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Development of A Novel Prediction Model for Assessing Malignant Transformation of Oral Epithelial Dysplasia

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ABSTRACT

Introduction: Nomograms are effective statistical tools that may be integrated into medical practice to calculate treatment outcomes, diagnose diseases, and guide treatment decisions based on patient-specific variables. The current study aimed to develop a novel nomogram to stratify patients with oral epithelial dysplasia (OED) into different risk groups based on their clinic-pathological data.

Materials and Methods: Clinico-pathological data of all cases of OED reported during a twelve-year period were retrospectively retrieved. The presence of malignant transformation (MT) among them was confirmed from the departmental cancer registry. Bivariate regression analyses and multivariate logistic regression were used to analyze the risk factors and the role of multiple independent variables, respectively. A p-value < 0.05 was considered statistically significant. An OED nomogram was constructed from the above data.

Results: A novel OED nomogram was constructed using three variables - induration, texture, and clinical type. The Receiver operating characteristic (ROC) curve demonstrated an area under the curve (AUC) of 0.753, indicating fair predictive potential. MTR of our study population was 9.8%.

Conclusion: The OED nomogram serves as a valuable tool for predicting MT in OED patients. Its application in dental science for stratifying patient risk enables clinicians to plan treatment and follow-up visits efficiently.

Keywords: Nomogram; Oral cancer; Oral epithelial dysplasia; Oral potentially malignant disorders.

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Introduction

Oral Squamous Cell Carcinoma (OSCC) is a highly aggressive and disfiguring malignancy that represents a growing concern in global health due to its rising incidence and substantial morbidity and mortality. In India, it is the most common cancer after breast cancer, and it is the second most common cause of cancer death within the country (Globocan 2022) [1]. Unlike other types of cancers, OSCC most often follows a potentially malignant disease. Oral Potentially Malignant Disorders (OPMD) usually display histopathological changes characteristic of epithelial disorganization and dysmaturation, termed Oral Epithelial Dysplasia (OED). They have a Malignant Transformation Rate (MTR) of 0.13 – 48.4% [2,3]. The risk factors associated with the malignant transformation (MT) of OEDs have been described. Yet, research fails to explain a definitive predictive factor or biomarker to predict malignant transformation in OED.

The treatment modality for OED is very diverse, ranging from mere wait and watch to surgical excision to the newly researched area of immunotherapy [4]. The dark cloud still lies in the subjectivity of assigning cases to each treatment modality, which mainly relies on the histopathological grading of OED, a system with very high inter- and intra-observer variation. Surgical excision is done for patients with a higher risk of MT, whereas clinical follow-up for patients at lesser risk is considered adequate. This stratification of patients into high-risk and low-risk categories is predominantly based on observational studies and remains susceptible to clinician discretion and potential bias.

Numerous clinically applicable tools have been evaluated to enhance diagnostic and prognostic accuracy; however, none have demonstrated universal applicability, and the majority show suboptimal sensitivity and specificity; even when employed in combination or within specialized clinical settings. Consequently, there remains a critical need for innovative approaches to improve risk stratification and outcome prediction in patients with OED, particularly to accurately identify those at highest risk of progressing to OSCC. The advancement of predictive statistical tools presents valuable opportunities to enhance the precision of preventive and therapeutic strategies. Nomograms, as visual predictive instruments, enable clinicians; regardless of their statistical expertise—to estimate outcome probabilities through intuitive, two-dimensional graphical representations derived from comprehensive risk factor analyses. Nomograms are simple and user-friendly statistical tools that can be used to predict the probability of an event. In our context, a nomogram can be customized according to the population of our area and a prediction model may be devised for assessing MT in OED cases. The present study aims to develop a statistical model (Nomogram) to predict the malignant transformation risk of OED in the Kerala population using the available clinicopathological and follow-up data of OPMD patients.

