

Turmeric: A Randomized Clinical Trial

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ABSTRACT

Background: Oral submucous fibrosis (OSMF) is a potentially malignant condition with characteristic Oral chronic, insidious disease that is associated with significant functional morbidity and an increased risk for malignancy. The anti-inflammatory and antioxidant properties of curcumin are responsible for its chemo preventive action.

Material and method: A total of 20 clinically diagnosed patients with OSMF and give 9-month turmeric therapy. They all are habit of gutaka and tobacco placed in oral cavity.

Result: The opening of mouth is significantly increase during individual taking the turmeric (Mean and SD is 1.4 and 0.45) similarly the burning section significantly reduce (Mean and SD is 2.4 and 0.29).

Conclusion: Turmeric is considered a safe, nontoxic, and effective alternative for many conventional drugs due to its distinguished therapeutic properties and multiple effects on various systems of the body. Curcumin due to its properties should be used in patients with OSMF as application of it is beneficial and inexpensive too.

Keywords: Curcumin, malignant.

INTRODUCTION

Oral submucous fibrosis (OSF) is "an insidious, chronic disease affecting any part of the oral cavity and sometimes the pharynx. Although occasionally preceded by and/or associated with vesicle formation, it is always associated with juxta-epithelial inflammatory reaction followed by fibro-elastic change of the lamina propria, with epithelial atrophy leading to stiffness of the oral mucosa and causing trismus and inability to eat." [1] Worldwide, estimates of OSF show a confinement to Indians and Southeast Asians, with an overall prevalence rate in India of approximately 0.2–0.5%, and a gender prevalence of 0.2–2.3% in males and 1.2–4.57% in females. [2]

Although a number of factors have been worked upon, no single pathophysiology has been agreed on and, hence, no effective treatment has come to light. Thus, the management of OSMF poses a great challenge. [2] Turmeric (*Curcuma longa*) is a medicinal plant extensively used in Ayurveda, Unani and Siddha medicine as a home remedy for various diseases. [1] A large number of studies have revealed that Curcumin has wide therapeutic actions such as anti-inflammatory, antioxidant and anticancer properties. Curcumin have been studied for treatment of OSF by Hastak *et al.*, [3] Chainani-Wu *et al.* (2008), Das *et al.* [4] and Rai *et al.* [5] The purpose of study is to evaluate the turmeric in oral submucous fibrosis in our

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department in medical college. There is no more study is turmeric based in this region.

Aim

To determine the effect of turmeric in treatment of oral sub mucous fibrosis patient

Selection criteria for samples

A total of 20 clinically diagnosed patients with OSF (diagnosed on the basis of reduction in interincisal distance on maximum mouth opening and palpable fibrous bands involving oral mucosa) within the age range of 18–50 years and interincisal opening in the range of 15–30 mm were selected. These patients were asked to discontinue all the habits of tobacco or areca usage 1-month prior to the commencement of the treatment.

RESULT

Table 1: Statistics analysis: One sample *t* test results

P value and statistical significance:	Confidence interval:	Intermediate values used in calculations
- The two-tailed P value is less than 0.0001 - By conventional criteria - This difference is considered to be extremely statistically significant	- The hypothetical mean is 0.0000 The actual mean is 1.4000 - The difference between these two values is 1.4000 - The 95% confidence interval of this difference: From 1.1894 to 1.6106	$t = 13.9133$ $df = 19$ - standard error of difference = 0.101

Table 2: Variation of Mouth Opening.

No of individuals	Age /sex	Mouth opening				Variation
		1 st vist	3M	6 M	9M	
	Visit					9 month
1.	M/22	22	22.5	23	23	1 CM
2.	M/44	20.5	21	22.5	22.5	2CM
3.	M/26	24	24	24.8	25	1CM
4.	M/45	16.5	16.8	18.2	18.5	2CM
5.	M/34	19	19.6	20.6	21	2CM
6.	M/44	22.4	23	23.5	23.5	1.1CM
7.	F/33	26.6	27.3	28.3	28.5	1.9CM
8.	M/32	22.5	22.8	23.4	23.5	1CM
9.	M/27	27.4	28.3	28.6	29	1.6CM
10.	F/24	24	24.5	25	25	1CM
11.	F/53	24	24.5	25	25	1CM
12.	M/28	28.5	29.3	29.5	30	1.5CM
13.	M/22	24	24.5	24.5	24.5	0.5CM
14.	F/35	22	22.5	23	23.5	1.5CM
15.	M/44	20.5	21	22.5	22.5	2CM
16.	M/26	24	24	24.8	25	1CM
17.	F/33	26.6	27.3	28.3	28.5	1.9CM
18.	M/32	22.5	22.8	23.4	23.5	1CM
19.	F/24	24	24.5	25	25	1CM
20.	F/53	24	24.5	25	25	1CM
n=20						

Table 3: Data comparision

No of individuals	Mean	SD	P -Value
N=20	1.4	0.45	less than 0.0001

In this study variation of mouth opening during the peroid 9 Month increase in mouth opening .The increase of mouth opening average is 1.4cm during this period.(Table 2).The mean and standerdaviation of that variation is 1.4 and0.45 and p-vauue is less than 0.0001(Table 3).These statical value show significanc vartaion .(Table1)

Table 4: Statistics analysis: One sample *t* test results.

