Oncotype DX® Newsletter

October 2011 Volume : 1 Issue : 2

Leading the way to individualized cancer treatment

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Welcome to the Oncotype DX® Newsletter

Welcome to Genomic Health's Quarterly Newsletter. The goal of this newsletter is to provide those who are speaking on genomics with updates on relevant information from Genomic Health. If you do not wish to receive this newsletter, please re.fer to the information listed at the bottom of this e-mail to unsubscribe.

LATEST NEWS

The Irish HSE National Cancer Control Programme approved the use of the Oncotype DX® breast cancer assay. The NCPE now considers Oncotype DX a cost-effective approach to target chemotherapy use in lymph-node-negative, oestrogen-receptor-positive, early-stage breast cancer in Ireland. This makes Ireland the first country in Europe with full reimbursement for Oncotype DX.

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ANNOUNCEMENTS

Genomic Health Announces Positive Preliminary Results of Oncotype DX® Study in DCIS Breast Cancer to be Presented at SABCS

Genomic Health, Inc. announced positive preliminary results from a study of Oncotype DX® in patients with DCIS (ductal carcinoma in situ of the breast) conducted by the Eastern Cooperative Oncology Group (ECOG).

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Step by Step Guide for Getting Oncotype DX available in English, German, French and Italian

Genomic Health has developed a new brochure to assist you and your office staff in ordering Oncotype DX.

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Genomic Health Announces Launch of NCI RxPONDER Trial Utilizing Oncotype DX® in Women with Node-Positive Breast Cancer

Genomic Health, Inc. announced the launch of RxPONDER S1007 (Rx for Positive Node, Endocrine Responsive Breast Cancer) in April, a clinical trial being led by SWOG, one of the largest National Cancer Institute (NCI) supported cancer

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St. Gallen International Expert Consensus 2011 acknowledges predictive significance of Oncotype DX® for adjuvant chemotherapy

The international breast cancer conference in St. Gallen is one of the most important and influential meetings setting the standards for diagnosis and treatment of early breast cancer.

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At the 2011 ASCO Annual Meeting in Chicago, Genomic Health presented 10 abstracts encompassing its research in breast, colon and prostate cancer. Selected abstracts on breast cancer and colon cancer are summarized below.

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Slide Module reviewing the Value of Intermediate Recurrence Scores

Ordering Oncotype DX from Europe

PATIENT CASE STUDIES

CHEMO/NO CHEMO: For which patient, would you recommend adjuvant chemotherapy+ hormonal therapy?

41-year-old patient with 1.2-cm tumor

Menopausal Status: Premenopausal
Tumor Type: Invasive Ductal Carcinoma
Tumor Size: 1.2 cm
ER Status (IHC): 95%
PR Status (IHC): 95%
HER2/neu Status: Negative (FISH)
Histologic Grade: 2
Ki67: 36%
Lymph Node Status: Negative (0/13)
Case submitted from: Spain

» See Result

46-year-old patient with 1.8 cm tumor

Menopausal Status: Premenopausal
Tumor Type: Invasive Ductal Carcinoma
Tumor Size: 1.8 cm
ER Status (IHC): Positive (3+)
PR Status (IHC): Negative
HER2/neu Status: Negative
Histologic Grade: 2
Ki67: 20%
Lymph Node Status: Negative
Case submitted from: Israel

» See Result

RECENT PUBLICATIONS

The following articles have been published recently that relate to Oncotype DX:

1 Prognostic and Predictive Markers in Stage II Colon Cancer: Is There a Role for Gene Expression Profiling? Kelley RK, Venook AP, Clin Colorectal Cancer. 2011 Jun;10(2):73-80. Epub 2011 Apr 22.

2 Know ledge About Genomic Recurrence Risk Testing Among Breast Cancer Survivors. Lipkus IM, Vadaparampil ST, Jacobsen PB, Miree CA.J Cancer Educ. 2011 Jun 19. [Epub ahead of print]

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For more information about Oncotype DX, please refer to w w w.oncotypedx.com (now available in French, Spanish, and German)

