

Toluidine blue staining identifies high-risk primary oral premalignant lesions with poor outcome.

Cancer Research. 2005 Sep 1;65(17):8017-21.

Zhang L, Williams M, Poh CF, Laronde D, Epstein JB, Durham S, Nakamura H, Berean K, Hovan A, Le ND, Hislop G, Priddy R, Hay J, Lam WL, Rosin MP.

Abstract

There is a pressing need for the development of visual aids that will facilitate the detection of oral premalignant lesions (OPLs) with a high-risk of progression. Preliminary data suggest that toluidine blue stain may be preferentially retained by OPLs with high-risk molecular clones. In this study, we monitored OPLs from 100 patients without any history of oral cancer for an average of 44 months in order to evaluate the association of toluidine blue status with clinicopathologic risk factors, molecular patterns (microsatellite analysis on seven chromosome arms: 3p, 9p, 4q, 8p, 11q, 13q, and 17p) and outcome. Toluidine blue-positive staining correlated with clinicopathologic risk factors and high-risk molecular risk patterns. Significantly, a >6-fold elevation in cancer risk was observed for toluidine blue-positive lesions, with positive retention of the dye present in 12 of the 15 lesions that later progressed to cancer ($P = 0.0008$). This association of toluidine blue status with risk factors and outcome was evident even when the analysis was restricted to OPLs with low-grade or no dysplasia. Our results suggest the potential use of toluidine blue in identifying high-risk OPLs.

PMID: 16140975 [PubMed - indexed for MEDLINE] Free Article

Analysis of oral lesion biopsies identified and evaluated by visual examination, chemiluminescence and toluidine blue (ViziLite Plus with TBlue).

Oral Oncology. 2008 Jun;44(6):538-44. Epub 2007 Nov 8.

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Abstract

Conventional visual examination and palpation remains the gold-standard for the identification of oral mucosal lesions. The purpose of this study was to investigate the adjunctive value of a chemiluminescent light source (ViziLite, Zila Pharmaceuticals, Phoenix, Arizona) and application of pharmaceutical grade toluidine blue (TBlue(630), Zila Pharmaceuticals, Phoenix, Arizona) to further assess lesions identified during the conventional oral soft tissue examination. Lesions deemed clinically suspicious by visual examination under incandescent light were further assessed under chemiluminescence and then application of toluidine blue stain. Differences between the conventional visual examination and chemiluminescent examination were noted on four characteristics which may aid in lesion identification. Tissue retention of toluidine blue stain was documented.

Each suspicious lesion was biopsied and diagnosed based upon routine histopathology. Both adjunctive exams were evaluated by comparing the histologic diagnosis. The additive value of toluidine blue stain retention was assessed in lesions diagnosed as "serious pathology" defined as severe dysplasia, carcinoma in situ and squamous cell carcinoma. Ninety-seven clinically suspicious lesions in 84 patients were identified. The chemiluminescent exam improved the brightness and/or sharpness of margin in 61.8% of identified lesions. Biopsied lesions with toluidine blue stain retention reduced the false positive rate by 55.26% while maintaining a 100% negative predictive value (NPV). Chemiluminescence was shown to increase the brightness and margins of mucosal lesions in a majority of cases and therefore may assist in identification of mucosal lesions not considered under traditional visual examination. Toluidine blue stain retention was associated with a large reduction in biopsies showing benign histology (false positive biopsy results), while maintaining a 100% NPV for the presence of severe dysplasia or cancer. Practitioners may consider use of these adjuncts in practice, however the results presented are based upon experienced providers in referral centers for mucosal disease or cancer centers and therefore positive findings may be an indication for referral to experienced providers.

PMID: 17996486 [PubMed - indexed for MEDLINE]

Clinical evaluation of chemiluminescent lighting: an adjunct for oral mucosal examinations.

J Clin Dent. 2006;17(3):59-63.

