ROLE OF ANTIOXIDANTS ON ORAL SUBMUCOUS FIBROSIS: A CLINICO – PATHOLOGICAL STUDY

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ABSTRACT: BACKGROUND: Oral submucous fibrosis is a chronic progressive scarring disease of oral cavity and oropharynx characterized by epithelial atrophy and juxta epithelial inflammatory reaction with progressive fibrosis of the lamina propria and deeper connective tissue. In India, the first mention of this disease in literature dates back to the time of "Sushruta" as "Vidari". However, in modern literature, Schwartz in 1952 first described it as "atrophica idiopathica mucosae oris". Antioxidants protect by physically separating the free oxygen radicals from the susceptible molecules. Providing molecules that effectively compete with the oxygen. Rapidly repair the damage caused by the free radicals. Lysing & inactivating free radicals, removing damaged molecules. Body's multilevel defense systems against free radicals. **AIMS & OBJECTIVES:** The present study was undertaken to see effect of various antioxidant drugs on oral submucous fibrosis clinically as well as histopathologically. **MATERIAL & METHODS:** This study comprises of 64 patients suffering from oral submucous fibrosis. History, examination and investigation of patients were done in detail as per predesigned proforma. **OBSERVATIONS:** Submucous fibrosis was seen from 2nd to 6th decade of life. Males were more commonly affected (65.625%) than females (34.375%). The incidence of submucous fibrosis is higher in Hindus (87.5%) than Muslims (12.5%). Maximum number of the patients were between 1 and 2 years duration or between 5 and 10 years duration (16 cases in each group). Table shows that 50% of the patients suffering from oral submucous fibrosis had been chewing pan – masala and betel nut. In our series of study maximum cases were of severe grade trismus (32.81%). In this study we gave antioxidant drugs to the patients for a period of 2-3 months. Symptoms of burning sensation of mouth were relieved in 64.51% of cases by antioxidant therapy. Repeated painful ulcerations of mouth were relieved in 70% cases by antioxidant therapy. Suppleness of oral tissue was improved in 80.00% cases by antioxidant therapy. The symptom of trismus was relieved in 26.19% cases by antioxidant therapy. Out of 64 cases of oral submucous fibrosis 36 cases improved on therapy (56.25%) No patient got complete cure by therapy and there were 16 cases who failed on therapy (25%). There were 12 cases (18.75%) that did not come for follow up. **CONCLUSION:** Thus our work is showing that anti-oxidant drugs are overall favourable for early cases of oral submucous fibrosis clinically as well as histopathologically. So we conclude that anti-oxidant therapy should be regularly used in cases of oral submucous fibrosis.

KEYWORDS: OSMF, Histopathological changes, Role of Antioxidants.

INTRODUCTION: Oral submucous fibrosis is a chronic progressive scarring disease of oral cavity and oropharynx characterized by epithelial atrophy and juxta epithelial inflammatory reaction with progressive fibrosis of the lamina propria and deeper connective tissue. The resulting stiffness of the oral mucosa then causes a progressive decrease in mouth opening.

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In India, the first mention of this disease in literature dates back to the time of “Sushruta” as “Vidari”. Oral submucous fibrosis first described as “atrophica idiopathica mucosaeoris”¹

Oral submucous fibrosis is a condition, which carries high risk of malignant transformation i.e. 3-7.6%.²

ANTIOXIDANTS PROTECTS by physically separating the free oxygen radicals from the susceptible molecules. Providing molecules that effectively compete with the oxygen. Rapidly repair the damage caused by the free radicals. Lysing & inactivating free radicals, removing damaged molecules. Body's multilevel defense systems against free radicals.

(a) **Enzymes:** there are certain enzymes in body which protects from free radical superoxide dismutase, Glutathione peroxidase and catalase.

(b) **VITAMINS:** Vitamin A/B-carotenoid, Vitamin E, Vitamin C

Antioxidant drugs contain Alpha Lipoic acid Vit. A, Vit. E, Vit. C. as well as minerals selenium, zinc, Copper & manganese indifferent compositions.

AIMS & OBJECTIVES: The present study was undertaken to see effect of various antioxidant drugs on oral submucous fibrosis clinically as well histopathologically.

MATERIAL & METHODS: This study comprises of 64 patients suffering from oral submucous fibrosis who attended the department of Rama Medical College, Kanpur.

