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Prospective Evaluation of a 12-gene assay on patient treatment decisions and physician confidence in mismatch repair proficient stage IIA colon cancer

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Abstract

We report the Onco*type* DX colon assay's influence on patient treatment decisions, physician confidence, and concordance between physicians and patients. 221 consecutive patients were enrolled and tumor specimens assessed. Prior to and after receiving assay results, patients and physicians completed surveys including their treatment preference and other factors. Knowledge of assay results was associated with improved patient-physician concordance and confidence.

Background—The Onco*type* DX Colon Cancer Assay is a validated predictor of recurrence risk in patients with resected stage II colon cancer. We previously reported that Onco*type* DX led to a change in treatment recommendations for 45% of patients with T3 MMR-P stage II tumors in a prospective study. Here, we report the assay's influence on patient treatment decisions, physician confidence, concordance between physicians and patients, and patient decisional conflict.

Methods—Consecutive patients with resected stage IIA colon cancer were enrolled. Tumor specimens were assessed by the 12-gene assay (RT-PCR) and MMR (IHC). Prior to and after receiving these results, patients completed surveys including their treatment preference, their current and preferred roles in treatment decision-making, and indicators of decisional conflict. Physicians completed similar pre- and post-assay survey items.

Results—Out of 221 enrolled, 139 T3 MMR-P patients were evaluable for patient reported analyses and 150 patients were evaluable for physician-reported analyses. Pre-assay: 46% of patients chose Observation, 3% 5FU, 7% Oxaliplatin, 4% Other and 41% were undecided. Post-assay: 75% chose Observation, 12% 5FU, 11% Oxaliplatin, and 2% Other. Post-assay, 94% of defined treatment decisions were concordant between patients and physicians compared to 60%

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pre-assay. Physicians reported the assay influenced their treatment decisions and increased confidence in treatment recommendations for 69% and 84% of patients, respectively. The majority of patients (86%) reported that the assay influenced their treatment decisions. Patient decisional conflict was significantly lower after learning the assay results ($p < 0.001$).

Conclusions—In this prospective study, knowledge of the 12-gene assay results influenced treatment decisions for most patients and physicians, increased physician confidence, improved concordance between patients and physicians, and decreased patient decisional conflict.

INTRODUCTION

Background

Each year in the world, more than 1,350,000 people are diagnosed with colorectal cancer (CRC) and approximately 700,000 men and women die from the disease[1]. Among patients diagnosed with stage II colon cancer, 75% to 80% are cured by surgical resection and have a low absolute benefit of adjuvant chemotherapy[2]. A small subset of these patients benefit from the addition of 5FU therapy, with or without oxaliplatin[3-4]. However, identification of this subset of patients is challenging.

The Oncotype DX® Colon Cancer Assay is a 12-gene prognostic assay that measures gene expression in formalin-fixed paraffin-embedded colon cancer tissue by quantitative reverse transcription polymerase chain reaction (RT-PCR) and generates a Recurrence Score® result that provides an estimate of the risk of recurrence. In the assay development study, the relationship between tumor gene expression and recurrence was evaluated in a pooled analysis of 1,851 stage II and III patients enrolled to four independent National Surgical Adjuvant Breast and Bowel (NSABP) clinical trials and a Cleveland Clinic study, where patients were treated with surgery plus adjuvant fluorouracil plus leucovorin (5FU/LV) or surgery alone [5]. Here, 48 genes were found to be significantly associated with risk of recurrence; of these, seven recurrence genes, and five reference genes were selected to stratify patients into groups with low, intermediate, and high likelihoods of recurrence [5]. The 12-gene prognostic assay was subsequently validated in four large independent studies including >3,000 patients with stage II and III colon cancer[6-9] and hence achieves level IB evidence[10].