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Abstract

OBJECTIVE: The purpose of this study was to describe the utility of oral chemiluminescent lighting (FDA-cleared ViziLite) as an adjunct to standard visual examination (SVE) to enhance visualization of mucosal lesions, particularly those "clinically suspicious" for oral pre-cancer or cancer. Subjects were considered at risk for oral cancer or pre-cancer if they have no a priori knowledge of the presence or absence of an oral lesion at the time of examination.

METHODOLOGY: Five-hundred and one consecutive consenting subjects, over 40 years of age and with a positive tobacco history, received a standard visual examination with conventional incandescent lighting, followed by chemiluminescent lighting. All lesions were recorded, and for lesions detected by both screening modalities, comparisons were made of the subjective parameters of lesion brightness, sharpness, surface texture, and relative size.

RESULTS: A total of 410 epithelial lesions were detected in 270 subjects by standard visual examination, of which 127 were clinically "suspicious" for oral cancer and pre-cancer. Ninety-eight lesions were also visualized by chemiluminescent lighting as "aceto-white" (CL+), in addition to six lesions not previously seen by standard visual examination. Seventy-seven of the CL+ lesions (78.5%) were clinically suspicious; all "suspicious" lesions with an ulcerative component and ulcerated lesions consistent with trauma were CL+. Leukoplakias were significantly more likely to be CL+ than erythroplakias ($p < 0.01$). Overall, those lesions illuminated by chemiluminescent lighting appeared brighter, sharper, and smaller compared to incandescent illumination.

CONCLUSION: The results of this study suggest that oral chemiluminescent lighting, when used as a screening adjunct following the standard visual oral examination, provides additional visual information. Leukoplakias may be more readily visualized by chemiluminescence. Studies are underway to explore the clinical significance and predictive value of oral chemiluminescent lighting.

PMID: 17022366 [PubMed - indexed for MEDLINE]

Acetic acid wash and chemiluminescent illumination as an adjunct to conventional oral soft tissue examination for the detection of dysplasia: a pilot study.

Quintessence Int. 2004 May;35(5):378-84.

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Abstract

Population-based oral cancer screening appears to be a promising health promotion strategy (especially in high-risk individuals) with significant increases in quality-adjusted life years saved. However, the current protocol, conventional visual inspection, and palpation of oral soft tissues for the early detection of pre-malignant or malignant changes, appears to be deficient. The adjunctive application of technology to highlight such lesions may increase the diagnostic yield. The purpose of this pilot study was to collect data, which might support the hypothesis that oral soft tissues exhibit features similar to the cervical epithelium following an acetic acid wash and visual inspection under chemiluminescent illumination. The data provides strong evidence to support the hypothesis. Epithelium with hyperkeratinization, hyperparakeratinization, and/or chronic inflammatory infiltrate reflects the diffuse, low-level, blue-white chemiluminescent light more strongly and appears amplified. Similarly, epithelium with an altered nuclear-cytoplasmic ratio also reflects the diffuse, low-level, blue-white chemiluminescent light. In such cases, the lesions become clinically discernible and appear "acetowhite." Large-scale studies are required to further refine issues related to the selectivity and specificity of the technology.

PMID: 15130078 [PubMed - indexed for MEDLINE]



CLINICAL RESEARCH ABSTRACTS

The efficacy of oral lumenoscopy (ViziLite Plus) in visualizing oral mucosal lesions.

Special Care Dentistry. 2006 Jul-Aug;26(4):171-4.

Epstein JB, Gorsky M, Lonky S, Silverman S Jr, Epstein JD, Bride M.

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Abstract

Early diagnosis of oral mucosal lesions has been advocated as a means of improving outcomes of cancer therapy. Improved visualization of mucosal lesions may aid in diagnosis by guiding tissue sampling or referral. This multicenter study reports the effect of chemiluminescent light (ViziLite) upon visualization of mucosal lesions. The chemiluminescent light did not appear to improve visualization of red lesions, but white lesions and lesions that were both red and white showed enhanced brightness and sharpness.

PMID: 16927741 [PubMed - indexed for MEDLINE]