History, examination and investigation of patients were done in detail as per predesigned proforma. Histopathological examination of biopsy tissue from oral mucosa was done in patients who had taken pre-therapy and post-therapy (if and when required). X-ray of temporomandibular joint was requested (whenever needed).

OBSERVATIONS: Present study was done in the department of Rama Medical College, Kanpur. Total 64 cases were randomly selected in regard to detail study of oral submucous fibrosis and their therapy.

S. NO	Age group (yrs)	Total Cases	
		No.	%
1.	0-10	-	-
2.	Above 10-20	6	9.375%
3.	Above 20-30	22	34.375%
4.	Above 30-40	22	34.375%
5.	Above 40-50	10	15.625%
6.	Above 50-60	4	6.25%
Total	64	42%	

TABLE 1: SHOWING THE AGE INCIDENCE AMONGST 64 CASES OF SUBMUCOUS FIBROSIS

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The cases of submucous fibrosis were seen from 2nd to 6th decade of life according to above table. It is obvious that highest incidence of submucous fibrosis was found between the age group 20 to 30 and 30 to 40 years (34.375%). Lowest incidence (6.25%) was in age group of 50-60 years.

S.No.	Age Group (yrs)	Male		Female	
		No	%	No	%
1.	0-10		-	-	-
2.	Above 10-20	4	6.25%	2	3.125%
3.	Above 20-30	18	28.125%	4	6.25%
4.	Above 30-40	10	15.625%	12	17.75%
5.	Above 40-50	6	9.375%	4	6.25%
6.	Above 50-60	4	6.25%	-	-
	Total	42	65.625	22	34.375

TABLE 2: SHOWING SEX INCIDENCE AMONGST 64 CASES OF ORAL SUBMUCOUS FIBROSIS

Males were more commonly affected (65.625%) than females (34.375%) except in age group of 30 to 40 years where females were more affected (18.75%) than males (15.625%).

S. No.	Religion	Total cases		Male		Female	
		No.	%	No.	%	No.	%
1.	Hindu	56	87.5 %	40	62.5%	16	25.00%
2.	Muslim	8	12.5%	2	3.125%	6	9.375%
	Total	64	100%	42	65.625	22	34.375

TABLE 3: RELATION SHIP BETWEEN RELIGION AND INCIDENCE OF ORAL SUBMUCOUS FIBROSIS AMONGST 64 CASES (MALES AND FEMALES)

The incidence of submucous fibrosis is higher in Hindus (87.5%) than Muslims (12.5%). Hindu male suffers more (62.5%) than Muslim males (3.125%). Similarly Hindu females suffer more (25.00%) than Muslim females (9.375%). However, Muslim females suffer more (9.375%) than Muslim Males (3.125%).

S. NO	Duration (yrs)	No. of case	Percentage
1.	0-1	14	21.8%
2.	Above 1-2	16	25.0%
3.	Above 2-5	8	12.5%
4.	Above 5-10	16	25.0%
5.	Above 10	6	9.35%
6.	Above 15-20	4	6.20%

TABLE 4: SHOWING DURATION OF DISEASE AMONGST 64 CASES OF SUBMUCOUS FIBROSIS

The above table shows that maximum number of the patients were between 1 and 2 years duration or between 5 and 10 years duration (16 cases in each group). 4 patients were diagnosed

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accidentally and therefore, duration of disease could not be ascertained. N. B. – Minimum duration of disease was of 1 month and maximum was of 30 years.

S. NO	Habit	No. of case	Percentage
1.	Pan Masala alone*	32	50.00%
2.	Betel nut chewing with tobacco and betel nut with smoking	16	25.00%
3.	Tobacco chewing only	6	9.375%
4.	Betel nut chewing only	4	6.25%
5.	Betel nut chewing with tobacco	2	3.125%
6.	No habit	2	3.125%
7	Smoking only	-	--
8	Tobacco chewing with betel nut	2	3.125%

TABLE 5: SHOWING INCIDENCE OF HABITS AMONG 64 CASES OF SUBMUCOUS FIBROSIS

Pieces of roasted betel nut with powdered slaked lime and powdered tobacco + undisclosed flavouring agent.

The above table shows that 50% of the patients suffering from oral submucous fibrosis had been chewing pan – masala alone. Next common habit was betel chewing with tobacco and betelnut with smoking (25% of cases). In 9.375% of cases we found habit of tobacco chewing only. Habit of betel nut chewing only was found in 6.25% cases. In one case (3.125) there was no such habit which could be blamed for sub – mucous fibrosis. The table thus shows that overall 87.5% of cases were chewing betel nut in one way or other.