The first validation study utilized tumor samples from 1,436 stage II patients enrolled to the Quick and Simple and Reliable (QUASAR) trial of adjuvant 5FU/LV versus surgery alone to demonstrate that the 12-gene Recurrence Score result is a significant predictor of recurrence[6]. Next, the assay was validated in 690 stage II patients enrolled to the Cancer and Leukemia Group B (CALGB) 9581 clinical trial[7]. In addition, the NSABP group validated the assay in 892 stage II and III patients treated with 5FU chemotherapy with or without oxaliplatin enrolled to the C-07 trial, wherein the potential utility of the assay was demonstrated for stage III as well as stage II patients[8]. Finally, the SUNRISE study in Japan validated the assay in 597 stage II and III patients treated with surgery alone, providing further insight into the natural history of stage III colon cancer and the corresponding heterogeneity of recurrence risks without chemotherapy treatment[9].

Decision Impact Study

The Decision Impact clinical trial was conducted to evaluate the impact of the Recurrence Score result on joint patient and physician treatment decisions among patients with T3 MMR-P stage II colon cancer. Before and after the prognostic assay results were provided, patients and physicians separately completed questionnaires related to planned treatment, degree of confidence in the chosen treatment plan, and utility of the assay in making the treatment decision. We previously reported primary physician-based analyses, where it was shown that knowledge of a patient's Recurrence Score result led to a 45% change in physician treatment recommendations (95% CI: 36% to 53%) among 141 evaluable patients[11]. Furthermore, we found that lower Recurrence Score values were associated with de-escalation of physicians' recommended treatment strategies (e.g., from chemotherapy prior to the result to observation alone after the result) while higher scores were associated with escalated recommendations (e.g., observation to chemotherapy) with $p = 0.01$. We now report the trial's other prospective analyses on pre- vs. post-assay patient-reported and physician-reported outcomes, including the influence of the Recurrence Score result on patients' treatment decision making and decisional conflict, confidence in treatment recommendations, and shared decision making between patients and physicians.

PATIENTS AND METHODS

Patient and Physician Data Collection

In this prospective multi-center study, 221 consecutive patients with stage IIA (T3N0) Cancer were enrolled by 105 physicians across 17 academic and community sites within the Mayo Clinic Cancer Research Consortium network. Treating physicians were not required to have prior experience with Oncotype DX and received training on the assay, which consisted of reviewing product materials and mock cases. To be eligible for study participation, patients agreed to both Mismatch Repair (MMR) testing by immunohistochemistry and evaluation by the Oncotype DX Colon Cancer Assay. Patient and physician materials emphasized the merely prognostic (rather than predictive) nature of the assay. Prior to and after obtaining the Recurrence Score results, patients and physicians independently completed surveys that included planned treatment, including observation alone versus 5FU-monotherapy (5FU) versus 5FU + oxaliplatin. The baseline patient survey further included "undecided" as a treatment option. Physicians also completed pre- and post-assay surveys indicating whether they were confident in their treatment decisions, whether they believed the Oncotype DX Colon Cancer Assay would (or did) provide additional clinically relevant information, and whether the assay results had directly influenced their treatment recommendations. Before and after learning their Recurrence Score results, patients completed the Decisional Conflict Scale[12], a clinically validated 16-item instrument utilized to assess perceptions of personal uncertainty in making decisions about health care treatment options and satisfaction with treatment decision-making. All patient and physician surveys were independently completed in the physician's office directly after each patient's appointment. For analysis purposes, observation, 5FU alone, and 5FU + oxaliplatin were described as definitive treatment decisions/recommendations, though physicians and patients were allowed to specify other treatment plans.

Statistical Methods

All analyses were pre-specified in a statistical analysis plan. The distribution of physician treatment recommendations and distribution of patient treatment preferences (after discussion with physicians) both before and after the Recurrence Score result were reported and analyzed for patient-physician concordance. Other questionnaire items related to physician and patient confidence in the assay, its influence on the patient's treatment decision process, and patients' actual versus preferred roles in their own treatment decisions were summarized descriptively.