Materials and Methods

This retrospective observational study was performed by reviewing the records of the Department of Oral Pathology & Microbiology, Government Dental College, Kottayam, between 2009 to 2021. The study was conducted after receiving the approval of the Institutional Ethics Committee (IEC/M/24/2022/08/DCK). This retrospective study included all cases histopathologically diagnosed as OED reported during the above-mentioned time frame. The demographic and clinicopathological data were retrieved from the archives, which included the age, gender, medical history, habit history, site, size, texture, color and number of lesions, presence/ absence of induration, presence of palpable Lymph Nodes (LN), and clinical and histopathological diagnosis. Patients newly diagnosed with an OPMD concomitant with OSCC, cases without sufficient data, and those without at least two years of follow-up data were excluded. The habit history included smoking, chewing tobacco, consuming alcohol, or having a combination of all three.

According to size, the lesions were categorized into small (≤ 2 cm^2) and large lesions (> 2 cm^2) and according to texture, as homogenous and non-homogenous lesions. Lesions were categorized by clinical color presentation into uniform (predominantly white or red) or mixed-colored lesions, defined as mucosal lesions containing concurrent intermingled red and white areas (erythro-leukoplakia). and into white, red and mixed colored lesions according to color. The histopathological slides were graded according to the WHO dysplasia grading system (2022) into mild (MED), moderate (ModED), and severe epithelial dysplasia (SED) by two oral pathologists independently. In case of disparity, the opinion of a senior oral pathologist was considered final. Data regarding malignant transformation among the cases was retrieved from the departmental cancer registry. biopsies confirmed malignant transformations of cases.

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Statistical Analysis

Data was summarized in Microsoft Excel and analyzed using STATA version 14.1 (Stata Corp, 4905 Lakeway, College Station, Texas, USA). Bivariate regression analyses were used to identify the risk factors for malignant transformation of epithelial dysplasia. P values from the chi-square test and odds ratio with 95 % CI were used for statistical inference. Multivariate logistic regression analysis was performed to understand the roles of multiple independent variables. P value < 0.05 was considered statistically significant. The Hosmer-Lemeshow test was used to assess the goodness of fit of a logistic regression model. Area Under Curve (AUC) in the receiver operating characteristic (ROC) curve analysis was calculated to assess the validity of the nomogram.

Results

Characteristics of the study population

A total of 344 patients have been included in the study, of which 20.3% (n = 70) belong to an age range of < 50 years and 79.7 % (n = 274) of them belong to an age range of ≥ 50 years. 71.2 % (n = 245) of patients were males and 28.8 % (n = 99) were females. Among these dysplastic cases, Leukoplakia (OLK) included 68.6 % (n 236), Erythroplakia (ELK) 12.5% (n = 43), Oral Submucous Fibrosis (OSMF) 6.1% (n = 21), Oral lichen planus (OLP) 1.45% (n = 5), other types of lesions (Lichenoid reactions, Smokers palate, Smokeless tobacco pouch keratosis and Discoid lupus erythematosus) 11.33 % (n = 39). Malignant transformation was noted in 34 cases (9.8%) (Figure 1). In this study, the percentage of MT is more commonly seen among the < 50 years age group, males, those who have a trauma history, a combination of habits, and those without systemic diseases. Patients with mixed-colored lesions, more than one lesion, small lesions, lesions with non-homogeneous texture, indurated lesions, and palpable LNs showed a higher chance for MT. We also noticed that lesions like ELK, OLP, OSMF, and lesions on the tongue, floor of the mouth (FOM), and palate show a high risk for malignancy.

Thirty four cases underwent malignant transformation

Bivariate regression analyses of risk factors for malignant transformation of oral epithelial dysplasia