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This e-newsletter contains forward-looking statements within the meaning of the Priv ate Securities Litigation Reform Act of 1995, including statements relating to our plans to analy ze, submit and present the complete data from this study at the 2011 San Antonio Breast Cancer Sy mposium; the expectation that these preliminary study results will be confirmed in the complete analy sis of the study data; our plans to commercially launch Oncoty pe DX testing for DCIS patients by the end of 2011; the ability of Oncoty pe DX testing to indiv idualize cancer treatment for DCIS patients; the ability of the company to dev elop additional tests in the future; the scope, success or results of clinical trials and the timing of such activ ities; the applicability of clinical study results to actual outcomes; the ability of the company's tests to impact clinical practice and, the ability of the company's test to be adequately reimbursed. Forward-looking statements are subject to risks and uncertainties that could cause actual results to diff er materially and reported results should not be considered as an indication of future perf ormance. These risks and uncertainties include, but are not limited to: the applicability of clinical study results to actual outcomes; the risks and potential delay s associated with such studies; the risks and potential delay s associated with the commercialization of current and future products; the risks and uncertainties associated with the regulation of our tests; the risks associated with competition; and the other risks set f orth in the company's filings with the Securities and Exchange Commission, including the risks set f orth in the company's Quarterly Report on Form 10-Q f or the quarter ended March 31, 2011. These f orward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these f orward-looking statements.

genomic health

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Oncotype DX® Newsletter

Announcements

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Genomic Health Announces Positive Preliminary Results of Oncotype DX® Study in DCIS Breast Cancer

Genomic Health, Inc. announced positive preliminary results from a study of Oncotype DX in patients with DCIS (ductal carcinoma in situ of the breast) conducted by the Eastern Cooperative Oncology Group (ECOG), a clinical trials cooperative group supported by the National Cancer Institute.

The ECOG 5194 validation study met its primary endpoint by demonstrating that a pre-specified Oncotype DX DCIS Score can predict the risk of local recurrence, defined as either the development of a new invasive breast cancer or the recurrence of DCIS in the same breast. ECOG and Genomic Health plan to submit complete data from this study for presentation at the 2011 San Antonio Breast Cancer Symposium in December. Based on these positive findings, Genomic Health plans to make the Oncotype DX DCIS Score available to patients and physicians worldwide by year end.

Step by Step Guide for Getting Oncotype DX® available

Genomic Health has developed a new brochure to assist you and your office staff in ordering Oncotype DX**.** This brochure provides step by step instruction on the process to order the assay from around the world. By following the process, Genomic Health is able to deliver patient results in 7-10 days in most cases.
English | French | German | Italian

Genomic Health Announces Launch of NCI RxPONDER Trial Utilizing Oncotype DX® in Women with Node-Positive Breast Cancer

Genomic Health, Inc. announced the launch of RxPONDER S1007 (**Rx** for **Po**sitive **N**o**d**e, **E**ndocrine **R**esponsive Breast Cancer) in April, a clinical trial being led by SWOG, one of the largest National Cancer Institute (NCI) supported cancer cooperative groups. The trial is designed to determine the effect of chemotherapy in breast cancer patients with one to three positive nodes who have a Recurrence Score® (RS) result equal to, or less than, 25 as determined by the Oncotype DX breast cancer test.

"Based on results from the previous SWOG 8814, E2197 and transATAC studies, which support the use of Oncotype DX inpatients with node-positive breast cancer, as well as positive results from a decision impact study recently published in the *Journal of Oncology Practice*, many physicians have used the Oncotype DX test in their patients with node-positive breast cancer and certain payors have started covering the test's use in these patients," said Steven Shak, chief medical officer at Genomic Health. "We are excited to partner again with the NCI and national cancer cooperative groups on the RxPONDER trial as it will allow us to gain additional insights beyond the earlier studies by identifying a more precise Recurrence Score cut-off that can be used to determine when chemotherapy is not beneficial for patients in this population."

Latest News

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News Stories

Irish Times
A NEW breast cancer test will be made available from this week by the Republic's eight breast cancer treatment centres, the national cancer control programme (NCCP) has announced.
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Irish Health
A new breast cancer test, which helps determine if certain women need chemotherapy, is being made available to public patients 'from this week onwards', the HSE has said.
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RTE
A new breast cancer test will be available to to all public patients who require it from this week onwards.
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Featured Articles

St. Gallen International Expert Consensus 2011 acknowledges predictive significance of Oncotype DX® for adjuvant chemotherapy

http://annonc.oxfordjournals.org/content/early/2011/06/27/annonc.mdr304.full

The international breast cancer conference in St. Gallen is one of the most important and influential meetings setting the standards for diagnosis and treatment of early breast cancer. In the traditional consensus meeting concluding the 12th conference in March 2011 an expert panel updated the guidelines for diagnosis and treatment of early breast cancer. The panel consisted of 51 renowned breast cancer experts (Europe 27, North America 18, Australia 3, Japan 2, China 1).

Recently, the recommendations have been published in Annals of Oncology [1]. They support current understanding of breast cancer as a hererogenous disease with recognition of intrinsic biological subtypes and highlight the importance of treatment recommendations based on individual patient's underlying tumor biology.