Patients' self-reported descriptions of their actual and preferred roles in the treatment decision-making process were recorded on ordinal scales (ranging from patient-led decision-making to physician-led decision-making) before and after the assay results were provided, such that they could be compared between time points. In addition, each patient completed the Decisional Conflict Scale (DCS) before and after knowledge of their Recurrence Score result. For each time point, an overall DCS score and 5 subscores based on the 16 item questionnaire were calculated. Subscores were calculated only if there were at least two non-missing responses in the corresponding category, per recommendations associated with the tool[12]. A total score, derived as the weighted average of the subscores, was calculated only when all five subscores were non-missing. Mean changes for the total score and 5 subscores from pre-assay to post-assay were calculated, such that a mean decrease reflected less (or improved) decisional conflict. Pre- and post-assay DCS total scores were statistically compared using a paired sample t-test, after confirming approximate normality of the scores.

Due to known relationship between MMR status and prognosis in stage II colon cancer, wherein patients with MMR-deficient (MMR-D) tumors have a better prognosis than patients with MMR-proficient (MMR-P) tumors and are often treated without adjuvant chemotherapy[13], the analyses herein were restricted to patients with T3, MMR-P tumors. Missing data were excluded from corresponding analyses.

RESULTS

Out of 221 enrolled patients, responses from 139 and 150 patients with MMR-P tumors were evaluable for analyses of patient- and physician-reported outcomes, respectively (Table 1). Paired treatment recommendations were available for 139 patients and their physician pre-assay, and 138 patients and their physicians post-assay. Characteristics of patients enrolled and evaluable for these analyses are shown in Table 2; eligibility and other trial details were described previously[11].

Patient Treatment Decisions

Similar to the physicians' decisions, patients' decisions regarding treatment showed changes from pre- to post-knowledge of assay results. Before the assay results were available, 64 (46%) patients selected observation alone, 13 (9%) selected chemotherapy, 5 (4%) chose other and 56 (41%) were undecided. Of the 82 patients with defined (i.e., excluding "undecided") treatment decisions pre-assay, 27 patients (33%; 95% CI: 23% to 43%) changed their decisions after viewing the assay results (Table 3), either toward escalation or

reduction of treatment intensity. Of the 76 patients with definitive pre- and post-assay treatment decisions (i.e., excluding both “undecided” and “other”), 22 (29%, 95% CI: 19% to 41%) patients changed their treatment recommendations after learning the assay results. Of these, 9 (41%) decreased their planned treatment intensity, while 13 (59%) increased treatment intensity. Most patients who were undecided before the assay (42 of 56, or 75%) chose observation after the assay results.

Patient-Physician Treatment Decision Concordance

Of the 82 patient and physician pairs with defined pre-assay treatment decisions (i.e., excluding patient selections in the “undecided” category), 49 (60%) of the treatment decisions between patients and physicians were concordant (Table 4). After receiving and discussing the assay results, patients and physicians largely indicated preferences for the same treatment, with 130 (94%) of 139 patient-physician pairs reporting concordant treatment decisions (Table 5).

Patient Decisional Conflict

A total of 135 patients completed the pre- and post-assay Decisional Conflict Scale instruments so that impact of the assay results could be evaluated. Differences in mean decisional conflict scores are shown, overall and within individual subscales, in Table 6. Statistically significant decreases in patient decisional conflict were observed overall ($p < 0.001$) and within each of the 5 subscales: Effective Decision ($p = 0.001$), Informed ($p < 0.001$), Support ($p = 0.005$), Uncertainty ($p < 0.001$), and Values Clarity ($p < 0.001$).

Patient Roles in Treatment Decision-Making

At baseline, patients reported a high level of concordance (90%) between the role they felt they were actually playing and their preferred role in treatment decision-making, with most patients preferring some degree of collaboration (equal or somewhat patient- or physician-led) with their physician (Table 7). Post-assay concordance between patients’ actual and preferred roles was similarly high (88%), with both patients and physicians preferring some degree of collaboration (Table 8). When patients’ actual roles were compared pre- and post-assay, 58 (43%) of the 136 responses changed, with 33 patients (24%) reporting an increased patient role, while 25 patients (18%) reported a decreased role (Table 9). Patients’ preferred roles also changed after the assay (58 of 136 responses, or 43%), with 37 patients (27%) desiring an increased role relative to their physicians while 21 patients (15%) desired a lesser role (Table 10).

