

Efficacy of Ayurvedic Medicine in the treatment of Oral Leucoplakia –A randomized, single blind study

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ABSTRACT:

This Study evaluates the efficacy of some Ayurvedic medicine in the treatment of Oral leucoplakia. 30 clinically and histologically diagnosed patients of oral leucoplakia were randomly selected from the O.P.D of CRIA, New Delhi, for the study. All the patients were kept in a single group. The duration of Treatment was 90 days. The result was assessed both clinically and histologically. Post treatment follow-up was done for 2months. Clinically the patients had 56.7% complete remission, 33.3% had partial response.and in 10% of patients no progression was found. Similar results were also found histological. The observed results suggest that this regimen can be effectively and safely used for the management of oral Leucoplakia.

सारांश:

प्रस्तुत शोध में मुखगत ल्यूकोप्लौकिया रोग में आयुर्वेदिक औषधि के प्रभाव का अध्ययन किया गया है। 30 चिकित्सकीय एवं कोशिकागत जांचो द्वारा प्रतिष्ठापित मुखगत ल्यूकोप्लौकिया के रोगियों को अनिश्चित आधार पर सी.आर.आई.ए. नई दिल्ली की ओ.पी.डी. से चुना गया। सभी रोगियों को एक ही ग्रुप में रखा गया। चिकित्सा का काल 90 दिन था। परिणाम को चिकित्सकीय एवं कोशिकागत अन्वेषण के आधार पर प्रमाणित किया गया। चिकित्सकीय अध्ययन भी 2 माह तक किया गया। चिकित्सकीय जांचो के आधार पर रोगियों में 56.7 पूर्ण रिमिशन, 33.3 में कुछ सुधार तथा 10 रोगियों में रोग की पुरारुपति नहीं पाई गई। कुछ ऐसे ही नतीजे कोशिकागत जांचो में भी पाये गए। इन नतीजों से यह निष्कर्ष निकलता है कि मुखगत ल्यूकोप्लौकिया रोग में इस चिकित्सा से सकारात्मक एवं उपद्रव रहित परिणाम मिलते हैं।

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INTRODUCTION:

The most common pre-cancerous lesion in the oral cavity is Leucoplakia. Tobacco chewing and smoking is the most common cause for the disease. The NOO_ radicals found in the tobacco are carcinogenic. Hence free radical scavengers are essential for the treatment in tobacco chewer or, smokers to prevent the formation, decrease the progression of pre-cancerous lesion in to malignancy. Anti oxidants and micro nutrients has a major role as a chemo preventive agent.

AIMS AND OBJECTIVES:

- i. To evaluate the efficacy of Ayurvedic Medicine in oral Leucoplakia.
- ii. To Rule out the etiological factors responsible for oral leucoplakia.

Materials & Methods:

- i. 30 clinically and histologically diagnosed Oral Leucoplakia Patients were taken in to this study.
- ii. All the patients are kept in one group.
- iii. Patients were clinically evaluated in every 14th day.
- iv. Therapy was given for 3 months.
- v. Clinical objective response was evaluated by measuring the lesion.
- vi. Medicine used was-
 - a. Ashwagandha churna- 6gm
 - b. Sudha Sheelajatu- 500mg. **thrice in a day.**
 - c. Irimedadi Tail +Sudha Tankan for Local Application- **Twice In a day.**
 - d. Pachvankal Kasaya – Mukh purana, **Twice in a day.**

Procurement of Drug:

All the Medicines were procured from IMPCL Ltd.

Exclusion Criteria:

1. Malignancy.
2. Age more then 61 year.
3. Diabetic persons.
4. Unwilling to give written consent.
5. Pregnant women.

Inclusion Criteria:

1. Age 16 to 60.
2. Both Sex.
3. Cooperative Patient.
4. Willing to continue in the Study.
5. Not suffering from any systemic disease

ASSESSMENT CRITERIA:

- | | |
|-----------------------|-----------------------|
| 1. Complete Remission | 100% Reduction |
| 2. Partial Remission | > 75% Reduction |
| 3. Stable | < 50% Reduction. |
| 4. Progression | Unequivocal Response. |

HISTOLOGICAL RESPONSE:

- | | |
|---|---|
| 1. Normal- Post Treatment -o (Numerical Value.) | |
| 2. Atypical Hyperplasia- | 1 |
| 3. Mild Dysplasia- | 2 |
| 4. Moderate Dysplasia- | 3 |
| 5. Severe Dysplasia - | 4 |

RESULTS & OBSERVATION:**Clinical response: Table No.1 (n=30)**

Sl. No.	Response	No. of patients	Percentage
1	Complete	17	56.7
2	Partial	10	33.3
3	Stable	03	10
4	Progression	00	00
	Mean	7.5	
	SD	6.58	

Table no. 2 (n=30) Histological Response:

Sl. No.	Stages	No. Of Patients BT	No of Patients AT
1	Atypical Hyperplasia	13	N=9 A. h=4
2	Mild Dysplasia	9	N=5,A.h=4
3	Moderate Dysplasia	6	N=3 M.d=2A.h=1
4	Severe Dysplasia	2	A.h=2
	Total	30	N-17,Ah-11,M.d-2

Key: N-normal, A.h-Atypical Hyperplasia., M.d-mild Dysplasia.

Table-3 Showing Sex Incidence.

Sl. No.	Sex	No. of Patients.	%
1	Male	25	83.3
2	Female	5	16.7
	Total	30	

Table no.-4 Showing Site of Lesion.

Sl.No.	Site of Lesion	No. Of Patients.	%
1	Tongue	02	6.67
2	Gingival	00	0
3	Lip	00	0
4	Palate	00	0
5	Bucal Mucosa	27	90
6	Floor of The mouth	01	3.33

RESULT & DISCUSSION:

The Statistical Analysis of Histological response showed that the response was significant. It was noted that 17 No. of patient's complete response was found, in 10 No. of patient's partial response was found, and in 3 No. of patient's condition was stable. Histological response shows that before treatment out of 13 Atypical Hyperplasia, 9 shows normal and 4 patient shows atypical hyperplasia. Similarly out of 9 mild dysplasia 4 shows normal and 5 shows atypical hyperplasia. out of 6 moderate dysplasia 3 become normal and in 2 patients mild dysplasia is seen and in 1 patient atypical hyperplasia is seen. Similarly in 2 severe hyperplasia patients it changes to atypical hyperplasia. So out of 30 patients 17 patient become normal, 11 patients become atypical hyperplasia and 2 changes to mild dysplasia which is significant.

Oral Leucoplakia is white patch in the oral mucosa which is not scrapped off. Tobacco chewing and smoking is most common etiological factors for the disease.

So far as the sex is concerned out of 30 patients 25 was male and 5 was female. In present study it was noted that the clinical response of Patients is significant. No side Effect, toxicity of any kind was found during the study.

Thus the regimen appears to be a very effective treatment in oral Leucoplakia.

Results show that this regimen can protect cells against cell damage and plays a protective role against progression of dysplasia. Ashwagandha & Sudha seelajatu contains micro nutrients and has anti oxidant effects hence act as a chemo preventive agent and also act as a free radical scavenger. Irimedadi tail and panchvalkal kasaya act as sotha nasak dravya. So this Ayurvedic regimen appears to be a very good treatment option for oral leucoplakia. However this is a preliminary study. Further study should be performed to evaluate the efficacy of Ayurvedic Medicines in the Treatment of Oral Leucoplakia.

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