genomic health

Oncotype DX® Newsletter

February 2012 Volume : 2 Issue : 3

Leading the way to individualized cancer treatment

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- **Step-by-Step Guide for Getting Oncotype DX assays available in English, German, French, and Italian**
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Welcome to the Genomic Health's Quarterly 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 refer to the information listed at the bottom of this e-mail to unsubscribe.

FEATURED ARTICLES

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EVENTS & ONLINE RESOURCES

- **European School of Oncology – e-oncoreview**
  Expert: William Wood, Emory University Hospital, Atlanta, GA, USA
  Discussant: Nigel Bundred, University Hospital of South Manchester, Manchester, United Kingdom Now with the introduction of a genomic assay for DCIS, we should consider how this assay will be integrated with existing risk assessment tools for DCIS and ultimately treatment decisions.
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- **e-cancer.TV**
  A test to predict risk of recurrence in DCIS
  Prof. Joseph Sparano,Albert Einstein Cancer Center, New York, USA, discusses a study validating a multigene test to predict risk of recurrence in breast cancer patients with ductal carcinoma in situ (DCIS)...
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- **Medscape**
  Breast Cancer
  Must All DCIS Patients Undergo Radiation?
  Medscape Hematology-Oncology 2012
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- **Slide Kits Available for download**

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  Colon Cancer Core Slide Module

  Breast Cancer Core Slide Module

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  DCIS Score slide module

Ordering Oncotype DX

PATIENT CASE STUDIES

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

PATIENT A
61-year-old patient with 0.6-cm and 0.9-cm tumors

Menopausal Status: Postmenopausal

Tumor Type: Infiltrating Ductal Carcinoma(IDC), Ductal Carcinoma in Situ (DCIS)

Tumor Size: 0.6 cm, 0.9 cm

ER Status (IHC) : Positive (95%)

PR Status (IHC): Positive (95%)

HER2/neu Status: Negative (FISH)

Histologic Grade: 2

Lymph Node Status: Negative (0/2 SLNs)

General Health: Excellent

Case submitted from:
G. THOMAS Budd. MD
» See Result

PATIENT B
62-year-old patient with 0.6 cm tumor*

Menopausal Status: Postmenopausal

Tumor Type: Infiltrating Ductal Carcinoma(IDC)

Tumor Size: 0.6 cm

ER Status (IHC): Positive (strong)

PR Status (IHC): Positive (strong)

HER2/neu Status: Negative(IHC)

Histologic Grade: 2

Lymph Node Status: Negative (0/2 SLNs)

General Health: Bipolar, irritable bowel syndrome, hypertension, gastoresophageal reflux disease, hypothyroidism, asthma, cholecystectomy

Other Information: *Aditional 1.2-cm and 1.3-cm tumors found on re-excision

Case submitted from:
Terry P. Mamounas. MD. MPH
» See Result

RECENT PUBLICATIONS

Recently published Oncotype DX related articles:

1 Joh JE, Esposito NN, Kiluk JV, Laronga C, Lee MC, Loftus L, Soliman H, Boughey JC, Reynolds C, Lawton TJ, Acs PI, Gordan L, Acs G. The Effect of Oncotype DX Recurrence Score on Treatment Recommendations for Patients with Estrogen Receptor-Positive Early Stage Breast Cancer and Correlation with Estimation of Recurrence Risk by Breast Cancer Specialists. Oncologist. 2011;16(11):1520-6. Epub 2011 Oct 20. PubMed PMID: 22016474.

2 Kamal AH, Loprinzi CL, Reynolds C, Dueck AC, Geiger XJ, Ingle JN, Carlson RW, Hobday TJ, Winer EP, Goetz MP. Breast medical oncologists' use of standard prognostic factors to predict a 21-gene recurrence score. Oncologist. 2011;16(10):1359-66. Epub 2011 Sep 20. PubMed PMID: 21934103.

» More

For more information about Onco*type* DX, please refer to www.onco*type*dx.com (now available in French, Spanish, and German)

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This e-newsletter contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to our plans to analyze, submit and present the complete data from this study at the 2011 San Antonio Breast Cancer Symposium; the expectation that these preliminary study results will be confirmed in the complete analysis of the study data; our plans to commercially launch Onco*type* DX testing for DCIS patients by the end of 2011; the ability of Onco*type* DX testing to individualize cancer treatment for DCIS patients; the ability of the company to develop additional tests in the future; the scope, success or results of clinical trials and the timing of such activities; 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 differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: the applicability of clinical study results to actual outcomes; the risks and potential delays associated with such studies; the risks and potential delays 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 forth in the company's filings with the Securities and Exchange Commission, including the risks set forth in the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011. These forward-looking statements speak only as of the date hereof. Genomic Health disclaims any obligation to update these forward-looking statements.

