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Cuadros Celorrio, Marta
HER2 en la selección de candidatas a tratamiento con Trastuzumab. Determinación del estado de HER2 en mujeres con cáncer de mama./ Marta Cuadros Celorrio y Román Villegas Portero. - Sevilla: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía; Madrid: Ministerio de Sanidad y Consumo, 2008.
98 p.; 24 cm.
I. Villegas Portero, R  II. Andalucía. Agencia de Evaluación de Tecnologías Sanitarias III. España. Ministerio de Sanidad y Consumo

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Este documento se ha realizado en el marco de colaboración previsto en el Plan de Calidad para el Sistema Nacional de Salud, al amparo del convenio de colaboración suscrito por el Instituto de Salud Carlos III, organismo autónomo del Ministerio de Sanidad y Consumo, y la Fundación Progreso y Salud de Andalucía

Edita: Agencia de Evaluación de Tecnologías Sanitarias de Andalucía
Avda. de la Innovación s/n
Edificio Renta Sevilla, 2ª planta
41020 Sevilla
España – Spain
© de la presente edición: Ministerio de Sanidad y Consumo.
© de los contenidos: Consejería de Salud – JUNTA DE ANDALUCÍA
ISBN: 978-84-96990-02-9
NIPO:354-07-044-9
Depósito Legal: SE-2903/08
Imprime: Tecnographic, S.L.

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Breast cancer is a very important public health problem, because of as its high incidence as the mortality it causes; and it gives rise to more than 16,000 cases a year in Spain.

Between 20 percent and 30 percent of breast cancers are characterized by amplification of HER2 gene, playing an important role in its pathogenesis and biologic aggressiveness. Hence HER2 status detection forms part in the general anatomical, pathological diagnosis of breast cancer.

The importance of determining HER2 status lays on the fact that breast cancer patients with HER2 amplification are more reluctant to conventional chemotherapy and hormonal treatments and they account for lower survival rate. Thus the HER2 analysis is an essential requisite to determine which patients are eligible to be treated with trastuzumab. Nonetheless, there has not been reached a consensus on the most appropriate method to use, although the most employed techniques are: Immunohistochemistry (IHC) and Fluorescence In Situ Hybridization (FISH) techniques.

The aim of this systematic review is determining the effectiveness (analytical validity, and clinical validity), clinical utility and cost of HER2 diagnostic tests (IHC vs. FISH) to correctly select breast cancer patients who are candidates to be treated with trastuzumab, for the Health National System to assess it. In order to deal with this general objective, we divided its paper into two sections that respond, specifically, to:

1. Diagnostic tests assessment commonly used to detect HER2 status, IHC vs. FISH, and selecting patients subject to be treated with trastuzumab.
2. Cost-effectiveness analysis of diagnostic regimens in breast cancer patients according to HER2 status by means of:
   2.2. Estimating incremental cost-effectiveness ratio of different diagnostic strategies addressing HER2 for trastuzumab treatment assignation with respect to base case.
   2.3. Results’ soundness analysis taken from sensitivity analysis on the model’s main parameters.
   2.4. Estimating costs related to wrong diagnosis of HER2 overexpression.
The cost-effectiveness ratio of different diagnostic strategies is 6,495.04€/QALY in the case of diagnostic alone through IHC, 6,545.36€/QALY when FISH is realised alone, and 6,667.38€/QALY and 6,868.13€/QALY in the combined strategies, confirming through IHC+2 or IHC+3, respectively.

The strategy to follow IHC alone dominates the combined strategies FISH, confirmatory for IHC+2 or IHC+2/3. The strategy to follow FISH alone is not dominated by IHC, costing more but it is also more effective that the former and entailing 11,641.20€ per additional QALY. However, taking into account that the costs lost due to wrong diagnosis caused by low sensitivity and specificity of IHC, there results in an incremental cost of IHC of 5,995.08€ with respects to FISH. Consequently, Fish results as the dominant strategy over the rest of alternatives.

The recommendations on determining the state of HER2 will help guarantee that physicians and their patients have at their disposal more accurate information when choosing the best treatment for breast cancer. We recommend the following intervention tree:

- Screening of HER2 in every breast-related case with IHC, employing diagnostic tests passed by FDA and/or EC or highly standardised and validated immunohistochemical protocols.