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ORAL SUBMUCOSAL FIBROSIS-A CLINICOPATHOLOGICAL STUDY

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ABSTRACT

Background: Oral submucosal fibrosis(OSF) is a common presentation in ENT OPDs of India with a prevalence of 6.42% due to increased areca-nut and tobacco chewing. Though considered premalignant, biopsy is not routinely indicated for all cases. **Objectives:** 1. To establish clinico-histopathologic correlation in OSF cases 2. To identify high risk OSF cases needing urgent histopathologic examination. **Materials and Methods:** A hospital-based cross-sectional observational study was conducted on 100 OSF cases from October'15 to October, 2016. Clinical staging was established based on presence and severity of symptoms, no. of sites involved, size of mouth opening and degree of tongue protrusion. The clinical stage was correlated with histological findings. **Results:** M:F=5:1. 6 out of 100(6%) of OSF cases turned out to be malignant, of which 5(83.33%) were predicted to be high risk on clinical staging.2 of 8 cases(25%) predicted to be high risk were found to have severe dysplasia. Out of 80 low risk cases, 65(81.2%) had no dysplasia and 15(18.75%) had mild dysplasia. There was significant correlation of clinical staging with histologic findings. **Conclusion:** The clinical staging method used in this study can categorise OSF cases into high risk, moderate risk and low risk which will decide need for urgent biopsy, close follow up and reassurance respectively.

Limitations: 1. Small sample size 2. No follow-up.

INTRODUCTION

Oral sub mucous fibrosis(OSMF) is a chronic and potentially pre- malignant condition of the oral cavity characterized by inflammation and a progressive fibrosis of the lamina propria and deeper connective tissues.[1] OSMF is predominantly seen in Indians and South-east Asians where Indian prevalence is 0.2% to 0.5%.[2] Etiology is multi-factorial but tobacco and areca-nut chewing have been established as main cause.[3,4] Several treatment modalities have been tried over the years but with limited success. Risks of malignancy is rare;[5] but requires close monitoring in selected cases.

OSMF may be malignant but as the rate of malignant transformation is low so all cases need not to be biopsied. A classification system is necessary to reduce the chances of negative biopsies. Several classifications, staging and grading systems have been proposed with each having its own advantages and drawbacks leading to confusion.[6] Most grading systems emphasize on symptoms alone which are subjective. An objective scoring system can assist practitioners in risk-categorization of OSMF.

OBJECTIVES OF THE STUDY

1. To establish clinico-histopathologic correlation in OSF cases.
2. To identify high risk OSF cases needing urgent histopathologic examination.

MATERIALS AND METHODS

A cross sectional OPD based study on 100 patients was done. A clinical risk score has been ascertained based on symptoms, risk factors and oral cavity examination. A clinical risk score system is proposed as following taking various clinical parameters which have been previously found to have significant correlation with the risk of malignancy in previous studies:

	Score 1	Score 2	Score 3
Severity of symptoms	No/mild symptoms	moderate	Severe/incapacitating
Number of sites involved 1.floor of mouth 2.buccal mucosa 3.anterior pillars 4.tongue mucosa 5.soft palate 6.retromolar trigone	1-2	3-4	5-6
Size of mouth opening	>45 mm	20-45mm	<20 mm
Degree of tongue protrusion	Tip touching the lower lip	Tip touching incisors	Tip not touching incisior
Ulcers	absent	Single	Multiple

A total score of 0 – 5 indicates low risk, a score of 6-10 indicates moderate risk and a score of 11 – 15 indicates high risk.

Incisional biopsy has been done from the margin of the lesion and histology has been graded as no dysplasia, mild dysplasia, moderate dysplasia, severe dysplasia and malignancy.

RESULTS

Mean age of the patients was 52.39 ±7.45 years(30-69). 65% of the patients were with age ≥50 years. Only 6.0% of the patients were <40 years. M:F=1.5:1. Majority (57.0%) were smokers(p<0.0); 12.0% of the patients were ex-smokers. 80% had h/o long standing areca-nut or tobacco chewing or both.

Following assessment of clinical risk factors, 79.0% of the patients had mild symptoms which was significantly higher (Z=9.66;p<0.0001). 10.0% of the patients had incapacitating symptoms. Of the sites involved, buccal mucosa (63%) was the most common involved site followed by palate(17%) and faucial part (9%).