According to bivariate regression, the risk of MT of OED was higher on mixed-colored lesions (OR = 3.52, 95 % CI: 1.65 - 7.50, P = 0.001), and lesions with non-homogenous texture (OR = 3.43, 95 % CI: 1.66 - 7.10, P = 0.001) but less in smaller lesions (OR = 0.28, 95 % CI: 0.09- 0.82, P = 0.02) The study showed that clinical lesion diagnosis is also a significant parameter in MT. ELK showed a significantly higher MTR (OR = 7.16, 95 % CI: 1.48 - 34.46, P = 0.01) than other lesions. Indurated lesions (OR= 3.13, 95 % CI: 1.44 - 6.76, P = 0.004) and lesions with ModED and SED had higher MTR (OR = 0.49, 95 % CI: 0.24 - 1.02, P = 0.05). Bivariate regression showed that the risk of MT of OED did not increase with factors like age, gender, habit, medical and trauma history, number of lesions, site of occurrence of lesions, and the presence of palpable lymph nodes. Table 1 summarizes baseline clinicopathologic characteristics of the study population and bivariate regression analyses of risk factors for MT of OED. The heat map (Figure 2) provides an immediate visual of how each variable correlates with MT and others, adding weight to the regression analysis. Strongest positive correlations were noted between malignant transformation and clinical diagnosis, texture, and induration. Feature correlation heatmap illustrating the pairwise correlation coefficients between clinicopathological variables and malignant transformation in oral epithelial dysplasia. Higher positive correlations are shown in red, while negative correlations are in blue, as indicated by the color bar. Key predictive variables such as texture, colour, induration, and clinical diagnosis show stronger associations with malignant transformation.

Multivariate regression analyses of risk factors for malignant transformation of oral epithelial dysplasia

Multivariate regression was done to consider confounding factors. Multivariate regression showed that the texture of the lesion (non-homogenous lesions, OR = 3.44, 95 % CI: 1.25 - 9.49, P = 0.01), induration of lesions (OR = 2.81, 95 % CI: 1.24, 6.36, P = 0.01), and clinical type of lesions [ELK (OR = 7.50, 95 % CI: 1.52 - 36.88, P = 0.01), OSMF (OR = 11.00, 95 % CI: 1.56 - 77.28, P = 0.01), OLP (OR = 16.12, 95 % CI: 0.95 - 273.59, P = 0.05) increases MTR. Table 2 summarizes the multivariate regression analyses of risk factors for the MT of OED.

Formation and validation of nomogram

The nomogram was constructed based on the odds estimates of multivariate analysis (Figure 3). Nomogram for predicting the risk of malignant transformation in oral epithelial dysplasia. The nomogram assigns points to clinical diagnosis, lesion texture, and induration. The points are summed to obtain a Total Score (0–60).

The Total Score represents a relative point scale and should not be interpreted as a percentage. The corresponding predicted probability of malignant transformation is obtained by mapping the Total Score to the probability scale, which ranges from approximately 0.01 to 0.60 (1%–60%) in the present model. The nomogram assigns weighted points to the three variables retained in the multivariate model—clinical diagnosis, lesion texture, and induration. The points corresponding to each patient's characteristics are summed to obtain a Total Score, which ranges from 0 to 60 in the present nomogram. Importantly, this point scale is distinct from the probability scale and does not represent percentage risk. The calculated Total Score is subsequently mapped onto the Predicted Probability scale, which represents the model-estimated probability of malignant transformation. In the present model, the displayed predicted probability ranges from approximately 0.01 to 0.60 (1%–60%). Therefore, the Total Score should first be calculated by summing the points for the relevant clinical variables, after which the corresponding probability of malignant transformation can be read from the probability axis. The area under the curve (AUC) measures the discrimination power of the nomogram. AUC assessed the validation of the nomogram. The AUC for this model was 0.753. (Figure 4). Hosmer-Lemeshow test showed a P value of 0.2661 (P value > 0.05 is considered significant). The nomogram has a sensitivity of 77.8% and a specificity of 70.0%. Receiver operating characteristic (ROC) curve evaluating the discriminatory performance of the nomogram model for predicting malignant transformation in oral epithelial dysplasia. The area under the curve (AUC) is 0.753, indicating fair predictive accuracy in distinguishing between cases with and without malignant transformation.

