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+DrOroscope effective oral cancer screening device with AI Diagnosis

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Abstract:

Various studies have shown that screening at population level has reduced the cost of expenditure spent on medical facilities and it even improves the quality of life at a significant level. Research in medical field has boosted the economy of the country in considerable percentage directly or indirectly.

Population level screening and establishing a registry for Oral cancer and Oral health in India is not practically viable due to the limited resources such as sufficient infrastructure and lack of specialists. So there is dearth need of trained paramedical people and low cost screening devices and other facilities such as tele medicine. DrOroscope device has been designed especially for screening oral precancerous lesions and early cancers with cost effectiveness also along the data can be stored in central server (Registry), this will also facilitate tele medicine facility. A Multi centric comparative study under (NHM) National Health Mission was done in Andhra Pradesh state in India at for teaching govt Hospitals by the specialist Doctors

Introduction:

Most cancers rank as a main purpose of demise and an essential barrier to growing lifestyles expectancy in each and every country of the world. According to estimates from the World Health Organization (WHO) in 2019, Cancer is the first or second leading cause of death before the age of 70 years.[1]

Cancer incidence and mortality are rapidly growing worldwide. The motives are complicated however reflect both getting aging and growth of the population, as well as adjustments in the prevalence and distribution of the main danger or risk factors for cancer, several of which are associated with socioeconomic development. The numbers of new cancer cases and cancer deaths were extracted from the GLOBOCAN 2020 database for all cancers combined and for 36 cancer types[1]. GLOBOCAN expected that most cancers cases in India could boom to 2.08 million, accounting for a upward thrust of 57.5% in 2040 from 2020. The expected number of cancer cases and crude incidence rate in India for the year 2022 turned into 14,61,427 (100.4/1,00,000), with a more of woman cases 7,49,251 (105.4/1,00,000) estimated as compared to that in males 7,12,176 (95.6/1,00,000)[2].

The increasing oral cancer cases are the vital challenge concern for community health as it's far one of the not unusual sorts of cancers in India. The economic burden towards the affected person (patient) could be very excessive throughout the treatment of oral cancer and most of the sufferers depart the remedy halfway which similarly adds to the mortality charge. Prevention, early diagnosis, and timely remedy are critical elements to address most oral cancers-related burden. The awareness needs to be spread among the population about the causes and fatalities of oral cancer, the importance of quitting tobacco, alcohol, and maintaining oral hygiene**.**[3]

Various conventional clinical techniques such as physical and histopathological examination, staining, biopsy, spectroscopic and radiological etc., are used routinely to detect oral cancer. The early detection and diagnosis of cancer play key role to check different parameters like physical, psychological, and financial losses to the patient. Upon early diagnosis, well timed and proper treatment can be initiated that may enhance the survival rate much as 90%[3]. Due to the potential limitations in the conventional visual oral examination, alternative screening methods are currently being developed to facilitate the detection of OSCC and OPMDs with the intention of applying them globally.[4]

Most Oral cancer detections in early stage refers to pre-cancerous tissue. The earlier a cancer is detected, the more likely it's far that it is able to be treated correctly. Light-based (optical) techniques, which include chemiluminescence and autofluorescent strategies, work on the neoplastic and preneoplastic tissues which have passed through abnormal metabolic or structural modifications have distinct absorbance and reflectance properties whilst uncovered (exposed) to specific wavelengths of light. Within the last decade, light-based technology has been adapted and marketed to be used inside the oral cavity (chemiluminescence: ViziLite, ViziLite Plus, MicroLuxTM/DL; Autofluorescence; VELscopeTM).[4]

However, previous reviews of the early literature found a lack of evidence to support the use of these commercially available devices as screening aids in the detection of OPMD and OSCC in low-risk populations.[4] Clinical identification again depends on the knowledge and experience of the doctor. This suggests use of adjunctive diagnostic aids. Nevertheless, the use of diagnostic armamentarium of paramount important in conjunction to visual examination, such as the VELscope, OralID, ViziLite, Identafi etc.[6]

Hence, the study is an attempt to evaluate and compare the role of Light-based (optical) devices for early screening and diagnosis of oral premalignant and early malignant lesions and also to evaluate the efficacy between the two screening devices VELscope and DrOroscope.