That the prognostic and predictive significance of Oncotype DX has been evaluated in 13 independent clinical studies including more than 4,000 patients allowed the experts to base their decision on a considerable body of evidence. In 2009 the panel made a general recommendation about the use of validated multigene assays. The updated 2011 recommendations clearly distinguish Oncotype DX from other genomic and molecular markers.

The experts consider Oncotype DX and Mammaprint® as prognostic tests that may "indicate a prognosis so good that the doctor and patient decide that chemotherapy is not required" [1]. A clear majority of the panel (84.4% in the original voting) solely considers Oncotype DX to have a predictive validity in hormone receptor-positive disease and agrees „that the 21-gene signature (Oncotype DX) may also be used where available to predict chemotherapy responsiveness in an endocrine responsive cohort where uncertainty remains after consideration of other tests" [1].

Notably, the experts do not consider node positivity per se to mandate adjuvant chemotherapy [1].

The Oncotype DX assay has become part of clinical reality in adjuvant decision-making in hormone receptor-positive early breast cancer. Results of studies on its clinical impact consistently show that the use of the assay leads to an average 30% change rate in adjuvant treatment recommendations [2]. In the majority of cases patients are spared adjuvant chemotherapy as a result of low Recurrence Score® values., while detection of a high Recurrence Score value in some patients identify as likely to benefit from adjuvant chemotherapy.

The inclusion of Oncotype DX in the St. Gallen guidelines is an important recognition of its value in enabling more individualized treatment decisions by the international medical community.

Reference:

1. Goldhirsch A, Wood WC, Coates AS, Gelber RD, Thürlimann B, Senn HJ & panel members. Strategies for subtypes – dealing with the diversity of breast cancer: highlights of the St. Gallen International Expert consensus on the Primary Therapy of Early Breast Cancer 2011. Ann Oncol 2011; 22:1736-1747

2. Hornberger J, et al. Meta-Analysis of the Decision Impact of the 21-Gene Breast Cancer Recurrence Score® in Clinical Practice. SABCS 2010. Poster P2-09-06

Onco*type* DX® Update from ASCO 2011

For Downloadable slides click here

At the 2011 ASCO Annual Meeting in Chicago, Genomic Health presented 10 abstracts encompassing its research in breast, colon and prostate cancer. Selected abstracts on breast cancer and colon cancer are summarized below.

Breast Cancer –Predictive significance of the Recurrence Score for neoadjuvant treatment

Two studies supported previously presented data regarding Onco*type* DX® in the neoadjuvant setting.

- Norakizu Masuda and colleagues [1] presented the results of an exploratory study investigating the role of the Recurrence Score in predicting response to neoadjuvant exemestane therapy given for 24 weeks in 64 postmenopausal ER+ BC patients.

  Clinical response to neoadjuvant endocrine therapy was strongly correlated with the Recurrence Score. The greatest likelihood of clinical response to neoadjuvant exemestane was observed in patients with low and intermediate Recurrence Scores. When adjusted for the effects of tumor size and PgR Allred Score, the Recurrence Score was the strongest predictor of undergoing breast conserving surgery following neoadjuvant endocrine therapy.

- A study by Nancy Peacock and colleagues [2] evaluated ixabepilone in combination with cyclophosphamide as neoadjuvant treatment for ER+/ER-, HER2- breast cancer.

  Results of the interim analysis presented revealed a correlation between the Recurrence Score result and the likelihood of pathological complete response (pCR) to neoadjuvant chemotherapy. All patients who achieved pCR in this study had High Recurrence Score disease.

Breast cancer: Recurrence Score is an independent prognostic variable

Two studies added to the existing evidence showing the Recurrence Score cannot be consistently predicted by traditional clinicopathologic variables or by other molecular markers such as ki-67 or uPA/PAI-1.

- Nicky Liebermann and colleagues [3] evaluated the Recurrence Score and traditional clinicopathologic measures in a large cohort (N=1,864) of ER+, N-, HER2- patients from Clalit and Maccabi Health Services in Israel.

  They found the Recurrence Score to be poorly correlated with age and tumor size, and moderately correlated with tumor grade. There was a wide distribution of Recurrence Score values across age, tumor size, tumor grade and combinations of clinical and pathological variables.

- Degenhardt et al [4] evaluated correlations for central grade, centrally assessed ki-67, uPA/PAI-1 and the Recurrence Score from patients (n=1509 for central grade, n=522 for ki-67, n=202 for uPA/PAI-1) enrolled in a large randomized German adjuvant study (PlanB).