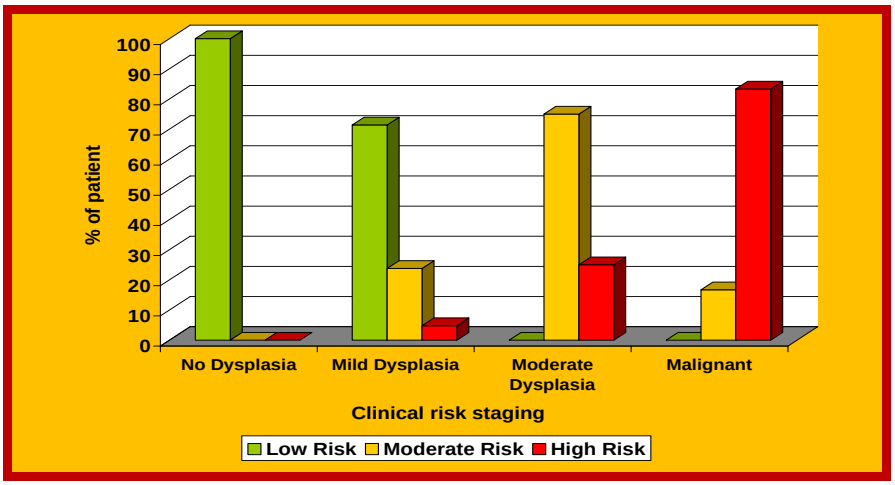
9.0% had mouth opening <20 mm. Majority had mouth opening between 20-45 mm(p<0.0001). Majority had tongue protrusion upto lower lip (Z=9.40;p<0.0001); 10% had tongue protrusion not reaching incisors. In 75.0% of the cases only 1 site was involved followed by 2 sites (21.0%) (Z=7.64;p<0.0001). In majority (88%); ulcer was not present 7% and 5% had single and multiple ulcer/vesicles respectively.

Based on the clinical risk factors, patients were grouped into risk groups using the scoring system as proposed above. 80% belonged to the low risk group, 12% fell in the moderate risk group and 8% in the high risk group.

Following histopathologic examination, 65% had no evidence of dysplasia, 21% had mild-moderate dysplasia, 8% had severe dysplasia and 6% were malignant.

Fischer Exact test showed that showed that proportion of malignant cases was significant higher for the patients with moderate to high risk (p<0.0001).

Corrected Chi-square test showed that there was significant association between clinical risk staging and HPE findings. (χ^2= 102.38; p<0.0001).



HPE CLI-NICAL RISK	*NO DYSPLASIA*	*MILD-MODERATE DYSPLASIA*	*SEVERE DYSPLASIA*	*MALIGNANT*
LOW RISK	*65*	*15*	*0*	*0*
MODERATE RISK	*0*	*5*	*6*	*1*
HIGH RISK	*0*	*1*	*2*	*5*

DISCUSSION

The M:F ratio in this group was 1.5 : 1. Majority of prior studies have shown a female predominance. However, many Indian studies have demonstrated male preponderance.[2,7] This could be attributable to an increased accessibility of males to tobacco and arecanut chewing habits.[8,9]

In the current study, 65% of the patient were > 50 years while 6% were < 40 yrs of age. OSF in most prior studies have been mostly reported in middle age group.

6% of the cases were malignant. Prior long term follow – up studies show a malignant transformation rate of OSF in the range of 7-13%.[7,10] However, this was a cross-sectional study.

Buccal mucosa was the most commonly involved site followed by palate. Similar results have been seen in prior studies by Haider et al and Punnya et al.[11,12]

For this study, we devised a clinical risk score based on a number of clinical parameters including severity of symptoms, number of sites involved, degree of mouth opening and tongue protrusion and presence and number of ulcers. Most prior classification systems have considered either symptom grading or degree of mouth opening and were mostly subjective. A classification system somewhat similar to the one proposed here was used by Bose and Balan in 2007.[13] However, the semiquantitative scoring system proposed here is more objective and has clinical relevance to pathophysiologic stages of the disease from stomatitis to fibrosis to sequelae and complications.

In this study, 80% were low risk and 8% were high risk based on clinical staging. Demographic studies have shown overall malignancy risk of OSF to be low ranging from 7-11%.[7,10]

Following statistical analysis, the current study showed a significant correlation *between clinical risk staging and histologic grading.*

Cinna et al found that the tight packing of collagen fibers increased as the disease progressed from early to advanced stages and also proposed incorporating functional staging with histopathological staging would be a more reliable indicator of severity.[17] Debnath S et al corrrelated histological stage with the frequency of trismus, but not of trismus[16] There was no significant correlation between clinical staging and histopathological grading in the study in Rajasthan by goel et al.[18] Khanna JN and Andrade NN incorporated clinical staging and histologic grading into a single classification system.[19]

However, this study had a few limitations. Biopsy from margins of lesions in accesible parts of oral mucosa. Cheek flexibility wasn't considered in the scoring. No morphometric analysis of collagen was done in HPE.

The currently proposed semiquantitative clinical risk classification system if validated in further studies can prove to be a very useful, easy-to-use and objective clinical tool to determine the need for urgent biopsy or stringent follow-up.

The risk score can be used to determine further management. Those with low risk (Score 1-5) can be managed with sympytomatic treatment alone without any need for follow-up. Those at moderate risk (Score 6-10) can be followed up at frequent intervals to assess for an increase in score and urgent biopsy may not be necessary. The high-risk group (score 11-15) needs an urgent biopsy to rule out malignancy or severe dysplasia with more stringent follow-up.

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