Materials and methods

A multi-centric study, conducted at Government Dental College and Hospital Vijayawada, RIMS Government Dental College Kadapa, KGH Vishakhapatnam, Government General Hospital Srikakulam, as comparison between VELscope and DrOroscope, for the project under NHM in the department of Oral Medicine and Radiology. A total of 1730 patients attended the department at Government Dental College and Hospital Vijayawada, a total of 647 patients at RIMS Govt. Dental College Kadapa, 45 patients at KGH Vishakhapatnam and 40 patients at Government General Hospital Srikakulam were selected for the study who fulfilled the inclusion criteria.

Inclusion criteria:

- Age group of patients (Male and female) is 18 years and above.
- Patients with any deleterious habits such as smoking, tobacco chewing, alcohol etc.
- Patients with any oral premalignant lesions.
- Patients who have systemic diseases.
- Patients with symptoms associated with oral premalignant lesions.

Exclusion criteria:

- Healthy patients.
- Patients with no history of deleterious habits.
- Patients with no oral premalignant lesions.

All patients provided informed consent and completed a detailed questionnaire, which included information on demographics, smoking and alcohol use, current medications, and general health. The core of the study started with a thorough clinical examination of the lesion under aseptic and sterile environment and followed by examination using both the devices VELscope and DrOroscope which was carried out by experienced examiners.

Results

The present study was performed in 2430 patients using both devices VELscope and DrOroscope after taking required information related to the study. The results obtained when compared the efficacy of DrOroscope with VELscope revealed that the ease of use of device intraorally was more comfortable compared to VELscope and features such as accessibility to the posterior regions in oral cavity, 360˚ rotation of device to obtain image of the lesion and capability to distinguish Benign and Malignant lesions were feasible and successfully accomplished by DrOroscope. Both the devices had a clarity of image and marginal detection of lesions. Analysis of images was done proficiently with DrOroscope compared to VELscope. Software application and storage and transfer of data were of high quality in DrOroscope when compared to

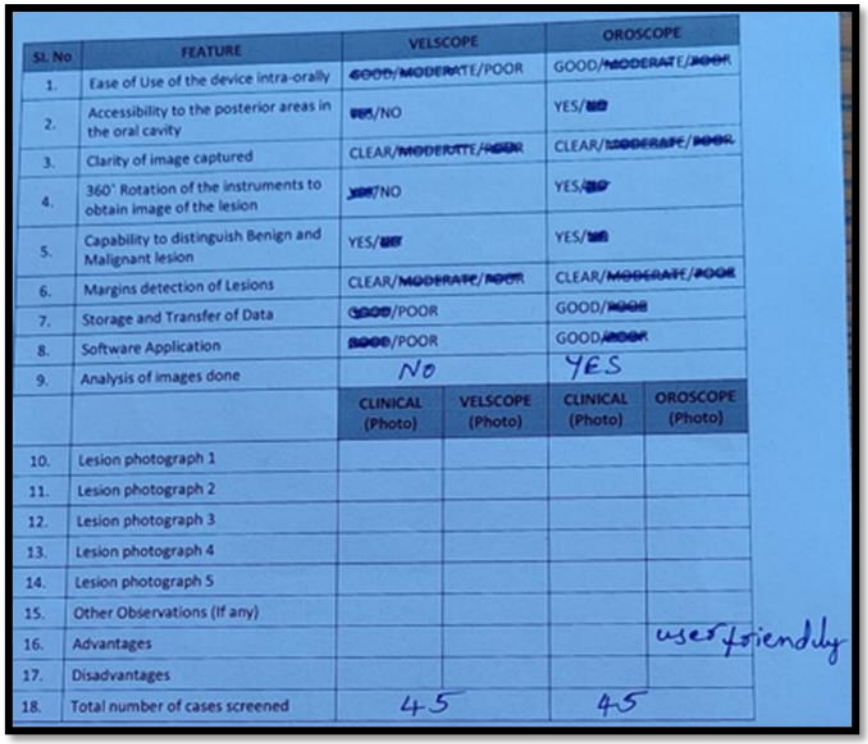
VELscope. In DrOroscope the diagnosis was based on software and in VELscope it was by examiner's capability. (Table-1-4)

