Efficacy of Utility of Droroscope for Detection of Potentially Malignant Disorders & Malignant Disorders

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Abstract:- Introduction: Early diagnosis of oral cancer ameliorates the constancy of outcomes. Efficacious untimely screening of PMDs through diagnostic addition may ease preliminary diagnosis. However certain hindrance and fetch of existing diagnostic add-on limit their extensive use. Droroscope is an economical fluorescence visualization device using blue light (400-460nm) that expose abnormal oral tissue that cannot be glimpse by white light. Droroscope is a palmtop intraoral device with 3 lights (red, blue, green-amber). Aim: To evaluate the efficacy of Droroscope in the early detection of PMDs & malignant disorders. Objective: To observe the borders of the lesion under various monochromatic lights & to identify the specificity & sensitivity of the device in identifying lesions. Material & methods: 20 patients over 18 years of age with a clinical diagnosis of PMDs & Malignant disorders. Patient with a clinical diagnosis of oral cancer, patients suffering from systemic diseases were excluded in this study. Droroscope examination: The lesion will then be visualized with blue & green lights of the device & findings will be noted along with photographs. Lack of fluorescence on blue light will be regarded as being positive for dysplasia. Visibility of blood vessels near the surface under green light will be taken as positive change for dysplasia. Correlation between the findings of the device and histopathological findings will be done. Results: The sensitivity and specificity of this device as per the sample were 100% and 98.3%. So, DROROSCOPE was statistically effective in detecting lesions malignancy.

Keywords:- Droroscope, Potentially Malignant, Malignant Disorders.

I. INTRODUCTION:

An intend of this research is to instigate a lucrative fluorescent visualization device using blue light (400-460nm) to determine abnormal oral tissues that cannot be glimpse by white light. This technique has been hitherto used with the Velscope, & avail oneself of the autofluorescent possessions of healthy & abnormal tissue. DROROSCOPE is a hand held intraoral device with 3 lights, (red, and blue, green-amber) & that device recently made in INDIA concept. (1)

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II. RESEARCH QUESTION:

Is there efficacy of utility of DROROSCOPE for detection of potentially malignant disorders & malignant disorders?

> Hypothesis:

Research hypothesis assumes that there is statistically significant difference in efficacy of utility of DROROSCOPE for detection of potentially malignant disorders & malignant disorders.

> Aim:

To evaluate the efficacy of DROROSCOPE for the early detection of oral potentially malignant & malignant disorders.

Objective:

- To observe the borders of the lesion under various monochromatic lights, i.e. red, blue, green-amber.
- To identify proper site for cytology/ biopsy under various lights.
- To identify the specificity & sensitivity of the device in identifying lesions. (formula)

➤ Inclusion Criteria:

- Subjects who consent to participate in the study.
- Participants who will be 18 years and above.
- Subjects diagnosed clinically with PMDs & malignant disorders.
- Subjects diagnosed clinically with PMDs & malignant disorders induced by oral substance abuse habits.

> Exclusion Criteria:

- The patients who are below 18 years of age.
- The patients who are not willing to participate.
- Medically compromised patients.

> Droroscope Examination

The contemporary device DrOroscope is a palmtop, portable, noninvasive, high efficiency, well functioning, budget-friendly device used for diagnosis of various malignant and PMDs. The device can be looker-on with 3 parts

- 1. Working end (Oral end)
- 2. The shaft/handle

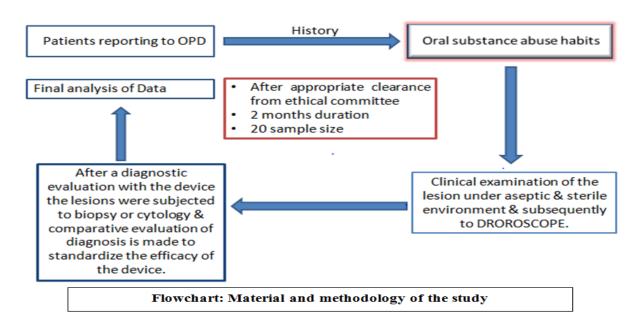
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3. Tail end/connector end

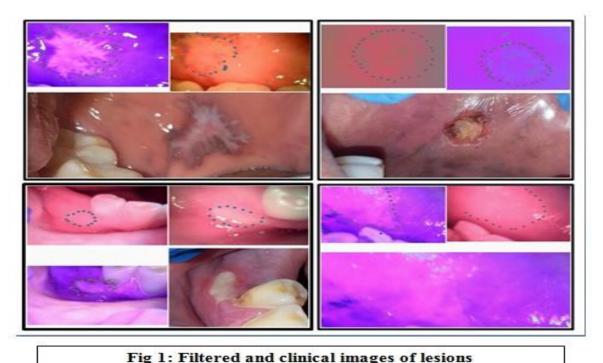
The working end/oral end of the device presents with an LED (Light emission diode) which can release 3 different wavelengths of light (Blue, Red & amber) and a camera. The shaft attaches the working end & the tail end ease the grip. The shaft has a command switch with which the potency of the released wavelength can be attuned to suite the gleam of screening zone.

