



FORMACIÓN
MÉDICA
CONTINUADA

PROGRAMA DE FORMACIÓN MULTIDISCIPLINAR EN CÁNCER DE MAMA

GEICAM



CASO CLINICO

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Madrid



- Mujer postmenopásica de 56 años de edad, con masa en CSE de mama derecha que se diagnostica ella misma por palpación. Terapia hormonal substitutiva con dos fármacos por síntomas menopáusicos y osteoporosis durante los últimos 5 años.
- Exploratoriamente, existía una zona empastada de unos 3 cm de diámetro en CSE de mama derecha, sin afectación de la piel ni fijación a tejidos profundos. No se palpaban adenomegalias axilares ni supraclaviculares. No se palpaban organomegalias abdominales. La piel y la mama contralaterales eran normales.
- Una mamografía bilateral fue informada como BI RADS 3 derecha, pero una RMN demostró lesión muy sospechosa de comportamiento maligno, unifocal, de límites mal definidos, en CSE de mama derecha, sin aparente afectación axilar

-Una biopsia con aguja gruesa permitió obtener cilindros cuyo informe histopatológico fue:

-CARCINOMA INFILTRANTE que infiltra todos los cilindros estudiados.

- Los receptores de estrógenos eran del 80% y los de progesterona de 60%.

-El Herceptest fue de una cruz (negativo)

- Se realizó biopsia del ganglio centinela, que no demostró afectación en el estudio intraoperatorio, así como mastectomía radical modificada con reconstrucción inmediata

- El estudio anatomopatológico final fue:
 - carcinoma lobulillar clásico de 2 cms de diámetro, que respeta ampliamente los bordes de la tumorectomía
 - receptores de estrógenos 80%
 - receptores de progestágenos de 50%
 - her2 negativo (1+); CI SH negativo
 - Ki67 de 18%
 - no afectación de los 3 ganglios centinelas aislados tras estudio I HQ y PCR

- Un PET corporal fue normal (estadio T1 N0 M0)



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PATIENT REPORT

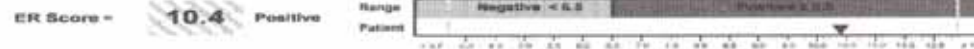
Patient: Dominguez-Macaya, Carmen
Sex: Female
DOB: 03/15/1948

Regulation: RH3NL4
Order Received: 10/06/2009
Date Reported: 10/23/2009

QUANTITATIVE SINGLE GENE REPORT

The Oncotype DX assay uses RT-PCR to determine the RNA expression of the genes below. These results may differ from ER, PR, or HER2 results reported using other methods or reported by other laboratories.*

The ER, PR, and HER2 Scores are also included in the calculation of the Recurrence Score.

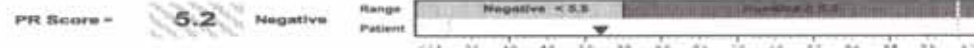


The ER Score positive/negative cut-off of 6.5 units was validated from a study of 761 samples using the 1D5 antibody (immunohistochemistry) and 607 samples using the SP1 antibody (immunohistochemistry). The standard deviation for the ER Score is less than 0.5 units.*

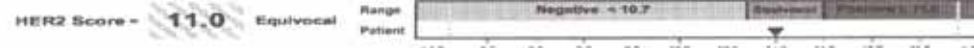
Clinical Experience:

For ER positive breast cancer, the magnitude of tamoxifen benefit increases as the ER Score increases from 6.5 to ≥ 12.5 †.

Please note: The Average Rate of Distant Recurrence reported on Page 1 based on the Recurrence Score was determined in patients who received 5 years of tamoxifen treatment and takes into account the magnitude of tamoxifen benefit indicated by the ER Score.



The PR Score positive/negative cut-off of 5.5 units was validated from a study of 761 samples using the PR636 antibody (immunohistochemistry) and another study of 607 samples using the PR636 antibody (immunohistochemistry). The standard deviation for the PR Score is less than 0.5 units.*



The HER2 positive cut-off of ≥ 11.5 units, equivocal range from 10.7 to 11.4 units, and negative cut-off of ≤ 10.7 units were validated from concordance studies of 755 samples using the HercepTest™ assay (immunohistochemistry) and another study of 558 samples using the PathVysion™ assay (FISH). The standard deviation for the HER2 score is less than 0.5 units.*

References:

- ER Score based on quantitative ESR1 expression (estrogen receptor); PR Score based on quantitative PGR expression (progesterone receptor); HER2 Score based on quantitative ERBB2 expression.
- ASCO Breast Cancer Symposium 2007 Abstracts #87 by E.S. Barlow et al., and #82 by F.L. Baehner et al.
- ASCO Annual Meeting 2008 Abstract #510 by S. Paik et al.
- ASCO Breast Cancer Symposium 2008 Abstracts #13 by F.L. Baehner et al., and #41 by F.L. Baehner et al.

Laboratory Director: Patrick Joseph, MD

CLIA Number 05D1018272

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

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¿Qué terapia adyuvante recomendaría Vd a la paciente?