Sl.No	FEATURE	VELSCOPE		OROSCOPE	
1.	Ease of Use of the device intra-orally	~~GOOD/MODERATE~~/POOR		GOOD/~~MODERATE/POOR~~	
2.	Accessibility to the posterior areas in the oral cavity	~~YES~~/NO		YES/~~NO~~	
3.	Clarity of image captured	CLEAR/~~MODERATE/POOR~~		CLEAR/~~MODERATE/POOR~~	
4.	360° Rotation of the instrument to obtain image of the lesion	~~YES~~/NO		YES/~~NO~~	
5.	Capability to distinguish Benign and Malignant lesion	~~YES~~/NO		YES/~~NO~~	
6.	Margins detection of Lesions	CLEAR/~~MODERATE/POOR~~		CLEAR/~~MODERATE/POOR~~	
7.	Storage and Transfer of Data	~~GOOD~~/POOR		GOOD/~~POOR~~	
8.	Software Application	~~GOOD~~/POOR		GOOD/~~POOR~~	
9.	Analysis of images done	NO		YES	
		CLINICAL (Photo)	VELSCOPE (Photo)	CLINICAL (Photo)	OROSCOPE (Photo)
10.	Lesion photograph 1				
11.	Lesion photograph 2				
12.	Lesion photograph 3				
13.	Lesion photograph 4				
14.	Lesion photograph 5				
15.	Other Observations(If any)		Diagnosis is Dependant on Examiners capability		Diagnosis is done by software
16.	Advantages				Ease of use
17.	Disadvantages				
18.	Total number of cases screened	1730		1730	

Table:1 Results obtained at Vijayawada

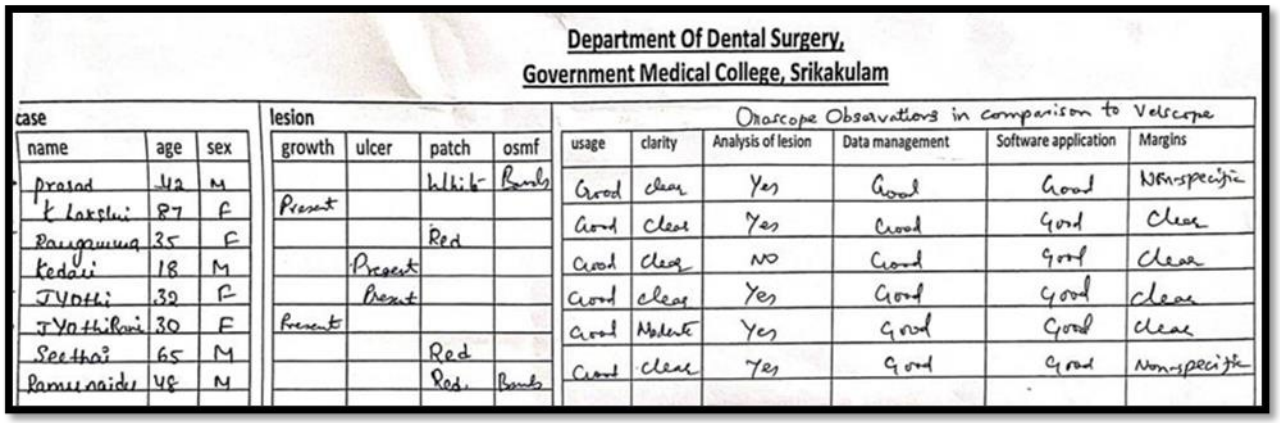
Sl.No	FEATURE	VELSCOPE		OROSCOPE	
1.	Ease of Use of the device intra-orally	~~GOOD/MODERATE~~/POOR		GOOD/~~MODERATE/POOR~~	
2.	Accessibility to the posterior areas in the oral cavity	~~YES~~/NO		YES/~~NO~~	
3.	Clarity of image captured	CLEAR/~~MODERATE/POOR~~		CLEAR/~~MODERATE/POOR~~	
4.	360˚ Rotation of the instruments to obtain image of the lesion	~~YES~~/NO		YES/~~NO~~	
5.	Capability to distinguish Benign and Malignant lesion	~~YES~~/NO		YES/~~NO~~	
6.	Margins detection of Lesions	CLEAR/~~MODERATE/POOR~~		CLEAR/~~MODERATE/POOR~~	
7.	Storage and Transfer of Data	~~GOOD~~/POOR		GOOD/~~POOR~~	
8.	Software Application	~~GOOD~~/POOR		GOOD/~~POOR~~	
9.	Analysis of images done	NO		YES	
		CLINICAL (Photo)	VELSCOPE (Photo)	CLINICAL (Photo)	OROSCOPE (Photo)
10.	Lesion photograph 1				
11.	Lesion photograph 2				
12.	Lesion photograph 3				
13.	Lesion photograph 4				
14.	Lesion photograph 5				
15.	Other Observations(If any)		Diagnosis is dependent on examiner's capability		Diagnosis is done by software
16.	Advantages				Ease of use
17.	Disadvantages		Requires a dark room		
18.	Total number of cases screened	647		647	