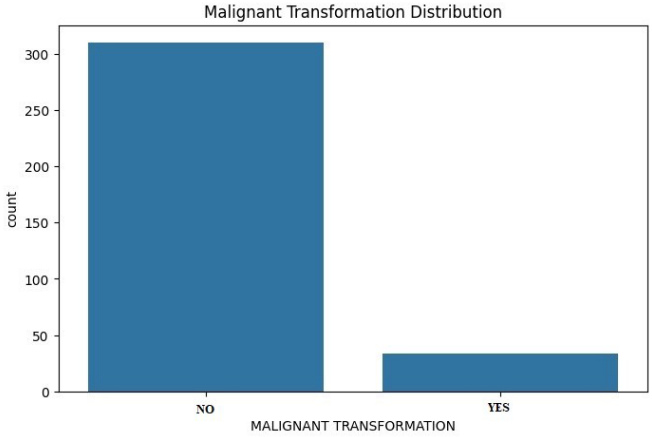


Figure 1. Percentage distribution of malignant transformation among the study population.

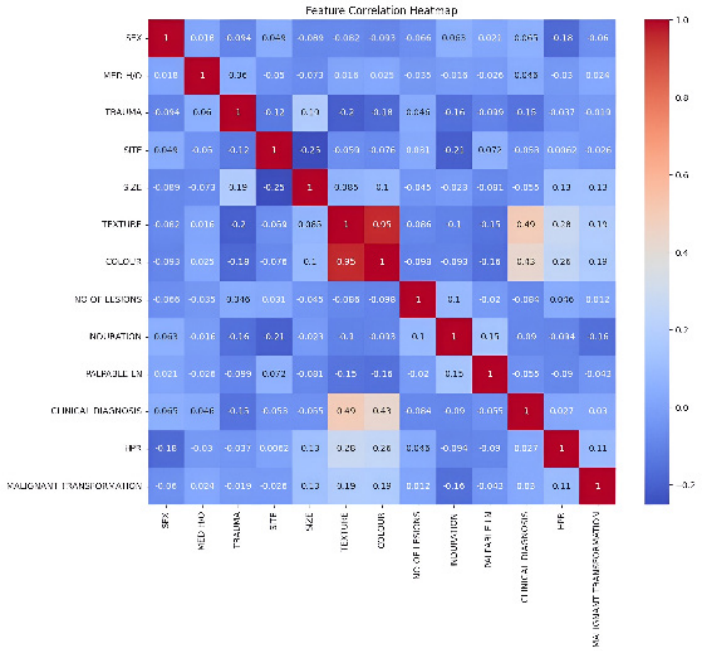


Figure 2. Heatmap showing correlation among clinical, demographic, and lesion-related variables with malignant transformation.

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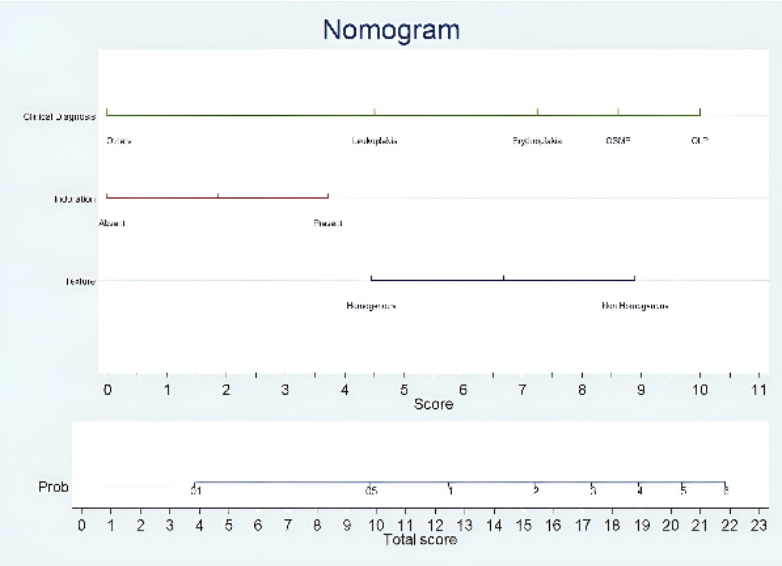


Figure 3. Nomogram prediction model.