P value and statistical significance:	Confidence interval:	Intermediate values used in calculations
- The two-tailed P value is less than 0.0001 - By conventional criteria - This difference is considered to be extremely statistically significant	- The hypothetical mean is 0.0000 - The actual mean is 2.4000 - The difference between these two values is 2.4000 - The 95% confidence interval of this difference: From 2.1239 to 2.6761	- t = 18.1917 - df = 19 - standard error of difference = 0.132

Table 5: Variation of Burning Sensation With VAS score.

No of individuals	Age /sex	Burning Sensation				Variation
	Visit	1 st vist	3M	6 M	9M	VAS
1.	M/22	Moderate 4	Moderate4	Mild 2	Mild 2	2
2.	M/44	Sever 6	Sever 6	Moderate4	Moderate 3	3
3.	M/26	Mild 2	Mild 2	No pain0	No pain 0	2
4.	M/45	V. Sever 7	V. Sever 7	Sever 6	Moderate 5	2
5.	M/34	Moderate 4	Moderate4	Mild 2	Mild 2	2
6.	M/44	Mild 2	Mild 2	No pain0	No pain 0	2
7.	F/33	Mild 2	Mild 2	No pain0	No pain 0	2
8.	M/32	Moderate 4	Moderate4	Mild 2	Mild 2	2
9.	M/27	Mild 2	Mild 2	No pain0	No pain 0	2
10.	F/24	Moderate 4	Moderate4	Mild 2	No pain 0	4
11.	F/53	Moderate 4	Moderate4	Mild 2	Mild 2	2
12.	M/28	Mild 2	Mild 2	No pain0	No pain 0	2
13.	M/22	Moderate 4	Moderate4	Mild 2	Mild 2	2
14.	F/35	Moderate 5	Moderate4	Mild 2	Mild 2	3
15.	M/44	Sever 6	Sever 6	Moderate4	Moderate 3	3
16.	M/26	Moderate 5	Moderate4	Mild 2	Mild 2	3
17.	F/33	Mild 2	Mild 2	No pain0	No pain 0	2
18.	M/32	Moderate 5	Moderate4	Mild 2	Mild 2	3
19.	F/24	Moderate 5	Moderate4	Mild 2	Mild 2	3
20.	F/53	Moderate 4	Moderate4	Mild 2	Mild 2	2
n=20						

Table 6: Data Comparison.

No of individuals	Mean	SD	P -Value
N=20	2.4	0.59	less than 0.0001

In this study variation of Burning sensation during the period 9 Month decrease. The decrease of burning sensation average is 2.4 VAS during this period. (Table 5). The mean and standard deviation of that variation is 2.4 and 0.59 and p-value is less than 0.0001 (Table 4). These statistical values show significance variation. (Table 6)

DISCUSSION

Curcumin has been reported to possess fibrinolytic action in liver and lung fibrosis in studies conducted by Kuttan *et al.* [6] and Li *et al.* [7]

The etiology and pathogenesis of the disease is not well known; hence, it is believed that OSMF is caused by many factors. Pindborg, in 1968, [8] and Caniff *et al.*, in 1986, [9,10] described the disease as a reaction to capsaicin, an irritant in chilies, but this was not completely proved in experimental work [11]. Although a number of factors have been thought to be responsible, yet no effective treatment is available for this disease. [12]

When the overall improvement was considered, the change in mouth opening was statistically significant ($P = 0.001$); however, the improvement in mouth opening average was 1.4 cm which was similar to the result of a study conducted by Das *et al.* [13] in 2010, where they noticed an improvement of 0.87 cm in mouth opening. Although the improvement in mouth opening was not significant ($P = 0.109$), we still recorded an improvement of 0.69 cm, which could be due to the fact that this was a short-term study p value for test of the difference in the pre and post interincisal opening between the test (curcumin) and control group was found to be 0.0002, which is statistically significant. Thus, it can be concluded from the statistical analysis that test and control group shows a significant increase in IIO from baseline to 3 months. Post treatment follow-ups for control group showed a statistically significant decrease in mouth opening after comparing 6 monthly and 9 monthly observations with 3 months observations (post treatment). [14]

One new treatment modality which is gaining recognition is the use of turmeric in OSMF. Curcumin is the principal curcuminoid and comprises approximately 2-5% of turmeric. [15] The change in burning sensation on VAS was statistically significant ($P < 0.001$), which was similar to the observations by Das *et al.* [13] and Agarwal N [16]

CONCLUSION

Turmeric is a popular spice used in Indian curry. Turmeric is considered a safe, nontoxic, and effective alternative for many conventional drugs due to its distinguished therapeutic properties and multiple effects on various systems of the body. To our knowledge, till date no human randomized clinical trials have been reported in the literature to evaluate the efficacy of curcumin over any standard medicinal management modality for OSF. Curcumin due to its properties should be used in patients with OSMF as application of it is beneficial and inexpensive too. But still further researches are required to check for bio-efficacy of curcumin in various other disease.

CONFLICTS OF INTEREST

The authors declare they have no potential conflict of interests regarding this article.

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