Table 2: Results obtained at Kadapa



Sl. No	FEATURE	VELSCOPE	OROSCOPE
1.	Ease of Use of the device intra-orally	GOOD/MODERATE/POOR	GOOD/MODERATE/POOR
2.	Accessibility to the posterior areas in the oral cavity	YES/NO	YES/NO
3.	Clarity of image captured	CLEAR/MODERATE/POOR	CLEAR/MODERATE/POOR
4.	360° Rotation of the instruments to obtain image of the lesion	YES/NO	YES/NO
5.	Capability to distinguish Benign and Malignant lesion	YES/NO	YES/NO
6.	Margins detection of Lesions	CLEAR/MODERATE/POOR	CLEAR/MODERATE/POOR
7.	Storage and Transfer of Data	GOOD/POOR	GOOD/POOR
8.	Software Application	GOOD/POOR	GOOD/POOR
9.	Analysis of images done	NO	YES
		CLINICAL (Photo) / VELSCOPE (Photo)	CLINICAL (Photo) / OROSCOPE (Photo)
10.	Lesion photograph 1		
11.	Lesion photograph 2		
12.	Lesion photograph 3		
13.	Lesion photograph 4		
14.	Lesion photograph 5		
15.	Other Observations (If any)		
16.	Advantages		user friendly
17.	Disadvantages		
18.	Total number of cases screened	45	45

Table 3: Results obtained at Vishakhapatnam



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case			lesion				Oroscope Observations in comparison to Velscope					
name	age	sex	growth	ulcer	patch	osmf	usage	clarity	Analysis of lesion	Data management	Software application	Margins
prasad	42	M			White	Both	Good	clear	Yes	Good	Good	Non-specific
K Lakshmi	87	F	Present				Good	Clear	Yes	Good	Good	Clear
Rangamma	35	F			Red		Good	Clear	NO	Good	Good	Clear
Kedari	18	M		Present			Good	Clear	Yes	Good	Good	clear
JYothi	32	F		Present			Good	Clear	Yes	Good	Good	clear
JYothirani	30	F	Present				Good	Moderate	Yes	Good	Good	clear
Seethai	65	M			Red		Good	clear	Yes	Good	Good	Non-specific
Ramunaidu	48	M			Red.	Both						

Table 4: Results obtained at Srikakulam

Discussion

OSCC is a major health problem worldwide. It's among the most common cancers seen in both Indian men and women as can be gauged from the records of the National Cancer Registry Program.[6] Oral squamous cell carcinoma (OSCC) contributes remarkably 84-97% oral cancer. OSCC generally results from potentially malignant lesions or normal epithelium. Potentially malignant disorders (PMDs) such as oral submucosal fibrosis, erythroplakia, leukoplakia, candidal leukoplakia, dyskeratosis, and lichen planus are pointers of the preclinical phase of oral cancer. Tobacco consumption including smokeless tobacco, betel-quid chewing, inordinate alcohol consumption, poor oral hygiene, nutrient-deficient diet, and sustained viral infections,

i.e. Human papilloma virus(HPV) are some of the pitfalls associated with the circumstance of oral cancer.[3] Lack of knowledge, exposure to extreme environmental conditions, and behavioral threat factors are pointers of a wide variation in the global prevalence.[3]

Potentially malignant disorders (PMDs) are a group of lesions which have a thorough inclination to transfigure into malignancy if left undressed/observed. The subtle changes in their clinical stage may demand histopathological evaluation leaving the patient morbid for a while in attaining a definitive opinion. In this process of minimizing the morbidity, precise evaluation of the lesion borders, a new device was founded i.e., DrOroscope.[6] DrOroscope is a portable fluorescent visualization device using blue light(400-460nm) and green amber light to differentiate from inflammatory tissues and to detect abnormal oral tissues that cannot be seen by white light. Fluorescent visualization fashion has been preliminarily used with the VELscope, and utilizes the autofluorescent properties of healthy and abnormal tissues.[5]

