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Original Article

Evaluation of efficacy of chemiluminescence for diagnosis of leukoplakia

Astha Chaudhry [a,*], Manjunath M [b]

[a] Department of Oral Medicine and Radiology, Faculty of Dental Sciences, SGT University, Budhera, Gurgaon, India
[b] Department of Oral Medicine and Radiology, V.S. Dental College and Hospital, Bengaluru, India

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ABSTRACT

Objective: Leukoplakia is the most common potentially malignant disorder preceding oral cancer. Chemiluminescence has been developed as an adjunct to conventional examination for the diagnosis of these potentially malignant disorders. This study was conducted to assess the efficacy of chemiluminescence in the diagnosis of leukoplakia and to compare the results with histopathological examination.
Study design: A total of 50 patients with leukoplakia were included from the outpatients attending the Department of Oral Medicine and Radiology, Dental Hospital, Bengaluru, Karnataka, India. These patients were subjected to conventional oral examination followed by chemiluminescent examination with Vizilite (Zila, Fort Collins, CO, USA) and biopsy for histopathological confirmation.
Results: The sensitivity, specificity, positive predictive value, and negative predictive value of chemiluminescence were 93.75%, 55.56%, 78.95%, and 83.3%, respectively. The overall accuracy of chemiluminescence was 80%. A statistically significant association was observed between histopathology results and chemiluminescence results.
Conclusion: Although it is an easy, safe, minimal time consuming, and noninvasive technique, it has only adjunctive utility and it does not replace biopsy for the diagnosis of leukoplakia.

1. Introduction

Oral cancer is the sixth most common malignancy around the globe [1]. The annual incidence [2] for oral cancer is around 275,000 with India having the highest incidence rate of oral cancer worldwide. Despite advances in cancer therapies, the 5-year survival rate is just 50% [3]. This is due to detection of oral cancer at the symptomatic advanced stages. However, if diagnosed at an early asymptomatic stage, oral cancer is often curable and inexpensive to treat. Therefore, the focus has now shifted toward the prevention of oral cancer. Primary prevention including changing habits and lifestyle are slow to implement. So, secondary prevention i.e. early diagnosis and prompt treatment has become extremely important for the oral health care professional.

The natural history of oral cancer also demonstrates that it is preceded by a precancerous stage in the form of potentially malignant disorders (PMDs) [4]. The most common PMD is leukoplakia. The diagnosis of leukoplakia is mainly clinical. But clinical examination cannot distinguish between dysplastic and nondysplastic leukoplakia.

For diagnosis of dysplasia, biopsy and histopathological examination has been the gold standard. But the invasiveness of scalpel biopsy has urged the need for the development of noninvasive adjunctive tools at both clinical and molecular level to assess the oral lesions of uncertain biologic significance. These include vital staining, oral CDx brush biopsy (CDx Diagnostics, Suffern, NY, USA), and visualization techniques.

The visualization techniques are appurtenants to the standard visual and tactile oral examination under incandescent light. They function under the assumption that during carcinogenesis mucosal tissues undergo abnormal metabolic or structural changes that show different absorbing and reflecting properties when exposed to various forms of light or energy [5]. Chemiluminescene (light emission from chemical reaction) has been used previously to detect cervical neoplasia [6,7]. Vizilite (Zila, Fort Collins, CO, USA) is a recently introduced chemiluminescent technique that allows the dysplastic areas i.e. cells with altered nuclear cytoplasmic ratio to preferentially reflect the low energy blue white light emitted by the device and appear aceto-white with brighter, sharper, and distinct margins. It is an easy, safe, and non-invasive technique [3].

The aim of the study was to assess the efficacy of a commercially available chemiluminescent kit (Vizilite) in the diagnosis of leukoplakia and to compare the results with the histopathological examination.

* Corresponding author at: House No. 617, 1st Floor, Sector 9, Gurgaon 122001, Haryana, India. Tel.: +91 9711807733; fax: +91 124 2278151.
E-mail address: dr.asthac@gmail.com (A. Chaudhry).

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2. Materials and methods

A total of 50 adult patients of either gender or any race presenting with leukoplakia either homogenous or non-homogenous were selected from the outpatients attending the Department of Oral Medicine and Radiology, V.S. Dental Hospital, Bengaluru, India. The study was approved by the institutional review board and ethical clearance was obtained.

The procedure was explained to the patient and written consent was obtained. Each patient underwent a conventional soft-tissue examination under incandescent light where the lesion size, morphology, and texture were noted and documented photographically. This was followed by chemiluminescent examination and biopsy by the same examiner.

For chemiluminescent examination, commercially available Vizilite kit was used. It consisted of a Vizilite 1% acetic acid solution, a single-use chemiluminescent light stick, and a handheld retractor to hold the activated light stick. The capsule comprised an outer flexible plastic containing acetyl salicylic acid and an inner fragile glass vial containing hydrogen peroxide. When the capsule is flexed, the inner glass vial ruptures allowing the chemicals to react producing light of blue-white color for duration of 10 min in a wavelength range of 430–580 nm.

