Journal of Oral Biology and Craniofacial Research xxx (2017) xxx–xxx

Contents lists available at ScienceDirect

Journal of Oral Biology and Craniofacial Research

journal homepage: www.elsevier.com/locate/jobcr

Original Article

Role of Chemiluminescence examination as non-invasive diagnostic tool in early detection of Leukoplakia

Nidhi Jain[a], Anil Kumar Nagarajappa[b,c,*], Meenakshi Bhasin[d], Divya Pandya[e], Kaushal Pati Tripathi[f]

[a] Dept. of Oral Medicine and Radiology, Hitkarini Dental College and Hospital, Girls Hostel, Room # 204, Hitkarini Hills, Dumna Road, Jabalpur, M.P., 482005, India
[b] Former HOD Dept. of Oral Medicine and Radiology, Hitkarini Dental College and Hospital, Hitkarini Hills, Dumna Road, Jabalpur, M.P., 482005, India
[c] Currently Lecturer at Dep. of Oral Medicine and Radiology, College of Dentistry, Al-Jouf University, Sakaka, Zip Code: 42421, Kingdom of Saudi Arabia
[d] Dep. of Oral Medicine and Radiology, Hitkarini Dental College and Hospital, Hitkarini Hills, Dumna Road, Jabalpur, M.P., 482005, India
[e] Jabalpur Hospital and Research Centre, F2 Atul Vihar II SBI Colony Near Hathitaal Railway Crossing, Gorakhpur, Jabalpur, M.P., India
[f] Dept. of Peiodontology and Implantology, Hitkarini Dental College and Hospital, Boys Hostel, Room # 26, Hitkarini Hills, Dumna Road, Jabalpur, M.P., 482005, India

ARTICLE INFO

Article history:
Received 2 January 2017
Accepted 8 April 2017
Available online xxx

Keywords:
Chemiluminescent
Leukoplakia
Dysplasia
OSCCs
Toluidine blue
Viziliteplus

ABSTRACT

Objectives: To assess the efficacy of Chemiluminescent light (Vizilite plus) in enhancing visualization and its ability to highlight Leukoplakia lesion.
Material and methods: This was a cross-sectional study done on 40 study subjects. Subjects were inducted into the study irrespective of age and sex based on the specific inclusion and exclusion criteria. The lesion parameters like the location of the lesion, the shape of lesion, the size, the extent, borders and the presence or absence of any adjacent satellite lesions were assessed under Incandescent light followed by Toluidine blue and Vizilite plus examinations. Histopathological examination results were considered as the gold standard and TBLU and CHEM outcomes were compared to them.
Results: Vizilite plus examination method was most effective in assessing the size, borders and shape of the lesions followed by Toluidine blue and Incandescent light examinations. Toluidine blue and Vizilite plus examination methods demonstrated the sensitivity of 100% and specificity of 97.3%. They also demonstrated PPV of 100% and NPV of 75% with reliable accuracy of 97.5%.
Conclusion: Chemiluminescent light is a stepping stone and has the potential to revolutionize the diagnostic protocol for patients with potentially premalignant lesions. The device can be used as a general oral mucosal examination system and may in particular improve the visualization of potentially premalignant lesions.

1. Introduction

Oral squamous cell carcinoma is major cause of death and global health problem throughout the world. The incidence of oral cancer worldwide varies from 2 to 18% and in India it varies from 0.1 to 13.5%.[1] Oral Leukoplakia is one of the important potentially premalignant lesion of the oral cavity. Leukoplakia is thought to be precursor lesion of Oral Squamous cell carcinoma.[2] It has been defined as a predominantly white lesion of the oral mucosa that cannot be characterized as any other definable lesion. Leukoplakia is further classified as homogenous and non-homogenous types.[3] Malignant transformation rate of Oral Leukoplakia varies between 1.1% to 11.7%.[4] Prevention of malignant transformation is important as the 5-year survival rate of Squamous cell carcinoma is 50%,[5] early detection of dysplastic changes in Leukoplakia lesions can reduce the morbidity and mortality rate.[6]

Tobacco is found to be the main etiologic factor and contains many carcinogens which are collectively called as tar. Tar is found to be highly toxic and carcinogenic.[7] Leukoplakia is six times more common among smokers than among non smokers.[8] Alcohol is another independent risk factor. Certain studies have revealed the possible role of Human Papillomavirus infection too.[8]

* Corresponding author at: Dept. of Oral Medicine and Radiology, Hitkarini Dental College and Hospital, Hitkarini Hospital, Hitkarini Hills, Dumna Road, Jabalpur, M.P., 482005, India.
E-mail addresses: nidhi9797@gmail.com (N. Jain), omdrhdch@gmail.com, dranilomr73@gmail.com (A.K. Nagarajappa), meenakshibhasin85@yahoo.com (M. Bhasin), divyapandya854@gmail.com (D. Pandya), Jeevankaushal03@gmail.com (K.P. Tripathi).

http://dx.doi.org/10.1016/j.jobcr.2017.04.004
0976-5662/

To facilitate early detection of suspicious oral white lesions and dysplastic changes various clinical modalities are available like Toluidine blue test, Vizilite examination, VELscope and Brush biopsy. "Vizilite plus" is a recently introduced commercially available diagnostic tool devised for the early detection of potentially premalignant lesions and is based on the principle of Chemiluminescence.[9]

