# The Sensitivity and Specificity of Oral Tumors and Premalignant Lesions Diagnosis by Otolaryngologists

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## Abstract

**Background:** Tumors of the oral cavity are under estimated in general dental  and medical practice, some authors describe it as the forgetting disease, others wondering if the attention paid to this disease compared to its fatality (The 5-year survival rate is about 50%) is enough for disease control? However; this disease deserves a comprehensive assessment by all dental and medical fields assumed to examine the oral cavity regularly, especially otolaryngologist.

**Objectives:** To find out the sensitivity and specificity of clinical examination in diagnosing oral tumors and premalignant conditions by otolaryngologist.

**Methods:** A cross sectional retrospective study was conducted in the:

-*study design:* Cross sectional.

-*settings:* Ear Nose Throat (ENT)departments in Al-kindy Teaching Hospital and Al-Yarmouk Teaching Hospital.

*On* Patients attending ENT department with oral presentation.

*The outcome variables includes:* The sensitivity, specificity, positive predictive value ($Pv^{+ve}$), negative predictive value (PV-ve), and the accuracy of clinical examination in diagnosing oral tumors and premalignant conditions in ENT clinic.

**Results:** The results revealed a high sensitivity and specificity for otolaryngologist in diagnosing malignant conditions and premalignant lesions of the oral cavity.

**Conclusion:** The study highlights the need for fixed clinical criteria for early diagnosis of premalignant conditions and oral tumors.

**Keywords:** oral tumors, sensitivity, specificity, otolaryngologist.

## Introduction

The oral cavity is accessible to many dentists, physicians, and health workers in different disciplines, lesions of the oral cavity are very common but could be very dangerous as a first sign of cancer, so awareness of the involved doctors should be directed towards the highly suspicious lesions because most patients are asymptomatic for along period before they seek for help usually when there is an alarming pain. It's not surprising that the majority of the lesions are well advanced when detected [1].

One might think that oral malignancy is particularly amenable to early diagnosis because it has identifiable risk factors [2-4], a detec Table asymptomatic phase [5-7], and an available efficient screening modality [8-13]. The results of screening on the other hand are poor probably because of failure to focus on specific groups at risk, and the use of inadequate criteria for the clinical detection of early lesions, for these reasons this study focus on specific group of patients attending the ENT (Ear Nose and Throat) clinic suffering from oral complain and a suggested clinical criteria is set for clinical diagnosis of premalignant, and malignant lesions, and finally a suggested examination method to discover early lesions and the results are analyzed by calculating the sensitivity, specificity, positive predictive value ($P^{+ve}$), negative predictive value ($P^{-ve}$), and the accuracy for detection by an otolaryngologist, which is the main aim of this study.

## Methods

This is a cross-sectional study conducted during the period from 1999-2006. The study sample is 500 from the patients attending to the ENT clinic with oral complain in AL- Yarmouk Teaching Hospital, and AL-Kindy Teaching Hospital in Baghdad. One hundred seventeen patients are taken from the total sample suspected to have premalignant and malignant lesions. The presumptive diagnosis is made by depending on suggested criteria for the diagnosis of the premalignant and malignant lesions, and the biopsy is the gold standard for analyzing the data. The criteria to include a patient in this study as premalignant are: (1) white lesion that can not be rubbed off (2) red lesion (3) red and white lesion (4) persistent lesion for more than 2-weeks. The criteria to include a patient as malignant are :( 1)

ulcer or swelling persistent for more than 2-weeks after removal of all chemical, physical, thermal causes (2) persistent pain or sore throat, and for both premalignant and malignant lesions the presence of the lesion in a high risk site (the floor of mouth, the lateral border of the tongue, and the soft palate complex-the soft palate, the anterior pillar, and the retro molar trigon).

