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Decision-Making Methodology for Oral Mucosal Screening

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LEARNING OBJECTIVES:

After reading this article, the individual will learn:

- To identify and describe available technologies for early oral lesion detection.
- Why early detection technologies may or may not be implemented in a general dental practice routinely.

ABOUT THE AUTHORS

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Disclosure: *Dr. Huff reports no conflicts of interest.*

INTRODUCTION

Oral assessment with adjunctive mucosal screening technologies may assist in early detection of tissue changes that have the potential of becoming cancerous. Early identification of precancerous and cancerous lesions is essential to lowering the mortality and morbidity rates associated with oral dysplasia and cancer. However, the use of these screening tools is often reserved for patients with a high-risk profile. Since oral neoplastic lesions primarily originate in the epithelium, and due to a paradigm shift in the understanding of the etiology of oral dysplasia and cancer of the oral cavity, the routine application of effective early mucosal screening is appropriate for all adolescent and adult patients. Due to identified relationships with human papilloma virus (HPV) infection, suggested relationships with periodontal disease, and previously understood relationships with alcohol and tobacco use, prescreening patients based only on common risk factors is no longer appropriate practice; nearly every adult and adolescent is at risk for developing oral cancer.

During the 20th century, dentistry has experienced a paradigm shift from episodic care to a preventive focus. A growing understanding of the relationships between oral health and other systems of the body illustrate the importance of dentistry in overall health. Prevention and early diagnosis as well as management of dental disease have become standards of care. The development of tools and systems to screen for diseases in early stages has been a goal of healthcare. The United States Preventive Services Task Force, an independent panel of experts,

commissioned by the Agency for Healthcare Research and Quality, looked at pertinent issues related to clinical decision-making regarding prevention. Four domains were identified: (1) potential preventable burden, (2) trends in current practice, (3) potential harm of the intervention, and (4) potential costs.[1] Consideration of each of these domains may assist oral health providers in guiding the choice of preventive procedures incorporated into practice. For example, several systems have been developed which are touted to enhance the ability of oral health providers to detect early oral mucosal lesions.[2]

This paper describes the currently available early oral mucosal screening technologies and offers a methodology to assist the clinician in choosing the most appropriate screening protocols in his or her practice.

POTENTIAL PREVENTABLE BURDEN

In the United States, oral cancer accounts for about 35,000 cases and about 7,600 deaths annually.[3] A person dies from oral cancer every hour of every day in the United States alone. When found early, the survival rate is 80% to 90%. Unfortunately, at this time, most oral cancers are identified in late stages.[4] Early detection of potentially premalignant oral mucosal abnormalities is essential to winning the battle against cancer.

Epithelial dysplasia can present as innocuous red, white, or mixed patches on the mucosa in early stages, often mimicking minor soft tissue injury or inflammation. However, ruling out dysplasia is important because, depending on the studies cited, 12% to 42% of dysplasias become carcinoma *in situ* within 5 years, and 73% of those will progress to metastatic carcinoma.[5] Many HPVs are associated with oral lesions. Oncogenic HPVs have been identified in oral precancerous and cancerous neoplasia. There are 2 prominent pathways by which oral squamous cell carcinoma develops: the use of tobacco and alcohol (50%) and exposure to the HPV-16 or HPV-18 oncoviruses, which are also responsible for cervical cancer.[4]

When early diagnosis is made and appropriate intervention and treatment are rendered, the overall survival and patient morbidity is improved.[6] Although techniques for palpation and incandescent light visual examination have been taught in dental schools for decades, the overall 5-year survival rates for oral cancer have only improved about 5% since 1974, fluctuating around 55%.[7] Furthermore, in addition to the traditional risk factors of age, race, sex, alcohol and tobacco use,[8] marijuana use,[9] HPVs,[10] and periodontal disease[11] have been identified as risk factors. Despite promising case reports about early adjunctive visual screening tools,[12] a lack of understanding about the differences between visual screening tools and tissue sampling techniques combined with early reports of false positive results from cytological sampling have added to the challenge of incorporating early screening technologies into the general dental practice.[13]

TRENDS IN CURRENT PRACTICE

The conventional oral cancer (COE) screening examination as taught in dental curricula includes visual inspection and manual palpation of the external structures of the head and neck, as well as the internal anatomy of the oral cavity[14] (see Video 1 on the Web site dentalcetoday.com). Bimanual palpation is utilized to identify firm or nodular irregularities within the soft tissues. The overall physical appearance and symmetry should be observed for signs of neurological irregularities. Attention should be given to pigmented lesions with raised and irregular borders, nonhealing lesions, and scars that may hint to a history of skin cancer therapy. The ears, scalp, and lips are high-risk areas for solar-radiation induced malignancies. Firm and/or tender nodes should be investigated further for signs of disease or infection via blood testing and possibly aspiration biopsy.