  The data of this analysis showed that the high-RS group was predictive of high uPA/PAI-1, aggressive central grade and luminal B subtype, but the converse was not true i.e. these markers did not predict the RS Notably, there was also a substantial group of patients with high-risk tumors by central grade and luminal B subtype whose tumors had a low RS.

Breast Cancer: Pharmacoeconomic impact of Onco*type* DX-guided adjuvant decision-making

The results of a Canadian budget impact analysis were consistent with numerous other budget impact and cost studies worldwide demonstrating that the use of Onco*type* DX is at least cost-effective and potentially cost-saving.

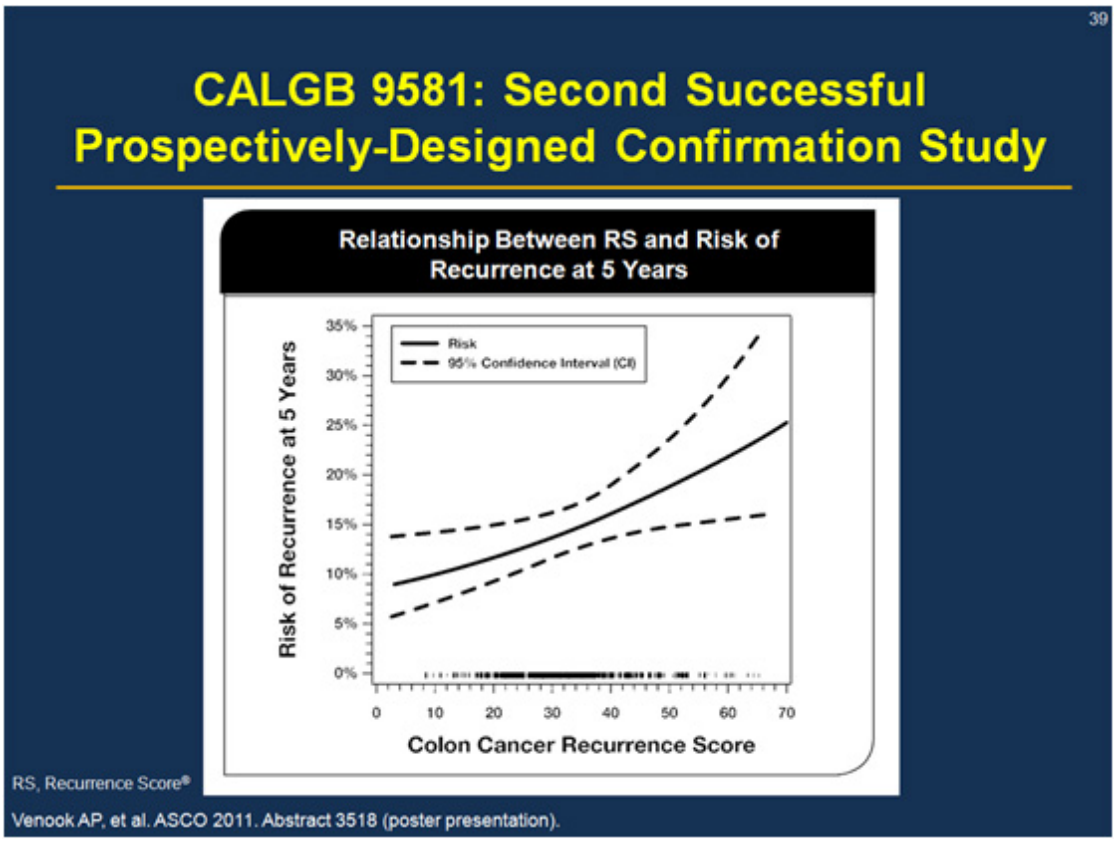
- Shazia Hassan and colleagues [5] performed an analysis assessing the impact on the healthcare system budget of adding the 21-gene breast cancer assay to the Ontario Canada Health Care System In this analysis, all patients with low Recurrence Scores and 50% of intermediate Recurrence Scores avoided chemotherapy. Budget impact results showed that using the 21-gene breast cancer assay routinely in Ontario could result in saving more than $11M (Canadian) per year to the health care system.

Colorectal Cancer: Confirmation of the prognostic significance of the 12-gene Recurrence Score in low/standard risk stage II colon cancer

In a previous study with 1,436 stage II colon cancer patients from the QUASAR trial, the continuous 12-gene Recurrence Score, (RS), T stage and MMR status were validated as a predictor of recurrence risk following surgery. The results from the CALGB study presented below are consistent with these data and represent the second large validation study of the continuous 12-gene Recurrence Score in predicting risk of recurrence for stage II colon cancer patients.

