A Safer, Better Treatment Option for Some Younger Women with Breast Cancer

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The initial treatment used for some younger women with an aggressive form of breast cancer may be about to change, based on results of a new clinical trial.

In the trial, the combination of the targeted drug ribociclib (Kisqali) and hormone therapy was much better at halting the growth of aggressive tumors that have spread in the body than standard treatment with a combination of chemotherapy drugs.

Women who received the ribociclib–hormone therapy combination lived for twice as long without their cancer getting worse, a measure called progression-free survival. They also had far fewer side effects.

“I believe this is practice changing," said Yen-Shen Lu, MD, of the National Taiwan University Hospital, who presented the results from the RIGHT Choice study at the San Antonio Breast Cancer Symposium on December 6. “These data provide clear evidence that [the ribociclib combination] is safe, it is efficacious, and it can avoid a lot of toxicity,” he said.

A crisis requires a rapid response

The most common type of breast cancer, called estrogen receptor (ER)–positive, HER2-negative breast cancer, is often found early and usually responds well to treatment. More than 90% of women who receive standard treatment will be alive without a recurrence of their cancer 5 years later.

However, a small proportion of patients will have disease that spreads rapidly (metastasizes) to the bones, liver, lungs, and other organs, causing symptoms or affecting organ function.

When cancer in an organ affects its ability to function, that is called a visceral crisis, explained Larissa Korde, MD, of NCI’s Division of Cancer Treatment and Diagnosis, who was not involved with the study.

“That’s where there’s enough tumor in another organ to be life-threatening,” she said. “For example, if it’s in the liver, the liver can’t do its work of clearing toxins from the body. Or if it’s in the lungs, a patient may not be able to get enough oxygen.”

For people at risk of or experiencing a visceral crisis, the standard treatment has been a combination of two chemotherapy drugs. The treatment usually shrinks tumors quickly but can have serious side effects, spurring researchers to look for less-toxic treatments.

Ribociclib has become a commonly used treatment for ER-positive, HER2-negative breast cancer that requires treatment beyond surgery and radiation therapy. It is a targeted therapy called a CDK4/6 inhibitor that shuts down certain processes that cancer cells need to divide.

The combination of ribociclib with a drug to block hormones (endocrine therapy) has recently become a standard treatment for postmenopausal women with hormone receptor–positive, HER2-negative metastatic breast cancer that isn’t immediately life threatening. But younger women who haven’t yet gone through menopause make up a substantial proportion of people diagnosed with breast cancer every year.

The proportion of breast cancers diagnosed in younger women ranges from around 20% in the United States to close to half—or even more—in the Middle East and parts of Asia. However, whether ribociclib plus hormone therapy could substitute for combination chemotherapy in younger women who have an aggressive form of ER-positive, HER2-negative breast cancer hasn’t been clear.

Fast relief with fewer side effects

An international research team led by Dr. Lu enrolled 222 premenopausal and perimenopausal women in their phase 2 clinical trial. The trial was funded by Novartis, which makes ribociclib.

About half of the women were experiencing a visceral crisis at the time they joined the study. The others had metastatic tumors that were causing substantial symptoms, though not yet at the level of a crisis, or rapidly advancing disease.

The team randomly assigned the participants to receive either ribociclib plus hormone therapy—consisting of goserelin (Zoladex), which blocks the production of hormones by the ovaries, and either letrozole (Femara) or anastrozole (Arimidex), drugs called aromatase inhibitors—or combination chemotherapy.

The chemotherapy combinations could include docetaxel (Taxotere) plus capecitabine (Xeloda), paclitaxel plus gemcitabine, or capecitabine plus vinorelbine, depending on the drugs normally used at the hospitals where the participants were treated.

Women in both groups could continue treatment as long as tumor growth was kept at bay and the side effects were tolerable.

At the San Antonio meeting, Dr. Lu presented the study results that had been collected through

April 2022. At that point, women who received the ribociclib combination had a median progression-free survival of 2 years, versus just over 1 year for those in the chemotherapy group.

“This result is [statistically] significant and clinically meaningful,” said Dr. Lu.

The time it took metastatic tumors to start shrinking, called time to response, was similar between the two groups.

Patients in the chemotherapy group had a higher risk of serious side effects, including nausea, vomiting, and diarrhea, than those in the ribociclib combination group. However, a drop in the number of white blood cells was more common in the women receiving the ribociclib combination.

Almost 25% of those receiving chemotherapy stopped taking at least one of the drugs due to side effects, compared with only 7% of women in the ribociclib combination group.

Adding to the drift away from chemotherapy

In addition to improving progression-free survival and having fewer side effects, the ribociclib combination has an additional advantage, said Dr. Korde. Unlike chemotherapy, which requires frequent visits to the clinic for infusions, both ribociclib and hormone therapy are pills that patients can take at home.

“That’s really important [for] quality of life,” she said.

The full results from the study still need to be reviewed and published before the ribociclib combination could become the standard of care, Dr. Korde added.

Some caution will also need to be used in interpreting the results from this trial since the study was a smaller phase 2 trial instead of a phase 3 study, Dr. Lu explained. Large phase 3 trials are usually needed to provide definitive answers about which treatment is better.

But considering the large difference in progression-free survival seen in this study, people might be less likely to volunteer for another study in which they might be assigned to receive chemotherapy, Dr. Korde explained.

Dr. Lu agreed, noting that “to conduct a phase 3 study ... would be quite difficult, and I don’t expect that in the future there will be one.”

However, “the progression-free survival difference between the two [groups] was so large that the likelihood [it] comes from chance alone is relatively small. And it’s extremely reassuring that you can get a fast response with this therapy,” Dr. Korde said.

“This is not the first time that we’ve looked at CDK4/6 inhibitors compared to chemotherapy, but this is the first time that we’ve seen it compared to combination chemotherapy,” explained Virginia Kaklamani, M.D., from UT Health San Antonio, during a session on the trial at the San Antonio meeting.

“I think with this study, we’re finding that chemotherapy … is probably not appropriate” for these younger patients as an initial treatment, she concluded.

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