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Evaluation of Oral Potentially Malignant Disorders (OPMDs) with S100A7

Abstract

Squamous cell carcinoma of the head and neck is a condition carrying a high mortality rate and significant morbidity. Currently, diagnosis and prognosis rely heavily on histopathologic staging and grading. The current system devised by the World Health Organization grades dysplastic lesions on severity and risk of malignant transformation; however, it fails to incorporate other factors that could prove useful in prognostication. This study evaluated the performance of Straticyte™, an AI-assisted histopathologic assay that utilizes the biomarker S100A7 and cell morphology to predict the transformation of dysplasia into oral squamous cell carcinoma. This multicenter study retrospectively enrolled patients with a biopsy of an oral lesion determined to be dysplasia. Charts were then reviewed to determine the rate of progression of dysplasia to squamous cell carcinoma. Finally, the Straticyte™ method was performed on archived biopsy samples and the relationship of this outcome and time to a positive diagnosis of oral cancer was evaluated. The analysis included 165 biopsies across all clinical sites. The Straticyte™ method showed an overall sensitivity of 1.00 and a specificity of 0.18. The positive and negative predictive values were 0.39 and 1.0, respectively. Kaplan-Meier curves demonstrated a negative correlation between time to cancer progression and higher grade of dysplasia, with elevated Straticyte™ scores also showing this relationship ($p = 0.0018$). Receiver-operator curves demonstrated similar aggregate area under the curve (AUC) as traditional dysplasia grading. The results of our study indicate that the Straticyte™ method may be useful in identifying those with OPMDs who are at risk of malignant transformation.