- Venook and colleagues [6] presented the results of the second validation study in colorectal cancer designed to determine the relationship between the RS and risk of recurrence and whether the RS provided significant information beyond the number of nodes examined, T stage, tumor grade, MMR status and lymphatic and/or vascular invasion. The study was performed in 690 evaluable patients with stage II colon cancer from the CALGB study 9581 representative of 1,672 stage II colon cancer patients originally enclosed.

  The RS was significantly associated with risk of recurrence beyond the known prognostic factors in stage II colon cancer. The average 5-year recurrence risk for T3 MMR-P patients was 13% in the low risk cohort, 16% in the intermediate risk and 21% in the high risk group.



Reference:

1. Masuda N et al. A study of the recurrence score by the 21-gene signature assay as a predictor of clinical response to neoadjuvant exemestane for 24 weeks in estrogen-receptor- positive breast cancer. Abstract #558
2. Peacock N et al. Ixabepilone and cyclophosphamide as neoadjuvant therapy in HER2-negative breast cancer with exploratory Onco*type* DX assessments: A Sarah Cannon Research Institute phase II trial. Abstract #1066
3. Liebermann N. et al.: Evaluation of recurrence score and traditional clinicopathologic assessments in a large ER-positive, lymph node-negative patient cohort. Abstract #632
4. Degenhardt T et al Prospective comparison of Recurrence Score, uPA/PAI-1, central grade and molecular classification in early breast cancer: interim results from the WSG-Plan B trial, Abstract 10594
5. Hassan S et al. A cost benefit analysis of the 21-gene breast cancer assay within a Canadian health care system. Abstract #6111
6. Venook AP et al. Validation of a 12-gene colon cancer Recurrence Score in patients with stage II colon cancer from CALGB 9581. Abstract #3518
7. Kerr D, et al. A quantitative multi-gene RT-PCR assay for prediction of recurrence in stage II colon cancer: Selection of the genes in 4 large studies and results of the independent, prospectively-designed QUASAR validation study ASCO 2009. Abstract 4000.

Predictive markers catalyst for Personalized Medicine in Oncology

Predictive markers catalyst for Personalized Medicine in Oncology. A predictive marker is defined as a marker that can be used to predict response to a given therapy. With a predictive marker it should be possible to select the therapy with the highest likelihood of efficacy for the individual patient. Clinical validation of a predictive marker requires a randomized trial in a relevant patient population that compares standard treatment with standard treatment plus the addition of the specific treatment. It also requires demonstration that the relative treatment benefit by this specific treatment is associated with the marker using the formal test for interaction with a significant p-value

- In breast cancer expression of the estrogen receptor is established as a predictive marker used in daily clinical oncology practice to predict sensitivity to endocrine therapy. Similarly HER2 is a predictive marker to predict sensitivity to trastuzumab or lapatinib.
- The value of Oncotype DX® as a predictive marker of chemotherapy benefit has been demonstrated in analysis of large randomized trials for treatment with tamoxifen [1] and for adjuvant chemotherapy [2, 3]. In the pivotal NSABP B-20 trial patients with tumors that had a high RS had the highest absolute benefit of chemotherapy (Hazard Ratio [HR] =0.26) and there was an absolute reduction of 28% in the rate of distant recurrence at ten years. Patients with low recurrence scores (RS <18) had minimal, if any benefit of chemotherapy. The test for interaction between chemotherapy treatment and RS was statistically significant ($p<0.05$). When RS was examined as a continuous variable in a Cox model a linear correlation between RS and the degree of chemotherapy benefit could be shown [2].

A prognostic marker can be defined as a marker present at a defined point in time which is correlated with the course of the disease if no further treatment is administered after this specific point in time. A prognostic marker supports the assessment of risks, e.g. if a patient with early breast cancer has a high or a low risk of recurrence. Some markers have such a strong prognostic effect that they define a group of patients with such a low risk of recurrence that the addition of therapy is unlikely to improve the patients overall outcome. As an example, Stage II colon cancer patients who are show to be MMR-D (Mismatch Repair Deficient) have been shown to have a risk below 10%, so the addition of chemotherapy is unlikely to benefit these patients.

- HER2 is an example for a negative prognostic factor. In breast cancer a higher HER2 gene amplification is associated with a higher risk of disease recurrence, a shorter disease-free and overall survival [4].
- The prognostic value of Oncotype DX has been validated in tamoxifen- and anastrozole-treated patients [3, 5, 6]. Its Recurrence Score® (RS) is correlated with the probability of distant recurrence at 10 years if no additional adjuvant chemotherapy is applied. The higher the RS value the higher the risk of recurrence. A low RS corresponds to a low risk of recurrence. However, the Recurrence Score really is a continuous quantitative prognostic parameter, i.e. a specific Recurrence Score value corresponds to a specific numeric risk of recurrence at 10 years.