The patient was asked to rinse the mouth with 30 ml of 1% acetic acid solution for 1 min following which the capsule was activated and assembled into the retractor. The acetic acid rinse served to remove the debris and glycoprotein barrier from the mucosa to enhance the penetration of light. The soft tissues were dried and examination was repeated by the same observer under chemiluminescent illumination after dimming the room lights. The lesions were again photographed and the presence of an "aceto-white" lesion was defined as a "positive" test, while the absence of such finding was defined as a "negative" test.

Depending on the size of the lesion and results of chemiluminescent examination, incisional or excisional biopsy of the lesion was done by the same examiner. The histopathological examination was done by a single pathologist to evaluate the dysplastic changes and grade them according to the World Health Organization criteria [8]. The presence of dysplasia was considered as "positive test" and absence of it was considered as "negative test" (Figs. 1–3).

The collected data were entered through the SPSS version 18 software (SAS Inc., Cary, NC, USA). Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of Vizilite were calculated.

The chemiluminescence results were compared with histopathological results using Chi-Square test with p-value set as ≤ 0.05.

3. Results

The demographic data of 50 patients enrolled in the study are given in Table 1. Out of 50 lesions examined, 37 (74%) were categorized as homogenous leukoplakia and 13 (26%) were categorized as non-homogenous leukoplakia (speckled leukoplakia).

On histopathological examination of these 50 lesions, 64% were diagnosed with dysplasia. Of these, 42% were categorized as mild dysplasia, 14% moderate dysplasia, 4% severe dysplasia, and 4% carcinoma in situ.

On Vizilite examination, 38 lesions (76%) showed aceto-white appearance. Among these 30 lesions (78.9%) were identified as dysplastic on histopathological examination. Out of the 12 lesions that were identified as negative by the chemiluminescence test, 2 lesions (16%) were identified as positive for dysplasia. The sensitivity of chemiluminescence test was 93.75% and specificity was 55.56%. The positive predictive value was 78.95% and negative predictive value was 83.3%. The overall accuracy of chemiluminescence was 80% (Table 2).

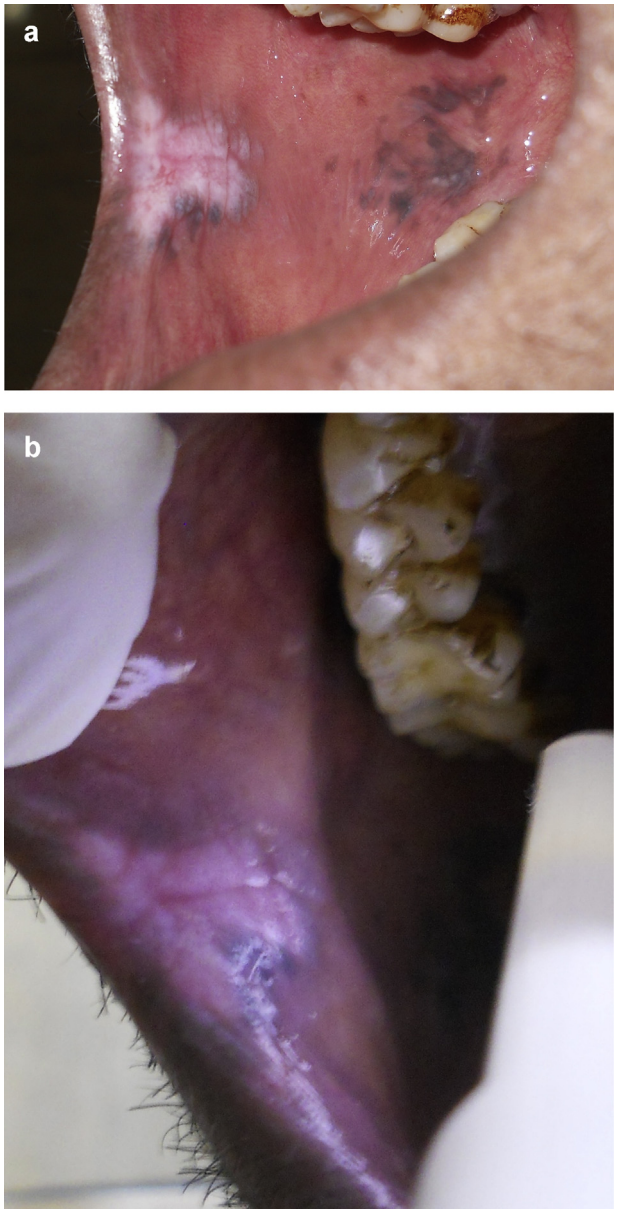

Fig. 1. (a) Non-homogenous leukoplakia on right retrocommisure. (b) Negative result on Vizilite examination.

A statistically significant association was observed between the chemiluminescence results and histopathology results ($\chi^2 = 15.354$) at the set p-value ($p \leq 0.05$).

4. Discussion

The 50 leukoplakias included in the study were mainly seen on the buccal mucosa in the patient age group 20–40 years. But the severity of dysplasia is more in the age group 60–80 years. In non-homogenous leukoplakias, 15% of cases showed no dysplasia whereas in homogenous leukoplakia 43% of cases showed no dysplasia. In both types of leukoplakia, the majority of the cases showed mild dysplasia.

In chemiluminescent examination, the number of false positives was 8 (21.1%) (Table 2). This is similar to the result obtained by Ram and Siar [3]. The high false positive rate was also confirmed by