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Leading the way to individualized cancer treatment

Oncotype DX® Newsletter

Featured Articles

Genomic Health launches Oncotype DX Breast Cancer Assay

With the increasing prevalence of ductal carcinoma in situ (DCIS) , there is a significant unmet need to determine which women with DCIS are at high risk of having either a DCIS or an invasive carcinoma local recurrence. The Oncotype DX® Breast Cancer Assay for DCIS patients is the first clinically validated genomic assay to provide an individualized prediction of the 10-year risk of local recurrence (DCIS or invasive carcinoma) to help guide treatment decision-making in women with ductal carcinoma in situ treated by local excision, with or without tamoxifen.

The Oncotype DX Assay for DCIS Patients is the first and only clinically-validated commercial genomic assay for patients with DCIS. This assay predicts the risk of local recurrence (DCIS or invasive carcinoma) and helps guide personalized treatment based on tumor biology as determined by the DCIS Score™. The DCIS Score was clinically validated in a prospectively designed study using patient samples from ECOG 5194. Besides the DCIS Score, the report includes quantitative ER and PR single gene expression values. The assay is run in Genomic Health's CLIA-certified, CAP-accredited reference laboratory.

Which Patients?

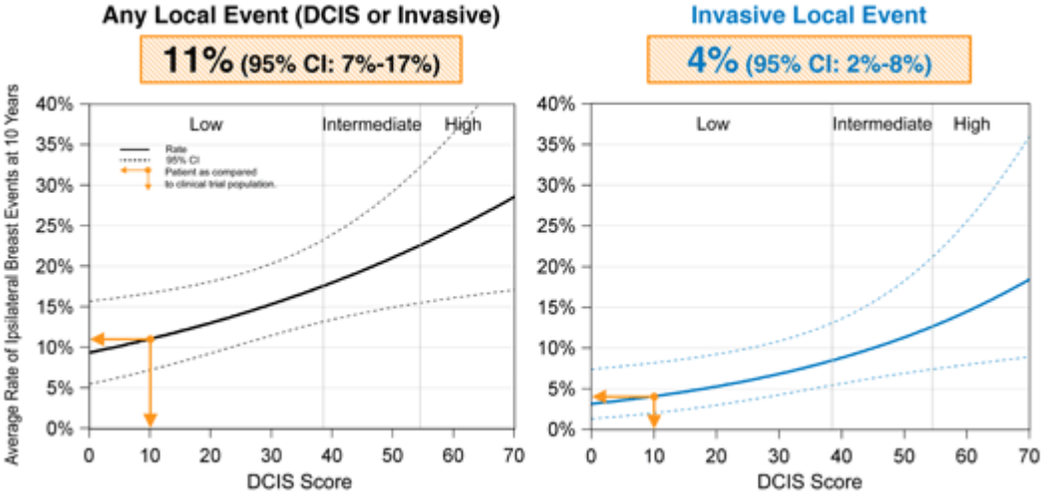
The Oncotype DX Breast Cancer Assay for DCIS can provide relevant information for women with ductal carcinoma in situ treated by local excision, with or without tamoxifen. The eligibility criteria for patients in the ECOG 5194 study was as follows:

Patients with low/intermediate grade, size < 2.5 cm or high grade, size < 1 cm were a minimum of 3 mm negative margins, Patients were treated with surgical excision alone and no radiation therapy was administered

- Tamoxifen use was allowed at the investigator's discretion beginning after May 2000. There was no collection of duration of tamoxifen treatment. Approximately 30% of patients received tamoxifen at some point.
- 97% of the patients were ER positive.

DCIS Score Result

DCIS is a heterogeneous disease. Currently there is no objective method to identify patients who are at a high risk of local recurrence or determine which recurrences will be invasive. It is important to have an accurate and reproducible assay that predicts the risk of recurrence for DCIS patients. Reflective of the continuum of DCIS tumor biology, the DCIS Score quantifies: (1) the likelihood of local recurrence (DCIS or invasive carcinoma) at 10 years. The DCIS Score result provides physicians and their patients with an individualized score to help inform your treatment plan.



1. Hughes LL, Wang M, Page DL et al. (2009). “Local excision alone without irradiation for ductal carcinoma in situ of the breast: a trial of the Eastern Cooperative Oncology Group”. J Clin Oncol, 27: 5319-5324.

The following is link to a presentation by Genomic Health’s Chief Medical Officer, Steve Shak, MD The Present and Future of Genomics in DCIS. This presentation reviews the DCIS validation study for the Oncotype DX assay presented at the 2011 SABCS Symposium. This presentation also discusses how the DCIS score was developed.
Click Here to View Presentation / PPT Slides

