TAILORx: New data on cohort with recurrence score 26-100 shows 93% cancer-free rate at 5 years

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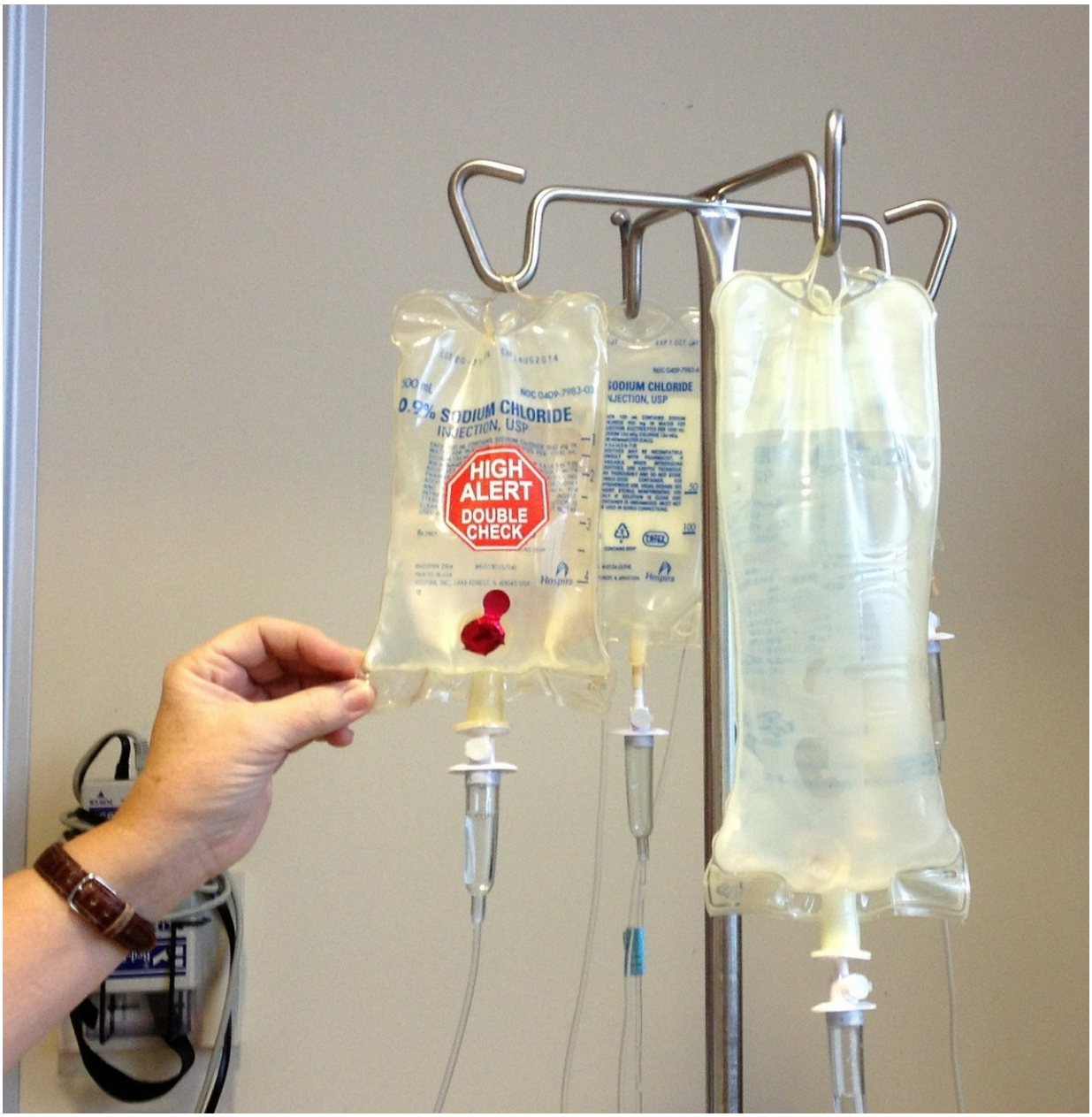

