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CLINICAL STUDY OF EFFICACY OF SHIRISHBEEJ CHURNA PRATISARAN ON ORAL TOBACCO TOXICITY DUE TO TOBACCO CHEWING SPECIAL REFERENCE TO SUBMUCOUS FIBROSIS

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ABSTRACT

Tobacco is the most widely distributed and commonly used drug in the world. Tobacco cultivation has a history of about 8000 years. Europeans were introduced to tobacco when Columbus landed in America in 1492.Portuguese traders introduced tobacco in India during 1600.India is the third largest country in the world in both tobacco production and consumption. Of 1.7 billion tobacco users, 182 million live in India. In India, oral use of smokeless tobacco (chewing or applying to teeth or gum) and smoking bidis are the dominant forms of tobacco consumption. Tobacco use is one of the main risk factors for a number of chronic diseases, including cancer, lung diseases, and cardiovascular diseases. In India tobacco causes the death of between 600000 and one million people a year. The tobacco users in India are increasing at a high rate; most of them are youngsters and students. So

it's our primary duty to create awareness about tobacco addiction and helps to common people to give up such harmful addiction.

KEYWORDS: Chewing tobacco, Sub mucous fibrosis, Pratisaran, Albizia. lebbeck Benth, Honey.

INTRODUCTION

Tobacco cultivation has a history of about 8000 years. Europeans were introduced to tobacco when Columbus landed in America in 1492. Portuguese traders introduced tobacco in India during 1600. Tobacco became a valuable commodity in barter trade and its use spread rapidly. Gradually tobacco got assimilated into the cultural rituals and social fabric due to presumed medicinal and actually addictive properties attributed to it.

India is the second largest producer and third largest consumer of tobacco in the world. The predominant forms of smokeless tobacco use in India are

1. Chewing tobacco - leaf, khaini, zarda, kiwam, gundi and betel quid with tobacco.
2. Arica nut mixture for chewing- pan masala, gutakha, Mainpuri tobacco, mawa.
3. Product for application – gudhaku, gul, creamy snuff, laldantamanjan, and mishri.
4. Product for gargling /sipping – tuibur, hidakphu.

Increase in the prevalence of smokeless tobacco use in India has resulted in increased disease and mortality burden in the country. Smokeless tobacco is a carcinogenic and the incidence of oral cancer in India is very high, which is attributable to the widespread habit of chewing tobacco. Other adverse health effects of tobacco chewing are gingival recession, dental caries, oral sub mucous fibrosis, leukoplakia, cardiovascular risk factors hypertension, diabetes, reproductive health problems, low birth weight babies, and overall mortality. Moreover, smokeless tobacco use enhances the frequency of public spitting, which has been increase the probability of communicable diseases like tuberculosis.

The above statistical data shows that India's tobacco problem is very much complex, with a large use of a variety of tobacco products and their easy availability in market. In modern science theory are not proper or satisfactory solution for these problems due to their side effects of drugs, much more expensive cost and unavailability in India. In contrast to that Ayurveda has a variety of natural medication in the treatment of various types of poisoning. Shirish (Albizzia lebbeck Benth.) is a large deciduous quick growing tree found throughout

India. In Ayurvedic classics "Dantadhavanaprayukta visha" described as disease this shows nearer relation to oral tobacco toxicity due to tobacco chewing. As Albizzia lebbeck Benth is having detoxification property, which is easily available, cost effective and may be effective for oral tobacco toxicity due to tobacco chewing.

Hence this intended study has been taken. So here the clinical study has been planned to find out the efficacy Shirishbeej churna pratisarana oral tobacco toxicity due to tobacco chewing and spread awareness of the hazards of tobacco chewing.

AIMS AND OBJECTIVES

1. To study the efficacy of shirishbeej churna pratisaran on oral tobacco toxicity due to tobacco chewing.
2. To assess the effect of shirishbeej churna pratisaran in oral tobacco toxicity due to tobacco chewing.
3. To create awareness on health hazards of tobacco chewing.

MATERIALS

Serial No	Sanskrit Name	Botanical Name
1.	Shirishbeejchurna	Allbezia lebbeck Benth
2.	Kshaudra	Honey

Collection of Material

- Identification, authentication and standardization had done from approved laboratory.
- Agmark standard Honey was purchased from a GMP Approved
- The drug was taken in a bulk quantity for the preparation of churna.

