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Quality of life measures in breast cancer clinical trials

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Quality of life measures tend to be most useful for clinical decision-making in trials in which quality of life is the primary outcome, according to a recent study published online January 7 in The *Journal of the National Cancer Institute.*

There has been increasing interest in the value of patient-reported symptom assessment in trials and their potential usage as primary or secondary endpoints in new trials. Both the World Health Organization and the U.S. Food and Drug Administration have endorsed quality of life, but they are not always incorporated into trials because of the additional resources needed for data collection. But quality of life measures remain important for women who have completed therapy and many have symptoms such as fatigue, cognitive complaints, sleep and sexual problems, and neuropathy. At the other end of the spectrum, for advanced breast cancer patients on palliative treatments with toxicities, it would be important to determine if any observed survival benefit is outweighed by that burden.

To determine how quality of life measures are used in clinical trials, Julie Lemieux, M.D., of the Université Laval in Québec, Canada, and colleagues, conducted a literature search for articles that reported a randomized clinical trial of breast cancer treatment in which quality of life was an endpoint.

Their review included 190 randomized clinical trials—103 on biomedical interventions, and 87 on non-biomedical interventions, such

as psychosocial interventions like the effect of group therapy on patient outcomes.

The authors found that QOL measures were most useful for clinical decisions in trials using non-biomedical interventions.

They also found that quality of life measurements should be included as a secondary endpoint in adjuvant therapy trials only when the medical outcome is expected to be about the same, or if the study focuses on a vulnerable population such as the elderly; or tests a new intervention for which quality of life information needs to be obtained. They should also be included in metastatic breast cancer trials when a minimal survival difference is expected; or treatments have substantial differences in toxicity.

They also write that when QOL is not the primary endpoint of a trial, "QOL results should ideally appear in a companion article published at the same time as the traditional medical outcomes article so that a full view of the risks and benefits of the intervention can be presented at the same time to clinicians."

In an accompanying editorial, Patricia A. Ganz, M.D., of UCLA, writes, "The large increase in the number of published studies identified in this high-quality systematic review reflects the increased acceptance of the patient's voice in assessing the outcome of trials as well as the participation of expert QOL investigators in the design, conduct, and analysis of clinical trials."

Ganz also writes, "Inclusion of well-validated measures of relevant symptoms should be a high priority for assessing the burden of breast cancer treatments, whether in survivors of breast cancer or in women with advanced disease receiving palliative care."