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Effect of 21-Gene Recurrence Score Results on Treatment Recommendations in Patients with Lymph Node-Positive, Estrogen Receptor-Positive Breast Cancer.

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Background: Results of recent *Oncotype DX*® studies indicate that the Recurrence Score (RS) can identify node-positive, estrogen receptor-positive (N+/ER+) patients who may not benefit from chemotherapy and have a low risk of distant recurrence with hormonal therapy alone. Based on these results, the *Oncotype DX*® breast cancer assay has been ordered for N+/ER+ patients. There are no data, however, on the impact of the assay on adjuvant treatment planning in N+ patients. We performed a survey to characterize the effect of the *Oncotype DX*® breast cancer assay on adjuvant treatment recommendations in N+/ER+ breast cancer.

Methods: U.S. medical oncologists (N=1,017) who ordered *Oncotype DX*® for at least 1 patient with N+/ER+ breast cancer were contacted and asked to complete a web-based survey regarding the single most recent N+/ER+ patient for whom the *Oncotype DX*® assay was ordered. The survey was developed through cognitive interviews with four medical oncologists, and the protocol was institutional review board approved. Results: We analyzed surveys from 160 individual physicians for 160 N+/ER+ patients. Physicians were in community practices (71%) more often than in academic practice settings, they were equally dispersed geographically, and they had a median of 11 years (range, 1–45) of practice experience. The median patient age was 61 years (range, 34–82), and 79% were postmenopausal. T1, T2, or T3 disease was reported in 62%, 35%, and 3% of patients, respectively (unknown in 1 patient). One, two, three, or 4+ nodes were reported in 69%, 18%, 6%, and 3%, respectively (unknown in 8 patients). Fifty-four percent of N+/ER+ patients had an RS <18; 38% had an RS of 18–30; and 8% had an RS ≥31. Before obtaining the RS, chemotherapy was planned in 89 patients (56%), endocrine therapy was planned in 46 patients (29%), there was no recommendation for 22 patients (14%), and other treatments for 3 patients (1%). After obtaining the RS, recommended treatment changed from hormonal therapy plus chemotherapy to hormonal therapy alone in 48 patients (35%) and from hormonal therapy to hormonal therapy plus chemotherapy in 14 patients (10%).

Discussion: These findings indicate that for N+/ER+ patients, the RS score is used more often (but not exclusively) in patients with 1–3 positive nodes and T1 or T2 stage disease. Treatment recommendations for these patients with N+ disease were frequently changed by the RS results, with an overall reduction in the recommendation for chemotherapy treatment.