Breast Cancer Patients Who Stop Hormone Therapy to Get Pregnant Did Not Have Worse Outcomes

Most women who interrupted endocrine therapy were able to conceive, and more than 60% gave birth.

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Breast Cancer Patients Who Interrupted Endocrine Therapy to Pursue Pregnancy Did Not Experience Worse Short-Term Recurrence Rates

Breast cancer patients who paused their endocrine therapy to try to get pregnant experienced short-term rates of breast cancer recurrence similar to women who did not pause therapy for pregnancy, and many went on to conceive and deliver healthy babies, according to results from the POSITIVE clinical trial presented at the San Antonio Breast Cancer Symposium, held December 6-10, 2022.

While breast cancer is most commonly diagnosed in middle-aged and older women, in the United States, about 5% of new diagnoses each year occur in women aged 40 or younger. These younger patients face some unique considerations, including fertility, said the North American study's lead author, Ann Partridge, MD, MPH, vice chair of medical oncology at Dana-Farber Cancer Institute and professor of medicine at Harvard Medical School.

"40% to 60% of patients who are diagnosed with breast cancer at age 40 or younger are concerned about their future fertility, especially if the disease occurs before they could decide whether to become a mother or not," she said.

Coauthor Olivia Pagani, MD, who is the international study chair on behalf of the International Breast Cancer Study Group, said only about 5% to 10% of younger breast cancer patients go on to become pregnant. While some retrospective studies have shown that pregnancy after cancer is feasible and safe, many women are concerned that breast cancer treatment will make it difficult to conceive or that pregnancy might exacerbate a woman's cancer, explained Pagani, who is also a member of the Swiss Group for Clinical Cancer Research, a faculty member at the Universities of Geneva and Lugano, and a member of the European School of Oncology.

Young women with early-stage hormone receptor (HR)-positive breast cancer are often treated with endocrine therapy, such as ovarian function suppression, aromatase inhibitors, or selective estrogen receptor modulators.

To examine the impact of pausing endocrine therapy to pursue pregnancy, researchers designed the single-arm POSITIVE clinical trial (Pregnancy Outcome and Safety of Interrupting Therapy for Women with Endocrine Responsive Breast Cancer). From December 2014 through December 2019, a total of 518 women aged 42 or younger who desired to become pregnant enrolled in the study, opting to pause endocrine therapy for approximately two years to try to get pregnant. Before pausing their treatment, women had completed between 18 and 30 months of adjuvant endocrine therapy.

The study enrolled patients from 116 centers across 20 countries; 23% from North America, 61% from Europe and 16% from Asia/Pacific and Middle East nations.

A data safety monitoring committee conducted three interim safety analyses. If more than 46 breast cancer recurrences occurred within approximately three years of average follow-up, the trial would have been suspended. That threshold was not reached.

At a median follow-up of 41 months, 44 participants had experienced a recurrence of breast cancer. The three-year rate of recurrence was 8.9%, similar to the 9.2% rate in an external control cohort from the SOFT/TEXT trials, which examined adjuvant endocrine therapy in premenopausal women.

Of 497 women followed for pregnancy status, 368 (74%) had at least one pregnancy, and 317 (63.8%) had at least one live birth, with a total of 365 babies born. These rates of conception and childbirth were on par with or higher than rates in the general public, Pagani said.

Trial participants were strongly recommended to resume endocrine therapy after a pregnancy attempt or success. To date, 76.3% have resumed their therapy, the authors said.

Partridge and Pagani said the study provides encouraging guidance to younger women diagnosed with breast cancer who may be hoping to have children. Any such decisions should be made in close consultation with health professionals, they noted.

“The POSITIVE Trial provides important data to support young women with HR-positive early breast cancer who are interested in a pregnancy and taking a break from endocrine therapy to pursue one,” said Partridge, who led the study in North America on behalf of the Alliance for Clinical Trials in Oncology.

“Pregnancy after breast cancer is a very personal decision for which, ideally, a woman should take into account not only her desire to carry a pregnancy, but her baseline fertility, prior and current treatment, and any fertility preservation strategy she may have pursued, as well as the underlying risk of cancer recurrence she faces,” Pagani said.

The researchers are continuing to follow the study participants to assess recurrence risk over time. They noted that the short follow-up to date is a limitation of the POSITIVE study, as HR-positive breast cancer can recur many years after an initial diagnosis.

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