



Radiotherapy

STUDY THE EFFICACY OF GAMMA & DELTA TOCOTRIENOL (50%) IN ORAL SUBMUCOUS FIBROSIS (OSMF): AN ORAL PREMALIGNANT CONDITION

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ABSTRACT **Introduction & Objective:** An oral premalignant condition that is oral submucous fibrosis (OSMF) which is categorized by inflammation and progressive fibrosis with malignant rate due to submucosal tissues resulting in marked rigidity and trismus. The present study objective was to evaluate the efficacy of an isoprenoid compounds in the form of gamma and delta tocotrienol (50%) by comparative with conventional treatment in OSMF.

Material and Method: This study was carried out in the groups confirmed OSMF which further divided into two sub-groups; each group has 15 patients elected from Aadhar Hospital, Hisar, India. The group X patients were given conventional treatment whereas group Y patients were given gamma and delta tocotrienol (50%) 400mg soft gel capsules, b.i.d orally) with conventional treatment for a period of six months.

Results: The obtained results were confirmed histopathologically and showed that combination of gamma and delta tocotrienol (50%) capsules significantly improved the patient's conditions in terms of burning sensation, pigmentation, extent of mouth opening and its effectiveness in the OSMF treatment as compared to conventional treatment alone.

Conclusion: The present study overall results concluded that gamma and delta tocotrienol (50%) with conventional treatment is a safe and reliable method which played a significant role in the treatment of OSMF.

KEYWORDS : Oral submucous fibrosis, premalignant condition, tocotrienol, treatment, safety

INTRODUCTION

In the 19th century, Schwartz (1952) was identified fibrosing condition in Indian women and described as "*Atrophica idiopathica mucosa oris*" and later, Pindborg (1966) [1] was characterised as chronic mucosal disease considered a potentially malignant disorder in any part of oral cavity and sometimes in pharynx [2-4]. Now-a-days, it is recognised oral submucous fibrosis (OSMF) which is premalignant condition with risk potential for malignancy. OSMF is also considered as Indian diseases which among in any age group but higher percentage 20-40 years of age in different states of India [5]. There is much factor for causation of OSMF but main contribution done by areca nut and it's commercially forms like chewable betel quid, tobacco (smoked/chewable), supari, gutka, pan masala etc. [6]. This disease condition was characterised by inflammation, increased deposition of submucosal collagen, and formation of fibrotic bands in the oral and paraoral tissues, which increasingly limit mouth opening. Presently, this premalignant condition is treated by various conventional treatment using corticosteroids, hyaluronidase, lycopene, vitamin C, vitamin E, antioxidants with or without tocotrienol [7-11] but till date no study is done on combination of gamma and delta tocotrienol with conventional therapy. In current study, oral administered of gamma and delta tocotrienol (50%) capsules efficacy was study along with the conventional treatment of intralesional injections in OSMF.

MATERIAL AND METHODS

The selection criteria of patients were included both males and females of all age groups with confirmed clinical features of burning sensation during spicy and hot food intake, pigmentation, trismus, ulceration, difficulty in mouth opening along with consents of their participation in the study. Thirty (30) patients were elected on the basis of above given criteria and divided into two groups; each group has 15 patients. The first group X has given conventional therapy and another group Y has given soft gel capsules of gamma and delta tocotrienol along with conventional therapy. Group X patients received conventional therapy which includes intralesional injection of triamcinolone acetonide (10mg/ml) is given at infected site of fibrosis in weekly once and antioxidant therapy. Additionally, the group Y patients were treated with combination of gamma and delta tocotrienol (50%) 400 mg soft gelatin capsules twice a day along with intralesional injection & antioxidant of conventional therapy at period of six month. The patient's parameters (burning sensation, ulceration, trismus, pigmentation, mouth opening) were monitored before as well as after treatment and measured their improvement in terms of percentages. The samples of gamma & delta tocotrienol (50%) capsules were provided by Jenome Biophar Pvt. Ltd., India for this study.

