Quality Resource Guide

Techniques for Early Cancer Detection

Author Acknowledgements

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Educational Objectives

Following this unit of instruction, the learner should be able to:

1. Understand the causes of delayed diagnosis of oral cavity and pharynx cancer.
2. Understand the current standard for identifying premalignant and malignant lesions.
3. Understand the essential principles for cytology-based, light-based, vital stain-based and molecular-based diagnostic adjuncts.
4. Apply objective criteria to assess the clinical utility and value of newly marketed adjunctive aids in one's practice.
5. Develop a disciplined protocol to routinely accomplish the conventional visual and tactile examination.

The following commentary highlights fundamental and commonly accepted practices on the subject matter. The information is intended as a general overview and is for educational purposes only. This information does not constitute legal advice, which can only be provided by an attorney.

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Introduction

For the year 2021, an estimated 54,010 individuals (38,800 men and 15,210) will be diagnosed with oral cavity and pharynx cancer in the United States.[1] The prevalence of oral cavity cancer in those over the age of 45 years is estimated to be 0.25%.[2] In 2017, there were approximately 383,415 individuals living with oral cavity and pharynx cancer in the United States and the overall 5-year survival rate is 66.2%.[3] The stage at which it is diagnosed remains the most important prognostic factor in predicting survival.[4,5] While the dental practitioner is often in the best position to first identify these cancers,[6] only 30% of patients diagnosed with oral cavity and pharynx cancer present with early-stage disease.[1] Clearly, the dental profession's success in identifying oral cavity and pharynx cancers at an early stage remains a dilemma. The purpose of this Quality Resource Guide is to discuss the causes of delayed diagnosis of oral cavity and pharynx cancer, review the current standard for identifying oral cavity and pharynx cancer and provide an update on currently available adjunctive devices with the promoted goal of improving the dental practitioner's ability to screen for and identify potentially malignant disorders (PMDs).

Delays in Detection of Oral Cavity and Pharynx Cancer

Patient Delay

An estimated 35% of the public does not seek dental care on an annual basis[7] and patient delay is the most important factor underlying the deferred detection of oral cavity and pharynx cancer.[8,9] Patient delay is defined as the interval between the patient's first awareness of a concern and his or her seeking assessment by a healthcare provider. Estimates for patient delay range from 3.5 months to 6 months. Psychosocial factors, health-related behaviors, socioeconomic status, education level, and health care access or availability have been proposed as important factors contributing to patient delay.[9,10]

Professional Delay

The most relevant parameter of professional delay is the time from the patient's first encounter with the healthcare system to the start of definitive treatment. Factors to consider here include practitioner experience and thoroughness, and access to care issues.[11-13] A 2007 review found only 41% of patients with oral cavity cancer began definitive therapy within 30 days of their initial presentation for assessment.[14] It is accepted that prolonged professional delay compromises successful therapy.[8,9,14]

Current Standard for Identifying Oral Cavity and Pharynx Cancer

Visually inspecting the patient for oral cavity and pharyngeal cancer represents an integral component of the conventional visual and tactile examination (CVTE)* that should be afforded all patients.[15] The CVTE is accomplished after a comprehensive review of the medical, social, and dental history.[16] The CVTE, which entails the use of appropriate lighting to accomplish a thorough visual and tactile assessment of accessible extra-oral and intra-oral tissues, remains the foundation upon which lesions are discovered.[4] Findings deemed suspicious for a PMD should be immediately biopsied or referred to a specialist. Findings deemed nonsuspicious should be monitored periodically for change and/or resolution.

** A detailed review of the CVTE may be found in the Quality Resource Guide, "Performance of an Oral and Head and Neck Examination"*

Adjunctive Devices

Numerous adjunctive devices are commercially available for dental practitioner use, with the promoted goal of improving the provider's ability to identify and/or assess PMDs. For convenience, these adjuncts may be categorized as:[17,18] (see **Tables 1-4**)

- cytology-based
- light-based
- vital stain-based
- molecular-based

Cytology-based Adjuncts

Cytology-based adjuncts are promoted to assess an observable PMD. They are specifically promoted to patients to "test common oral spots that may appear in your mouth from time to time."[19] All currently available products require shipment to an off-site laboratory for analysis. The appropriate CDT code to use is D7288, "brush biopsy – transepithelial sample collection."[15] Tested lesions that receive a "positive" or "atypical" result should undergo a scalpel biopsy to determine the definitive diagnosis.