A number of different factors work together to make this process possible, such as the fluorophore FAD, the histo-morphological changes in abnormal tissue, and the varying levels of hemoglobin. All these changes make the use of blue light successful in precisely detecting abnormalities in the tissue (such as dysplasia/cancer).[5] The autofluorescence of tissue and its potential use in cancer detection were described first in 1924[7]. Naturally occurring fluorochromes (e.g. collagen, elastin, keratin, FAD, NADH)[8] that are located in the epithelial cell lining and submucosa of the oral cavity show fluorescence in the green spectral range when excited with light between 375 and 440 nm[9]. Malignant or dysplastic alteration causes complete loss of the normal tissue fluorescence (fluorescence visualization loss) because of the disturbance in the distribution of these fluorochromes[11,12]
Recent studies have blamed the failure of the VELscope to distinguish high- threat lesions from low-risk lesions[13] and its high rate of false-positive results[14]. A *Rashid* in a methodical review stated that twelve studies in the literature satisfied the considered addition and rejection criteria for the use of the VELscope™ in the discovery of OPMD and malignancy. These studies were conducted in a variety of countries including Canada, the USA, the UK, Germany, Italy, and Australia and in the Indian study that had two arms, testing both VELscope and ViziLite. The frequence of vivisection verified OSCC or epithelial dysplasia amongst lesions ranged from 0.9% to 88%. One study was conducted in the community setting and a farther study in a routine sanitarium dental review clinic. The remaining studies were conducted in specialist conventions.[4]

diRuffano et al[15] have made the case that the value of a test is not simply measured by its accuracy, but depends on how the test result may affect patient's health in future. They argue that establishing benefits to patient's health must be the priority for diagnostic tests.
Jaishri S. Pagare, Virangana Moon conducted a comparative analysis between VELscope and ViziLite as adjunctive tools for oral cancer screening, making it a valuable resource for dental professionals, researchers, and individuals interested in this field stated that the VELscope

demonstrates a specificity of 61.39% and sensitivity of 83.3%. In contrast, ViziLite operates with a specificity of 27.8% and sensitivity of 77.3%. Both the VELscope and ViziLite systems offer portability, painlessness, and noninvasiveness, making them accessible for use by a wide range of operators after minimal training[16]. However, a common challenge faced by both systems is the difficulty in differentiating oral premalignant lesions from other pathologies, such as aphthous ulcers. This analysis, stated that the VELscope system offers advantages such as patient comfort due to the absence of chemicals, lack of odor, taste, and sensation during the examination, along with the benefit of repetition. Still, it has the debit of being precious and may induce heat during prolonged usage, it can serve to palliate patient anxiety regarding suspicious mucosal lesions in a general practice setting due to high negative prophetic value.[16] Also, a combined approach of VELscope examination and conventional oral examination may prove to be an effective individual tool for early discovery of malignant oral mucosal lesions. The study results showed that the low particularity of the autofluorescence examination for screening dysplasia and malignant lesions from benign lesions.

Based upon the results obtained and as mentioned in the previous studies, although its mechanism of action can be supported biologically, whether it can distinguish between dysplasia and benign inflammatory lesions is questioned when compared with DrOroscope. In previous studies, it is not clear whether observers had appropriate training before use or whether these figures are comparable with agreement in conventional visual inspection. In the present study, diagnosis given by DrOroscope was absolutely using software in contrary with VELscope which was examiner's capability.

Conclusion:

Both devices are simple to use, noninvasive and provide real-time results. But as the VELscope images are not supported by any software, they have to be interpreted by a specialist at point of care. In DrOroscope as the software gives point of care Diagnosis generated by AI based software and the backend tele medicine facility supported by a specialist, if necessary, in doubtful cases is the most useful feature apart from its intra oral nature which is more useful in limited mouth opening patients. In the literature, both techniques have been shown to enhance case detection of oral mucosal lesions. It is likely to generate high numbers of false positives, it may allow the dentist to be more vigilant in their examination and may also improve on patient awareness of oral cancer. By improving the detection and early intervention of potentially malignant mucosal lesions, these tools have the potential to significantly impact patient outcomes and reduce the burden on the healthcare system. More studies in primary care are necessary to draw valid conclusions on its feasibility as a screening adjunct. Diagnostic tests are often assessed by their performance based on a sensitivity and specificity analysis.

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