Influence of Oncotype DX Colon Cancer Assay on Patient and Physician Treatment

We previously reported that knowledge of a patient's Recurrence Score result led to a 45% change in physician treatment recommendations (95% CI: 36% to 53%)[11]; specifically, lower Recurrence Score results were associated with de-escalation of physicians’ recommended treatment strategies (e.g., from chemotherapy prior to the assay result to observation alone after the assay) while higher scores were associated with escalated recommendations (e.g., observation to chemotherapy) with $p = 0.01$. Table 11 shows the distribution of physicians’ and patients’ post-assay questionnaire responses regarding the

utility and influence of the assay. Overall, physicians reported that they were more confident in their treatment recommendations after ordering the assay for 126 (84%) of their 150 patients, and for a similarly high percentage (86%) of patients, physicians agreed that the assay provided additional clinically relevant information. Of note, physicians reported that the assay influenced their treatment recommendations for 103 (69%) of 150 patients. Similarly, 118 (86%) of 138 patients reported that their treatment decisions were influenced by the assay results.

DISCUSSION

For early stage colon cancer there are an increasing number of prognostic tools to help predict risk of recurrence. These tools include clinical calculators as well as recurrence assays utilizing gene expression profiles. In a recent randomized study involving patients with breast or colon cancer the use of decision aids was shown to decrease anxiety[14]. In our study, the patients with confirmed T3 MMR-P stage II colon cancer were prospectively enrolled to evaluate the impact and utility of the Oncotype DX Colon Cancer Assay on joint patient and physician treatment decisions and patient-reported roles in treatment decision-making.

We found that the prognostic assay results increased physicians confidence in treatment recommendations for 126 (84%) of 150 patients and provided additional clinically relevant information for 129 (86%) of 150 patients. The majority of patients (85%) further reported that the assay influenced their treatment decisions. Post-assay, 129 (96%) of 135 definitive treatment decisions (Obs, 5FU or Oxal) were concordant between patients and physicians compared to 49 (66%) of 74 definitive decisions pre-assay. Of note, 24 of the 25 pre-assay discordances between patients and physicians reflected a tendency for physicians to be more inclined to initially recommend chemotherapy while patients preferred observation (Table 4). Among patients with definitive pre and post-assay decisions, 22 (29%) of 76 decisions changed post-assay with intensity decreasing for 9 (12%) and increasing for 13 (17%). While patients reported uniformly high concordance between actual and desired roles in treatment decision-making at both time points, these roles changed for approximately 43% of patients from pre-assay to post-assay, with most patients favoring an increased role in their treatment decisions-making compared to the time of diagnosis. Patient decisional conflict was also significantly reduced after learning the assay results ($p < 0.001$).

In a setting of uncertainty regarding the potential benefit of adjuvant chemotherapy, the current study emphasizes the relevance of both effective communications and the use of decision aids. Prior studies evaluating the importance of provider-patient communications have demonstrated its positive impact on treatment decision-making and outcomes in patients with cancer. These outcomes include a higher level of satisfaction with treatment decisions and a higher level of adherence to a specific plan of care[15]. This is particularly important in the setting of adjuvant therapy for stage II colon cancer where the risk-benefit ratio is less well defined. Prior retrospective studies have shown that when patients with cancer are more actively engaged in decision-making, they have a higher level of feeling informed and a higher level of satisfaction with their plan of care[15].

In the current era of patient-centered communications and shared decision making, providers are expected to more actively engage patients in decisions, using their own medical knowledge and experience to guide those conversations. The process of shared decision-making is dynamic. Prior research has shown that physicians making recommendations in the setting of serious health issues such as colon cancer are less likely to be risk adverse in their recommendations when death is a potential outcome[16]. Prior patient surveys also suggest that patients are often *not* well-informed and they perceive recommendations to be heavily weighted toward taking medications[17]. The degree to which this is the case in cancer treatment decision-making is less clear. A recent study of informed decision making in prostate cancer indicated that patients were well-informed regarding treatment options, including risks and benefits, but were infrequently engaged in a shared decision making process[18].

Our study results suggest that patients who engage in discussions with their physicians, including prognostic assay results, had a higher level of concordance with their physician's recommendation for treatment compared to initial discussions in the absence of the assay results. This led to a meaningful and significant decrease in patient decisional conflict, with most patients feeling well informed. Importantly, patients felt that this process provided them with an active role in their own treatment decision-making.

