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. T be viewed at in the context of patients sometimes not feeling comfortable with the ideas of randomiz assignment and lifelong follow-up. We have analyzed a large cohort of stage I and II breast cancer p emphasis on participation in clinical trials. 7,985 patients were investigated, 5,532 of whom were ran of 9 randomized clinical trials of the ABC-SG between 1980 and 1999. 2,453 patients were not rand reasons and were treated according to treatment standards valid at the time. Descriptive, univariate multivariate survival analyses were performed. Median observation time was 75 months (12 to 241). analyses showed that the two patient cohorts were in general comparable. There were no severe im to known risk factors or treatment. Overall, 1,460 patients had died at the time of the analysis (18.3% was significantly different between patients participating in clinical trials and patients not doing so (5 10-yr OS: 69% vs. 64%, p<0.00001; calculated median survival time: 187.5 vs. 152.8 months). For r (1769 events, 22.2%), results were similar (5yr-RFS: 74% vs. 70%, 10yr-RFS: 58% vs. 55%, p=0.0(model, participation in randomized trials independently reduced the odds for dying from the disease confidence interval: 0.553-0.723, p<0.0001). Interaction analysis revealed that the survival differenc in different tumor stages, and most pronounced in postmenopausal women. From this data, we con(participation in prospective clinical trials improves patient survival irrespective of treatment actually r assurance mechanisms within the framework of clinical trials, early relapse detection, and effective s may be reasons for this result. Patients with early stage breast cancer do not only contribute to gene scientific progress by participating in randomized trials but also benefit individually from their particip

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3. Everolimus in combination with exemestane in the treatment of postmenopausal women wi estrogen receptor-positive metastatic breast cancer who are refractory to letrozole or anastrozole: Preliminary results of the BOLERO-2 trial.

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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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