Advocates of cytology believe it can be reliably used to assess innocuous lesions for benignity, precancer and cancer, especially for patients hesitant to undergo biopsy.[20,21] Cytology may also be a useful method for assessing a patient with multiple lesions throughout the mouth, where the attainment of multiple biopsies may be impractical.[22] Detractors contend cytology represents an unnecessary and often burdensome intermediate step since all "positive" or "atypical" results must be biopsied to determine the actual diagnosis.[23,24] Furthermore, while promoted as being reassuring, cytology is not diagnostic for a persistent lesion.[25,26]

Vital Stain-based Adjuncts

Toluidine blue (TB) is a metachromatic dye of the thiazine group that has an affinity to bind with DNA. It has been promoted as a chairside lesion assessment utility for decades to assess suspicious mucosal lesions.[27,28] After rinsing with 1% acetic acid solution, topical application of TB highlights rapidly dividing tissues such as inflammatory, regenerative and neoplastic epithelial tissues and exposed connective tissue.[25,27]

TB has been advocated as a utility to monitor PMDs for progression, to assess PMD margins, and to monitor post-cancer treatment patients.[29,30] However, false positive results are commonly encountered, especially in areas of inflammation.[22,30]

TB is currently not cleared by the FDA as a stand-alone adjunctive screening aid. It is cleared for marketing as a follow-on case assessment marking agent for the light-based adjunctive aids ViziLite® TBlue, Bio/Screen®, and MicroLux DL™. The premise is the TB allows for better visual lesion delineation of an area initially identified via the companion light-based adjunct.[32,33] It can help the provider decide which area within a lesion should be biopsied. The appropriate CDT code to apply when using TB is D0431, "adjunctive pre-diagnostic test that aids in the detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures."[15]

Light-based Adjuncts

Light-based adjuncts can be categorized into two basic groups (tissue reflectance and autofluorescence) based on the manner in which a specific spectrum of light is used to assess the reflective properties of the tissue. All devices are cleared for marketing by the FDA as chairside illumination aids to assist the practitioner in identifying new or potentially overlooked PMDs.[34] Some are also marketed to assist surgeons in defining appropriate surgical margins for excision.[27,35] The appropriate CDT code to apply when using a light-based adjunct is D0431, "adjunctive pre-diagnostic test that aids in the detection of mucosal abnormalities including premalignant and malignant lesions, not to include cytology or biopsy procedures."[15]

The tissue reflectance adjuncts (ViziLite® TBlue, Microlux DL™) utilize a blue-white light (wavelength of 430 and 580 nm) to analyze the tissues.[36] For the ViziLite® TBlue product, the light is generated through a reaction between acetylsalicylic acid and hydrogen peroxide (chemiluminescence), while the light for the Microlux DL™ product is produced by a battery powered light-emitting diode. The protocol for both regimens entails the use of a 60 second pre-rinse with a 1% acetic acid solution to remove the surface glycoprotein layer and cause cellular dehydration, to improve the exposure of cellular elements to the blue-white light.[22,36]

Table 1 - Cytology-based Adjuncts[17,18]

Adjunct	*Contact*
OralCDx Brush Test®	CDx Diagnostics, Suffren, NY
CytID™	Forward Science, Houston, TX
OralCyte™	ClearCyte Diagnostics, Seattle, WA

Table 2 - Vital Stain-based Adjuncts[18]

Adjunct	*Contact*
Toluidine chloride stain (component of ViziLite® Plus with TBlue®)	Den-Mat Holdings, LLC Lompoc, CA
OraBlu™	AdDent, Inc., Danbury, CT

Table 3 - Light-based Adjuncts[18]

Adjunct	*Contact*
ViziLite® TBlue*	Den-Mat Holdings, LLC Lompoc, CA
Microlux DL™*	AdDent, Inc., Danbury, CT
VELscope® Vx§	LED Dental, White Rock, British Columbia, Canada
Sapphire® Plus§	Den-Mat Holdings, LLC Lompoc, CA
Identafi®¶	DentalEZ, Malvern, PA
Bio/Screen®§	AdDent, Inc., Danbury, CT
DOE SE Kit§	DentLight Inc., Plano, TX
OralID™§	Forward Science, Houston, TX
ViziLite PRO§	Den-Mat Holdings, LLC Lompoc, CA

* *Tissue reflectance - average wavelength 490-510 nm*
§ *Autofluorescence - average wavelength 400-460 nm*
¶ *Three individual light spectrums: white light, amber light, autofluorescence*

Table 4 - Molecular-based adjuncts[18]