RESULT AND DISCUSSION:

The study was carried out on elected patient's conditions and the efficacy of gamma & delta tocotrienol (50%) capsules compared with

conventional therapy alone. The burning sensation condition was present in fourteen patients in Group X and thirteen patients in Group Y out of fifteen patients before treatment. The improvement condition results were summarised in Table 1. In another condition, ulceration & pigmentation was present in twelve & thirteen patients in Group X whereas fourteen patients in Group Y out of fifteen patients and study results were elaborated in Table 2 & Table 3 respectively.

The result of gamma & delta tocotrienol (50%) capsules with conventional therapy in Group Y has been shown 92%, 78% & 93 % whereas in case of conventional therapy treatment in Group X has been shown 64%, 67% & 85% in case of burning sensation, ulceration and pigmentation respectively. The combination of gamma & delta tocotrienol (50%) capsules with conventional treatment was showed better results when compared to the conventional therapy. In case of patients suffered from trismus, the gamma & delta tocotrienol (50%) capsules with conventional therapy has been shown 87% showed improvement as compared conventional therapy (only 60%; Table 4).

Table 1: Results of burning sensation after treatment

Burning sensation	Patients before treatment		Patients after treatment		Condition improvement in term of percentage
	Present	Not present	Present	Not present	
Group X (Conventional treatment)	14	1	6	9	64
Group Y (gamma & delta tocotrienol (50%) capsules with conventional treatment)	13	2	3	12	92

Table 2: Results of Ulceration after treatment

Ulceration	Patients before treatment		Patients after treatment		Condition improvement in term of percentage
	Present	Not present	Present	Not present	
Group X (Conventional treatment)	12	3	7	8	67
Group Y (gamma & delta tocotrienol (50%) capsules with conventional treatment)	14	1	4	11	78

Table 3: Results of Pigmentation after treatment

Pigmentation	Patients before treatment		Patients after treatment		Condition improvement in term of percentage
	Present	Not present	Present	Not present	
Group X (Conventional treatment)	13	2	4	11	84
Group Y (gamma & delta tocotrienol (50%) capsules with conventional treatment)	14	1	2	13	93

Table 4: Results of Trismus after treatment

Pigmentation	Patients before treatment		Patients after treatment		Condition improvement in term of percentage
	Present	Not present	Present	Not present	
Group X (Conventional treatment)	15	0	6	9	60
Group Y (gamma & delta tocotrienol (50%) capsules with conventional treatment)	15	0	2	13	87

Before the treatment the mouth opening of all patients were measured and divided into three categories, the first category, the opening of mouth is absent, the second category was opening of mouth is limited

Table 5: Category of patients during treatment of mouth opening and results after treatment

Groups	Patients Category before treatment			Mouth opening		
	I	II	III	I	II	III
X	6	5	4	Absent	Limited	Restricted
Y	6	5	4			

Patients condition after three to six-month treatment							
Conventional therapy (Group X)				Gamma & Delta tocotrienol (50%) capsules with conventional treatment (Group Y)			
Patient Category	Mild	Moderate	Excellent	Patient Category	Mild	Moderate	Excellent
I	5	Nil	Nil	I	3	3	-
II	-	2	Nil	II	-	3	2
III	-	-	-	III	-	3	1
No Improvement	1	3	4	No Improvement	0	0	0

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and third category was opening of mouth is restricted to some extent. After treatment, the patient's improvement conditions were divided into three stages mild (opening of mouth), moderate (insert 1-2 finger) and excellent (insert more than 2 finger) condition. The category and result of mouth opening was tabulated in Table 5 & Figure 1. This result showed that the patient improvement in Group X is less as compared to Group Y. In group X, observed mild improvements in 5 patients, only 2 patients showed moderate improvement and no excellent improvement in patient's conditions. Whereas treatment of group Y patient's, 3 patients showed mild improvement, 9 patients moderately improved and 3 patients showed excellent improvement out of fifteen patients.

CONCLUSION

The study group which was given the combination of gamma & delta tocotrienol (50%) 400mg softgel capsules with conventional therapy has shown to have significant improvement in an oral premalignant condition (OSMF) in six months periods. Additionally, this study revealed that gamma & delta isomer capsules of tocotrienol have significantly better effect as compared to conventional & tocotrienol individually.



Figure 1: Mouth opening after treatment of one month (I); three month (II) and six month (III) in Group Y patient