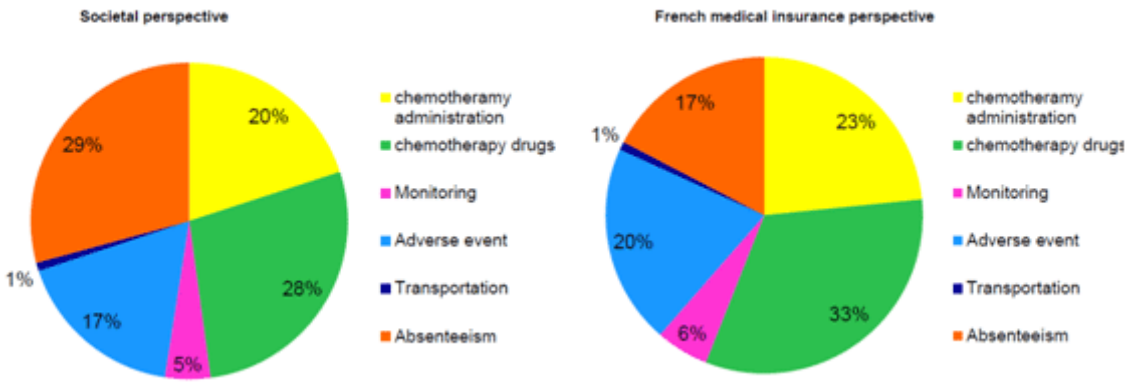
Economic analysis of chemotherapy costs for adjuvant therapy in breast cancer in France

In a poster presented at SABCS 2011, investigators from Hopital Tenon in Paris, France reported that using the Oncotype DX® assay in French clinical practice to inform chemotherapy decisions is expected to be cost-saving in the long term for ER+, N-, early stage invasive breast cancer patients.

The investigators conducted a retrospective analysis of medical records of patients having undergone surgery for breast cancer from January – July 2010 in their institution. Information on patient characteristics, pre-chemotherapy assessment, and relevant costs relating to treatment (chemotherapy, supportive care for adverse events, hospitalizations, laboratory tests, transport and sick leave) were collected. Patients were also interviewed, to collect data relating to transportation to and from the hospital as well as work absenteeism. Cost data was determined based on unit costs found in French insurance databases.

A Markov model was used to determine long term costs and clinical outcomes associated with the introduction of Oncotype DX to inform adjuvant chemotherapy decisions for ER+, N-, invasive breast cancer patients. The results showed that when compared to the conventional approach, using the Oncotype DX assay is estimated to decrease cost (- € 630 per patient avg.) as a result of patients who are spared unnecessary chemotherapy, and improve outcomes (0.13 life years gained per patient) when patients are reclassified as likely to benefit from chemotherapy following Recurrence Score® assessment. Another interesting finding was that the chemotherapy drug costs only comprised 1/3 of the total cost associated with chemotherapy treatment. The breakdown of costs was as follows:

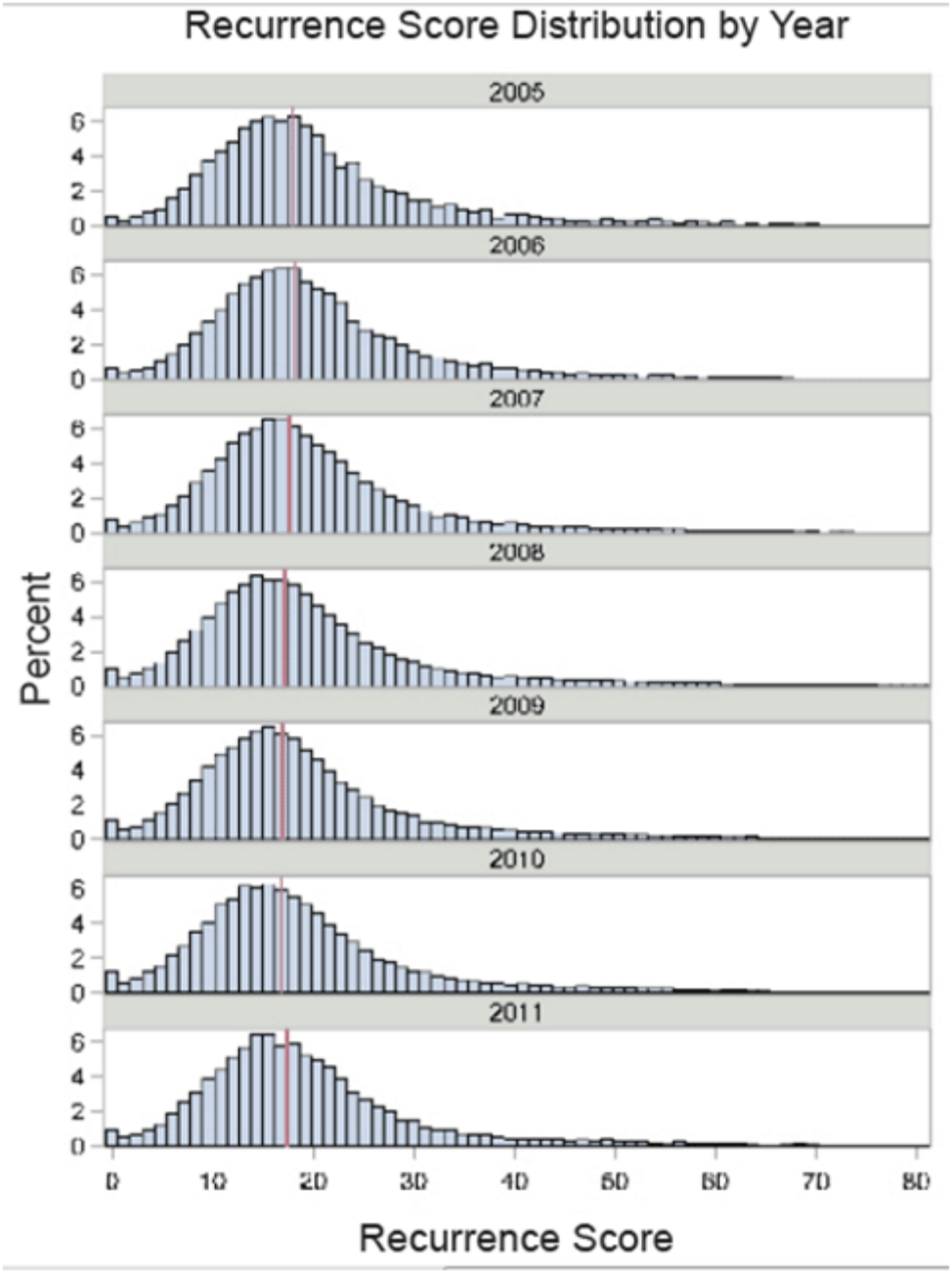
Figure 1- Distribution of costs, according to specific areas