S. NO	Amount of pan masala	No of Cases	Percentage
1.	0-25 grams	4	12.5%
2.	25-50 grams	8	25.0%
3.	50-75 grams	5	15.62%
4.	75-100 grams	15	46.8%

TABLE 6: TABLE SHOWING AMOUNT OF PAN MASALA PER DAY AMONGST 32 CASES OF ORAL SUBMUCOUS FIBROSIS

1 pouch of pan masala = 4 grams

According to above table maximum amount of pan masala (75-100 gm/day) was taken by 15 cases. Out of 32 cases only 4 cases taking least amount of pan masala (0-25 gms/day).

S. No	Duration of pan masala intake	No. of case	Percentage
1.	0-3	5	15.62%
2.	3-6	10	33.24%
3.	6-9	5	15.62%
4.	9-12	12	37.50%
Total duration	0-12 yrs	32	100

TABLE 7: SHOWING TOTAL DURATION OF PAN MASALA INTAKE AMONGST 32 PATIENTS OF ORAL SUBMUCOUS FIBROSIS

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There are 5 patients taking pan masala for the duration of 0-3 years. 10 Patients taking pan masala for the duration of 3-6 years, in the duration of 6-9 years there were 5 patients, and 12 patients were in the duration of 9-12 years.

Grade of trismus	No. of case	Percentage
Mild	10	15.62%
Moderate	13	20.31%
Severe	21	32.81%
No trismus	20	31.25%
Total	44	100

TABLE 8: SHOWING THE INCIDENCE OF VARIOUS GRADES OF DIFFICULTY IN OPENING MOUTH (TRISMUS) AMONGST 66 PATIENTS OF OSMF

In our series of study maximum cases were of severe grade (32.81%). The number of patient with moderate degree of trismus was 13 (20.31%). Mild grade of trismus was found in only 10 cases, (15.62%). There are 20 patients who did not complaint of any difficulty in opening mouth.

S.No	Histopathological Grading * Khanna & Andrade (1995)	No. of cases	Antioxidant therapy			
			Improvement		No improvement	
			No.	%	No.	%
1.	Grade I	8	6	75%	2	25%
2.	Grade II	6	5	80%	1	20%
3.	Grade III	6	2	75%	4	25%
4.	Grade IV	10	1	10%	9	90%
	Total	30	14	100%	10	100

TABLE 9: SHOWING THE EFFECT OF ANTIOXIDANT THERAPY ON HISTOLOGY OF 30 CASES OF BIOPSY PROVEN ORAL SUBMUCOUS FIBROSIS

There were 30 patients who gave consent for biopsy out of 64 patients. There were 8 patients in grade I out of which 6 showed improvement on antioxidant therapy. 2 patients did not show any improvement. In grade II out of 6 cases, 5 showed improvement and 1 patient did not came for follow-up. In grade III out of 6 only 2 patients gave positive improvement and four failed to show any improvement. In grade IV only 1 patient's post therapy biopsy specimen showed little pathological changes of improvement.

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Therapy	Grade	Total No of Cases	Improvement					No Improvement				
			No. of cases	Average I to I Distance		Average M to M Distance		No. of cases	Average I to I Distance		Average M to M Distance	
				Therapy		Therapy			Therapy		Therapy	
				Pre	Post	Pre	Post		Pre	Post	Pre	Post
Antioxdant Therapy*	Mild	10	9	3.7	4.9	2.2	2.9	1	3.6	3.8	2.3	2.5
	Moderate	13	2	2.26	3.06	1.16	1.8	11	2.3	2.5	1.2	1.3
	Severe	21	1	1.31	2.56	0.85	1.26	18	1.8	1.8	0.8	0.8

TABLE 10: SHOWING EFFECT OF ANTIOXDANTS THERAPY ON TRISMUS OF VARIOUS GRADES OF SEVERITY AMONG 44 PATIENTS OF SUBMUCOUS FIBROSIS

*Vitamin A or carotinoids Se, Zn. Fe and B Complex vitamin, Mn, Cu, Vitamin C;
Average I to I distance = Distance between upper and lower central incisors in cms.
Average M to M distance = Distance between upper and lower last molars in cms.
Normal average incisor to incisor space = 3.5 cm
Normal average molar to molar space = 1.5 cm
(This measurement deduced from 50 normal persons)

Note: If average improvement was less than 0.5 cm between incisor to incisor it was concluded to be failure as it was practically of no benefit to the patients.

