepted that validation of treatment standards can only originate in controlled trials. However, this has to be viewed at in the context of patients sometimes not feeling comfortable with the ideas of randomized assignment and lifelong follow-up. We have analyzed a large cohort of stage I and II breast cancer patients with special emphasis on participation in clinical trials. 7,985 patients were investigated, 5,532 of whom were randomized in 9 randomized clinical trials of the ABC-SG between 1980 and 1999. 2,453 patients were not randomized for various reasons and were treated according to treatment standards valid at the time. Descriptive, univariate, and multivariate survival analyses were performed. Median observation time was 75 months (12 to 241). Descriptive analyses showed that the two patient cohorts were in general comparable. There were no severe imbalances with respect to known risk factors or treatment. Overall, 1,460 patients had died at the time of the analysis (18.3%). Overall survival was significantly different between patients participating in clinical trials and patients not doing so (5-yr OS: 84% vs. 78%, 10-yr OS: 69% vs. 64%, p<0.0001; calculated median survival time: 187.5 vs. 152.8 months). For relapse-free survival (1769 events, 22.2%), results were similar (5-yr RFS: 74% vs. 70%, 10-yr RFS: 58% vs. 55%, p=0.01). In the Cox model, participation in randomized trials independently reduced the odds for dying from the disease (RR 0.63, 95% confidence interval: 0.55-0.72, p<0.0001). Interaction analysis revealed that the survival difference was equally present in different tumor stages, and most pronounced in postmenopausal women. From this data, we conclude that mere participation in prospective clinical trials improves patient survival irrespective of treatment actually received. Quality assurance mechanisms within the framework of clinical trials, early relapse detection, and effective secondary treatment may be reasons for this result. Patients with early stage breast cancer do not only contribute to general medical and scientific progress by participating in randomized trials but also benefit individually from their participation.

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2. Overall survival with adjuvant zoledronic acid in patients with premenopausal breast cancer with complete endocrine blockade: Long-term results from ABCSG-12.
3. Mature results from ABCSG-12: Adjuvant ovarian suppression combined with tamoxifen or anastrozole, alone or in combination with zoledronic acid, in premenopausal women with endocrine-responsive early breast cancer.

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