



Adjuncts for the evaluation of potentially malignant disorders in the oral cavity

Diagnostic test accuracy systematic review and meta-analysis—a report of the American Dental Association

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In 2017, an estimated 49,670 new cases of cancer in the oral cavity and pharynx will be diagnosed in the United States, with 9,700 disease-associated deaths.¹ Estimates for cancer in the oral cavity alone include 32,670 new cases and 6,650 deaths.¹ Most of these cancers will be squamous cell carcinomas.

Survival is highly stage dependent, with 83.7% of people surviving 5 years after diagnosis of localized cancer and 64.2% and 38.5% of people surviving with regional and distant metastases.²

Approximately 70% of all new cases are diagnosed at a late stage, underscoring the importance of proper patient



Supplemental material is available online.

ABSTRACT

Background. Oral squamous cell carcinoma is the most common manifestation of malignancy in the oral cavity. Adjuncts are available for clinicians to evaluate lesions that seem potentially malignant. In this systematic review, the authors summarized the available evidence on patient-important outcomes, diagnostic test accuracy (DTA), and patients' values and preferences (PVPs) when using adjuncts for the evaluation of clinically evident lesions in the oral cavity.

Types of Studies Reviewed. The authors searched for preexisting systematic reviews and assessed their quality using the Assessing the Methodological Quality of Systematic Reviews tool. The authors updated the selected reviews and searched MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials to identify randomized controlled trials and DTA and PVPs studies. Pairs of reviewers independently conducted study selection, data extraction, and assessment of the certainty in the evidence by using the Grading of Recommendations Assessment, Development and Evaluation approach.

Results. The authors identified 4 existing reviews. DTA reviews included 37 studies. The authors retrieved 7,534 records, of which 9 DTA and 10 PVPs studies were eligible. Pooled sensitivity and specificity of adjuncts ranged from 0.39 to 0.96 for the evaluation of innocuous lesions and from 0.31 to 0.95 for the evaluation of suspicious lesions. Cytologic testing used in suspicious lesions appears to have the highest accuracy among adjuncts (sensitivity, 0.92; 95% confidence interval, 0.86 to 0.98; specificity, 0.94; 95% confidence interval, 0.88 to 0.99; low-quality evidence).

Conclusions and Practical Implications. Cytologic testing appears to be the most accurate adjunct among those included in this review. The main concerns are the high rate of false-positive results and serious issues of risk of bias and indirectness of the evidence. Clinicians should remain skeptical about the potential benefit of any adjunct in clinical practice.

Key Words. Oral squamous cell carcinoma; potentially malignant disorders; diagnostic test accuracy; patients' values and preferences.

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evaluation for the prevention or early detection of disease.¹ Clinicians detect and assess oral potentially malignant disorders (PMDs) and oral squamous cell carcinomas (OSCCs) by using the combination of an intra- and extraoral conventional visual and tactile examination and the detection of dysplasia through tissue biopsy. However, although as many as 10% of patients will have some type of oral mucosal abnormality, only a small fraction of these abnormalities or lesions will be biologically and clinically significant.³

Conventional visual and tactile examination in the oral cavity is limited in its ability to help discriminate between similar-appearing lesions or disorders that may require considerably different treatments. To address analogous challenges at other anatomic sites, clinicians have used adjunctive tests or devices, simply known as *adjuncts*, such as mammography, the Papanicolaou smear, and colonoscopy, to assist in the detection and evaluation of disease. A number of adjuncts have become commercially available to aid in the evaluation and discrimination of oral mucosal lesions.⁴⁻⁸ These adjuncts can be divided into 3 broad categories: lesion detection or discrimination, lesion assessment, and risk assessment.

■ **Lesion detection or discrimination.** This category is composed mostly of light-based handheld adjuncts proposed to aid clinicians in the detection and margin discrimination of lesions by using the principles of autofluorescence and tissue reflectance. Some also would classify vital staining within this category.

■ **Lesion assessment.** This category of adjuncts is intended to assist clinicians in assessing the biological or clinical relevance of a mucosal abnormality through cytomorphologic analysis of disaggregated epithelial cells (cytologic testing). Some also would classify vital staining within this category.

■ **Risk assessment.** This category is composed of saliva-based adjuncts that involve using a number of biomarkers, including proteins, RNAs, and DNAs.

The purpose of this systematic review was to address the potential benefits and limitations of commercially available adjuncts to aid in the detection, discrimination, and assessment of oral mucosal lesions, particularly PMDs and OSCC in adult patients. This article is an update and major revision of the 2010 review⁶ which was performed by an expert panel of clinical and subject matter experts convened by the American Dental Association (ADA) Council on Scientific Affairs. The ADA Center for Evidence-Based Dentistry and the Cochrane Collaboration provided methodological support for the development and authorship of this review.

Adjuncts can be incorporated in the diagnostic pathway to triage before an existing test, replace an existing test, or add on to an existing test to increase accuracy.⁹ For this systematic review, we interpreted data from the included studies in the context of using adjuncts to triage the need for biopsy and not as

replacement for biopsy.¹⁰ Clinicians typically use triage tools in an early stage of the diagnostic process to identify patients with a particular finding that will be informative for subsequent steps in the testing pathway. These findings informed the development of a 2017 evidence-based clinical practice guideline by the ADA Center for Evidence-Based Dentistry,¹¹ which contains recommendation statements to guide the clinical decision-making process (eTable 1).

METHODS

This report follows the guidance of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses¹² statement and other methodological recommendations from the Cochrane Screening and Diagnostic Tests Methods Group.¹³

Selection criteria for the studies in this review.

Type of studies. We included cross-sectional and cohort diagnostic test accuracy (DTA) studies and randomized controlled trials (RCTs) in which the investigators assessed the effectiveness or accuracy of adjuncts. We excluded study designs such as case-control studies, case reports, case series, abstracts, and uncontrolled reports.

Type of participants and target conditions. Studies eligible for inclusion involved adult patients (aged 18 years or older), ideally in the context of primary care settings, seeking care with or without clinically evident lesions in the oral cavity, encompassing the labial mucosae, buccal mucosae, gingival or alveolar ridge mucosae, tongue, floor of mouth, hard and soft palate, and retromolar trigone. If clinically evident, lesions could manifest as seemingly innocuous or nonsuspicious, suspicious, or seemingly malignant. We excluded studies involving patients seeking care for cancers of the lips, oropharynx, and salivary glands.

Index tests and the criterion standard. Definitive diagnosis of PMDs and OSCC requires using a criterion standard wherein the patient undergoes a biopsy of the lesion followed by a histopathologic assessment. Studies not specifying any criterion standard were ineligible for inclusion in this systematic review. Other tests, devices, techniques, or technologies intended to facilitate clinical decision making are index tests. The aforementioned adjuncts act as index tests in the context of this review and are used as triage tools in practice. Adjuncts can have either a positive (with suspicion of target condition)

ABBREVIATION KEY. ADA: American Dental Association. CDC: Centers for Disease Control and Prevention. CVTE: Conventional visual and tactile examination. DTA: Diagnostic test accuracy. GRADE: Grading of Recommendations Assessment, Development and Evaluation. OSCC: Oral squamous cell carcinoma. PMD: Potentially malignant disorder. PVPs: Patients' values and preferences. RCT: Randomized controlled trial.

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