Standardization:

The drug sample is studied exomorphically and microscopically standardized from respected pharmacy. Analytical study report obtained from laboratory on demand for research work.

Method:

Upakrama	Pratisaran (Rubbing to internal oral cavity)
Drugs Name	Shirishbeejchoorna and Madhu.
Quantity	2 grams with honey.
Time	3 times in a day.Morning, afternoon and night.
Duration	10 to15 Minutes.
Form	Churna (Powder Form)
Duration of Treatment	30 Days.

Method of pratisarana

For pratisaran karma all the patients were advised to follow the given instruction, viz.

1. Patients were advised to do Pratisarana for 3 times morning afternoon and evening after proper cleaning of mouth.
2. Shirishbeejchurna should be taken in 2 grams quantity and mixed with adequate amount of madhu and make the churna in paste form.
3. It should be taken on tip of the index finger and gently massaged on teeth, gums, tongue, and buccal cavity for 10-15 min.
4. After that proper rinsing was advised with lukewarm water.
5. Same procedure was instructed for the madhu (Honey) and also application has been adopted by using tip of the index finger.

Instructions to the Patient

- Oral hygienic methods and their importance the reversal of the tobacco effects were explained.
- Also patients will be advised to keep abstain of tobacco addiction during the treatment period.

Sampling: Random sampling method was adopted for the selection of the patients.

1. **Grouping**:

A total number of 76 patients were registered for the present clinical study; out of them 60 patients completed the treatment. 6 patients from group A and 10 patients from group B have dropped out during study for some unknown reason. Therefore the data of remaining 60 patients were divided into 2 groups.

Group A (Trial Group):

30 patients of this group were treated by Shirish beeja choorna with madhu for mukhagat pratisaran for 30 days.

Group B (Control Group):

30 patients of this group were treated by madhu (Honey) for mukhagat pratisaran for 30 days.

Procedure for Data Collection:

Case papers were prepared with the consent of the patients and observations were noted

Follow up:

Patients were observed before, during and after treatment.

1st follow up …….. 10th day.

2nd follow up …….. 20th day.

3rd follow up ……..... 30th day.

Statement of limitation:

Patient selection criteria:-

1. Patients presenting with any of the symptoms or group of signs and symptoms described in mukhagata, dantadhavan pravritta visha lakshanas with addiction of tobacco chewing.
2. Patients presenting with submucous fibrosis with addiction of tobacco chewing.
3. Patients having H/O addiction of chewing tobacco with no diagnosed malignancies.

Inclusive criteria:-

1. Individual's between15 to60 age group.
2. Individual of both sexes.
3. Only tobacco chewers were selected.

Exclusion criteria:-

1. All types of known (diagnosed) malignancies.
2. All type of oral lesions having any type of known underlying systemic pathology such as syphilis, Systemic lupus erythematous etc.
3. All type of lesions without H/o addiction of tobacco chewing.
4. Any tubercular ulcer.
5. Patients having abnormal shape of denture.
6. Persons having addiction of smoking

Criteria for assessment:-

1. Subjective parameters:-

The sign and symptoms described in Ayurvedic Classical text.

2) Objective parameters:-

1. Counting number of lesions.
2. Measurement of each lesion in mm.
3. Photographs of each lesion.

On the basis of overall improvement in subjective criteria result are stated as:

1) Excellent: Improvement more than 75%
2) Good : Improvement between 50 to 74.9 %
3) Fair : Improvement between 25 to 49.9%
4) Poor : Improvement less than 25%

Assessment criteria with gradation

Symptoms or lakshanas according to grade were the main assessment criteria.

Grade 1:- (Excellent) having no signs and symptoms and no lesion in oral cavity at the end of the treatment.

Grade 2:- (Good) No lesions remaining inside oral cavity but signs and symptoms remained

Grade 3:- (Fair) Signs and symptoms decreased completely still the lesions are remaining in oral cavity.

Grade 4:- (Poor) No improvement in signs and symptoms.

RESULTS

Table No: -1 statistical result of subjective parameter according to percentage of relief in both groups.