Product	*Company*	*Biomarkers Assessed*
OraRisk® HPV Complete Genotype	OralDNALabs Eden Prairie, MN	51 HPV strains, both low risk and high risk
OraRisk® HPV 16/18/HR	OralDNALabs Eden Prairie, MN	High risk HPV strains 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68
SaliMark™ OSCC	PeriRx, LLC Broomall, PA	DUSP1, SAT, and OAZ1

The premise is that healthy cells absorb the blue-white light while dysplastic cells reflect the blue-white back to the examiner as "aceto-white."[25,37]

Autofluorescence adjuncts (VELscope® Vx, Sapphire® Plus, Identafi®, BioScreen®, DOE Oral Exam System, OralID™, ViziLite PRO) use light spectra in the 390 – 460 nm range to assess the autofluorescent character of the mucosal tissues.[36] A narrow band filter (either in the device viewfinder or via eyewear) is used to highlight the autofluorescent character of the examined tissue. The working premise is that dysplastic or carcinogenic tissues are associated with an altered autofluorescence signature, due to increased collagen destruction, specific nuclear/cytoplasmic ratios, and angiogenesis. Healthy tissue appears pale green during autofluorescence, while suspicious tissues appear dark (loss of fluorescence).[18]

Molecular-based Adjuncts

Salivary profiling continues to gain acceptance as a noninvasive and cost-effective diagnostic tool for a variety of oral diseases,[38] and the development of reliable, predictive salivary tests to assess PMDs for malignancy would be a "game changer."[2] While such a test is not yet available, three molecular-based adjunctive tests (**Table 4**) have been introduced to the dental marketplace as putative aids to assess for risk of oral cavity and pharynx cancer. The currently available molecular-based adjuncts require shipment to an off-site laboratory for analysis.

The OraRisk® HPV Complete Genotype and the OraRisk® HPV 16/18/HR are PCR–based saliva tests available for determining the presence of HPV.[39,40] The OraRisk® HPV Complete Genotype utility screens for 51 strains of HPV in saliva, while the OraRisk® HPV 16/18/HR utility tests for 14 oncogenic HPVs, to include HPV 16 and HPV 18.

The SaliMark™ OSCC adjunctive test is a case assessment utility to interrogate a PMD for malignancy risk.[41] The manufacturer claims that by determining the levels of mRNAs in saliva produced from genes DUSP1, SAT, OAZ1, MTATP6 and RPL30, oral lesions at high-risk for oral cancer may be discriminated from low-risk oral lesions.[42] It is marketed as a negative predictor, with a goal of reducing unnecessary biopsies.

A detailed review of Human Papilloma Virus (HPV) may be found in the Quality Resource Guide, "HPV and Oral Cancer."

Performance of Adjunctive Devices

An ideal diagnostic adjunct to assess PMDs should:

1) be simple, safe and acceptable to the public
2) detect early stage disease
3) preferentially detect lesions likely to progress
4) detect lesions which are manageable
5) have a high positive predictive value and a low false negative value.[22]

The performance of available adjuncts was assessed in a recently published vigorous review of the available quality evidence.[2] The investigators were able to determine the estimated sensitivity and specificity values for cytology, vital stain, and light-based diagnostic adjuncts when used to assess seemingly innocuous lesions and PMDs (**Table 5**).

The clinical implications of test accuracy are best appreciated by understanding the consequences of the results for patients. A test that yields high proportions of true positive and true negative results is the ideal. Unfortunately, most screening tests are less than completely accurate, making it important to appreciate the consequences for the patient of false positive and false negative results. A false positive occurs when the screening test labels the site as cancerous when it is not. This false result subjects the patient to needless worry and unnecessary biopsy. Conversely, a false negative test result gives the patient a false sense of security that there is no cancer when cancer is actually present, which without timely intervention will progress. Given the modest to poor sensitivity and specificity reported for all, the practitioner and patient need to be fully aware of these negative consequences when deciding whether to use one of these screening tests.

In applying their values, the authors calculated that for every 100,000 patients with a PMD, there would 250 true cancers. Thus the use of:

- *cytology* to assess the PMDs would miss 20 cancers (false negative) and misidentify 5,985 as cancers (false positive).
- *vital staining* would yield 33 false negatives and 28,927 false positives.
- *tissue reflectance* would yield 70 false negatives and 68,827 false positives.
- *autofluorescence* would yield 25 false negatives and 27,930 false positives.

