

Transcript Details

This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: <https://reachmd.com/programs/breaking-boundaries-breast-cancer/from-sabcs-to-your-practice-key-takeaways-from-the-2020-conference/11605/>

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From SABCS to Your Practice: Key Takeaways from the 2020 Conference

Announcer:

Welcome to *Breaking Boundaries in Breast Cancer* on ReachMD, sponsored by Lilly. Shortly after the 2020 San Antonio Breast Cancer Symposium, we caught up with Dr. William J. Gradishar, Professor of Medicine at the Robert H. Lurie Comprehensive Cancer Center at Northwestern University, who spoke with us about his panel called *View from the Trenches - What Will You Do on Monday Morning?*

Let's hear from Dr. Gradishar now.

Dr. Gradishar:

There were several key presentations that I thought are relevant to clinical practice starting next week. One is the RxPONDER trial, which was presented by Kevin Kalinsky. This is a follow-up in a sense to the TAILORx trial that evaluated node-negative patients – RxPONDER was a node-positive – and essentially this is a trial that sought to determine whether the addition of chemotherapy in ER+ patients who had 1-3 nodes was beneficial on top of endocrine therapy. As you recall in the TAILORx trial, we were able to define groups of patients who clearly did not benefit from chemotherapy and, as a result, could avoid it. So, the bigger issue is in node-positive patients where our natural instinct as oncologists is to worry that they're at higher risk and they must need chemotherapy. So, this was a very relevant trial many years in the making, and what it determined is that there clearly is a group of patients with 1-3 nodes who have lower scores less than 25 where the addition of chemotherapy adds no benefit, and that is in the postmenopausal patient population, whereas in patients, largely younger than the age of 50, there is still some benefit from chemotherapy. Now, whether that benefit is the equivalent of ovarian suppression is not directly addressed by this trial, but I think the fundamental bottom line is that we can avoid chemotherapy in a significant fraction of patients – even those with node-positive disease – whereas we still have to consider chemotherapy in patients who are younger, and in a sense, similar findings were also identified in the TAILORx node-negative population. So, I think this is directly applicable to practice on Monday morning.

The second abstract that I think is relevant is the monarchE trial, and the monarchE trial was presented at ESMO, showing that the addition of abemaciclib to endocrine therapy in high-risk patient and those are defined as clinical characteristics, bigger tumor, positive nodes, high proliferation – there are many details in the presentation itself – but suffice it to say, the addition of abemaciclib with short follow-up – at that time, 15 months – appeared to improve and decrease the risk of recurrence. Now with an additional three or four months of follow-up – still short – those primary endpoints have been allowed to be discussed because the number of events has been reached by the statistical plan, and indeed, the addition of abemaciclib to endocrine therapy in that high-risk population decreased, the risk of recurrence improved disease-free survival overall in the population with high proliferation greater than 20% and decreased the risk of distant disease recurrence. So, there are caveats to this: one is you have to consider these data early – there's only 19 months of follow-up. Number two: only 25% of patients have actually completed the abemaciclib portion of the trial. Almost 60% of the patients remain on the trial in that seg-segment of the trial. There are a significant fraction of patients who discontinue therapy, and 50-60% of patients required dose delays or dose reductions of abemaciclib. So, I think we will be getting more data out of this trial, but it is fairly compelling when you look at the early results, and I highlight early, that abemaciclib in this high-risk group does seem to confer a benefit. Whether that'll be maintained over the long haul will require longer follow-up.

The other trial which I think is important is the PENELOPE trial, which is similar but unique compared to monarchE and the PALLAS trial. PENELOPE was a trial conducted in patients who received neoadjuvant therapy with residual disease at the time of surgery. These were ER+ patients who would've typically then gone on to endocrine therapy. In this trial, patients either received endocrine therapy or the same plus palbociclib, and this was an effort to again determine whether a CD4/6 inhibitor could reduce the risk of recurrence, and the trial did not show that the addition of palbociclib had a statistically significant improvement in reducing the risk of

recurrence.

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