

## 乳がんに対するホルモン療法の延長は良好な結果をもたらす (Abstract LBA1 and LBA506)

10年間のホルモン療法はQOLを低下させることなく乳がんの再発を減少させる

Ten years of hormone therapy reduces breast cancer recurrence without compromising quality of life

第III相臨床試験の結果、ER陽性乳がん患者において、アロマターゼ阻害薬 (AI) による術後補助療法を5年から10年に延長することで、その後のがん再発が3分の1減少することが示された。追跡期間中央値6.3年の時点で、副次的評価項目である全生存期間に差はなかった。対側乳がん年間罹患率は、レトロゾール群においてプラセボ群よりも低く (0.21% vs. 0.49%)、乳がん予防効果が示された。患者の全体的なQOLは、2群間で同等であった。このスタディは、2016年American Society of Clinical Oncology年次集会プレナリーセッションで取り上げられた。

### Full Text

A randomized phase III clinical trial, MA.17R found that postmenopausal women with early breast cancer benefit from extending aromatase inhibitor (AI) therapy with letrozole from 5 to 10 years. Following five years of an AI and any duration of prior tamoxifen, women who received letrozole for five additional years had a 34% lower risk of recurrence than those who received placebo. The trial was led by the Canadian Cancer Trials Group with participation from the National Clinical Trials Network.

These results were discussed in ASCO's Plenary Session, which features four abstracts deemed to have the greatest potential to impact patient care, out of the more than 5,000 abstracts featured as part of the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting.

"Women with early-stage hormone-receptor positive breast cancer face an indefinite risk of relapse," said lead study author Paul Goss, MD, FRCP, PhD, director of Breast Cancer Research at Massachusetts General Hospital in Boston, Massachusetts and Professor of Medicine at Harvard Medical School. "The study provides direction for many patients and their doctors, confirming that prolonging aromatase inhibitor therapy can further reduce the risk of breast cancer recurrences. Longer AI therapy also showed a substantial breast cancer preventative effect in the opposite, healthy breast."

Overall survival was not significantly different in MA.17R between the two groups but Dr. Goss notes that because of the slow chronic relapsing nature of hormone-receptor positive breast cancer, overall survival has proved difficult to demonstrate in clinical trials. Because of this, most endocrine therapies for breast cancer have gained regulatory approval based solely on improvement of disease-free survival.

Patient overall quality of life was comparable between the two groups. Small differences in physical role functioning in favor of placebo was observed but these were not considered clinically significant. "A large proportion of women with early breast cancer are long-term survivors. As hormone therapy is given over a long period of time, measuring how women feel is very important," said Julie Lemieux, MD, lead author of the analysis of patient-reported outcomes from MA.17R, and a researcher at the Centre hospitalier universitaire de Québec in Canada.

The trial enrolled 1,918 postmenopausal women who had received five years of any one of three AI therapies either as initial treatment or after any duration of prior tamoxifen. Although patients were allowed to enroll up to two years after completing previous AI therapy, about 90% began receiving letrozole or placebo within six months of completing prior therapy.

Patient-reported quality of life was measured using the standard SF-36 questionnaire, which covers various areas of physical health and mental health, and a menopause-specific questionnaire, MENQOL. Of the 1,918 study participants, 1,428 were eligible to complete initial quality of life assessments. These were repeated at 12, 24, 36, 48 and 60 months, with more than 85% of women completing the questionnaires at follow-up.

Impact on Risk of Recurrence and New Breast Cancer (LBA1 - Plenary): Women in the extended letrozole group had a 34% lower risk of breast cancer recurrence. The annual incidence of contralateral breast cancer was lower in the letrozole group than in the placebo group (0.21% vs. 0.49%), indicating a breast cancer prevention effect. At five years of follow-up, 95% of women receiving letrozole and 91% of those receiving placebo were breast cancer free. The five-year overall survival was 93% for women receiving placebo and 94% for those receiving letrozole (not statistically significant).

This study received funding from the Canadian Cancer Society Research Institute, the National Institutes of Health and Novartis.

Quality of Life Findings (LBA506): Overall, there were no significant differences in either overall quality of life or menopause-specific quality of life between women who took letrozole for five years and those who received placebo. Small differences in physical role functioning were detected in favor of placebo but these were less than that considered clinically meaningful.

This study received funding from the Janssen Research & Development.

In 2012, there were more than six million women around the world who survived at least five years after breast cancer diagnosis; the vast majority of these women have estrogen receptor-positive breast cancer, and may wish to consider these findings.

"These data are important to the millions of women around the world with ER positive breast cancer, and suggest that longer durations of widely-available therapy reduce the risk of cancer recurrence, and prevent second cancers from arising," said Harold J. Burstein, MD, FASCO, ASCO expert in breast cancer. "Ten years of any therapy is a long time. Fortunately, most women tolerate extended treatment reasonably well, with few side effects. Now, women can talk with their clinical team and make informed decisions to extend adjuvant endocrine therapy, or not."

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