The findings from France are consistent with studies from several other countries. In another study presented at SABCS which reviewed the published health economic studies on the Oncotype DX Breast Cancer Assay, Paolo Pronzato from Genoa, Italy reported that Oncotype DX was either cost savings or cost effective in studies from Australia, Canada, Hungary, Israel, Japan, Singapore and USA.

With over 200,000 assays performed, the Oncotype DX® Breast Cancer Assay is highly standardized

In a report from Genomic Health presented at SABCS of 207,691 invasive breast cancer cases assayed between January 2005 and March 2011, there were highly consistent distributions over time for the reference gene average and Recurrence Score® (RS) results. Additionally, quantitative single gene expression levels for ER, PR, and HER2 (reporting initiated in 2008) had highly consistent distributions and associations over time. The average and median RSs are 19.5 and 17, respectively.



Reference genes play an important role in normalizing the expression of the cancer-related genes. Normalization can compensate for sources of preanalytical variability such as delays to fixation, duration of fixation, different fixatives and sample age which can affect RNA quality.

The distribution of the average non-normalized level of expression for the five reference genes (which is related, in part, to the degree of RNA degradation in individual blocks) remained consistent over time, with non-systematic variation in the median value within approximately 0.5 units.

Strict quality control and quality assurance processes have resulted in consistent performance of the Oncotype DX Breast Cancer assay and consistent distributions over time for the Recurrence Score result, reference gene average, and quantitative single gene expression levels and their associations. All specimens, FFPE blocks, slides and tubes are bar-coded and tracked by our computer system from the moment they enter the GHI laboratory and they are tracked throughout the process all the way through to report generation. Also, routine monitoring of the ongoing performance of the Oncotype DX Breast Cancer assay shows that it continues to perform within the originally defined analytical parameters, which is critical for ensuring consistency with the studies that validated the Recurrence Score result as a predictor of breast cancer recurrence risk and anticipated hormone and chemotherapy benefit.

Spotlight on Oncotype DX Colon Cancer Assay Gene: Cell Cycle and Ki67

Cell Cycle Gene Group:

In contrast to the Oncotype DX Breast Cancer Assay, where higher expression of cell cycle genes (STK15, MYBL2, Ki-67 and CCNB1) is associated with increased risk of recurrence [1-2], higher expression of the colon cell cycle genes (cMYC and Ki-67 and MYBL2) is associated with a lower risk of recurrence [3-4]. This is consistent with other reported evidence that cell cycle gene expression correlates with a good prognosis in colon cancer [5-8]. Increased expression of these cell cycle genes in colon cancer may thus represent a different biological property than cell cycle gene expression in breast cancer, where it has been associated with proliferation. In colon cancer, increased expression of these genes may instead represent tightened control of various stages of the cell cycle in response to DNA damage or misalignment of chromosomes during mitosis. With tighter cell cycle control, a tumor could reduce the likelihood of chromosomal instability and aneuploidy [9], which are associated with poor outcome [10-13].

Ki-67 (MK167; Antigen identified by monoclonal antibody Ki-67)

The Ki-67 gene encodes a protein which is synthesized from late G1 through M phase of the cell cycle, and is localized to the nucleus. There are several reports where high expression of Ki-67 in colon cancer is correlated with a lower risk of recurrence [6-8]. Although the Ki-67 antigen is the classic IHC marker for cell proliferation, Garrity et al. reported only a weak correlation in colon cancer between Ki-67 levels and S-phase (the standard measure of proliferation) [6]. Consequently, in colon cancer, expression of this gene may not actually signify rapidly dividing tumors, but rather represent part of an important cell cycle control mechanism.

