Short communication

Oxford Overview

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Published: 20 December 2007
This article is online at http://breast-cancer-research.com/content/9/S2/S24

Breast Cancer Research 2007, **9(Suppl 2):**S24 (doi:10.1186/bcr1822)

The Early Breast Cancer Trials Collaborative Group (EBCTCG) is a global organization of trialists that has conducted randomized clinical trials of therapies in early breast cancer. This organization, with its Data Management and Analysis Center in Oxford, England, has conducted meta-analyses of a variety of therapies, producing information that is not available from individual trials. This process has become known as the Oxford Overview.

The first organizational meeting of the trialists was held in 1984 [1]. Over the past two decades, the Oxford Overview has produced a number of publications that have increased our understanding of the impact that various therapeutic approaches have on overall survival and breast cancer specific events, in addition to potential adverse events. Recent updates of the therapeutic modalities have included polychemotherapy, tamoxifen and ovarian oblation/suppression [2], and radiation therapy [3]. The Oxford Overview process aims to include all of the randomized evidence, thus providing insights that would not be available from examining individual trials. Of particular importance to this process is the requirement of the Oxford Overview for long-term follow up, which has provided information on outcomes out to 15 years that it would simply not be available from individual trials.

The EBCTCG has held main meetings every 5 years. The most recent meeting was held in September 2006. Areas of focus included updated information on polychemotherapy, anthracyclines, tamoxifen and ovarian ablation/suppression. New meta-analyses were considered in postmastectomy radiation therapy, aromatase inhibitors, taxanes and high-dose chemotherapy. An overview on use of luteinizing-hormone releasing hormone analogues for ovarian function suppression was recently published [4]. In addition, material from the ongoing analyses was presented by Richard Peto at the 2006 San Antonio Breast Cancer Symposium and the 2007 American Society of Clinical Oncology Annual Meeting. It is anticipated that main publications of these analyses will occur over the next 2 years as the data are finalized and analysis completed.

The question arises as to whether the Oxford Overview process will diminish in value or become obsolete as the sample size of patients enrolled in clinical trials continues to increase. The number of patients enrolled in the recent generation of trials has been in the 4,000 to 7,000 range, which is many times greater than was the case when the EBCTCG was formed several decades ago. It is clear that the Oxford Overview process remains highly relevant despite the changing character of the clinical trials. The Oxford Overview provides the mechanism for gaining knowledge relating to end-points such as survival and adverse events that is not possible with even a large individual trial. It is anticipated that this will be clearly seen in the aromatase inhibitor overview, which is in the final stages of analysis and includes some very large clinical trials such as ATAC (Arimidex, Tamoxifen Alone or Combination) and BIG (Breast International Group) 1-98.

Additional advantages of the overview process include the collaboration and communication that are inherent in the conduct of meta-analyses. The Oxford Overview also has the potential to expand analysis into areas such as biomarkers. Such an expansion would greatly enhance the value of the overview process, but it would require even greater sharing of data than currently exists. A general rule is that the clinical trials groups do not submit data for the Oxford Overview until publication of results regarding protocol-specified end-points has been accomplished. Involvement in the Oxford Overview should have the impact of expediting publications by the different trial organizations. It is clear that the success of the Oxford Overview is a function of the commitment by the trialists because it is their data that are being analyzed. Because commitment to this process requires expenditure of effort, which in turn requires financial support, there is an element of altruism that is not insignificant.

In summary, the Oxford Overview will continue to be successful to the extent that it provides information of value to investigators and ultimately to patients in a timely manner. Publications of ongoing analyses should provide unequivocal

evidence over the next several years of the continuing importance and value of the Oxford Overview.

Acknowledgement

This article has been published as part of Breast Cancer Research Volume 9 Supplement 2, 2007: Controversies in Breast Cancer. The full contents of the supplement are available online at http://breast-cancer-research.com/supplements/9/S2.

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