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Oral Biopsy Score: A Quantitative Approach to Clinical Decision Making for Biopsies in Suspicious Oral Lesions

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Abstract

Oral potentially malignant lesions are often underdiagnosed, leading to malignant transformation, progression, and spread of disease. It is also responsible for poor survival outcomes. To save these life years, early detection is a must. Unfortunately, it requires specialist access in many clinical settings. For faster, uniform screening, a quantitative approach, the oral biopsy score (OBS), has been formulated for risk stratification and sooner decision making. The OBS consists of risk factors such as tobacco/alcohol/areca nut use, size of the lesion, morphology, duration, location, and induration of the lesion. Each of these categories has an upper and lower score assigned. Depending on the added score, the inference will guide us in performing the biopsy or keeping it under surveillance. We advocate for validation of the OBS through multicentric prospective studies to assess its diagnostic performance. Incorporation into artificial intelligence-assisted image analysis will enhance the accuracy of the diagnosis. Ultimately, we believe the OBS can play a pivotal role in early detection of oral cancer, leading to reduction in morbidity and improvement in survival.

Keywords
- biopsy
- oral lesions
- oral cancer
- leukoplakia
- erythroplakia
- oral potentially malignant disorder
- oral biopsy score

Introduction

Oral potentially malignant disorders (OPMDs) and early oral cancers pose significant diagnostic and management challenges in clinical practice.[1] Despite increasing awareness about the importance of early detection, a substantial number of oral cancers are diagnosed at advanced stages, largely due to delays in detection, referral, and biopsy of suspicious lesions.[2] Presence of factors like tobacco/alcohol/areca nut use, size, duration, location, and characteristics of lesions pose a higher risk of malignant transformation in oral cavity cancer, especially in the Indian population.[3] For this critical need, we propose a structured and practical scoring system, the oral biopsy score (OBS), which aims to assist in clinical decisions regarding when to biopsy oral lesions. OBS is designed to be a user-friendly, practical tool to help general practitioners, dentists, and oral medicine specialists quickly recognize which oral lesions need urgent biopsy and histopathological testing. It is designed taking into consideration the known clinical signs that suggest a higher risk of malignant changes, combining with important patient risk factors with morphology of the lesion. Based on the malignant transformation rates, values have been given to the following risk factors.

Framework of the Oral Biopsy Score

The OBS assigns scores based on the following parameters, categorized into three domains, that is, patient habit, lesion

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morphology, and duration. Each parameter is scored as an "upper score" or "lower score," reflecting the presence or absence of high-risk factors ►**Table 1**.