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A new analysis from TAILORx, the largest ever breast cancer treatment trial, is published today in *JAMA Oncology*. It reveals the clinical outcomes with chemotherapy in a subset of 1,389 women with a high

Recurrence Score (RS) of 26-100. The outcomes are similar to the B20 trial (Paik et al, JCO, 2006). The new data shows that the estimated rate of freedom from recurrence of breast cancer at a distant site was 93% at five years, an outcome much better than expected with endocrine therapy alone. The results are also being featured as late-breaking information at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona.

This finding adds to the limited data on outcomes of patients with a high RS of 26-100, treated with taxane and/or anthracycline-containing chemotherapy regimens plus hormone therapy. It adds to the evidence base supporting the use of the Recurrence Score, a 21-tumor gene expression assay, to guide the use of adjuvant chemotherapy in early breast cancer.

TAILORx was designed and conducted by the ECOG-ACRIN Cancer Research Group with primary funding from the National Cancer Institute, part of the National Institutes of Health.

"The initial results of TAILORx gave clinicians high-quality data to inform personalized treatment recommendations for women," said lead author Joseph A. Sparano, M.D., associate director for clinical research at the Albert Einstein Cancer Center and Montefiore Health System in New York, and vice chair of the ECOG-ACRIN Cancer Research Group. "This new analysis provides the largest data set on outcomes in patients with early breast cancer and high Recurrence Score results. It confirms the importance of using the test to identify the minority of patients who will receive a significant benefit from adding adjuvant chemotherapy to endocrine therapy."

Between 2006 and 2010, the TAILORx trial enrolled 10,273 women with hormone-sensitive, HER2-negative, axillary node-negative breast cancer at 1,182 sites in the United States, Australia, Canada, Ireland,

New Zealand, and Peru. Patients' tumors were analyzed using the 21-tumor gene expression test and assigned a risk score (on a scale of 0-100) for cancer recurrence.

This analysis pertains to the women in TAILORx who had a score in the high-risk range (26 and above). These women were assigned to receive chemotherapy and hormone therapy, following surgery. High-risk women were given the option to voluntarily join a prospective registry. Sufficient baseline and follow up information was available on 80% of these women (1,389 of 1,737) for inclusion in this analysis. There was a high adherence to chemotherapy assignment (94%).

Physicians were able to select one of several commonly used chemotherapy regimens. The majority of the patients (84%) received taxane and/or anthracycline-containing chemotherapy regimens. The most common regimens were docetaxel/cyclophosphamide (42%), anthracycline without taxane (24%), and anthracycline and taxane (18%). No chemotherapy was administered in 6% (non-adherence) and cyclophosphamide/methotrexate/5-fluoruracil (CMF) was administered in 4%.

Clinical outcomes in TAILORx with chemotherapy and a high RS of 26-100 ranged by type of chemotherapy. Distant recurrence-free interval (DRFI) rates ranged from 92-96% at five years in patients treated with taxane and/or anthracycline therapy. The regimen containing cyclophosphamide, methotrexate and 5-fluoruracil (CMF) had a DRFI rate of 89%.

The expected rates in TAILORx were based on the treatment effect of chemotherapy observed in B20: 79% at five years and 65% at nine years.

The genomic assay used in the trial was the Oncotype DX Breast Recurrence Score(r) test from Genomic Health, Inc., Redwood City,

California.

More information: Joseph A. Sparano, MD et al. Clinical Outcomes in Early Breast Cancer With a High 21-Gene Recurrence Score of 26 to 100 Assigned to Adjuvant Chemotherapy Plus Endocrine Therapy: A Secondary Analysis of the TAILORx Randomized Clinical Trial. *JAMA* Oncol. Published online September 30, 2019. DOI: 10.1001/jamaoncol.2019.4794

Provided by ECOG-ACRIN Cancer Research Group

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