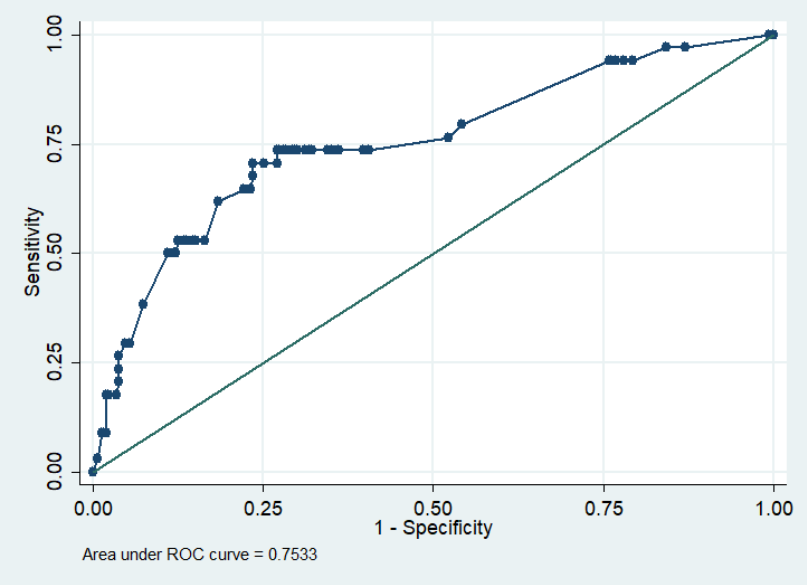


Figure 4. Receiver operating characteristic (ROC) curve.

Table 1. The demographic and baseline clinicopathologic characteristics of the study population and bivariate regression analyses of risk factors for malignant transformation of oral epithelial dysplasia.

Variable	No malignant transformation		Malignant transformation		Bivariate regression	
	N	Percentage	N	Percentage	OD (95% CI)	P value
Age	62		8	11.4	Reference	
≤50	248	88.6	26	9.5	1.00 (.97,1.03)	0.65
≥50		90.5				
Gender	92	92.93	7	7.07	Reference	
Female	218	88.98	27	11.02	1.62(.68, 3.87)	0.27
Male						
Medical history	25	92.59	2	7.41	0.71 (0.16, 3.14)	0.65
Yes	285	89.91	32	10.09	Reference	
No						
Trauma	65	89.04	8	10.96	1.15(0.55, 2.68)	0.72
Yes	245	90.41	26	9.59	Reference	
No						
Habit history	44	91.67	4	8.33	Reference	0.61
No	22	88	3	12	1.5 (0.30, 7.29)	0.62
Smoking	92	93.88	6	6.12	0.71(0.19,2.67)	
Chewing	1	100	0	0.00	1	0.45
Alcoholism	151	87.79	21	12.21	1.52(0.49,4.69)	
Combination of habits						
Clinical diagnosis	221	93.64	15	6.36	1.25(0.27, 5.71)	0.76
Leukoplakia	31	72.09	12	27.91	7.16(1.48,34.46)	0.01
Erythroplakia	17	80.95	4	19.05	4.35(0 .72, 26.12)	0.10
OSMF	4	80.00	1	20.00	4.62(0.33, 63.06)	0.25
OLP	37	94.87	2	5.13	Reference	
Others						
No of lesions	286	90.22	31	9.78	Reference	0.82
1	24	88.89	3	11.1	1.15 (0.32, 4.04)	
>1						
Size	211	87.55	30	12.45	0.28 (.097, 0.82)	0.02
	99	96.12	4	3.88	Reference	
Small						
Large						
Color of lesion						
White	218	93.97	14	6.03	Reference	0.14
Red	17	85	3	15.00	2.74 (0.71, 10.50)	0.001
Mixed	75	90.12	17	18.48	3.52 (1.65,7.50)	
Texture of lesion	219	93.99	14	6.01	Reference	
Homogenous	91	81.98	20	18.02	3.43(1.66, 7.10)	
Non-homogenous						0.001
Induration	46	79.31	12	20.69	3.13(1.44, 6.76)	
Yes	264	92.31	22	7.69		0.004
No						
Palpable LN	17	85.00	3	15.00	1.66(0.46, 6.01)	0.43
Yes	293	90.43	31	9.57	Reference	
No						
Histopathology	172	92.97	13	7.03	Reference	0.05
MED	100	87.72	14	12.28	Moderate & severe	
ModED	38	84.44	7	15.56	dysplasia	
SED					0.49	
					(0. 24,1.02)	

OSMF–oral submucoud fibrosis; OLP–oral lichen planus; FOM–floor of mouth; MED–mild epithelial dysplasia; ModED–moderate epithelial dysplasia; SED–severe epithelial dysplasia.

