

# タモキシフェン術後補助療法は5年間より10年間の方が優れている(Abstract # S1-2)

ATLAS: タモキシフェン術後療法を10年間に延長することにより乳がんの遅発性再発リスクが軽減し生存期間が改善した

ATLAS: Extending duration of adjuvant tamoxifen treatment to 10 years reduced risk for late breast cancer recurrence and improved survival

10年間のタモキシフェン術後補助療法は現在の標準的な5年間のタモキシフェン投与と比べ、エストロゲン受容体(ER)陽性乳がん女性に対する遅発性再発および乳がん死からの保護効果が高いとの国際的な研究—Adjuvant Tamoxifen — Longer Against Shorter (ATLAS)の結果が示された。この結果は2012 CTRC-AACRサンアントニオ乳がんシンボジウムで発表され同時にLancetに掲載された。研究者らはER陽性乳がん女性6,846人を組み入れた。半数はリンパ節転移陽性でありタモキシフェンを5年間投与されていた。患者はさらに、5年間治療を継続する群またはそこで治療を中止する群に無作為に割り付けられた。診断後5~9年間の再発率や死亡率に対して治療群による違いは少なかった。しかし、診断後10年目以降20年目まででは、タモキシフェンを継続した女性は5年後に中止した女性よりも再発率が25%低く、乳がん死亡率が29%低かった。診断後5~14年の乳がん死リスクは、治療を継続した者で12.2%であったのに対し、中止した者では15%であった。一absolute gainは2.8%であった。最も有益性が高いのは診断後10~14年であった。

# Full Text

Ten years of adjuvant treatment with tamoxifen provided women with estrogen receptor-positive breast cancer greater protection against late recurrence and death from breast cancer compared with the current standard of five years of tamoxifen, according to the international ATLAS (Adjuvant Tamoxifen — Longer Against Shorter) study.

"Five years of adjuvant tamoxifen is already an excellent treatment that substantially reduces the 15-year risk for recurrence and death from estrogen receptor (ER)-positive breast cancer, but ATLAS now shows that 10 years of tamoxifen is even more effective," said Christina Davies, M.D., a coordinator in the Clinical Trial Service Unit at the University of Oxford in the United Kingdom.

She presented the results at the 2012 CTRC-AACR San Antonio Breast Cancer Symposium. The results were simultaneously published in the *Lancet*.

"The main additional benefit from continuing tamoxifen treatment is to reduce breast cancer mortality during the second decade after diagnosis," Davies said. "We already knew that five years of tamoxifen reduces breast cancer mortality in this late period by almost a third in comparison with no tamoxifen. We now know that 10 years of tamoxifen is even better, approximately halving breast cancer mortality during the second decade after diagnosis."

Researchers enrolled 6,846 women with ER-positive breast cancer between 1996 and 2005. Half had node-positive disease. All the women had been using tamoxifen for five years, and the researchers randomly assigned them to continue treatment for another five years or to stop immediately.

After about eight years of follow-up, the researchers observed 1,328 breast cancer recurrences and 728 deaths after recurrence. The treatment allocation had little effect on either recurrence rates or death rates during the period five to nine years after diagnosis. However, during the second decade following diagnosis, the women who continued tamoxifen treatment had a 25 percent lower recurrence rate and a 29 percent lower breast cancer mortality rate compared with women who stopped after five years.

Risk for death from breast cancer five to 14 years after diagnosis was 12.2 percent among those who continued use versus 15 percent among those who stopped — an absolute gain of 2.8 percent. The researchers observed the greatest benefit during 10 to 14 years after diagnosis.

Davies noted that continuing tamoxifen use can increase side effects, with endometrial cancer being the most life threatening. Because endometrial cancer is generally curable, the cumulative risk for death between five and 14 years after diagnosis was 0.4 percent versus 0.2 percent. Because this risk is heavily outweighed by the reduction in breast cancer deaths, overall mortality was significantly reduced by longer treatment. In premenopausal women, for whom tamoxifen is often the endocrine treatment of choice, there was no apparent excess of endometrial cancer.

"Many women with ER-positive breast cancer take tamoxifen, or some other adjuvant endocrine treatment, but the current recommendation is to stop after five years," said Davies. "ATLAS showed that protection against breast cancer recurrence and death is greater with 10 years than with five years of tamoxifen use. Women and their doctors should be aware of this evidence when deciding how long to continue tamoxifen, or any other endocrine treatment."

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