Impact of Oncotype DX™ on decision making in breast cancer clinical practice.

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Background: The Oncotype DX Recurrence Score (RS) has been validated to predict the likelihood of distant recurrence as well as response to hormonal therapy (HT) and chemotherapy (CT). This study was designed to determine if the RS influenced treatment decisions in a community based, oncology practice.

Methods: The experience with the RS in the community practice of four oncologists was reviewed. RS was ordered on tumors from 74 patients (pts) with ER (+) stage I or II BC. Demographic information and details of pathology were extracted from medical records. 10-year relapse free survival was calculated using Adjuvant Online. Physician (MD) treatment (Rx) recommendation prior to knowledge of RS was compared to MD Rx recommendation after RS and the Rx actually administered.

Results: RS was obtained in 72/74 pts (97%). 2 pts (3%) had insufficient tumor tissue. In 4 pts MD Rx recommendation prior to RS and/or actual Rx received were unknown. 68/72 pts were evaluable: 67 female and 1 male. Median age was 54 yrs (range 35-77) and mean tumor size was 1.2 cm (SD 0.6 cm). Tumor grade was 44 % grade 1, 35 % grade 2, and 21% grade 3. The distribution of RS was similar to that observed in previous studies. Mean RS was 22 (range 5-68); 32 pts (47%) were low risk (RS<18), 22 pts (32%) were intermediate risk (RS 18-30), and 14 (21%) pts were high risk(RS≥31). The correlations of RS with patient age (R²=0.04) and tumor size (R²=0.07) were low. The rank correlation of RS with tumor grade (R²=0.34) was modest. Although some correlation was seen between the likelihood of distant recurrence based on the RS and the likelihood of relapse based on Adjuvant Online (R²=0.43), there was a highly significant difference (p<0.0001). Knowledge of the RS altered MD Rx recommendation in 14/68 (21%) pts and altered actual Rx administered in 17/68 (25%) pts. Prior to knowing RS, MD Rx recommendation was HT in 51% and combined HT + CT in 49%. Post RS, MD Rx recommendation was HT in 51%, CT alone in 6%, and HT + CT in 42% pts. Actual Rx administered was HT in 68%, CT in 4% and HT + CT in 28%. Of the 14 pts in whom MD Rx recommendations changed, 7 went from CT to HT and 7 went from HT to CT. The decision to switch from CT to HT was generally associated with low RS, while the decision to switch from HT to CT was generally associated with high RS. The odds of the MD Rx recommendation changing from HT to CT was 111x higher if RS was high versus low risk, and from CT to HT was 18x higher if RS was low versus high risk.

Conclusion: TheOncotype DX Recurrence Score assay changed systemic adjuvant therapy in 25% of pts with early stage BC. It is likely that genomic information will play an increasingly important role in clinical decision-making for individual BC patients.