PROGRAMA DE FORMACIÓN MULTIDISCIPLINAR EN CÁNCER DE MAMA

1. Tratamiento hormonal aislado
2. Quimioterapia con antraciclinas x 4 ciclos
3. Quimioterapia con antraciclinas x 4 ciclos → TH por 5 años
4. Quimioterapia con antraciclinas x 6 ciclos
5. Quimioterapia con antraciclinas x 6 ciclos → TH por 5 años
6. Quimioterapia con taxanos
7. Quimioterapia con taxanos → TH por 5 años



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PATIENT REPORT

Patient: [REDACTED]
Sex: Female
DOB: 03/15/1948
Medical Record/Patient #:
Date of Surgery: 09/15/2009
Specimen ID/Block ID: 09-19401

Requisition: R0H3NL4
Order Received: 10/06/2009
Date Reported: 10/23/2009

ASSAY DESCRIPTION

Oncotype DX[®] Breast Cancer Assay uses RT-PCR to determine the expression of a panel of 21 genes in tumor tissue. The Recurrence Score[®] is calculated from the gene expression results. The Recurrence Score range is from 0-100.

RESULTS

Recurrence Score = **27**

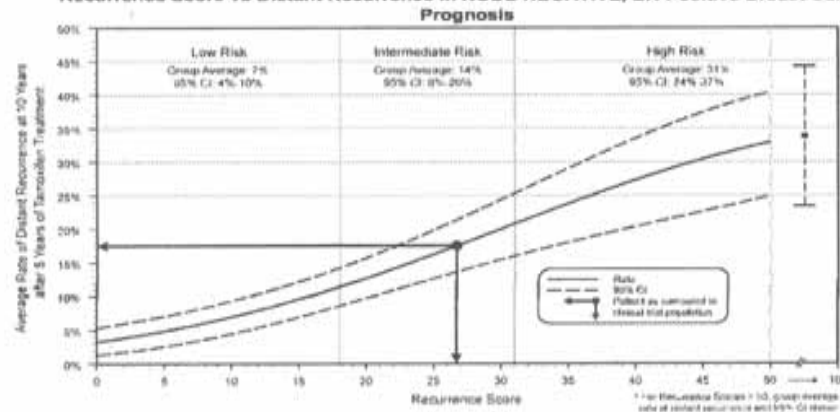
Test Results should be interpreted using the Clinical Experience information contained in this report which is derived from clinical studies involving patient populations with specific clinical features as noted in each section of the Clinical Experience. It is unknown whether the findings summarized in the Clinical Experience are applicable to patients with features different from those described.

CLINICAL EXPERIENCE: PROGNOSIS FOR NODE NEGATIVE, ER-POSITIVE PATIENTS

The Clinical Validation study included female patients with Stage I or II, Node Negative, ER-Positive breast cancer treated with 5 years of tamoxifen. Those patients who had a Recurrence Score of 27 had an Average Rate of Distant Recurrence of **18%** (95% CI: 14%-21%).

The following results are from a clinical validation study of 658 patients from the NSABP B-14 study. *N Engl J Med* 2004; 351: 2817-26.

Recurrence Score vs Distant Recurrence in NODE NEGATIVE, ER-POSITIVE Breast Cancer



Node Negative

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PATIENT REPORT

Patient: [REDACTED] **Requisition:** RDHCNL4
Sex: Female **Order Received:** 10/06/2009
DOB: 03/15/1948 **Date Reported:** 10/23/2009

RESULTS

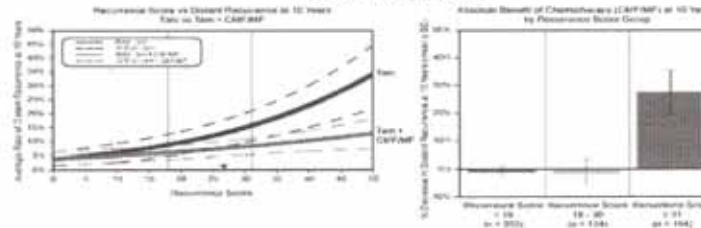
Recurrence Score = 27

Test Results should be interpreted using the Clinical Experience information contained in this report which is derived from clinical studies involving patient populations with specific clinical features as noted in each section of the Clinical Experience. It is unknown whether the findings summarized in the Clinical Experience are applicable to patients with features different from those described.

CLINICAL EXPERIENCE: CHEMOTHERAPY BENEFIT FOR NODE NEGATIVE, ER-POSITIVE PATIENTS

The following results are from a clinical study involving 651 patients from the NSABP B-20 Study. The study included female patients with Stage I or II, Node Negative, ER-Positive breast cancer. Patients were randomized to either tamoxifen alone or tamoxifen plus CMF or MF chemotherapy. For patients in the pre-specified group with Recurrence Scores ≥ 31 , the group average 10-year rates (95% CI) of distant recurrence were 40% (29%, 54%) for Tam alone and 12% (6%, 18%) for Tam + CMF/MF. *J Clin Oncol* 2006; 24(23): 3726-34.

**Node Negative, ER-Positive Breast Cancer
Chemotherapy Benefit**



Node Negative

Laboratory Director: Patrick Joseph, MD

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ONCOTYPE

Quimioterapia adyuvante con docetaxel y ciclofosfamida
x 4 ciclos

Letrozol por 3 años → tamoxifeno x 2 años

Acido Zoledrónico 4 mg IV al año