The camera of the device seizes the images and can shift the same to laptop or an android device. The tail end of the device has a cable with a facilities to attach it to any android device (mobile or tablet) or a laptop computer and can be handled through an application software in which the integral filters will ease the differentiation of clinical pictures with those captured by the device. It needs <1 min for capturing the images. For prevention of cross infection practitioner uses disposable sleeves. (1)

III. MATERIALS AND METHOD:



IV. OBSERVATIONS & ANALYSIS:



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V. STATISTICAL ANALYSIS

- Formula:
- Sensitivity = [true positives/(true positive + false negative)] $\times 100$
- Specificity = [true negatives/(true negative + false positives)] ×100
- Chi-square test is used for inter-group comparison of distribution of categorical variable.
- ANOVA technique is used for inter-group statistical comparison of means of continuous variables.

VI. RESULTS

• The patient distribution was statistically analyzed.

Total patient	Male patient	Female patient	Mean age(year)
20	14	6	39.6

Table 1:- Distribution of patient gender-wise

• The total data was categorized.

PMDs	12	
Malignant disorders	8 .	

Table 2:- Lesion wise distribution of patient

- 14 cases were diagnosed as high risk lesion by histopathological confirmation after surgical biopsy.
- The sensitivity and specificity of this device as per the sample were 100% and 98.3%. So, **DROROSCOPE** was statistically effective in detecting lesions malignancy.

Paired sample statistics						
	Mean	Std.Deviation	Std. Error Mean			
Clinically filtered 1	4.63210	2.7507242	1.1502936			
Blue light filtered PMDs	6.01173	3.6257723	1.4156908			
Clinically filtered	7.3216	2.43359	1.22219			
Blue light filtered MDs	4.0260	.56577	.32673			

Table 3: details the statistics of the area of the lesion with & without blue filter

Paired Samples Test			Paired Differences				t	Sig.
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference			(2-tailed)
					Lower	Upper		
PMDs	Clinical vs. blue light	-2.24603	1.8308	.76870	-3.107	2021	-2.168	.028
MDs	Clinical vs. blue light	1.48775	2.3098	1.10393	-2.028	5.014	1.346	.291

Table 4: Details paired differences between clinical vs. blue light filtered pictures of the lesion

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VII. DISCUSSION:

The cancer is related with morbidity and they influence the caliber of life. In Asia, oral cancer is the 6^{th} most common cancer and in India, oral cancer is on 3^{rd} most common cancer. $^{(2,3)}$

The survivorship of the patients who endure from oral cancer can be filling out by observing the following three main factors:

- Preliminary diagnosis of the lesion
- accurate diagnosis of the lesion
- treatment modality

Histopathological examination of the biopsied specimen gives the final confirmatory diagnosis of any lesions. Several techniques have been established which aid in the preliminary diagnosis of malignant or premalignant lesions, such as OralCDx, Toluidine coloring, ViziLite, Identafi, and VELscope. In the literature a number of articles explain the importance of these aids with opportunities and obstacles. ^(4, 5, 6, 7)

To fill up the scarcity with finer possessions DROROSCOPE - a novel diagnostic device was design & the effectiveness of the device is assessed through the study.

Study & year	Instrument	Sensitivity	Specificity	
Poh et al. 2006	VELscope	97%	94%	
Scheifele et al.,2004	OralCDX	92.3%	94.3%	
Farah et al 2008	VELscope	100%	96%	
Present Study 2019- 2020	DROROSCOPE	100%	98.3%	

VIII. CONCLUSION

DROROSCOPE can be contemplating as a novel diagnostic aid due to its extent of pros (economic, noninvasive, high efficiency, well functioning, budget-friendly device and increased sensitivity & specificity under prop diagnostic accuracy). The accessibility of 3 different wavelengths in one further marks the corporality of use which can be controlled in cogent manner which is fruitful in the diagnosis of malignancy and potentially malignant lesions with the determination of error-free biopsy borders or sites.

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- ➤ Conflicts of interest:

There are no conflicts of interest.

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Fig 2: DROROSCOPE

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