1. Tobacco/alcohol/areca nut use (ever user)
   Upper: 1 (If the patient has history or is current user of above product)
   Lower: 0 (If the patient has no history of any of the above habits)
   These substances are International Agency for Research on Cancer (IARC) group 1 carcinogens, and their chronic use significantly elevates the risk of malignant transformation.[4]
   A systematic review by Asthana et al showed that smokeless tobacco products had a significant risk of oral cancer (4.44, 95% confidence interval [CI] = 3.51–5.61).[5] Another meta-analysis by Gandini et al concluded that tobacco smoking also has a high risk of causing oral cancer (relative risk [RR] = 3.43; 95% CI: 2.37–4.94).[6] Alcohol consumption significantly increases cancer risk in India, with a pooled odds ratio (OR) of 2.32 (95% CI: 1.50–3.47) in case–control studies and nearly doubles the risk of oral cavity cancer (OR: 1.92, 95% CI: 1.54–3.96).[7] Also, data from the IARC show that areca nut chewing also has a significantly high risk of causing oral cancer, independently (pooled adjusted RR, 7.9; 95% CI, 7.1–8.7).[8] According to Global adult tobacco survey 2 (GATS 2),more than 30% of all adult Indians consume tobacco. Tobacco is IARC approved Group 1 carcinogen. ACC Hence, tobacco, alcohol, and areca nut usage have been noted and given a score of 1.
2. Size of the lesion
   Upper: 1 ($>$ 2 cm)
   Lower: 0 ($<$ 2 cm)
   Larger lesions, particularly those exceeding 2 cm in diameter, are more likely to harbor dysplastic or malignant changes. A systematic review by Pimenta-Barros et al found that larger leukoplakic patches showed higher risk of malignant transformation (RR = 2.08, 1.45–2.96, $p < 0.001$).[9] Lesions of size more than 2 cm are more likely to have been there for a while, making malignant transformation probable. Therefore, the upper score of 1 has been allotted to larger lesions.
3. Duration of the lesion
   Upper: 1 ($>$ 5 years)
   Lower: 0 ($<$ 5 years)
   Lesions persisting for over 5 years are more likely to have undergone dysplastic changes without intervention, warranting an upper score of 1. Chronicity is a well-known predictor of malignant transformation.[9]
4. Site of the lesion
   Upper: 1 (Located on the tongue or floor of the mouth for all patients and located on the bucco-alveolar complex for patients with history of any habit)
   Lower: 0 (Located on the bucco-alveolar complex for patients with no history of habit and any other location for all patients)
   High-risk anatomical sites include the lateral tongue, floor of the mouth, and buccal mucosa-buccal alveolar complex (especially in chronic tobacco/areca nut abusers).[9]
5. Lesion morphology: homogeneity
   Upper: 2 (Heterogeneous, includes speckled, nodular, verrucous varieties)
   Lower: 0 (Homogeneous)
   Nonhomogeneous oral leukoplakia has a higher transformation rate than homogeneous types. A study from Southern Iran indicated a higher risk of malignant transformation in nonhomogeneous lesions (OR = 6.26).[10] Moreover, the meta-analysis by Pimenta-Barros et al also showed that heterogeneous leukoplakia had a higher risk of malignant transformation (RR = 4.23, 95% CI = 3.31–5.39, $p < 0.001$; nonhomogeneous: RR = 21.88, 95% CI = 16.44–27.81).[9]
6. Erythroplakia/proliferative verrucous leukoplakia
   Upper: 3 (Erythroplakia/proliferative verrucous leukoplakia)
   Lower: 0 (Other)
   These lesions are considered high-risk for malignant transformation (40–50%). A study by Wadde et al showed that approximately 40 and 9% cases of oral erythroplakia exhibit mild and moderate dysplasia, respectively, on the first biopsy.[11]
7. Ulcer with induration/irregular margins
   Upper: 3 (Ulcer with induration or irregular margins)
   Lower: 0 (Other)
   Features such as induration and irregular margins are clinical indicators of malignancy.
8. Nonhealing ulcers
   Upper: 3 (Nonhealing ulcer for $>$ 3 weeks)
   Lower: 0 (Resolves within 2–3 weeks)
   Persistence without resolution is a clinical red flag, as observed by the Pimenta-Barros et al review.[9]

Scoring and inference

The total score guides clinical decision-making:

Score $>$ 3: Immediate biopsy is recommended. Lesions in this category are considered high-risk.

Score = 3: A period of two-weekly surveillance is advised after removal of causative agents. If the lesion does not regress, biopsy is indicated.

Score $<$ 3: Two-monthly surveillance is recommended, with reassessment upon symptom escalation.

This approach allows for clinical flexibility with a structure based on risk stratification.

Implications for Practice

The OBS is not intended to replace clinical judgment but to complement it. It serves as an adjunctive tool for early detection, helping clinicians in decision-making and promote standardization, thereby reducing variability between clinicians. Moreover, it improves record-keeping, communication, and follow-up processes, particularly valuable in primary care settings where access to specialists may be limited. The strength of the OBS lies in its simplicity. With appropriate training, it can be widely generalized to support frontline health care providers. The scoring system is limited by validation and need real-world data and it also involves interobserver variability but it makes the diagnosis objective and data-friendly. OBS scoring system is designed for treatment-naive oral lesion, thus oral submucous

Table 1 Oral biopsy score assessment

	Upper limit	Lower limit
Tobacco/alcohol/areca nut use	1	0
Size > 2 cm (largest diameter)	1	0
Duration of lesion (> 5 years)	1	0
Located on: 1. Tongue and floor of the mouth (all) 2. Buccal mucosa and bucco-alveolar complex (for abuser)	1	0
Heterogeneous/nonhomogeneous (includes speckled, nodular, verrucous)	2	0
Erythroplakia/proliferative verrucous leukoplakia	3	0
Ulcer with induration/irregular margins	3	0
Nonhealing ulcer for more than 3 weeks	3	0
Inference		
Score	Decision	
> 3	Biopsy	
3	Two-weekly surveillance (after removal of cause, if any. And if there is no improvement in 2 weeks, then biopsy)	
< 3	Two-monthly surveillance (on follow up, action as per score. Reassess sooner if symptoms escalate)	

fibrosis and any prior history of oral cavity cancers should be excluded.

Conclusion

The OBS is a novel, practical tool created to assist clinicians in diagnosing OPMD or malignancy through timely biopsy. By combining well-known risk factors into a simple scoring system, the OBS makes it easier to detect oral cancer early. It is strongly recommended to validate the OBS through multicentric prospective studies and real-world database.

Patient Consent

Patient consent is not required.

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Conflict of Interest

None declared.

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