When examining the mouth and oral structures, adequate lighting is essential. Although adjunctive screening tools are readily available, their use is often reserved for those patients assumed to be at higher risk for developing oral cancer due to classical risk factors (ie, men aged more than 50 years, history of smoking, genetic history of familial cancer, etc). This type of prescreening is unfortunate because current understanding of the literature suggests that due to widespread potential for HPV exposure, both men and women are at risk even if they do not possess the classical risk factors.

Visualization of all areas of the mouth and oropharynx should be given careful attention. High-risk areas for oral

squamous cell carcinoma include the retromylohyoid vestibule, the tonsillar pillars, the anterior floor of the mouth, the base of the tongue, and the lateral borders of the tongue. Any pigmented, white, or red lesions that cannot be easily wiped off should be considered to be suspicious, and a thorough review of the history of the anomaly should be obtained. Erythematous lesions may be due to benign inflammation secondary to injury, due to post-nasal sinus drainage, or signs of early premalignancy. Raised erythroplakic, leukoplakic, or mixed lesions are considered suspicious.[15] Persistent lesions should be considered for biopsy in order to attain a definitive diagnosis. Adjunctive screening aids have been developed to assist in visual inspection of the oral cavity. These aids allow for early discovery of lesions that might otherwise have been overlooked, patient education concerning early findings, and as a means of strengthening a decision to refer for surgical management.

Chemiluminescence, initially marketed as Vizilite (Zila Pharmaceuticals) is an adjunctive visual screening aid based on the reflection of visible light off hyperactive keratinizing cells. It requires a prerinse of dilute acetic acid to remove the glycoprotein barrier established by saliva and to dehydrate superficial mucosal cells so that areas of increased nuclear:cytoplasmic ratio can better be visualized using a proprietary light source (see Video 2 on the Web site dentalcetoday.com). It has been approved for patients who are known to be at risk for oral cancer.[16] Positive findings discovered with the Vizilite Plus (Zila Pharmaceuticals) may be marked for visualization in incandescent lighting and for photographic documentation with a commercially prepared and stabilized vital dye, TBlue^{630}, which is only available as part of the Vizilite Plus system for use on findings previously found during the Vizilite examination. Toluidine blue is used for surgical margin identification and for oral cancer research,[17] but it is not available in a ready-to-use and convenient form except as TBlue^{630}.

Other manufacturers have adopted a similar basis for their products (Orascoptic DK and Microlux DL [both manufacturered by AdDent]), but they utilize a LED visual light source rather than chemiluminescence. Due to the proprietary nature of TBlue^{630}, it is difficult to photodocument findings with the AdDent products. Chemiluminescent-like systems are helpful in highlighting the appearance of white, or even mixed, lesions because they work on the basis of reflection. Although these systems are relatively simple to use, patients may object to the taste of the acetic acid prerinse, and there is a limited window of opportunity for the examination to be completed before the tissues are rehydrated.

Another visual screening technology, direct tissue fluorescence visualization, was introduced in 2006. This technology is dependent on the natural biofluorescent properties of cellular metabolites[18] and by the loss of fluorescence associated with the progression of dysplasia that causes breakdown of the collagen matrix.[19] Rapidly reproducing cells typically do not exhibit the same natural fluorescence as healthy cells. Therefore, areas of dysplastic stroma or inflammatory infiltrate where collagen cross-link patterns are disrupted appear dark, and healthy tissues appear in variations of green or blue, depending on their collagen substructure and the product being used to conduct the examination. No dyes or rinses are utilized with this technology, and it is easily implemented into practice. Direct tissue fluorescence has been cleared for use by the FDA as a safe screening tool in all patient populations as well as for use in surgical margin delineation.[17] The addition of direct tissue fluorescence visualization to the oral cancer screening protocol has been proven effective in finding dysplastic lesions that had not been identified by COE alone in a stable low-risk population (Table).[20]