There are several limitations to this study. First, it was restricted to patients with stage II colon cancer and therefore its applicability to other cancer patient groups is uncertain. However, the results of this study are concordant with other treatment decision making studies involving different types of cancer[19]. This study is also potentially limited by the uncertainties of adjuvant therapy benefit in stage II colon cancer. It is conceivable that if the benefits of chemotherapy were more clearly defined, the results may have varied. Lastly, the Oncotype DX assay was validated as a prognostic rather than predictive assay; that is, it produces a score indicating risk of recurrence that may be useful in treatment decision-making, but the results alone to do not predict differential response to treatment.

In conclusion, this study demonstrated a beneficial impact of the Oncotype DX Colon Cancer Assay as a decision making tool that provides both physicians and patients with greater confidence in their treatment decisions when used in conjunction with provider-patient communications. The assay results also decrease patient decisional conflict and increase the concordance between physician and patient treatment choices.

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CLINICAL PRACTICE POINTS

- **What is already known about this subject?**

  Whether and how aggressively to treat individual patients with stage II colon cancer remain challenging questions requiring patient-specific factors such as prognosis and patient preferences. It was previously reported in a prospective study that the Onco*type* DX colon assay led to a change in physicians' treatment recommendations for 45% of patients with T3 MMR-P stage II tumors.

- **What are the new findings?**

  Our new findings additionally suggest that knowledge of the 12-gene assay results further influenced treatment decisions for most patients and physicians, increased physician confidence in their own treatment recommendations, improved concordance in treatment preference between patients and physicians, and decreased patients' feelings of decisional conflict.

- How might it impact on clinical practice in the foreseeable future?

  The Oncotype DX Colon Cancer Assay as a decision making tool that provides both physicians and patients with greater confidence in their treatment decisions when used in conjunction with provider-patient communications.

Table 1

Patient accounting.

Category	Number of patients for patient-reported analyses	Number of patients for physician-reported analyses
Enrolled	221	221
Protocol ineligible (T4, synchronous tumors)	2	2
Ineligible for analyses	29	18
Missing post-assay patient treatment decision	11	
Pathology ineligible for Recurrence Score result	2	2
Uncertain MMR status	16	16
MMR-D	51	51
Eligible MMR-P	139	150

Table 2

Patient and Tumor Characteristics.

Characteristic	Values	Protocol Eligible N=219*	Evaluable for patient-reported outcomes N=139	Evaluable for physician-reported outcomes N=150
Age, years	Mean	64.7	63.4	63.1
	Range	27-87	27-87	27-87
Gender, n (%)	Female	108 (49.3)	56 (40.3)	62 (41.3)
	Male	111 (50.7)	83 (59.7)	88 (58.7)
Race, n (%)	White	206 (94.1)	130 (93.5)	138 (92.0)
	Black	8 (3.7)	5 (3.6)	7 (4.7)
	Other, unknown	5 (2.3)	4 (2.9)	5 (3.3)
Performance status, n (%)	ECOG 0	143 (65.3)	93 (66.9)	98 (65.3)
	ECOG 1	76 (34.7)	46 (33.1)	52 (34.7)
WHO tumor grade, n (%)	High	32 (14.6)	14 (10.1)	16 (10.7)
	Low	187 (85.4)	125 (89.9)	134 (89.3)
Tumor Type, n (%)	Adenocarcinoma NOS	200 (91.3)	131 (94.2)	141 (94.0)
	Mucinous Carcinoma	12 (5.5)	4 (2.9)	5 (3.3)
	Other	7 (3.2)	4 (2.9)	4 (2.7)
Lymphatic invasion, n (%)	Absent	201 (91.8)	129 (92.8)	140 (93.3)
	Present	18 (8.2)	10 (7.2)	10 (6.7)
Vascular invasion, n (%)	Absent	204 (93.2)	130 (93.5)	140 (93.3)
	Present	15 (6.8)	9 (6.5)	10 (6.7)
Tumor Location, n (%)	Left-sided	67 (30.6)	53 (38.1)	56 (37.3)
	Right-sided	132 (60.3)	74 (53.2)	79 (52.7)
	Transverse colon	20 (9.1)	12 (8.6)	15 (10.0)
Tumor size	Mean	5.1	4.9	4.8
	Range	1-25	1-25	1-25
Number of lymph nodes examined	Mean	22.0	21.5	22.4
	Range	3-134	3-119	3-134

Abbreviations: ECOG, Eastern Cooperative Oncology Group; NOS, not otherwise specified; WHO, World Health Organization.