Prediction of chemotherapy benefit must be formally demonstrated in clinical studies where patients are randomized to chemotherapy or not. For the individual patient, it cannot be inferred from prognosis. The Recurrence Score is both a prognostic marker for the risk of recurrence and a predictive marker of chemotherapy benefit. This is acknowledged by the international medical community. The updated St. Gallen guidelines acknowledge the prognostic significance of the assay and support that Oncotype DX is the only marker to predict chemotherapy benefit for ER-positive breast cancer [7].

Reference:

1. Paik et al. Expression of the 21 Genes in the Recurrence Score Assay and Prediction of Clinical Benefit from Tamoxifen in NSABP Study B-14 and Chemotherapy in NSABP Study B-20 SABCS 2004; Abstract #24.
2. Paik S et al. Gene Expression and Benefit of Chemotherapy in Women With Node-Negative, Estrogen Receptor-Positive Breast Cancer. J Clin Oncol 2006; 24:3726-37
3. Albain K et al., Prognostic and predictive value of the 21-gene recurrence score assay in postmenopausal, node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: a retrospective analysis of a randomized trial. Lancet Oncol 2010; 11:55-65
4. Weigel MT, Dowsett M, Current and emerging biomarkers in breast cancer: prognosis and prediction.Endocr Relat Cancer. 2010 Sep 23;17:R245-62.
5. S Paik et al. Multigene assay to predict recurrence of Tamoxifen-treated, node negative breast cancer, NEJM 2004, 351:2817-26
6. Dowsett M, et al. Prediction of Risk of Distant Recurrence Using the 21-Gene Recurrence Score in Node-Negative and Node-Positive Postmenopausal Patients with Breast Cancer Treated with Anastrozole or Tamoxifen: A TransATAC Study. J Clin Oncol. 2010; 28:1829-34
7. Goldhirsch A, Wood WC, Coates AS, Gelber RD, Thürlimann B, Senn HJ & panel members. Strategies for subtypes – dealing with the diversity of breast cancer: highlights of the St. Gallen International Expert consensus on the Primary Therapy of Early Breast Cancer 2011. Ann Oncol 2011; 22:1736-

Can Health Care Systems afford Onco*type* DX®? An independent assessment from Ontario, Canada

The Toronto Health Economics and Technology Assessment (THETA) Collaborative is a multidisciplinary research collaboration based at the University of Toronto. It was established in 2007 and supports effective policy decision-making regarding new drugs and health technologies in Ontario. THETA is funded by the Ontario Ministry of Health and Long-Term Care and Health Quality Ontario, an independent agency with the legal mandate to promote health care that is supported by the best available scientific evidence by making recommendations to the Minister concerning the Government of Ontario's provision of funding for health care services and medical devices.

In 2010 THETA performed an economic evaluation of the Onco*type* DX-guided adjuvant chemotherapy decision-making in women with ER+ early breast cancer. In summary, this analysis found that providing Onco*type* DX to women with node-negative ER-positive early breast cancer is cost-effective regardless of their risk classification by Adjuvant Online!. It also found chemotherapy to be cost-effective for women with high and intermediate Recurrence Score values [1].

The analysis was presented to the Ontario Health Technology Advisory Committee (OHTAC) in August 2010 resulting in the committee's recommendation to give patients access to Onco*type* DX within the context of a field evaluation.

Details on the THETA study

Background and rationale

For THETA investigators existing cost-effectiveness analyses of Onco*type* DX had some limitations the most relevant for them being a limited range of treatment strategies considered and no separate consideration of intermediate risk. Thus, they performed their analysis with immense rigor. Their objective was to provide guidance on the use of Adjuvant Online! (AOL) and/or Onco*type* DX and associated chemotherapy decisions.

Methods

It was assumed that AOL and Onco*type* DX could be provided separately or sequentially and chemotherapy was considered for each risk group, resulting in 1,000 unique strategies for the provision of AOL, Onco*type* DX, and chemotherapy. It was further assumed that all patients would receive tamoxifen and chemotherapy as additional treatment where specific chemo regimens were modeled for higher risk women. Investigators modified a Markov model developed by Tsoi and colleagues [2] using data from the NSABP B-14 and B-20 clinical trials. Using this model a cost-effectiveness analysis was performed for every single treatment strategy. All strategies were compared to each other in order to identify the most cost-effective ones. The model was run probabilistically with 10,000 Monte Carlo simulations with a lifetime horizon based on the Ontario public payer perspective and a 5% discount rate.

