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乳腺癌是全球女性最常见的恶性肿瘤,占全年新增病例数的 11.7%。人表皮生长因子受体 2 (human epidermal growth factor receptor 2, HER-2) 是影响乳腺癌患者预后的主要标志物之一。抗 HER-2 靶向药物已被证明可以显著改善 HER-2 阳性乳腺癌患者的生存和预后,而 HER-2 阴性患者却缺乏有效靶向药物。近期的临床试验表明,HER-2 阴性患者中的低表达状态人群可获益于新的靶向药物,且 HER-2 低表达乳腺癌具有独特的生物学行为和临床特征,这表明沿用原有的阴、阳二分类来区分 HER-2 状态不足以满足临床诊治需求,对 HER-2 零、低及过表达状态进一步细分具有重要意义。

目前临床上 HER-2 状态检测使用免疫组化和荧光原位杂交,但组织病理结果需要通过侵入性手术或空芯针活检取材,且对肿瘤整体的评估有限,需要一种无创、整体的手段对乳腺癌 HER-2 状态进行鉴别。

MRI 技术具有良好的软组织分辨率,被认为是评估乳腺癌最准确的手段。T1WI、T2WI 和动态对比增强是乳腺 MRI 检查的常规序列,在乳腺癌鉴别诊断中起到重要作用。

本研究分析了乳腺癌患者治疗前 MRI 图像,根据免疫组化和荧光原位杂交结果将 HER-2 状态分为阴性(零、低表达)和阳性(过表达)。首先对各组的临床病理特征及 MRI 特征进行单因素分析。通过独立样本 *t* 检验、Mann-Whitney *U* 检验及 χ^2 检验分析 HER-2 阴、阳性组间差异;通过单因素方差分析、Kruskal-Wallis *H* 检验及 χ^2 检验分析 HER-2 零、低和过表达组间差异。然后选择单因素分析结果中 $P < 0.1$ 的因素进行 logistic 回归分析,得到与 HER-2 低表达相关的独立预测因素,构建预测 HER-2 低表达的临床-影像联合模型。结果显示,MRI 影像特征对乳腺癌 HER-2 表达状态具有鉴别诊断价值,联合临床病理特征(PR 阳性、Ki-67 低于 40%、肿块形状不规则和瘤内 T2WI 高信号)可提示 HER-2 低表达乳腺癌,有助于临床医师对 HER-2 低表达患者制订合理的治疗方案,实现精准诊疗。详见内文第 6 页。

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About the cover

Breast cancer is the most common malignant tumor among women worldwide, accounting for 11.7% of new cases in the year. Human epidermal growth factor receptor 2 (HER-2) is one of the major markers affecting the prognosis of breast cancer patients. Anti-HER-2 targeted drugs have been shown to significantly improve the survival and prognosis of HER-2-positive breast cancer patients, whereas HER-2-negative patients lack effective targeted drugs. Recent clinical trials have shown that HER-2-negative patients with HER-2 low-expression status can benefit from new targeted drugs, and that HER-2-low breast cancer has unique biological behavior and clinical characteristics, which suggests that differentiating HER-2 status along the conventional negative and positive classification is not sufficient to meet the needs of clinical diagnosis and treatment, and that it is of great significance to further subdivide the HER-2 zero, low, and overexpression status.

Currently, immunohistochemistry and fluorescence in situ hybridization are used for HER-2 detection in clinical practice, but the histopathological results need to be obtained through invasive surgery or core needle biopsy, and have limited assessment of the overall tumor, so there is a need for a non-invasive and holistic means of distinguishing the HER-2 status of breast cancer.

MRI technology has good soft tissue resolution and is considered the most accurate means of evaluating breast cancer. T1WI, T2WI and dynamic contrast enhancement are routine sequences in breast MRI examinations and play an important role in the differential diagnosis of breast cancer.

In this study, pre-treatment MRI images of breast cancer patients were analyzed, and HER-2 status was categorized into negative (including HER-2-zero and HER-2-low) and positive (HER-2-overexpression) based on immunohistochemistry and fluorescence in situ hybridization results. Firstly, univariate analysis of clinicopathologic features and MRI features were performed in each group. Differences between HER-2 negative and positive groups were analyzed by independent samples *t*-test, Mann-Whitney *U* test and χ^2 test; differences between HER-2 zero, low and overexpression groups were analyzed by one-way ANOVA, Kruskal-Wallis *H* test and χ^2 test. Then the factors with $P < 0.1$ in the results were selected for logistic regression analysis to obtain the independent predictors associated with HER-2 low expression, and a clinical-MRI model for predicting HER-2 low expression was constructed. The results showed that MRI imaging features had differential diagnostic value for HER-2 expression status in breast cancer. Combining clinicopathologic features and MRI features (PR positivity, Ki-67 lower than 40%, irregular mass shape, and intratumoral T2WI hyperintensity) can indicate HER-2 low-expression breast cancer, which can help clinicians formulate a reasonable treatment plan for HER-2-inexpression patients to realize precise diagnosis and treatment. Please see page 6.

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