All patients are examined by a suggested way for cancer detection as follows: (1) the use of a fibroptic head light which is better than the head mirror in detection of early mucosal lesions (2)the use of laryngeal mirror which is better tolerated than tongue depressors and can be used to see difficult areas by reflection of light (3) for inspection of the anterior 2/3 of the floor and the ventral surface of the tongue, the tongue should touch the palate and the mandible is horizontal during examination (4) examination of the posterior floor of mouth, retro molar trigon, and posterior ventrolateral aspect of the tongue necessitating grasping the anterior one third of the tongue with a 2 by 2 inch gauze sponge, distracting it to the contralateral labial commisure and withdrawing it from the oral cavity as far as possible (5) the posterior floor of mouth and its contiguous structures can be seen by applying external pressure in the area of the submandibular gland on the epsilateral side.

### Statistical Analysis:

The results of the study were analyzed statistically by using the following procedures [14]

Evaluating the validity of the clinical diagnosis by otolaryngologist when compared with the standard tests (biopsy). Data were analyzed using the following procedure:-The sensitivity and specificity are two measures of the validity of a screening test.

The *SENSITIVITY* is defined as the probability of testing positive if the disease is truly present and is calculated by: Sensitivity= (True positive by the test)/ (True positive +false negative) x100%.

The *SPECIFICITY* is defined as the probability of screening negative if the disease is truly absent and is calculated by: Specificity = (True negative by the test)/(True negative+ false positive) x100%.

The *PREDICTIVE VALUE POSITIVE ($P^{V+}$)* or the yield of the test is the probability that a person actually has the disease given that he or she tests positive and is calculated by: $P^{V+}$= (True positive by the test)/ (Total positive by the test) x100%.

The *PREDICTIVE VALUE NEGATIVE ($P^{V-}$)* is the probability that an individual is truly disease-free given a negative screening test and is calculated by: ($P^{V-}$) = (True negative by the test)/ (Total negative by the test) x100%.

The *ACCURACY* = (True positive + True negative) /Total number 100 % [14].

## Results

Among the 500 patients attending the ENT clinic with oral complain, 16 patients selected depending on the suggested clinical criteria assumed to have a premalignant lesion, the sensitivity for detection by otolaryngologist is 81.2%, the specificity is 90.2%, $P^{+ve}$ value is 24%, $P^{-ve}$ value is 99.2%, the accuracy is 89.9%, and the prevalence of these lesions in ENT clinic is 3.7% as shown in **(Table-1).**

On the other hand 63 patients are diagnosed to have malignant lesion by using the suggested clinical criteria, the sensitivity for detection by otolaryngologist is 76.2%, the specificity is 87.4%, $P^{+ve}$ value is 47.5%, $P^{-ve}$ value is 96.1%, the accuracy is 85.9%, and the prevalence of these lesions in the ENT clinic is 13% as shown in **(Table -2)**

The overall results for both premalignant and malignant lesions 79 patients are: the sensitivity for detection by otolaryngologist is 77.2%, the specificity is 86.7%, $P^{+ve}$ value is 52.1%, $P^{-ve}$ value is 95.3%, the accuracy is 85.2%, and the prevalence of both premalignant and malignant lesions in the ENT clinic is 15.8% as shown in **(Table -3).**

*(Table-1)*
*Distribution of Premalignant Lesions by Clinical Examination, and By Histological Diagnosis*

| Diagnosis by clinical examination | Histopathological diagnosis | | Total |
|---|---|---|---|
| | diseased | Free of disease | |
| Positive +ve | 13 | 41 | 54 |
| Negative –ve | 3 | 380 | 383 |
| Total | 16 | 421 | 437 |

Sensitivity: 81.2%. Specificity: 90.2%. $p^{+ve}$: 24%. $P^{-ve}$: 99.2%. Aquracy: 89.9%.Prevalence: 3.7%

**\* The patients with malignant lesions are excluded in this Table.**

*(Table-2)*
*Distribution of Malignant Lesions by Clinical Examination, and by Histological Diagnosis*

| Diagnosis by clinical examination | Histopathological diagnosis | | Total |
|---|---|---|---|
| | diseased | Free of disease | |
| Positive +ve | 48 | 53 | 101 |
| Negative –ve | 15 | 368 | 383 |
| | 63 | | 484 |
| Total | | 421 | |

