The decision to use chemotherapy in stage II colon cancer is challenging. There is a need to balance toxicity, risk of recurrence, and expected absolute benefit of treatment. Current guidelines recommend consideration of adjuvant chemotherapy for "higher risk" stage II patients based on clinical and pathological factors.20-22 Evidence for these conversion trials is limited. For the 75% of stage II patients who have T3/4, microsatellite-deficient (MMR-P/MSI-low) tumors, there are no informative data.3 There is a need for standardized, validated markers of recurrence risk to inform adjuvant treatment decision-making in stage II colon cancer, particularly for patients with T3/4 MMR-P/MSI-low tumors.

Development and Validation of the OncoType DX Colon Cancer Assay in Stage II Colon Cancer

All 346 U.S. medical oncologists who ordered the OncoType DX assay for three or more stage II colon cancer patients were contacted through mail and e-mail. 138 accessed the survey online.

- 4 of whom were ineligible
- 10 physicians did not complete the survey
- 116 eligible physicians completed the survey (84% response rate)
- 90% of physicians were in community setting and had an average of 16 years in practice.
- Half of the oncologists saw more than 40 newly diagnosed colon cancer patients in a typical year
- Treatment patterns of the surveyed physicians were typical of those previously reported in stage II colon cancer.
- Patient characteristics were representative of the contemporary stage II colon cancer population: 80% of patients had T3/4 tumors and 73 lesions examined (Table 1).

The 12-gene colon cancer Recurrence Score® (RS) (Genomic Health, Inc., Redwood City, CA) assay was developed using data from 1,851 stage II/III patients in four large, independent studies conducted with the NCI/NCAP and the Cleveland Clinic.

The 12-gene RS was validated as a predictor of recurrence risk in stage II colon cancer patients following surgery in two prospective validation studies: University of California Los Angeles (UCLA) and The Cleveland Clinic.23,24 A recent prospective study, the QUASAR trial, confirmed that the 12-gene RS can predict risk of recurrence in stage II colon cancer.25,26 A score of 18 or greater indicates a high risk of recurrence. The vast majority (86%) of physicians came from a community setting and had an average of 16 years in practice.

- The survey was conducted from December 2010 to December 2011.
- The treatment intensity decreased more often for lower RS values (trend test p-value = 0.0035) (Table 4).

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