1. Paik S, Shak S, Tang G, Kim C, Baker J, Cronin M, Baehner FL, Walker MG, Watson D, Park T, Hiller W, Fisher ER, Wickerham DL, Bryant J, Wolmark N: A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer. N. Engl. J. Med 2004, 351:2817-2826.

2. Paik S, Tang G, Shak S, Kim C, Baker J, Kim W, Cronin M, Baehner FL, Watson D, Bryant J, Costantino JP, Geyer CE, Wickerham DL, Wolmark N: Gene expression and benefit of chemotherapy in women with node-negative, estrogen receptor-positive breast cancer. J. Clin. Oncol 2006, 24:3726-3734.

3. O'Connell M, Lavery I, Yothers G, Paik S, Clark-Langone KM, Lopatin M, Watson D, Baehner FL, Shak S, Baker J, Cowens J, Wolmark N: Relationship between tumor gene expression and recurrence in four independent studies of stage II/II colon cancer patients treated with surgery alone and surgery plus 5-FU/LV. J Clin Oncol 2010, 28:3937-3944.

4. Validation of a 12-gene colon cancer recurrence score (RS) in stage II colon cancer (CC) patients (pts) from CALGB 9581. A. P. Venook, D. Niedzwiecki, M. Lopatin, M. Lee, P. N. Friedman, W. Frankel, K. Clark-Langone, C. Yoshizawa, C. Millward, S. Shak, R. M. Goldberg, N. N. Mahmoud, R. L. Schilsky, M. M. Bertagnolli. American Society of Clinical Oncology (ASCO) Annual Meeting, Chicago IL, 2011: Abstract # 77737.

5. Anjomshoaa A, Lin Y, Black MA, McCall JL, Humar B, Song S, Fukuzawa R, Yoon H, Holzmann B, Friederichs J, van Rij A, Thompson-Fawcett M, Reeve AE: Reduced expression of a gene proliferation signature is associated with enhanced malignancy in colon cancer. Br. J. Caner 2008, 99:966-973.

6. Garrity MM, Burgart LJ, Mahoney MR, Windschitl HE, Salim M, Wiesenfeld M, Krook JE, Michalak JC, Goldberg RM, O'Connell MJ, Furth AF, Sargent DJ, Murphy LM, Hill E, Riehle DL, Meyers CH, Witzig TE: Prognostic value of proliferation, apoptosis, defective DNA mismatch repair, and p53 overexpression in patients with resected Dukes' B2 or C colon cancer: a North Central Cancer Treatment Group Study. J. Clin. Oncol 2004, 22:1572-1582.

7. Salminen E, Palmu S, Vahlberg T, Roberts P, Söderström K: Increased proliferation activity measured by immunoreactive Ki67 is associated with survival improvement in rectal/recto sigmoid cancer. World J. Gastroenterol 2005, 11:3245-3249.

8. Allegra CJ, Paik S, Colangelo LH, Parr AL, Kirsch I, Kim G, Klein P, Johnston PG, Wolmark N, Wieand HS: Prognostic value of thymidylate synthase, Ki-67, and p53 in patients with Dukes' B and C colon cancer: a National Cancer Institute-National Surgical Adjuvant Breast and Bowel Project collaborative study. J. Clin. Oncol 2003, 21:241-250 .

9. Kops GJPL, Weaver BAA, Cleveland DW: On the road to cancer: aneuploidy and the mitotic checkpoint. Nat.Rev. Cancer 2005, 5:773-785.

10. Jen J, Kim H, Piantadosi S, Liu ZF, Levitt RC, Sistonen P, Kinzler KW, Vogelstein B, Hamilton SR: Allelic loss of chromosome 18q and prognosis in colorectal cancer. N. Engl. J. Med 1994, 331:213-221.

11. Choi S, Lee KJ, Bae Y, Min K, Kwon M, Kim K, Rhyu M: Genetic classification of colorectal cancer based on chromosomal loss and microsatellite instability predicts survival. Clin. Cancer Res 2002, 8:2311-2322.

12. Chang S, Lin J, Lin T, Liang W: Loss of heterozygosity: an independent prognostic factor of colorectal cancer. World J. Gastroenterol 2005, 11:778-784.

13. Sinicrope FA, Rego RL, Halling KC, Foster N, Sargent DJ, La Plant B, French AJ, Laurie JA, Goldberg RM, Thibodeau SN, Witzig TE: Prognostic impact of microsatellite instability and DNA ploidy in human colon carcinoma patients. Gastroenterology 2006, 131:729-737.