The VELscope (LED Dental) was the first application of direct tissue fluorescence visualization. Findings with the VELscope can be predictably documented with photography and with videography[21] (see Video 3 on dentalcetoday.com). A second product, the Identafi 3000 (Trimira Remicalm), was introduced to the market in early 2009. It is touted to be more portable than the VELscope and adds an additional screening tool if a lesion is discovered under violet lighting. Amber lighting, the manufacturer claims, enhances the ability to discern hypervascularity of lesions of lost flourescence, which may be related to an increased likelihood of dysplasia (see Video 4 on dentalcetoday.com). A similar effect may be obtained by photographing lesions through the VELscope with the camera flash turned on rather than off. The

portability of the battery-operated nature of the Identafi 3000 must be weighed against a less intense lighting ability and more difficult photodocumentation ability than the VELscope permits. Both of these products are now available as improved second-generation products: the VELscope Vantage and the Identafi 3000 Ultra.

Table. A retrospective study comparing the oral mucosal abnormal findings with 2 different screening protocols.[20]

Years of Study	Oral Cancer Screening Protocol	Number of Patients	Surgical Biopsy Results	
			Benign	Premalignant
December 1, 2005 to December 1, 2006	COE	959	2 of 2	0 of 2
December 1, 2006 to December 1, 2007	COE + VELscope	905	2 of 12	10 of 12

Once a lesion is discovered by some form of visualization, either by the COE alone or by the addition of chemiluminescence or direct tissue fluorescence visualization to the COE, the clinician may decide that more information is needed prior to referral for surgical management. This information can be gathered through minimally invasive tissue sampling, which has been referred to as a tertiary level of screening.[22] Currently, 2 prominent systems are available that utilize brushes to collect cells from suspicious lesions, presumably from all of the epithelial layers. The Oral CDx BrushTest (CDx Laboratories) uses a simple rotary technique with a circular brush to collect the sample. The sample is smeared onto a glass slide, fixed with an alcohol-based solution, and shipped to CDx Laboratories, where a computerized screening system identifies irregular cells. The results are reported as "atypical, warranting further investigation," "positive," or "negative for epithelial abnormality." A similar tissue collection technique using a standard cytology brush is utilized for liquid-based cytology, which can be processed in several educational institutions. The entire brush is placed in a vial containing a proprietary liquid alcohol-based medium. The vial containing the brush and cells is shipped to the laboratory for processing by SurePath protocol (TriPath Imaging). Once centrifuged, slides are processed for modified Papanicolaou staining. An oral pathologist's opinion is sent to the clinician, typically with a recommendation for appropriate follow-up therapy. A third brush cytology system, which is available currently in Canada, is OralAdvance (Perceptronix). Once a brush sample is submitted, the cells are processed similarly to other liquid-based cytology specimens, but then they are quantitatively evaluated for ploidy, or the chromosomal content of abnormal cells, which may be suggestive of dysplastic activity.

Brush cytology, regardless of the system chosen, is not diagnostic, but it may be useful in patient education and in strengthening the evidence-based referral for surgical intervention and biopsy. Any suspicious lesion where the cause cannot be identified by history that persists for more than 14 days should be strongly considered for a biopsy procedure in order to attain a more definitive diagnosis. Surgical biopsies may be performed with a diode laser or a scalpel. Since marginal tissue may be ablated with peripheral heat generated by a laser, the scalpel technique is typically preferred.

There are essentially 2 types of biopsies: excisional and incisional. Excisional biopsies remove the entire lesion, a border of normal tissue of at least 5 mm, and a clean connective tissue base.[23] Incisional biopsies include a piece of the lesion, and preferably some healthy border tissue. A tissue punch may also be used for either excision of a small lesion or for incisional biopsies. When there is a medium to high level of suspicion that a lesion is malignant based on the clinical presentation, an incisional biopsy should be preferred to excisional removal so that the appropriate anatomical field for management can be adequately identified by the specialist to whom the case will be referred. Photodocumentation of all lesions to be biopsied is essential for effective continuity of care and for monitoring the outcome of suspicious lesions.