Results

Of the 100 strategies compared, the most cost-effective strategy was to provide Onco*type* DX regardless of the AOL score and to give chemotherapy to the intermediate and high recurrence scores.

Providing Onco*type* DX to women with N-, ER+ early stage breast cancer appears cost-effective regardless of the AOL score. The highest incremental cost-effectiveness ratio (ICER) of $29,000 per QALY (still well below the Canadian willingness to pay of $75,000 / QALY) was found for patients at low risk determined by Adjuvant Online! . Onco*type* DX was cost-saving in patients at high AOL risk.

Chemotherapy was cost-effective only in patients at intermediate or high Onco*type* DX risk. The highest ICER of $64,000 per QALY was in patients at low AOL and intermediate Onco*type* DX risk. Chemotherapy was more expensive and did not improve overall patients' outcomes when given to patients at low Onco*type* DX risk.

Reference:

1. Paulden M et al. Gene Expression Profiling for Guiding Adjuvant Chemotherapy Decisions in Women with Early Breast Cancer: A Cost-Effectiveness Analysis of 1,000 Strategies for the Provision of Adjuvant! Online, Onco*type* DX, and Chemotherapy, *Value in Health* 2011, 14: PCN72
2. Tsoi DT et al. Cost-effectiveness analysis of recurrence score-guided treatment using a 21-gene assay in early breast cancer. *Oncologist*: 2010, 15, 457-465

Recent Publications

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The following articles have been published recently that relate to Oncotype DX®:

1 Prognostic and Predictive Markers in Stage II Colon Cancer: Is There a Role for Gene Expression Profiling? Kelley RK, Venook AP, *Clin Colorectal Cancer*. 2011 Jun;10(2):73`-80. Epub 2011 Apr 22.

2 Knowledge About Genomic Recurrence Risk Testing Among Breast Cancer Survivors.Lipkus IM, Vadaparampil ST, Jacobsen PB, Miree *CA. J Cancer Educ*. 2011 Jun 19. [Epub ahead of print]

3 Prospective transGEICAM study of the impact of the 21-gene Recurrence Score assay and traditional clinicopathological factors on adjuvant clinical decision making in women with estrogen receptor-positive (ER+) node-negative breast cancer.Albanell J, González A, Ruiz-Borrego M, Alba E, García-Saenz JA, Corominas JM, Burgues O, Furio V, Rojo A, Palacios J, Bermejo B, Martínez-García M, Limon ML, Muñoz AS, Martín M, Tusquets I, Rojo F, Colomer R, Faull I, Lluch *A. Ann Oncol*. 2011 Jun 6. [Epub ahead of print]

4 RT-PCR-based gene expression profiling for cancer biomarker discovery from fixed, paraffin-embedded tissues. Scott A, Ambannavar R, Jeong J, Liu ML, Cronin *MT. Methods* Mol Biol. 2011;724:239-57.

5 Personalized medicine and oncology practice guidelines: a case study of contemporary biomarkers in colorectal cancer.Kelley RK, Van Bebber SL, Phillips KA, Venook *AP. J NatlComprCancNetw*. 2011 Jan;9(1):13-25.

6 Comparison of the prognostic and predictive utilities of the 21-gene Recurrence Score assay and Adjuvant! for women with node-negative, ER-positive breast cancer: results from NSABP B-14 and NSABP B-20.Tang G, Shak S, Paik S, Anderson SJ, Costantino JP, Geyer CE Jr, Mamounas EP, Wickerham DL, Wolmark *N. Breast Cancer Res Treat*. 2011 May;127(1):133-42. Epub 2011 Jan 11.

7 The effects of oncotype DX recurrence scores on chemotherapy utilization in a multi-institutional breast cancer cohort.Ademuyiwa FO, Miller A, O'Connor T, Edge SB, Thorat MA, Sledge GW, Levine E, Badve S.

8 Breast Cancer Res Treat. 2011 Apr;126(3):797-802. Epub 2011 Jan 1.Translating tumor biology into personalized treatment planning: analytical performance characteristics of the Oncotype DX Colon Cancer Assay.Clark-Langone KM, Sangli C, Krishnakumar J, Watson *D. BMC Cancer*. 2010 Dec 23;10:691.