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

PATIENT A
61-year-old patient with 0.6-cm and 0.9-cm tumors

Menopausal Status: Postmenopausal
Tumor Type: Infiltrating Ductal Carcinoma (IDC), Ductal Carcinoma in Situ (DCIS)
Tumor Size: 0.6 cm, 0.9 cm
ER Status (IHC): Positive (95%)
PR Status (IHC): Positive (95%)
HER2/neu Status: Negative (FISH)
Histologic Grade: 2
Lymph Node Status: Negative (0/2 SLNs)
General Health: Excellent

CASE SUBMITTED BY:
G. Thomas Budd, MD

PATIENT B
62-year-old patient with 0.6-cm tumor*

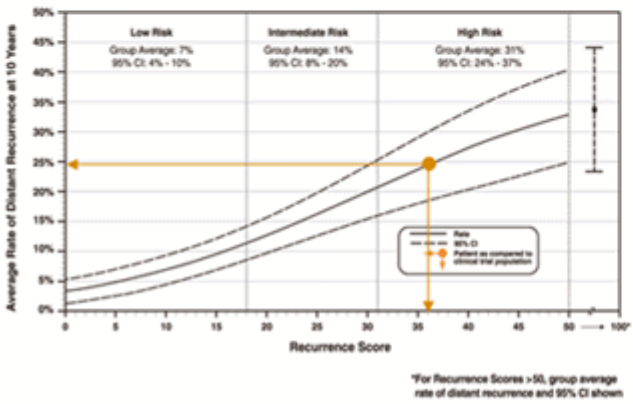
Menopausal Status: Postmenopausal
Tumor Type: Infiltrating Ductal Carcinoma (IDC)

Tumor Size: 0.6 cm
ER Status (IHC): Positive (strong)
PR Status (IHC): Positive (strong)
HER2/neu Status: Negative (IHC)
Histologic Grade: 2
Lymph Node Status: Negative (0/2 SLNs)
General Health: Bipolar, irritable bowel syndrome, hypertension, gastroesophageal reflux disease, hypothyroidism, asthma, cholecystectomy
Other Information: *Additional 1.2-cm and 1.3-cm tumors found on re-excision

CASE SUBMITTED BY:
Terry P. Mamounas, MD, MPH

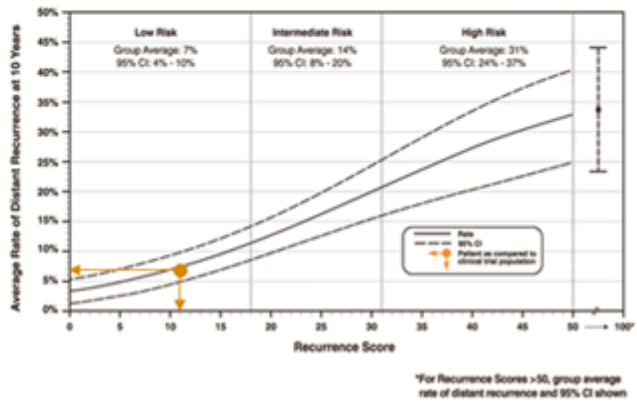
PATIENT A RESULTS
Clinical Experience

Patients with a Recurrence Score of **36** in the clinical validation study had an Average Rate of Distant Recurrence at 10 years of **25% (95% CI: 19%-30%)**.



PATIENT B RESULTS
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%)**.

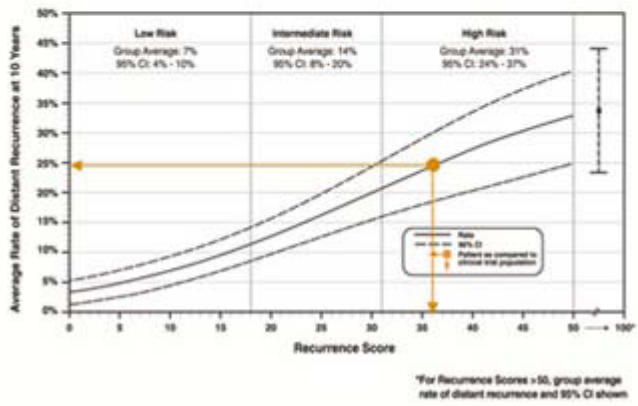


61 year old patient with 0.6-cm and 0.9-cm tumors:

PATIENT A RESULTS

Clinical Experience

Patients with a Recurrence Score of **36** in the clinical validation study had an Average Rate of Distant Recurrence at 10 years of **25% (95% CI: 19%-30%)**.