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Table 2. Multivariate regression analyses of risk factors for the malignant transformation of epithelial dysplasia.

Variable	*Multivariate regression*	
	OD (95% CI)	*P value*
	Texture of the lesion	
Homogenous	*Reference*	
Non-homogenous	*3.44 (1.25, 9.49)*	*0.01*
	Induration	
No induration	*Reference*	
Induration	*2.81 (1.24, 6.36)*	*0.01*
	Clinical diagnosis	
Others	*Reference*	
OLK	*3.49 (.65, 18.69)*	*0.14*
ELK	*7.50 (1.52,36.88)*	*0.01*
OSMF	*11.00 (1.56, 77.28)*	*0.01*
OLP	*16.12 (0.95,273.59)*	*0.05*

MOLK–oral leukoplakia; ELK–erythroplakia; OSMF–oral submucous fibrosis; OLP–Oral lichen planus.

Discussion

Oral Epithelial Dysplasia (OED) is an umbrella term describing the histological appearance of most OPMDs. These lesions present a significant challenge in clinical decision-making due to its variable MTR. Nomograms are extensively used in medical decision making to estimate outcomes, diagnose diseases and guide treatment decisions based on patient-specific variables [5–9]. They provide an easy-to-use, graphical method for clinicians to make complex calculations without the need for computers. By stratifying the patient's lesion into a final mathematical score, nomograms enable the clinician to effectively communicate to them, the risk involved and accordingly plan treatment and follow up. In this study, we developed and validated a predictive nomogram tailored for the Kerala population to estimate their risk of malignant transformation. A novel OED nomogram was developed after assessing all the clinicopathological risk factors. Studies around the world have reported varying data regarding MT, ranging from 0.3 to 48.4% [2,3]. Mohideen et al in their systematic review and meta analysis reported a MTR of 48.4% in Proliferative Verrucous Leukoplakia patients [3]. With the absence of PVL cases in our study, our population reports a significantly high MTR (9.8%).

Risk factors for Malignant Transformation

Malignant transformation among the OPMD cases was highest in ELK (27.9%), followed by OLP (20%), OSMF (19.05%) and OLK (6.36%). Bivariate regression analysis showed ELK to have the highest MT risk (OR = 7.16, p = 0.01), confirming its well-known aggressive malignant potential [2,10–12]. We observed a notably increased MTR for OLP (20%), against a low MTR (0.3 to 14.3%) reported in the literature [13]. Our study population included clinical cases of OLP having a histological diagnosis of OED. Only five such cases were present in this study and one case among them showed MT. This highlights the fact that OLP has an increased chance of transforming into malignancy if its histology shows features of OED. Our result on multivariate analysis showed a high OR of 16.12, but with a borderline p-value (0.05), suggesting a trend but needing more validation. OSMF patients also showed high MTR, which falls within the range reported in the literature [14]. Smaller lesions in accordance with existing literature had less malignant potential [10]. Mixed-colored lesions (OR = 3.52, p = 0.001), non-homogeneous texture (OR = 3.43, p = 0.001), and lesion induration (OR = 3.13, p = 0.004) were significant predictors, reinforcing the role of clinical appearance in risk assessment. Histopathology (ModED and SED), though is a well-recognized risk factor, showed borderline significance, suggesting a trend but requiring further validation. It also adds value to the possibility that lesions showing a lower dysplasia grade may also develop into cancer. Although ModED-SED is a well-established predictor of malignant transformation in the literature, histopathological grade demonstrated only

