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Utility of the 40 gene expression profile (40-GEP) test in refining risk of metastasis in high-risk cutaneous squamous cell carcinoma (HR-cSCC) patients stratified through a clinicopathological prognostic nomogram.

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Introduction & Objectives: Risk stratification for cutaneous squamous cell carcinoma (cSCC) is challenging due to tumor heterogeneity associated with poor outcomes. Several tools exist, including clinical staging systems and 40-GEP testing. The purpose of this study is to evaluate the performance of a cSCC nomogram published by Rentroia-Pacheco, et al1 and test the additional prognostic value of the 40-GEP.

Materials & Methods: Castle Biosciences retrospective cSCC cohort (n=760) of high (64.9%[493/760]) or very-high risk (35.1%[267/760]) NCCN tumors were categorized into 2 groups (low-risk group, LRG=0-20%, n=737; high-risk group, HRG=≥21%, n=23) by the nomogram, and compared to the results of 40-GEP testing. Kaplan-Meier (KM) curves were generated to determine 3-year metastasis-free survival (MFS).

Results: Overall MFS was 89.2% (95%CI:87.0-91.4%). Nomogram risk bins showed MFS rates of 90.2% (95%CI:88.1-92.4%) in the LRG and 56.5% (95%CI:39.5-80.9%) in the HRG. However, 88.5% (77/87) of all metastases** were in tumors categorized as LRG. In the LRG, 40-GEP identified patients at increased risk of metastasis (Class 2A predicted risk: 39.1% (288/737), true metastases: 59.7% (46/77)); Class 2B predicted risk: 3.3% (24/737), true metastases: 10.4% (8/77)) with 3-year MFS rates of 84.4% (95% CI 80.3-88.7%) and 70.8% (95% CI 54.8-91.6%), for Class 2A and 2B respectively.

Conclusion: The nomogram classified 9 out of 10 tumors that metastasized as lower risk. However, the 40-GEP classified 70% of tumors missed by the nomogram as high-risk Class 2. These data demonstrate that 40-GEP improves risk stratification of NCCN high or very high-risk patients who were categorized as low-risk by this nomogram.