Out of 44 patient 21 patients were of severe grade, out of which 20 failed to respond. Out of 13 moderate grades, 11 failed to respond and in mild grade consisting of 10 patients, 9 responded favourably.

S. No	Symptoms of oral submucous fibrosis	No. of cases	Antioxidant therapy			
			Improvement		No improvement	
			No.	%	No.	%
1.	Burning sensation and intolerance to chilies and spices	31	20	64.51	11	35.48
2.	Repeated painful ulceration of mouth	10	7	70.00%	3	30.00%
3.	Difficulty in protruding out tongue	13	1	7.60%	12	92.30%
4.	Suppleness of oral mucosa	40	32	80.00%	8	20.00%
5.	Fibrous bands on palpation Total	40	14	35.00%	26	65.00%
6.	Trismus	42	11	26.19	31	73.80%

TABLE 11: SHOWING THE EFFECT OF ANTIOXIDANTS ON THE SYMPTOMS AMONGST 64 PATIENTS OF SUBMUCOUS FIBROSIS

In this study we gave antioxidants drugs to the patients for a period of 2-3 months. Symptoms of burning sensation of mouth were relieved in 64.51% of cases by antioxidant therapy. Repeated painful ulcerations of mouth were relieved in 70% cases by antioxidant therapy. Symptoms of difficulty in protruding out tongue was relieved in 7.60% of cases by antioxidant

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therapy. Suppleness of oral tissue was improved in 80.00% cases by antioxidant therapy. The symptom of trismus was relieved in 26.19% cases by antioxidant therapy.

S No.	Result	No. of cases	Percentage
1.	Improvement	36	56.25
2.	Cured	0	0.00
3.	Failure	16	25.00
4.	No follow up	12	18.75%
	Total	64	100%

TABLE 12: SHOWING RESULTS OF ANTIOXIDANT THERAPY AMONG 64 CASES OF SUBMUCOUS FIBROSIS

Above table showing the results of administration of anti-oxidant drugs for 2-3 months duration. There were 36 cases improved on therapy (56.25%) No patient got complete cure by therapy. There are 16 cases who failed on therapy (25%) there are 12 cases (18.75%) that did not come for follow up.

Amongst 16 failed cases.- 3 patients developed leukoplakia of oral cavity and 2 patients developed squamous cell carcinoma

DISCUSSION: Sixty four patients of oral submucous fibrosis studied in E.N.T. department of Rama Medical College, Kanpur between June 2002 to July, 2003. These constituted 0.220% (incidence) of total patients attending ENT out-patient department between the said duration. This finding is in accordance to wahi et al (1970)³ and Mehta et al (1972)⁴. According to Pindborg et al (1966)⁵ prevalence is highest in South India. This indicated prevalence of OSMF is less in north India as compared to south India. It could be because south Indian population used to take more spicy food.

In our study we found highest incidence of oral submucous fibrosis in 3rd and 4th decade of life i.e. 44 out of 64 cases (68.75% of all cases) were between the age of 20 to 40 years. This finding corresponds exactly with. Desai⁶ who recorded 44 out of 64 cases i.e. 68.75% to be in 3rd and 4th decades. Wahi et al (1970)³; Zachariah et al (1996)⁷ and Mehta et al (1972)⁴ have also reported highest incidence between 3rd and 4th decade of life.

Findings of the study are however not consistent with the findings of Shankarnarayan (1990)⁸ who observed that peak age frequency of occurrence is atleast a decade earlier than that described in western literature.

Males were affected more than females i.e. out of 64 cases 42 (65.625%) were male while 22 (34.375%) were females.

The incidence of the disease in our series was more in Hindus (87.5%) than Muslims (12.5%). Hindu male was affected more (62.5%) than Muslim male (3.125%). Similarly Hindu females were affected more (25%) than Muslim females (9.375%). This can be explained on the basis that Hindu constitutes major part of population in U.P. However. The notable part was that among Muslim, females were affected more 9.375% than Muslim males 3.125% we do not know the exact reason for it.

The duration of disease ranged from 1 month to 30 years. However, maximum cases were reported of 1- 2 years duration. Desai (1957)⁶ had reported maximum cases of the duration between 2 -5 years.