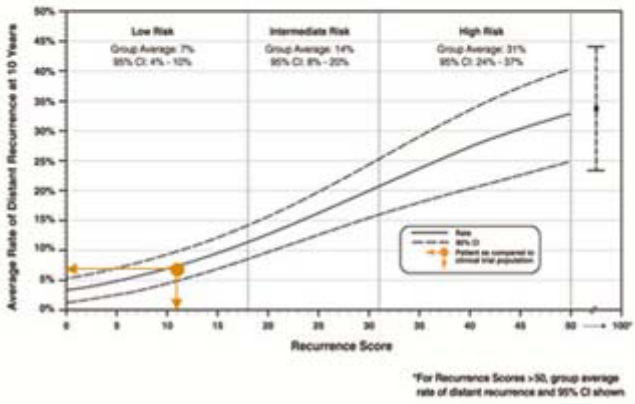


62 year old with 0.6 cm tumor*:

PATIENT B RESULTS

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%)**



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

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Recent Publications

Recently published Oncotype DX related articles:

1 Joh JE, Esposito NN, Kiluk JV, Laronga C, Lee MC, Loftus L, Soliman H, Boughey JC, Reynolds C, Lawton TJ, Acs PI, Gordan L, Acs G. The Effect of Oncotype DX Recurrence Score on Treatment Recommendations for Patients with Estrogen Receptor-Positive Early Stage Breast Cancer and Correlation with Estimation of Recurrence Risk by Breast Cancer Specialists. Oncologist. 2011;16(11):1520-6. Epub 2011 Oct 20. PubMed PMID: 22016474.

2 Kamal AH, Loprinzi CL, Reynolds C, Dueck AC, Geiger XJ, Ingle JN, Carlson RW, Hobday TJ, Winer EP, Goetz MP. Breast medical oncologists' use of standard prognostic factors to predict a 21-gene recurrence score. Oncologist. 2011;16(10):1359-66. Epub 2011 Sep 20. PubMed PMID: 21934103.

3 Sparano JA, Goldstein LJ, Childs BH, Shak S, Brassard D, Badve S, Baehner FL, Bugarini R, Rowley S, Perez EA, Shulman LN, Martino S, Davidson NE, Kenny PA, Sledge GW Jr, Gray R. Relationship between quantitative GRB7 RNA expression and recurrence after adjuvant anthracycline chemotherapy in triple-negative breast cancer. Clin Cancer Res. 2011 Nov 15;17(22):7194-203. Epub 2011 Sep 20. PubMed PMID: 21933890.

4 Gray RG, Quirke P, Handley K, Lopatin M, Magill L, Baehner FL, Beaumont C, Clark-Langone KM, Yoshizawa CN, Lee M, Watson D, Shak S, Kerr DJ. Validation Study of a Quantitative Multigene Reverse Transcriptase-Polymerase Chain Reaction Assay for Assessment of Recurrence Risk in Patients With Stage II Colon Cancer. J Clin Oncol. 2011 Dec 10;29(35):4611-9. Epub 2011 Nov 7. PubMed PMID: 22067390.

5 Geffen DB, Abu-Ghanem S, Sion-Vardy N, Braunstein R, Tokar M, Ariad S, Delgado B, Bayme M, Koretz M. The impact of the 21-gene recurrence score assay on decision making about adjuvant chemotherapy in early-stage estrogen-receptor-positive breast cancer in an oncology practice with a unified treatment policy. Ann Oncol. 2011 Nov;22(11):2381-6. Epub 2011 Mar 1. PubMed PMID: 21363879.

6 Partin JF, Mamounas EP. Impact of the 21-gene recurrence score assay compared with standard clinicopathologic guidelines in adjuvant therapy selection for node-negative, estrogen receptor-positive breast cancer. Ann Surg Oncol. 2011 Nov;18(12):3399-406. Epub 2011 May 3. PubMed PMID: 21537874.

7 Paik S. Is gene array testing to be considered routine now? Breast. 2011 Oct;20 Suppl 3:S87-91. PubMed PMID: 22015300.

8 Kim C, Tang G, Pogue-Geile KL, Costantino JP, Baehner FL, Baker J, Cronin MT, Watson D, Shak S, Bohn OL, Fumagalli D, Taniyama Y, Lee A, Reilly ML, Vogel VG, McCaskill-Stevens W, Ford LG, Geyer CE Jr, Wickerham DL, Wolmark N, Paik S. Estrogen receptor (ESR1) mRNA expression and benefit from tamoxifen in the treatment and prevention of estrogen receptor-positive breast cancer. J Clin Oncol. 2011 Nov 1;29(31):4160-7. Epub 2011 Sep 26. PubMed PMID: 21947828; PubMed Central PMCID: PMC3208536.

9 Tang G, Cuzick J, Costantino JP, Dowsett M, Forbes JF, Crager M, Mamounas EP, Shak S, Wolmark N. Risk of recurrence and chemotherapy benefit for patients with node-negative, estrogen receptor-positive breast cancer: recurrence score alone and integrated with pathologic and clinical factors. J Clin Oncol. 2011 Nov 20;29(33):4365-72. Epub 2011 Oct 17. PubMed PMID: 22010013; PubMed Central PMCID: PMC3221521.