POTENTIAL HARM OF THE INTERVENTION

It may be argued that screening every patient with adjunctive screening technologies leads to unnecessary

false positives when a clinical finding is thought to be cancer but biopsy proves that the finding is normal tissue. By this definition, false positives found with adjunctive screening technologies would seem to be better than the risk of a false negative results from a COE alone. However, when adjunctive screening is used to identify lesions that are other than normal tissue, false positive rates have been shown to be reduced by appropriate screening and follow-up protocol.[20]

POTENTIAL COSTS

The amount of time that it takes for a dentist to complete a traditional oral health exam has been estimated to be about 3 to 6 minutes, and adjunctive visualization may take another 3 to 5 minutes. Therefore, fees for oral cancer screening examinations should justifiably be higher when adjunctive technologies are implemented. If lesions are discovered, additional costs may be incurred by further investigative techniques. If brush cytology is utilized, there is typically a fee for sample collection as well as a laboratory processing fee. Since definitive diagnosis can only be made by surgical biopsy,[4] additional surgical and laboratory fees are unavoidable. The cost of physical and emotional stress on the patient when untoward findings are discovered should not be underestimated. Despite the cost of diagnosis, the cost of delayed diagnosis is much greater in terms of increased morbidity and mortality as well as costs to the practitioner for potential malpractice suits.[24]

It may be argued that availability of adjunctive screening tools increases overtreatment; however, proper implementation of adjunctive screening technology may, in fact, reduce surgical costs through evidence-based referrals. Because dentistry is a moral profession based on the premises of nonmaleficence and benevolence, dentists should be proactive in utilizing diagnostic modalities that allow them to be "caring and fair in their contact with patients."[25]

CONCLUSION

Incorporation of adjunctive mucosal screening technology into the general dental practice is an individual decision made by the oral health provider. Using the 4 domains suggested for consideration when making this decision, it could be argued that the benefit must outweigh the risk. Early mucosal lesions that harbor dysplasia can be difficult to detect by conventional oral examination techniques alone. With available technologies, the risks of overlooking potentially life-threatening lesions are minimized, thus increasing the benefit to the patient and to society as a whole.

Technology will continue to advance, and practitioners will make decisions to include, or not to include, adjunctive screening technologies into their practices. Informed patients, however, also know what is available. The clinician must be prepared and able to defend his or her position on the role of oral cancer adjunctive screening technologies to patients who entrust him or her with their care and in a court of law if necessary.

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1. **Which of the following statements best reflects the current philosophy of dentistry?**
   a. Care should be episodic.
   b. A shift toward prevention focus is included in the standard of care.
   c. Screening is unethical due to a higher risk than benefit ratio.
   d. Treatment of oral disease is independent of other body systems.

2. **Which of the following has the closest correlation to increased risk of developing an oral carcinoma?**
   a. Obesity.
   b. Dental caries.
   c. HPV.
   d. Asthma.

3. **A routine oral exam should include which of the following?**
   a. Visualization of all areas of the mouth and oropharynx.
   b. Palpation of the greater omentum.
   c. Auscultation of the greater trochanter.
   d. Percussion of the stapes.

4. **A prerinse of dilute acetic acid:**
   a. is used to prepare the mouth for a surgical biopsy.
   b. arrests the growth of oral lesions.
   c. removes the glycoprotein barrier in the mouth.
   d. changes the color of a premalignant lesion.

5. **What is the appearance of dysplastic tissue when using direct tissue fluorescence visualization?**
   a. Green.
   b. Blue.
   c. Pale area.
   d. Dark area.

6. **Brush biopsies are prepared for the laboratory by:**
   a. drying suggestive cells on a nylon brush.
   b. collecting cells from several areas of the mouth.
   c. minor debridement with a brush over the lesion and preserving the sample.
   d. leaving the brush in the mouth until it is moist.

7. **The cost of screening for oral cancer:**
   a. is too great to incorporate into routine care.
   b. should be absorbed in the overhead of the provider's practice.
   c. is unjustifiable.
   d. is minimal compared to the cost of late diagnosis.

8. **Which of the following techniques is used to obtain a diagnosis of an oral malignancy?**
   a. Surgical biopsy.
   b. Direct tissue fluorescence visualization.
   c. Chemiluminescence.
   d. Brush cytology.

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