All the patients were in habit of taking pan masala, betel, tobacco and betel nut and smoking cigarettes or bidi except one. 50% of all patients had habit of chewing pan masala, 25% of all patients had additional habit of smoking, 6.25% chewed betel nut only, 3.125% had habit of chewing betel with betel nut similarly tobacco and betel nut habit was in 3.125% . Thus 87.5% of patients were having betel nut habit was in 3.125%. Thus 87.5% of patients were taking betel nut in one way or other. These findings are in agreement with reports given by LAl (1953)⁹, Wahi et al (1966)³, Sharan (1959)¹⁰ & Maruti (1990)¹¹. According to these authors betel nut causes degenerative change in connective tissue of oral mucosa followed by fibrosis.

Sheedat (1988)¹² suspected that occurrence of submucous fibrosis among those without an areca nut chewing habit is probably due to spontaneous genetic susceptibility. Merchant et al (2000)¹³ on the basis of studies of Sinor et al (1990)¹⁴ and Maher et al (1994)¹⁵, quoted that the condition almost never develops in people who do not chew areca nut.

To record improvement in opening of mouth we used an objective method of measuring the distance between upper central incisor and lower central incisor and upper last molar to lower last molar with the help of caliper and scale. This method was first used by Sinha, and Jain (1978).¹⁶ the method is better and gives accurate idea about improvement of this distressing symptom. According to this normal and adequate opening of mouth being incisor to incisor distance between 3 to 3.5 cm and last molar to last molar distance being 1.5 cm.

18.75% of cases presented with Burning sensation and repeated painful ulcers of mouth our finding are not consistent with the finding of Sinha and Jain, (1978)¹⁶ reported these symptoms in 27.25% of cases which corresponded with Desa (1957)⁶ and Mathew et al (1967).

6.25% i.e. out of 64 cases presented with Intolerance to chilli and spicy meals. In our series of study findings are corresponding with the findings of Maher et al (1994)¹⁵ who observed these findings in 8.26% of cases.

Our pre-therapy histopathological findings of stratified squamous epithelium showing keratinisation and chronic inflammatory cells, dense fibrosis in submucous space, atrophy and absence of gland tissue and blood vessels and capillaries are in agreement with the findings of Desa (1957)⁶ Pindborg et al (1965)⁵. In our study we have also done histopathological study two month after completion of therapy. No literature is available regarding it except of Sinha, and Jain, (1978)¹⁶. We found following histopathological changes in post-therapy cases.

1. Keratinization and chronic inflammatory cells are markedly reduced.
2. Fibrous tissue is decreased in sub-mucous layer.
3. Appearance of gland cells.
4. Blood vessels dilatations and new capillaries formation.
5. These are all histological features of improvement.

Out of 64 patients, 44 patients of trismus were given therapy amongst these patients' 42 cases came for follow up, 11 patients reported favorably, 31 patients showed no improvement.

In our series of study 44 patients of trismus were given antioxidant therapy. In mild grade of trismus out of 10 patients 9 patients showed clinical improvement in interincisal distance from 3.7 cm (mean) to – 4.9 cm. These findings are correlation with the Ramchandra Reddi (1993)¹⁷ who observed 80% improvement in their cases. Molar to molar distance from 2.2 (mean) to 2.9 cm.

In moderate variety only 2 cases showed significant interincisal and intermolar improvement. This observation contrast with Reddy (1993)¹⁷ who did not observed any improvement in moderate variety.

In severe variety only one patient showed improvement and 20 patients failed to show any improvement. This is again in accordance with Ramchandra Reddi (1993)¹⁷.

In our work we considered failure case to be one in which opening of mouth did not increase more than 0.5 cm.

In our study 33 patients were treated by antioxidant therapy 31 came for follow up 20 showed (64.51%) improvement or decreasing severity of Effect on burning sensation and Intolerance to chilli and spicy meals while 11 cases showed no relief. Our findings are in agreement of publications of Borle et al (1991) who observed 58.18% relief from these symptoms in their cases. In our study 70% cases of OSMF got relieved by antioxidant therapy while 30.00% cases keep on complaining for repeated painful ulcers of mouth. This is not bearing significant resemblance to paper of Rao (1962) who showed only 20% improvement in vitamin A & E.

CONCLUSION: Out of 64 cases of oral submucous fibrosis when followed up for 2-3 months on antioxidant therapy. Among these 12 patients did not came for follow up, 16 patients had failed on therapy and 36 patients showed decrease in symptoms on therapy. Thus our work is showing that anti-oxidant drugs are overall favourable for early cases of oral submucous fibrosis clinically as well as histopathologically. So we conclude that anti-oxidant therapy should be regularly used in cases of oral submucous fibrosis.

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