Table 5 - Estimated sensitivity and specificity values for adjunctive devices[2]

Adjunct	*Sensitivity/Specificity for Innocuous Lesions*	*Sensitivity/Specificity for Suspicious Lesions*
Cytology	0.96 / 0.90	0.92 / 0.94
Vital Stain	ND	0.87 / 0.71
Tissue Reflectance	0.00 / 0.76	0.72 / 0.31
Autofluorescence	ND	0.90 / 0.72

ND: Not determined due to insufficient data

The authors determined that, at present, there is insufficient evidence to adjudicate the clinical performance of molecular-based adjuncts.[2] One proof of concept study addressing the SaliMark™ OSCC product reported sensitivity and specificity values of 91.7% and 59.0%, respectively.[42] Based on that data, for every 100,000 PMDs assessed, the yield would be 20 false negatives and 58,853 false positives.

The value of routine salivary screening for oral HPV as a method of assessing risk for oropharyngeal cancer is controversial. High-risk HPV prevalence in the oral mucosa is estimated at 7.3% for men and 1.4% for women[43] and an estimated 10,500 individuals would need to be tested to yield one case of cancer.[44] Unfortunately, there are no available interventions to reduce or prevent the downstream future development of HPV associated oral cancer in patients who are identified as HPV-positive and considered to be at-risk. Of note, HPV risk screening could incur significant anxiety for those who screen positive for a high-risk HPV even though the clinical outcome of a positive lab test result is not yet established.[45]

Summary

Disciplined performance of CVTE on a regular basis remains the standard to identify PMDs. Any PMD or equivocal lesion should be immediately biopsied or referred to a specialist. Lesions deemed innocuous should undergo periodic monitoring for change and/or resolution. Evidence supporting the use of available adjunctive devices in clinical practice to discover or assess PMDs is low and their use is associated with a high burden of false positive results. At present their utility is very limited. Commercially available adjunctive devices should be reserved for patients who decline a biopsy, decline referral to a specialist, or when multiple lesions are present and biopsy site selection could be enhanced. Routine use of adjunctive devices for PMD detection is not recommended.

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1. **The prevalence of oral cavity cancer is estimated to be:**
   a. 0.1%.
   b. 0.25%.
   c. 0.35%.
   d. 0.5%.

2. **The most important factor contributing to the delayed diagnosis of oral cavity and pharynx cancer is:**
   a. the clinician's failure to use innovative technologies on a routine basis.
   b. the patient's tardiness to obtain an evaluation.
   c. lack of examination consistency.
   d. professional delay.

3. **Components of a proper examination to identify a potentially malignant disorder include all of the following except:**
   a. A comprehensive review of the medical, dental, and social history
   b. A thorough visual and tactile extra-oral and intra-oral examination
   c. Referral or biopsy of any discovered lesion deem suspicious
   d. Saliva testing for the presence of a high-risk HPV

4. **All of the following statements regarding TB are true, except for one. Which one is the exception?**
   a. It is a metachromatic dye with an affinity to bind DNA.
   b. It is marketed as a case-assessment utility with the MicroLux DL™ product.
   c. It is cleared by the FDA as a standalone adjunctive screening aid.
   d. The presence of inflammation is associated with increased high false positive results.

5. **Of the available adjunctive devices to improve the clinician's ability to identify a potentially malignant disorder, which one uses the principle of tissue reflectance?**
   a. ViziLite® TBlue
   b. VELscope®
   c. Bio/Screen®
   d. ViziLite PRO®

6. **Of the available adjunctive devices marketed to improve the clinician's ability to identify a potentially malignant disorder, which one uses three (3) individual light spectrums to interrogate the tissues?**
   a. Bio/Screen®
   b. ViziLite PRO®
   c. OralID™
   d. Identifi®

7. **When using an autofluorescent adjunctive device, healthy tissues should appear:**
   a. dark blue.
   b. Pale magenta.
   c. pale green.
   d. bright white.

8. **A positive result from OraRisk® HPV 16/18/HR means:**
   a. the oral mucosa contains dysplastic cells.
   b. the oral mucosa contains cancerous cells.
   c. the oral mucosa will develop cancer.
   d. the oral mucosa contains one of 14 oncogenic HPV DNA.

9. **Which category of adjunctive aid is there insufficient evidence to assess their true value in clinical practice?**
   a. Cytology-based
   b. Light-based
   c. Vital stain-based
   d. Molecular-based

10. **Which category of adjunctive aid generates the lowest number of false positives results?**
    a. Cytology-based
    b. Light-based
    c. Vital stain-based
    d. Molecular-based

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