

乳がんの治療期間を短縮することで心臓における副作用リスクは低下する(Abstract 506)

HER2陽性乳がんに対するより短期間のトラスツズマブによる治療は、標準治療に比べ心臓における副作用は少なく有効性は同等である

Shorter trastuzumab treatment for HER2+ breast cancer as effective as standard treatment with fewer cardiac side effects

2018 ASCO Annual Meetingで、HER2陽性早期乳がん女性4,088人を対象とした第III相試験の結果、6か月間のトラスツズマブ投与は現在の標準的な12か月間の治療に比べ非劣性であることが明らかにされた。4年無病生存率は、6か月治療群で89.4%であり12か月治療群で89.8%であった。さらに、心臓疾患によりトラスツズマブを早期中止した女性は、6か月治療群ではわずか4%であったのに対し、12か月治療群では8%であった。この試験は、HER2陽性乳がん患者の多くにおいて、トラスツズマブによる治療期間を6か月に短縮する方向への最初のステップを示している、と筆者らは述べている。

Full Text

A phase III randomized clinical trial of 4,088 women with HER2-positive, early-stage breast cancer found that taking trastuzumab for 6 months was non-inferior to the current standard of 12 months. The disease-free survival rate at four years was 89.4% with 6 months of therapy and 89.8% with 12 months of therapy. In addition, only 4% of women in the 6-month arm stopped trastuzumab early because of cardiac problems, compared with 8% in the 12-month arm.

"The Persephone trial's researchers worked closely with patient advocates. Everyone involved in this study is very excited by these results," said lead study author Helena Earl, MD, Professor of Clinical Cancer Medicine at the University of Cambridge in the United Kingdom. "We are confident that this will mark the first steps towards a reduction of the duration of trastuzumab treatment to 6 months in many women with HER2-positive breast cancer."

This is the largest trial to date examining the impact of shortening the duration of trastuzumab treatment, according to the authors. The results of the trial, Persephone, is being presented at the 2018 ASCO Annual Meeting in Chicago.

Trastuzumab was granted FDA approval in the United States based on the results of three major trials reported in 2005. In these trials, the length of trastuzumab treatment was 12 months, and this treatment length quickly became the standard of care. Shortly thereafter, a small trial in Finland (FinHer) reported similar benefit from as little as 9 weeks of trastuzumab, prompting research interest in shortening treatment length to reduce side effects and costs.

In Persephone, half of the women took trastuzumab for 6 months and the other half for 12 months. Women also received chemotherapy (anthracycline-based, taxane-based, or a combination of both) while enrolled in the trial. The non-inferiority design allowed the trial to help determine whether reduced duration of treatment can be as good as the standard treatment within pre-specified limits, which are set before the trial starts.

The women in the trial were followed for a median of over five years. Researchers found that 89.4% of women in the 6-month arm and 89.8% in the 12-month arm were alive and free of breast cancer at four years. The trial demonstrated that 6 months of trastuzumab treatment was non-inferior to 12 months.

Only 4% of women who received trastuzumab for 6 months stopped treatment early due to heart problems, compared to 8% of those who took trastuzumab for 12 months.

"The use of trastuzumab has been a major advance for women with HER2-positive breast cancer by increasing the cure rate, but no treatment is free of side effects, and heart damage has always been a concern with this treatment. This new trial shows that a shorter length of treatment can benefit patients just as much as a longer treatment, with less risk of cardiac side effects. This is a win-win for patients with breast cancer who are receiving this common treatment," said ASCO President Bruce E. Johnson, MD, FASCO.

The researchers are currently analyzing their results to determine the impact of treatment length on quality of life, with qualitative feedback from trial participants. A detailed cost-effectiveness analysis is also underway.

Professor Earl stated that more research needs to be done to define the particular patients for whom treatment duration can be safely reduced. The researchers plan to analyze blood and tissue samples collected within the trial to look for biomarkers to identify different risk groups.

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