Vizilite plus is a painless, effective and fast procedure. The future of it is promising for the further development and evolution of oral-cancer diagnostic aids for enhancing the quality of the patient care.[10] Chemiluminescence refers to the emission of light during a chemical reaction. The most well known diagnostic aid using this principle is the Vizilite® system (Zila Pharmaceuticals, Phoenix, AZ, USA) introduced in 2002. This product aims at enhancing certain features of a lesion, such as brightness and sharpness of its borders.[11] Use of the light stick is intended to improve the visual distinction between normal mucosa and oral white lesions. Normal epithelium will absorb light and appear dark whereas hyper keratinized or dysplastic lesions appear white.[12] To reduce the number of false positives, the system has now been combined with Toluidine blue stain (Vizilite Plus®).[11] Studies assessing Toludine blue have shown a sensitivity and specificity ranging from 93.5 to 97.8% and 73.3 to 92.9%, respectively.[13] Use of Toluidine blue as a diagnostic aid for oral precancerous and cancerous lesions has been widely reported in the literature. But there is less information regarding the use of Chemiluminescence. Hence, this study aims to evaluate the efficacy of Chemiluminescence examination along with Toluidine blue dye as a potentially premalignant lesions screening aid.

2. Materials and methods

This study was planned and designed in the department of Oral Medicine and Radiology, Hithkarini Dental College and Hospital, Jabalpur, Madhya Pradesh, India. The study was approved by Institutional ethical committee. 40 study subjects presenting with Leukoplakia lesions irrespective of age, sex were recruited in to the study from subjects attending outpatient department of Oral Medicine and Radiology, Hithkarini Dental College and Hospital, Jabalpur, Madhya Pradesh, India. Subject's demographic data along with case history were recorded in a specially designed proforma. Study subjects were recruited in to the study based on specific inclusion and exclusion criteria as shown in Table 1. The study purpose and procedure was explained to the patient and written consent was obtained. Each subject underwent a conventional soft tissue examination under Incandescent light followed by Toluidine blue test and Vizilite plus examination. Intra-oral examinations were conducted by two trained Oral Medicine specialists under routine Incandescent operatory light using two dental mirrors and gauze, with digital palpation. Followed by intra-oral examination the subjects underwent 1% acetic acid solution mouth rinse for 30–60 s. All the lesion parameters like the location of the lesion, the shape of lesion, the size, the extent, borders and the presence or absence of any adjacent satellite lesions were obtained (Fig. 1). Lesions were photographed and data regarding the conventional visual examination were recorded. Secondly, TBLU screening procedure was performed by giving pre rinse solution of 1% acetic acid for 20 s to the subjects. This was followed by an application of pre-soaked swab of pharmaceutical grade 1% Toluidine blue, was applied over entire lesions. Dark staining lesions were considered as TBLU positive (Fig. 2) and those which did not take up the stain were considered TBLU negative. After that all parameters of the lesions were recorded. Then 20 s post rinse with water was given. This was followed by a post oral rinse with a 1% acetic acid solution for 30 s. Later on room lights were dimmed, the oral cavity was examined and each visually identified lesion was evaluated using a Chemiluminescent light. Examination with Vizilite plus was done according to the manufacturer's instructions. The subjects were asked to rinse their mouth with plain water and expectorate it after 1 min. The outer flexible capsule of the light stick was bent, breaking the inner fragile glass vial. The light stick was then shaken vigorously to mix the contents, and placed in the open end of the retractor and assembled. Vizilite plus capsule was activated and placed on the retractor. The suspected lesions that reflected the aceto-white light were considered Vizilite plus positive and lesions reflected dark (Fig. 3) were considered Vizilite negative. All parameters of the lesion were again recorded under Vizilite plus examination.

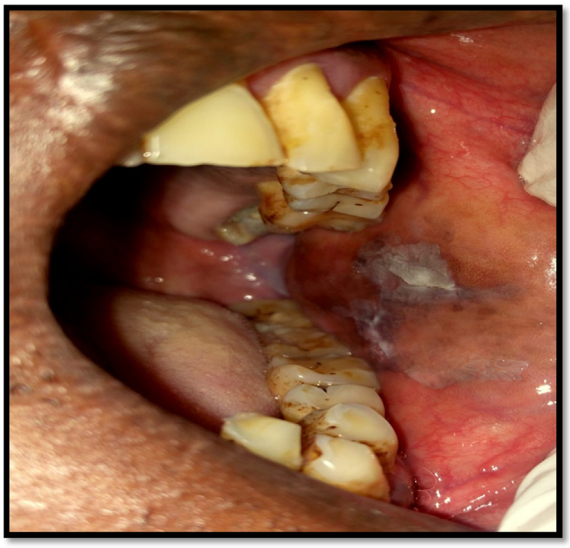

Fig. 1. Clinical view of lesion at buccal mucosa under Incandescent light.

Table 1
Inclusion and exclusion criteria of the study population.

Inclusion Criteria	Exclusion Criteria
1. All the subjects irrespective of age, sex or socio economic background with the habit of cigarette smoking or use of tobacco in any forms.	1. Subjects without any deleterious habits of tobacco usage.
2. Subjects diagnosed clinically having Leukoplakia.	2. Subjects with any systemic disorders or mentally unstable subjects.
3. Subjects who are willing to participate and approve the informed consent.	3. Subjects with dentures, sharp teeth and with parafunctional habits.
	4. Subjects with evidence of clinical lesions like Leukoedema, Linea alba buccalis or Fordyce's granules.
	5. Subjects with presence of frank malignancy.
	6. Any sub mucosal swelling or mass or benign tumour.
	7. Subjects who are allergic to any ingredients of the Vizilite plus kit.
	8. Subjects who are not willing to participate and approve the informed consent.

Please cite this article in press as: N. Jain, et al., Role of Chemiluminescence examination as non-invasive diagnostic tool in early detection of Leukoplakia, J Oral Biol Craniofac Res. (2017), http://dx.doi.org/10.1016/j.jobcr.2017.04.004