

Lymph Node Biopsy May Be Safely Omitted in Some Patients With Early Breast Cancer

Omission of sentinel lymph node biopsy did not change five-year recurrence rates.

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SAN ANTONIO – Skipping sentinel lymph node biopsy (SLNB) in patients with clinically node-negative, hormonal receptor (HR)-positive, HER2-negative early-stage [breast cancer](#) did not compromise regional control or survival after a median five years of follow-up, according to results from the [BOOG 2013-08](#) Phase III clinical trial, presented at the [San Antonio Breast Cancer Symposium](#) (SABCS), held December 9-12, 2025.

“Over the past [two decades](#), breast cancer care has shifted toward minimizing invasiveness while preserving oncologic safety,” said [Marjolein Smidt, MD, PhD](#), presenter of this study and professor at the Maastricht University Medical Center in the Netherlands.

[SLNB](#), which involves surgical removal and analysis of a lymph node closest to the primary tumor, is the preferred method for axillary staging in early-stage breast cancer. However, accumulating evidence suggests that SLNB provides mainly prognostic information and rarely alters systemic treatment decisions in patients whose lymph nodes showed no signs of cancer, Smidt added.

“In addition to the potential scarring and discomfort of having some lymph nodes surgically removed, patients undergoing SLNB also run the risk of experiencing long-term side effects like [lymphedema](#), which is swelling caused by the build-up of lymph fluid, often requiring physiotherapy,” said Smidt. The BOOG 2013-08 trial was designed to test whether omitting SLNB in clinically node-negative patients undergoing breast-conserving therapy is safe, she further explained.

The study enrolled 1,733 patients with early-stage breast cancer with tumors up to 5 cm in size, and whose lymph nodes were considered clear of cancer based on physical examinations, preoperative ultrasound, and tissue analysis experiments if indicated. All patients were treated with breast-conserving surgery and radiation at 25 hospitals in the Netherlands between 2015 and 2022. Patients were randomly assigned into either the group that would receive SLNB therapy or the group that would forgo it.

Based on the data from a median five-year follow-up with 1,574 evaluable patients—where 749 were in the SLNB arm and the rest had SLNB treatment omitted—the recurrence of the cancer in the lymph nodes surrounding the primary tumor was observed in 0.5% of patients in the SLNB arm versus 1.2% in the patients in the SLNB-omitted arm; the difference was not statistically significant.

The median five-year regional recurrence-free survival, which was the measure of patients who showed no signs of cancer spreading to lymph nodes further from the primary tumor, while being alive was also not significantly different between the two groups—96.6% for the SLNB arm and 94.2% for the SLNB-omitted arm.

“This study shows that we may be able to safely omit the sentinel node biopsy, especially in patients with early-stage HR-positive, HER-negative breast cancers, as 86.6% of the tumors in this trial population were of this type,” Smidt said.

Among patients with HR-positive tumors, adjuvant endocrine therapy was administered in 48.6% (SLNB arm) and 46.6% (SLNB-omitted arm).

“Hormone therapy can have a big impact on a woman’s quality of life, and needs careful consideration before being administered,” Smidt noted. “Even though endocrine therapy was prescribed less frequently compared to other similar studies on omitting SLNB, the risk of recurrence was still low in our study so far. Nevertheless, this group needs careful follow-up, because of well-known late recurrences,” she continued.

“In addition to having a positive impact on patients, the omission of SLNB is cost-effective, results in shorter patient care, and avoids complications—this can lead to better patient-reported outcomes and a smoother recovery overall,” said Smidt.

Limitations of this study include incomplete five-year follow-up for all participants and reliance on per-protocol analysis, as whole breast irradiation was the standard practice after breast conserving surgery at the time when the trial was set up, Smidt explained.

“Present day radiation therapies include protocols that are different, such as partial breast radiation. With the data from this trial, we cannot prove that omitting SLNB is also safe when patients are treated with other radiation protocols, but we can try to extrapolate the results in the future.”

The results mainly apply to HR-positive, HER2-negative early-stage tumors that were 2 cm or smaller in size; patients with larger tumors and other breast cancer subtypes were underrepresented in the trial, said Smidt.

The study was funded by the Dutch Cancer Society, Central Health Insurance, and the Netherlands Organization for Health Research and Development. Smidt reports receiving funding from Roche, Nutricia, and Servier Pharma, and material from Illumina.

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