

Comparative economics of a 12-gene assay for predicting risk of recurrence in stage II colon cancer

PharmacoEconomics

Authors

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Online Resource 1 Oncotype DX[®] Colon Cancer Assay sample physician report



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CLIA Number 05D1018272

Stage II Colon Cancer Report Following Surgery Alone

Patient/ID: DOE, JANE ELIZABETH
Sex: Female
Date of Birth: 01-Jan-1950
Medical Record/Patient #: 556677771
Date of Surgery: 25-Sep-2012
Specimen Type/ID: Colon/TRT004BI

Requisition: R000014
Specimen Received: 30-Sep-2012
Date Reported:
Ordering Physician: Dr. Harry D Smith
Submitting Pathologist: Dr. John P Williams
Study #: GHI 123456789

Recurrence Score[®] Result

48

Oncotype DX[®] Colon Cancer Assay uses RT-PCR to determine the expression of a panel of 12 genes in tumor tissue. The Recurrence Score[®] result is calculated from the gene expression results, and ranges from 0-100.

These findings are applicable to stage II patients with adenocarcinoma or mucinous carcinoma limited to the colon. It is unknown whether the findings apply to other patients outside these criteria.

Clinical Experience is based on a prospectively-designed validation study with a pre-specified analysis of the Recurrence Score result, in the context of T-Stage and MMR status (MMR proficient (MMR-P) or MMR deficient (MMR-D)), using patients from the surgery-alone arm of the QUASAR study (N=711).¹

Note: Determination of MMR status is important for treatment decision-making in stage II colon cancer. In this validation study, stage IIA MMR-D patients had a 3-year recurrence risk ranging from 3% to 7% across Recurrence Score results and are expected to have little if any clinical benefit from 5FU/LV adjuvant therapy. Use of this assay is generally not recommended for stage II MMR-D patients.

Relevance for Chemotherapy Benefit: Based on the results in QUASAR (N=1, 436) that randomized patients to surgery or surgery+5FU/LV, the proportional reductions in recurrence risk with 5FU/LV were similar across the range of Recurrence Score results, with larger absolute benefit at higher Recurrence Score results. In the parent QUASAR trial, 5FU/LV treatment resulted in ~20% relative risk reduction of cancer recurrence.

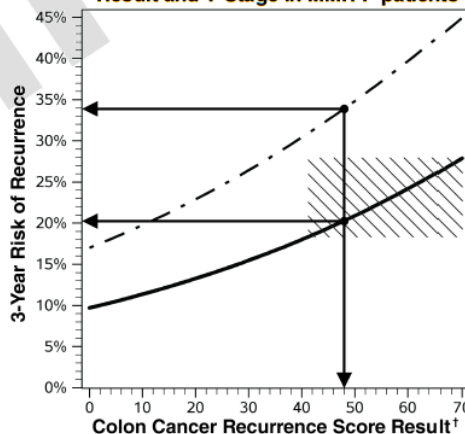
Stage II Recurrence Risk Following Surgery Alone

34% — · — · — T4, MMR-P
(95% CI: 24%-46%)

20% ————— T3, MMR-P*
(95% CI: 16%-26%)

* 2% of all patients with T4, MMR-D tumors had estimated recurrence risks that approximated (with large confidence intervals) those for patients with T3 stage, MMR-P tumors and were not included in this figure.

3-Year Recurrence Risk by Recurrence Score Result and T-Stage in MMR-P patients



[†]In the clinical validation studies, very few patients had Recurrence Score results > 70.

▨ = Higher Recurrence Risk

Impact of Nodes Assessed: For patients with ≥ 12 nodes examined the 3-year recurrence risk was lower than that shown in the Figure. For T3 MMR-P patients the reduction in risk ranged from 2% for low to 6% for high Recurrence Score results. For T4 MMR-P patients the reduction in risk ranged from 4% to 10%, respectively. For all MMR-P patients with < 12 nodes examined, the recurrence risk was 2-3% higher.

1. Gray RG et al., J Clin Oncol. 2011.

Laboratory Director: Patrick Joseph, MD

This test was developed and its performance characteristics determined by Genomic Health, Inc. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing. This test is used for clinical purposes. It should not be regarded as investigational or for research. These results are adjunctive to the ordering physician's workup.

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Stage II Colon Cancer Report Following Adjuvant Chemotherapy

Patient/ID: DOE, JANE ELIZABETH
Sex: Female
Date of Birth: 01-Jan-1950

Requisition: R000014
Specimen Received: 30-Sep-2012
Date Reported:

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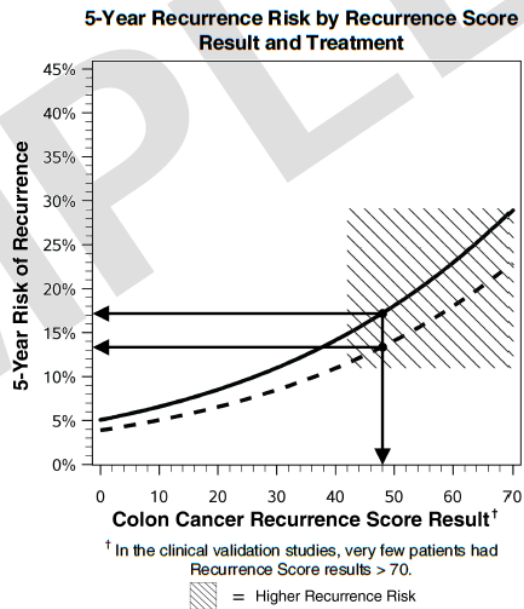
These findings are applicable to stage II patients with adenocarcinoma or mucinous carcinoma limited to the colon. It is unknown whether the findings apply to other patients outside these criteria.

Clinical Experience is based on a prospectively-designed clinical validation study (NSABP C-07) which randomized patients to 5FU/LV versus 5FU/LV+oxaliplatin, in which 264 patients were stage II, including 247 (94%) with T3 tumors. Out of 213 patients with available MMR status, 82% were MMR-P.¹

Stage II Recurrence Risk Following Adjuvant Chemotherapy

17% ——— 5FU/LV
(95% CI: 12%-24%)

13% - - - - 5FU/LV + oxaliplatin
(95% CI: 9%-19%)



Impact of MMR Status: Consistent with previous studies, patients with MMR-D tumors had generally lower recurrence risk than patients with MMR-P tumors. These results are not shown on the graph due to low number of events (6 recurrences in the 18% of stage II patients with MMR-D tumors).

Impact of Nodes Assessed: The recurrence risk for patients with ≥ 12 nodes examined was lower than the risk for those with < 12 nodes examined.

1. Yothers G, et al. J Clin Oncol. 2013.

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