*Includes 51 patents with MMR-D tumors which were not part of the analyses included in this report

Table 3

Impact of the Oncotype DX Recurrence Score results on patients' treatment decisions regarding adjuvant therapy.

Pre-assay Patient Decisions	Post-assay Patient Decisions				
	Observation	**5FU-based Monotherapy**	**5FU+Oxaliplatin**	**Other**	**Total**
Observation	51 37.0%	6 4.3%	7 5.1%	0	64 46.4%
5FU-based Monotherapy	4 2.9%	0	0	0	4 2.9%
5FU + Oxaliplatin	3 2.2%	2 1.4%	3 2.2%	1 0.7%	9 6.5%
Other	3 2.2%	1 0.7%	0	1 0.7%	5 3.6%
Undecided	42 30.4%	8 5.8%	5 3.6%	1 0.7%	56 40.6%
Total	103 74.6%	17 12.3%	15 10.9%	3 2.2%	138 100.0%

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Table 4

Concordance of pre-assay treatment decisions between physicians and patients.

Pre-assay Physician Recommendations	Pre-assay Patient Decisions					
	Observation	**5FU-based monotherapy**	**5FU+Oxaliplatin**	**Other**	**Undecided**	**Total**
Observation	39 28.3%	0	0	2 1.4%	22 15.9%	63 45.7%
5FU-based monotherapy	11 8.0%	2 1.4%	1 0.7%	3 2.8%	17 12.3%	34 24.6%
5FU +Oxaliplatin	12 8.7%	1 0.7%	8 5.8%	0	14 10.1%	35 25.4%
Other	2 1.4%	1 0.7%	0	0	3 2.8%	6 4.3%
Total	64 46.4%	4 2.9%	9 6.5%	5 3.6%	56 40.6%	138 100.0%

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Table 5

Concordance of post-assay treatment recommendations and decisions between physicians and patients.

Post-assay Physician Recommendations	Post-assay Patient Decisions				
	Observation	**5FU-based monotherapy**	**5FU + Oxaliplatin**	**Other**	**Total**
Observation	98 70.5%	0	0	0	98 70.5%
5FU-based monotherapy	0	16 11.5%	0	1 0.7%	17 12.2%
5FU +Oxaliplatin	5 3.6%	1 0.7%	15 10.8%	1 0.72	22 15.8%
Other	1 0.7%	0	0	1 0.72	2 1.4%
Total	104 74.8%	17 12.2%	15 10.8%	3 2.2%	139 100.0%

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Table 6

Patient Decisional Conflict Scale (DCS) results, including tests for differences in mean decisional conflict between pre- and post-Oncotype DX (ODX) assay timepoints, within subscales and overall (total).

Score	Post-ODX Mean DCS	Pre-ODX Mean DCS	Mean Change POST-PRE	95% CI for the Mean Change	P-value
Effective Decision	10.93	16.67	−5.74	(−9.21, −2.27)	0.001
Informed	14.38	23.70	−9.32	(−13.52, −5.12)	<.001
Support	10.86	15.49	−4.63	(−7.85, −1.41)	0.005
Uncertainty	20.93	33.06	−12.13	(−17.91, −6.35)	<.001
Values Clarity	14.88	23.15	−8.27	(−12.45, −4.09)	<0.001
Total	14.18	22.05	−7.88	(−11.25, −4.50)	<.001

Table 7

Pre-assay concordance of self-reported patient roles in treatment decisions-making: actual versus preferred.