9 Economic evaluation of the 21-gene signature (Oncotype DX) in lymph node-negative/positive, hormone receptor-positive early-stage breast cancer based on Japanese validation study (JBCRG-TR03).Kondo M, Hoshi SL, Yamanaka T, Ishiguro H, Toi *M. Breast Cancer Res Treat*. 2011 Jun;127(3):739-49. Epub 2010 Nov 17.

For comprehensive list of Oncotype DX publications

Upcoming Events and Online Resources

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E-cancer.TV

Oncotype DX® testing to determine adjuvant therapy for breast cancer patients

Prof Joan Albanell Mestres speaks in Spanish about his research into the clinical utility of Onco*type* DX testing in breast cancer patients. This test was used on a group of oestrogen receptor-positive node-negative breast cancer patients to decide if their adjuvant therapy should be hormone therapy alone or hormone therapy with chemotherapy. Following the Onco*type* DX test, treatment recommendations were modified in over 30% of patients. Prof Albanell Mestres discusses the need to identify biological factors that influence these results, explains how this test will improve the quality of care offered to patients and outlines some difficulties that must be overcome before this technology can be successfully employed.

http://www.ecancermedicalscience.com/tv/?play=779

http://www.ecancermedicalscience.com/tv/?play=782&rdt=1 (Espanol)

Medscape

Overview of Oncotype DX® Colon Assay

View a short interview with John Marshall, MD, Chief of the Division of Hematology and Oncology at Georgetown University Hospital and Associate Director for Clinical Research at the Lombardi Comprehensive Cancer Center in Washington, DC.

http://www.medscape.com/infosite/oncotypedx/index-colon

Prime Oncology

Genomic classifiers in clinical practice

Prime Oncology presents an educational monograph on the role of neo adjuvant therapy in endocrine-responsive breast cancer. This monograph includes discussions from three different authors covering neo adjuvant endocrine therapy, neo adjuvant chemotherapy, and biologic determinants of systemic therapy.

http://www.primeoncology.org/ASBS_Monograph

Slide Kits Available for download

Colon Cancer Core Slide Module

Breast Cancer Core Slide Module

Slide Modulereviewing the Value of Intermediate Recurrence Scores®

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Leading the way to individualized cancer treatment

Oncotype DX® Newsletter

41 year old patient with 1.2 cm tumor:

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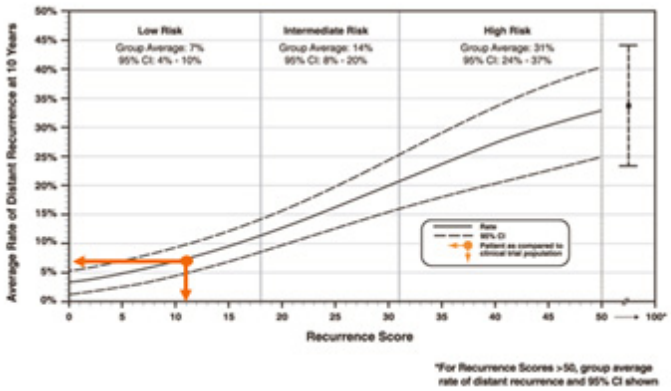
RESULTS

Recurrence Score = 11

CLINICAL EXPERIENCE

Patients with a Recurrence Score of **11** in the clinical validation study had an Average Rate of Distant Recurrence at 10 years of **7% (95% CI: 5%-10%).**



genomic health

Leading the way to individualized cancer treatment

Oncotype DX® Newsletter

46 year old with 1.8 cm tumor:

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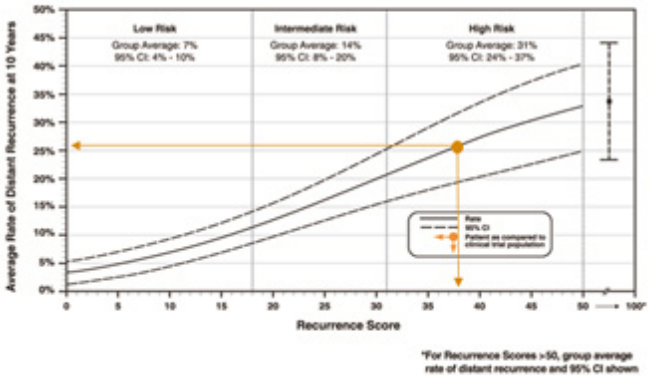
RESULTS

Recurrence Score = 38

CLINICAL EXPERIENCE

Patients with a Recurrence Score of 38 in the clinical validation study had an Average Rate of Distant Recurrence at 10 years of 26% (95% CI: 19%-32%).



*For Recurrence Scores >50, group average rate of distant recurrence and 95% CI shown