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Evaluation of HER-2/neu gene amplification by fluorescence in situ hybridization and immunohistochemistry in saudi female breast cancer.

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Source

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Abstract

BACKGROUND:

Amplification of the HER-2/neu oncogene and concomitant over-expression of its protein are detected in approximately 18% of invasive ductal carcinoma of the breast and is associated with poor prognosis. This study tested the use of fluorescence in situ hybridization (FISH) and immunohistochemistry (IHC) to evaluate the HER-2/neu **gene** status and to ascertain the concordance rate between the two methods.

PATIENTS AND METHODS:

Eighty two tumour samples containing representative tumour were divided for testing using each assay. HER-2/neu **gene amplification** is scored as a ratio of HER-2/neu **gene amplification** to chromosome 17. The ratio should be >2.2 to be considered as positive. 20 cells should be counted and an average score taken. An extra 20 cells should be counted if the ratio is between 1.8-2.2.

RESULTS:

Seventy five effective samples were used. HER-2/neu **gene** was amplified in 19 out of 75 cases (25%) whereas, HER-2 protein, by IHC was over-expressed in 18 out of 75 cases (24%). In the 44 negative cases by IHC analysis only 7 cases (16%) of them showed **amplification** by FISH. Three out of 13 cases (23 %) scored as +2 showed **gene amplification** by FISH while 9 cases out of 18 cases (50%) were scored as +3. High concordance with FISH results 37:44 (84 %) was noted in negative cases (0/+1 cases), while lower concordance 3:13 (23 %) was seen in +2 cases.

CONCLUSION:

This study revealed a significant concordance between FISH results and IHC results. The study also showed that HER2/neu **amplification** is higher in Saudi patients than other western populations. However, due to the inherent failures of the IHC assay, FISH should always be used when the IHC results are inconclusive. The rational algorithm for HER-2/neu testing would be to perform IHC first, followed by FISH to validate equivocal IHC results