Role you have actually been playing	Role you would have preferred n (%)				
	1 - Self	2	3	4	5 - Doctor
1: I prefer to make the decision about which treatment I will receive.	3 2.2%	0	0	0	0
2: I prefer to make the final decision about my treatment after seriously considering my doctor's opinion.	0	29 21.3%	5 3.7%	0	1 0.7%
3: I prefer that my doctor and I share responsibility for deciding which treatment is best for me.	0	2 1.5%	74 54.4%	3 2.2%	0
4: I prefer that my doctor makes the final decision about which treatment will be used, but seriously consider my opinion.	0	0	3 2.2%	15 11.0%	0
5: I prefer to leave all decisions regarding my treatment to my doctor.	0	0	0	0	1 0.7%

Table 8

Post-assay concordance of self-reported patient roles in treatment decisions-making: actual versus preferred.

Role you have actually been playing	Role you would have preferred n (%)				
	1 - Self	2	3	4	5 - Doctor
1: I prefer to make the decision about which treatment I will receive.	4 2.9%	2 1.5%	0	0	0
2: I prefer to make the final decision about my treatment after seriously considering my doctor's opinion.	1 0.7%	28 20.6%	2 1.5%	0	0
3: I prefer that my doctor and I share responsibility for deciding which treatment is best for me.	0	3 2.2%	81 59.6%	2 1.5%	1 0.7%
4: I prefer that my doctor makes the final decision about which treatment will be used, but seriously consider my opinion.	0	1 0.7%	2 1.5%	6 4.4%	0
5: I prefer to leave all decisions regarding my treatment to my doctor.	0	1 0.7%	1 0.7%	0	1 0.7%

Table 9

Change in role patients have actually been playing: pre- versus post-assay.

Pre-assay	Post-assay n (%)					
	1	**2**	**3**	**4**	**5**	**Total**
1 I make decision	0	1 0.7%	0	1 0.7%	1 0.7%	3 2.2%
2	2 1.5%	15 11.0%	16 11.8%	2 1.5%	0	35 25.7%
3	4 2.9%	13 9.6%	59 43.4%	2 1.5%	1 0.7%	79 58.1%
4	0	2 1.5%	11 8.1%	4 2.9%	1 0.7%	18 13.2%
5 Doctor makes decision	0	0	1 0.7%	0	0	1 0.7%
Total	6 4.4%	31 22.8%	87 64.0%	9 6.6%	3 2.2%	136 100.0%

Table 10

Change in role patients would have preferred: pre- versus post-assay.

Pre-assay	Post-assay n (%)					
	1	**2**	**3**	**4**	**5**	**Total**
1 I make decision	0	1 0.7%	0	1 0.7%	1 0.7%	3 2.2%
2	2 1.5%	14 10.3%	14 10.3%	1 0.7%	0	31 22.8%
3	3 2.2%	16 11.8%	60 44.1%	2 1.5%	1 0.7%	82 60.3%
4	0	4 2.9%	10 7.4%	4 2.9%	0	18 13.2%
5 Doctor makes decision	0	0	2 1.5%	0	0	2 1.5%
Total	5 3.7%	35 25.7%	86 63.2%	8 5.9%	2 1.5%	136 100.0%

Table 11

Physician and patient Post-Oncotype DX Colon Cancer Assay questionnaire results

	1 - Strongly Disagree	2 - Disagree	3 - Neither Agree Nor Disagree	4 - Agree	5 - Strongly Agree
PHYSICIAN					
I am more confident in my treatment recommendation after ordering the Oncotype DX Colon Cancer Assay.	3 (2.0%)	2 (1.3%)	19 (12.7%)	83 (55.3%)	43 (28.7%)
The Oncotype DX Colon Cancer Assay results provided additional clinically relevant information.	3 (2.0%)	2 (1.3%)	16 (10.7%)	83 (55.3%)	46 (30.7%)
The results of the Oncotype DX Colon Cancer Assay influenced my treatment recommendation.	7 (4.7%)	15 (10.0%)	25 (16.7%)	67 (44.7%)	36 (24.0%)
PATIENT					
I feel the test results influenced by treatment decision.	3 (2.2%)	2 (1.4%)	15 (10.9%)	35 (25.4%)	83 (60.1%)