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Chemotherapy in breast cancer: less is more!

Study data from the WSG [West German Study Group] presented at the SABCS demonstrate that, every year in Germany alone, 10,000 to 15,000 women with hormone-sensitive early breast cancer can be spared chemotherapy that is unnecessary yet has many side effects.

San Antonio (Texas, USA), Mönchengladbach (Germany), 12.11.2020 – Today, at the world's largest breast cancer conference, the San Antonio Breast Cancer Symposium (SABCS), Professor Nadia Harbeck and Professor Sherko Kümmel presented pioneering and practice-changing results from the ADAPT HR+/HER2- study. According to these results, the already known recurrence score can be used in combination with three weeks of preoperative antihormone therapy to examine whether a tumor responds so well to this therapy – which is in any case administered as standard after surgery – that there is no need for additional chemotherapy. This was the case in about half of the some 5,000 patients in the study population. Extrapolated to the situation in Germany, it can be assumed, according to Nadia Harbeck, that 10,000 to 15,000 patients a year who would not benefit from additional chemotherapy could be identified in this way. However, if chemotherapy is demonstrably necessary, it has been shown that a much higher pathologic complete response rate can be achieved with nab-paclitaxel (this is the first protein-bound variant of paclitaxel), as Sherko Kümmel outlined in a second presentation at the SABCS. He also demonstrated that this chemotherapy regimen is particularly beneficial for women with a high genomic risk (recurrence score >25).

Every year, approximately 70,000 women in Germany alone are confronted with a breast cancer diagnosis. Of them, 44,000 have hormone-sensitive disease; in other words, tumor growth is accelerated by the sex hormones estrogen and progesterone. This is why all of these women receive what is called antihormonal therapy as standard after surgery. Whether or not they need additional chemotherapy is so far apparent in only half of the 44,000 patients, specifically those whose recurrence risk can be reasonably estimated: patients with a low risk do not need additional chemotherapy whereas high-risk patients do. The other half of the patients fall into what is called the intermediate-risk group. It is not as yet possible to say clearly which patients in this group benefit from additional chemotherapy.

The results of the ADAPT HR+/HER2- study now bring clarity for women in the intermediate-risk group. The necessary measurements and tests are already a component of breast cancer work-ups; "We just haven't used these findings yet", said Nadia Harbeck at the WSG press conference. Women with HR-positive/HER2-negative early breast cancer affecting up to three lymph nodes and with an intermediate genomic recurrence risk should undergo three months of antihormonal treatment prior to surgery. The Ki-67 value, a marker of tumor growth, is determined initially at diagnosis from a tissue sample and then from the surgical specimen after the three weeks of antihormonal therapy.
If the Ki-67 value has fallen below 10% within three weeks, antihormonal therapy alone is sufficient postoperatively for the patients concerned. If the value is above this threshold, additional chemotherapy is required.

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For women in the intermediate-risk group with a Ki-67 value of 10% or below, the goal of antihormonal therapy without chemotherapy should therefore be to achieve the same treatment results as for women in the low-risk group. According to the ADAPT HR+/HER2- study results, this is precisely the case: the times to disease-free and distant metastasis-free survival are the same in both groups. This applies to pre- and postmenopausal women and also to women with zero or up to three lymph nodes affected.

The combination of investigating the genomic risk using Oncotype DX® and testing response to antihormonal therapy using the Ki-67 value therefore brings clarity for women with HR-positive/HER2-negative early breast cancer affecting up to three lymph nodes.

Nab-paclitaxel with a far higher rate of pathological complete response

Should it emerge that the patient concerned needs additional postoperative chemotherapy, the question turns to the combination from which she will most benefit. The WSG also focused on this issue in the context of the ADAPT HR+/HER2- study, and Sherko Kümmel also presented the results at the SABCS today.

He was able to demonstrate that it is not paclitaxel itself that should be used but nab-paclitaxel, its protein-bound variant. The proportion of patients who achieve what is called pathological complete response – i.e. a status in which a tumor is no longer detectable following preoperative therapy - was able to be increased from 12.9% to 20.8% with a regimen containing nab-paclitaxel. Moreover, it has also been shown for the first time that women in the high-risk group who have a recurrence score of >25 benefit particularly impressively from nab-paclitaxel chemotherapy. However, if the tumor displays a low Ki-67 value – in other words, if it responded well to antihormone therapy -, the response to chemotherapy tends to be disappointing.

What is the way forward?

The results of the ADAPT HR+/HER2- study are pioneering and practice-changing, as Professor Ulrike Nitz emphasized in her closing statement. Nevertheless, further questions remain to be answered in relation to women with HR-positive/HER2-negative breast cancer. For example, what can be offered to women who have not just 3 but 4 or more lymph nodes affected? What about women with a high recurrence score of >25, a good antihormone therapy response but a poor chemotherapy response? Could these groups potentially benefit from “intensified antihormonal therapy”? According to Ulrike Nitz, these issues “are being examined in the ADAPTcycle study right now and we will report on them in due course”.

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About WSG: The West German Study Group (WSG) is a national research institution that focuses on the design, organization and implementation of clinical studies in the field of breast cancer. The goals of our studies are to optimize existing therapies in terms of effectiveness and tolerability, avoid unnecessary therapies and individualize breast cancer therapy.

About ADAPT: The ADAPT study program examines ways to achieve patient-specific decision-making for the treatment of early breast cancer based on modern biological markers