borderline significance in our univariate analysis (OR = 0.49, 95% CI: 0.24-1.02, p = 0.05) and did not retain independent predictive value during multivariate logistic regression modelling. Consequently, it was excluded from the final nomogram in favour of clinical diagnosis, lesion texture, and induration. This finding should not be interpreted as indicating that histopathological grading lacks clinical utility; rather, it suggests that its independent predictive contribution was attenuated in our cohort when evaluated alongside prominent clinical features. High inter- and intra-observer variability inherent to dysplasia grading may also contribute to this attenuated effect. Future multi-center studies with larger sample sizes and prospective validation will be critical to determine whether forcing dysplasia grade into the model enhances its overall discrimination and clinical utility. Interestingly, factors like age, gender, systemic disease, trauma history, smoking, and alcohol use were not significantly associated with malignant transformation in this study.

OED Nomogram

We have developed an OED Nomogram model based on the results of our multivariate analysis. Our model, assesses clinico-pathological parameters such as induration, lesion texture and clinical diagnosis. It demonstrated good discriminative ability with an AUC of 0.753. Several previous studies have attempted to develop predictive models for MT in OPMDs. Goodson et al. (2019) developed the Newcastle Nomogram, a model based on age, gender, lesion type, site, and histopathology, achieving an AUC of 0.79 with high sensitivity (87%) and moderate specificity (63%) [15]. Wang et al. (2019) [9] focused specifically on OLK, using age, histologic grade, lesion site, and smoking history as predictors.

The nomogram had an AUC of 0.752, demonstrating moderate discrimination. Cai et al. (2021) [5] developed a dynamic nomogram using a large Chinese cohort of 6964 patients. It incorporated factors such as age, lesion site, dysplasia grade, and cancer history. The model achieved high predictive accuracy with AUC values of 0.913 (1-year), 0.934 (3-year), 0.928 (5-year), and 0.920 (7-year) at different follow-up period. Adeoye & Su (2023) [6] externally validated the nomograms by Cai et al. (2021) and Goodson et al. (2019) for OLK and OLP to compare their discriminatory performance, calibration, and net benefit. While the nomograms performed well in OLK (AUC 0.644–0.844), they did not outperform binary dysplasia grading in risk stratification. A biomarker based nomogram was developed by Zhang et al (2017) [16] integrating P53, CA9, age, and dysplasia degree, achieving a predictive accuracy of 0.881, suggesting strong discriminative ability. Our OED nomogram stands out among them as we have assessed the MTR of cases with OED, rather than taking all the OPMDs reported into consideration. The clinical application of this nomogram is significant, as it provides an objective tool for stratifying patients into high- and low-risk categories. Patients with a higher predicted risk may benefit from more aggressive interventions, such as early surgical excision or closer surveillance, while those at lower risk may be managed conservatively with periodic follow-ups. By reducing reliance on subjective histopathological grading alone, this model enhances decision-making and minimizes inter-observer variability.

One of the key strengths of this study is its use of real-world clinicopathological data from a well-defined population. Additionally, the inclusion of a validation step using ROC curve analysis strengthens the reliability of our findings. However, the study has some limitations. First, it is a retrospective study, which may introduce selection bias. Second, the sample size, while adequate, could be expanded further to improve generalizability. Lastly, external validation in different geographic and demographic populations is necessary to confirm the model's robustness. To further enhance the clinical utility of our model, future studies should focus on prospective validation with a larger cohort. Additionally, incorporating molecular and genetic biomarkers could refine the predictive accuracy of the nomogram. Artificial intelligence-based approaches, such as machine learning algorithms, may also provide more dynamic and adaptable risk assessment tools for OED.

Conclusion

Our study presents a clinically applicable OED nomogram for predicting malignant transformation in OED patients. With an AUC of 0.753 and well-balanced sensitivity and specificity, this model serves as a valuable tool for guiding patient management. Further research and external validation will be essential to ensure its broader applicability and effectiveness in clinical practice.

Conflict of Interest

There is no conflict of interest to declare.

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