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Upcoming Events and Online Resources

European School of Oncology – e-oncoreview
Expert: William Wood, Emory University Hospital, Atlanta, GA, USA
Discussant: Nigel Bundred, University Hospital of South Manchester, Manchester, United Kingdom

Now with the introduction of a genomic assay for DCIS, we should consider how this assay will be integrated with existing risk assessment tools for DCIS and ultimately treatment decisions. This session will review the existing markers used for DCIS and how the added information from a genomic classifier predicting the individual risk of local recurrence may be relevant for treatment decisions.

This archived session can be accessed at: http://www.e-eso.net/egrandround.do?methodcall=details&id=234

E-cancer.TV
A test to predict risk of recurrence in DCIS

Prof. Joseph Sparano,Albert Einstein Cancer Center, New York, USA, discusses a study validating a multigene test to predict risk of recurrence in breast cancer patients with ductal carcinoma in situ (DCIS).

This validation study was a collaboration between the Eastern Cooperative Oncology Group (ECOG), North Central Cancer Treatment Group and Genomic Health. It analysed tumour samples from E5194, an ECOG-led, multi-institutional study of patients with low-, intermediate- or high-grade DCIS who had been treated surgically but had not received radio-therapy.

The study demonstrated that the test could predict the ten year risk of recurrence for both DCIS and invasive cancer

This is the first time a multigene test has been has demonstrated an additional value beyond currently used prognostic markers in DCIS.

In this interview with Professor David Miles, a leading breast cancer expert from London, the role of Oncotype DX® in the management of invasive breast cancer was discussed.

Oncotype DX offers a novel and complimentary diagnostic test for women with node negative, ER positive and HER 2-, invasive breast cancer. It scores the breast tumour on 21 different genes involved in breast cancer, giving a Recurrence

Score® (between 0 and 100), which shows the likelihood of breast cancer returning within 10 years of the original diagnosis. Early findings from prospective- retrospective trials indicate that a low Recurrence Score may determine which patients do not need chemotherapy. It is not meant to replace current diagnostic tools but to work in partnership with the likes of for instance Adjuvant on-line, to provide both the oncologist and patient a more complete picture of their disease and how best to treat it.

This programme was supported by sponsorship from Genomic Health.

A new test to determine risk of recurrence in DCIS breast cancer

Dr. Larry Solin,Albert Einstein Medical Center, Philadelphia, USA, talks to ecancer.tv about the development of a multi gene test to predict risk of recurrence in breast cancer patients with ductal carcinoma in situ (DCIS).

This validation study was a collaboration between the Eastern Cooperative Oncology Group (ECOG), North Central Cancer Treatment Group and Genomic Health. It analysed tumour samples from E5194, an ECOG-led, multi-institutional study of patients with low-, intermediate- or high-grade DCIS who had been treated surgically but had not received radiation.

DCIS is an increasingly common non-invasive tumour. Dr Solin explains the significance of these findings, and outlines how they will help guide patients when deciding between surgery or a combination of surgery and radiotherapy. This is the first time a multigene test has been used to differentiate patients risk of recurrence after being diagnosed with DCIS and providing added value beyond traditional markers.

Medscape
Breast Cancer

Must All DCIS Patients Undergo Radiation?
Medscape Hematology-Oncology 2012

Slide Kits Available for download

Colon Cancer Core Slide Module

Breast Cancer Core Slide Module

Single Gene Slide Module

Ordering Oncotype DX Brochure #1

Announcements

Genomic Tools in Breast Cancer

Leading the Way towards Personalized Treatment will be a featured official satellite during this year's EBCC meeting in Vienna. The program will held on Wednesday 21st of March 2012 from 18:45-20:15 at Vienna Exhibition Center, Hall F1.

MMR testing now offered to qualify patients for Onco*type* DX® Colon Cancer Assay

The Onco*type* DX Colon Cancer Assay and MMR can now be ordered at the same time in a convenient one-step process by selecting the Sequential Assay option on the Onco*type* DX requisition form. We are pleased to announce the expansion of Genomic Health's colon cancer laboratory services to include immunohistochemistry (IHC) testing to assess mismatch repair (MMR) status for stage II colon cancer recurrence risk. MMR testing also enables the identification of the patients with T3 MMR-Proficient (MMR-P) tumors, standard risk patients constituting the majority (~70%) of stage II colon cancer in whom the Recurrence Score® provides valuable recurrence risk discrimination not available with conventional clinical and pathologic factors. Results from the recently published QUASAR validation study strongly support a paradigm in which the Onco*type* DX Colon Cancer Recurrence Score, MMR status, and T stage are used to determine recurrence risk for individual patients with stage II colon cancer. The QUASAR study results, which are highly consistent with several other published studies, demonstrate that MMR testing is clinically useful for identifying the ~15% of stage II patients with MMR-Deficient (MMR-D) tumor biology who have low recurrence risk.

Step-by-Step Guide for Getting Onco*type* DX assays available in English, German, French, and Italian

Genomic Health has developed a new brochure to assist you and your office staff in ordering Onco*type* DX tests
English | French | German | Italian