Human kallikrein 5 as a novel prognostic biomarker for triple-negative breast cancer: tissue expression analysis and relationship with disease course

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ABSTRACT. The purposes of this study were to analyze the expression and distribution of human kallikrein 5 (hK5) in triple-negative breast cancer (TNBC) tissues, to establish a standard operating procedure (SOP) for its immunohistochemical assay, and to evaluate the possibility of hK5 being a prognostic biomarker for TNBC. Recombinant hK5 protein and specific antibody were prepared, and the expression and distribution of hK5 in TNBC tissues were detected using immunohistochemistry. An SOP for immunohistochemical staining of hK5 in TNBC tissues was established to allow automatic staining under optimized conditions. The resulting images were digitized for evaluation and statistical analysis via a human scoring system. Our results showed that expression of hK5 protein could predict the progression of TNBC. Pearson’s chi-square test results showed that high hK5 expression in
tumor stromal cells was significantly correlated with distal metastasis (P = 0.039). A high staining score for lymphocyte infiltration in tumor stroma was significantly correlated with low histological grade of tumor (P = 0.025). Univariate and multivariate Cox regression analyses verified that the staining score for hK5 in tumor stromal cells may be a biomarker for poor prognosis in TNBC patients (univariate HR = 2.289, 95%CI = 1.362-3.848, P = 0.002; multivariate HR = 2.105, 95%CI = 1.189-3.727, P = 0.011). In conclusion, the expression level of hK5 in tumor stromal cells is a promising biomarker for poor prognosis in TNBC. Patients with high histological grade are more prone to distal metastasis and aggressive tumor progression.

**Key words:** Human kallikrein 5; Triple-negative breast cancer; Prognosis; Biomarker