Sensitivity: 76.2%. Specificity: 87.4%. $p^{+ve}$: 47.5%. $P^{-ve}$: 96.1%. Aquracy: 85.9%. Prevalence: 13%

**\*** The patients with premalignant lesions are excluded in this Table.

*(Table -3)*
*Distribution of Malignant and Premalignant Lesions by Clinical Examination, and By Histological Diagnosis*

| Diagnosis by clinical examination | Histopathological diagnosis | | Total |
|---|---|---|---|
| | diseased | Free of Disease | |
| Positive +ve | 61 | 56 | 117 |
| Negative –ve | 18 | 365 | 383 |
| | 79 | | 500 |
| Total | | 421 | |

Sensitivity: 77.2%. Specificity: 86.7%. $p^{+ve}$: 52.1%. $P^{-ve}$: 95.3%. Aquracy: 85.2%. Prevalence: 15.8%

## Discussion

An important starting point for designing proper prevention and early detection of oral tumors is to know the sensitivity and specificity for detection by different doctors and health workers.

### The sensitivity

The sensitivity for detection of oral tumors by physical examination varied from different researches, in this study its 76.2% while Mehta and others its 56% [15], Ikeda and others 73%[16], Downer and others 71%[17], Jullien and others 74%[18], Sankaranarayanan and others 76.6%[19],

and Mathew and others 94%[20]. Its is clear that the sensitivity vary greatly in population-based studies and those employing dentists as examiners have similar results for sensitivity 71%-74%[16-18] which is slightly less than that found in this study 76.2% conducted by physicians (otolaryngologist), even so these values are low compared to a sensitivity of 94% obtained in a study using other health care workers[20] both indicate a high rate of false negatives, this is probably due to lack of training in the detection of oral cancer and precancer and a failure to seek continuing education to maintain training.

The sensitivity of clinical examination in detection of premalignant lesions only is 81.2% which is far more better than for malignant lesions alone 76.2%, but its limited by the small sample and low prevalence of these lesions in this study 3.7%, however; the overall sensitivity for both lesions can give a better idea when we think seriously about premalignant lesions which is the present idea [19].

### The specificity:

The specificity for detection of oral tumors by visual examination is generally found to be high 98-99%[15,17,18,20] in most studies, in this study its 87.4% for the malignant lesions while Mehta and others its 98%[15], Ikeda and others 73%[16], Downer and others 99%[17], Jullien and others 99%[18], and Mathew and others 99%[20].

The highest results for sensitivity and specificity (94%, and 99%) are obtained in the study that use the most extensive training program [20] that might preclude the need for these programs for all medical and dental fields, specially when there is an evidence that oral visual inspection by trained providers is satisfactorily sensitive to detect oral precancer and cancer [15, 19- 22].

### The $P^{+ve}$, $P^{-ve}$, and the accuracy:

These values are now considered to be more practical in determining the validity of a test. The $P^{+ve}$ in this study is 24% for the premalignant lesions, and 47.5% for the malignant lesions both are not significant, while that of malignant and premalignant lesions together is significant 52.1% this can be explained by the low prevalence of the disease and small sample size, but still the $P^{-ve}$ is highly significant for all three categories: 99.2% for the premalignant lesions, 96.1% for the malignant lesions, and 95.3% for both lesions these values can give an idea about

**The accuracy:**

The accuracy on the other hand is significant for all three categories (premalignant, malignant, and both), it's 89.9%, 85.9%, and 85.2% respectively which reflect a high percentage of true results obtained by otolaryngologists.

## Conclusion

The study highlights the need for fixed clinical criteria for early diagnosis of premalignant conditions and oral tumors. These criteria can be standardized by the cumulative experience from different physicians and dentists.

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