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HER2+ breast cancer patients live longer if drugs given before surgery eradicate tumour

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Final analysis of results from a randomised clinical trial of lapatinib and trastuzumab given before surgery in patients with early HER2-positive breast cancer has found that women who had no signs of residual disease after treatment (known as a pathological complete response, pCR) survived longer without the cancer returning than patients who did not. This was more likely to happen in patients who received the two anti-cancer drugs together, rather than as single agents.

Speaking at the 12th European Breast Cancer Conference on Saturday, Dr. Paolo Nuciforo, principal investigator at Vall d'Hebron Institute of Oncology, Barcelona, Spain, presented results from nearly ten years of follow-up from the international NeoALTTO BIG-06 trial, in which patients were randomised to receive either trastuzumab or lapatinib alone or in combination.

He said: "Patients who achieved a pCR had significantly better long-term survival compared to those who did not achieve pCR. Although overall survival rates did not differ significantly between the three treatment groups, nearly twice as many patients achieved pCR if they received both drugs, 51% compared to 27.1% of patients receiving only one drug in the other two arms of the study combined."

HER2-positive breast cancer is a cancer that tests positive for a protein called human epidermal growth factor receptor 2 (HER2), which promotes the growth of tumour cells. Approximately one in five breast cancers are HER2-positive and it is an aggressive form of the disease.

However, with the development of trastuzumab and other drugs that block HER2 signalling such as lapatinib, prognosis for this disease has improved.

NeoALTTO BIG-06 enrolled 455 women with early HER2-positive cancer to receive either neoadjuvant trastuzumab or lapatinib alone or in combination. It is known as neoadjuvant therapy because it is given before surgery. After surgery the patients were given three cycles of chemotherapy followed by 34 weeks of whichever therapy they had originally been randomised to receive (known as adjuvant therapy).

With a median (average) of 9.7 years of follow-up, there were no signs of cancer recurrence (event-free survival) in 69% of patients receiving both drugs, 65% of the trastuzumab-only group and 63% of the lapatinib-only group. These differences were not statistically significant. Overall survival rates were 80% in the combination group, 77% in the lapatinib group and 76% in the trastuzumab group, with no statistically significant differences between the groups.

When the researchers compared women who had achieved pCR with those that had not in all three treatment groups, they found that event-free survival and overall survival were significantly better in women who had pCR; 77% of pCR patients survived nine years event-free compared to 61% of non-pCR patients, and 88% of pCR patients were still alive at nine years compared to 72% of non-pCR patients. Subgroup analysis showed that these associations were statistically significant in women who received the drug combination or who were hormone receptor negative, meaning they had tumours that did not have hormone receptors on the surfaces of the cancer cells.

Dr. Nuciforo said: "Although we might have expected a significantly higher overall survival in the group of women receiving the combination of lapatinib and trastuzumab where pCR rates were higher, this was not

the case. This was possibly due to the fact that the study was not powered to detect small differences in survival between the three groups.

"The results from this analysis show that patients who achieve pCR are significantly more likely to survive for longer than those who do not achieve pCR. This validates pCR as an early indicator of long-term outcome for HER2-positive disease and could help doctors decide on the best treatment. On one hand, patients not achieving a pCR may be at higher risk of recurrence, and giving extended therapy to them could potentially lower this risk. On the other hand, those patients who do achieve pCR could be spared additional toxic treatments.

"At present, all women with HER2-positive breast cancer receive toxic adjuvant chemotherapy after anti-HER2 neoadjuvant treatment to reduce the risk of recurrence after surgery. However, not all women have the same risk. If we could predict, for example with pCR, which patients are at high risk of their cancer recurring in three, five or ten years, we could give more aggressive adjuvant therapies only to these women and not to those women who have achieved pCR and are at low risk of recurrence."

Professor Emiel Rutgers is President of the European Breast Cancer Council, a member of the 12th European Breast Cancer Conference scientific committee and was not involved in the research. He said: "These are the final results from the NeoALTTO BIG-06 trial and they confirm that, with an average of nearly ten years' follow-up, achieving pCR in patients with HER2 positive breast cancer is associated with better long term outcome. This better long-term survival for patients who had a complete remission, and also for the greater number of patients who achieved pCR with dual blockade of HER2, resulted in a non-significant 4% better overall long-term survival. This non-significant difference is probably due to relatively small numbers of patients and limited number of events.

"Results with nearly seven years of follow-up were reported last year. This trial has the longest follow-up of randomised clinical trials looking at HER2 breast cancer and shows how important it is to follow patients for as long as possible to fully understand how drug combinations and other factors can affect survival.

"We can never say that a breast cancer patient is cured because the disease can come back even after 20 years. However, HER2 positive breast cancer tends to recur during the first five years after treatment. Therefore, if we can give these women the best chance of surviving beyond five years by achieving pCR, then the risk of recurrence thereafter is low, especially in hormone receptor negative tumours."

More information: Abstract no: 23, "Nine-year survival outcome of neoadjuvant lapatinib with trastuzumab for HER2-positive breast cancer (NeoALTTO, BIG 1-06): final analysis of a multicentre, open-label, phase 3 randomised clinical trial", Proffered papers session (live, with pre-recorded presentations), Saturday, 13.15 hrs CEST, Channel 3 (Dr Nuciforo's presentation will be at 14.05 hrs).

Provided by European Organisation for Research and Treatment of Cancer

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