Symptoms	Percentage of Relief	
	Group-A	Group-B
Oshthachimchimayana	46.7	29.9
Jivhamulagaurav	67.0	17.0
Dantaharsha	47.8	35.6
MukhagatDaha	66.9	39.2
Atilalastrava	68.6	39.2
Dantamoolshooth	82.5	69.7
Jivha shotha	0	0
Oshthamansa shotha	0	0

Table No:- 2 According to objective parameter effect after treatment/ change in lesion.

Lesion Area of type O.S.F in mm^2	Day-1		Day-30		Paired t	P
	Mean	S.D	Mean	S.D		
Group-A(n=33)	254.21	180.98	246.36	178.60	6.774	<0.001 HS
Group-B (n=26)	178.90	116.69	176.17	115.20	4.286	<0.001 HS

Table no:-3 Frequency distribution in both groups according to changes in lesion (Oral submucous fibrosis)

Lesion Area of type O.S.F in mm^2	Mean difference	S.D	Unpaired T	P
Group-A	7.8494	6.65656	3.874	<0.001 HS
Group-B	2.7277	3.24547		

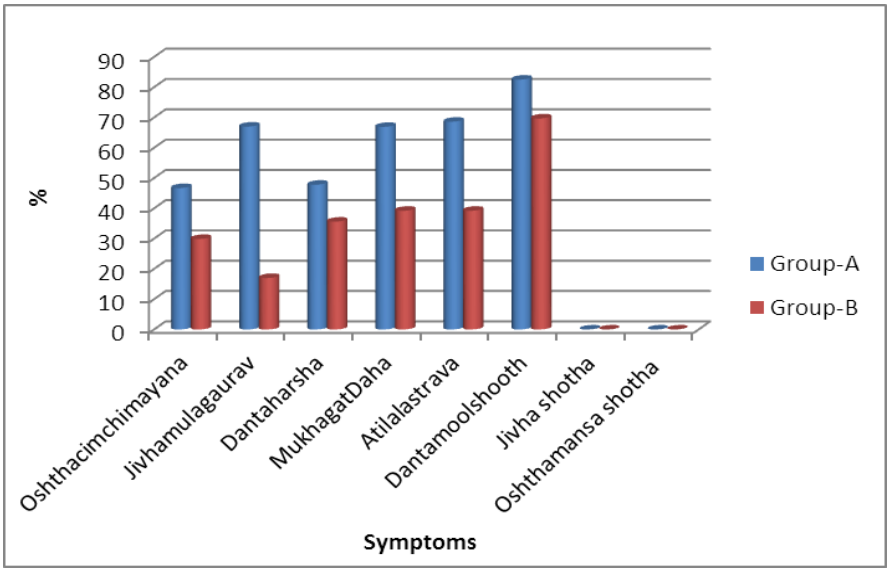
*O.S.F = Oral submucous fibrosis

Table No. 4 Overall effect of the drugs on symptoms–

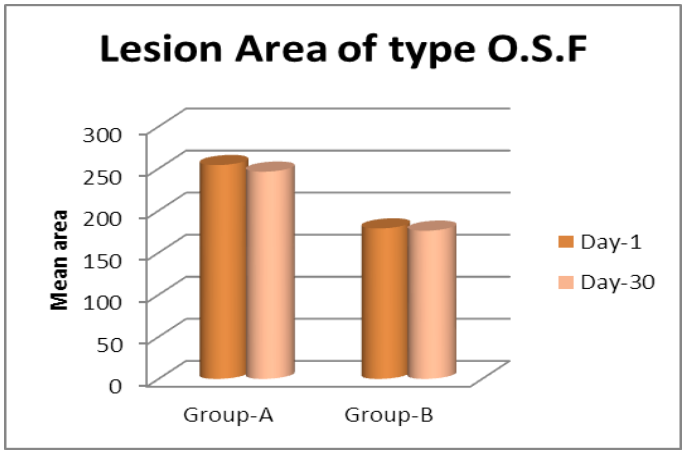
Overall Effect	No. of symptoms	
	Group-A	Group-B
No change (<25%)	1	2
Mild change (25% – 49.9%)	2	4
Moderate change (50% - 74.9%)	3	1
Good change (75% +)	1	0

Table no. 5 Overall results after treatment in both groups:

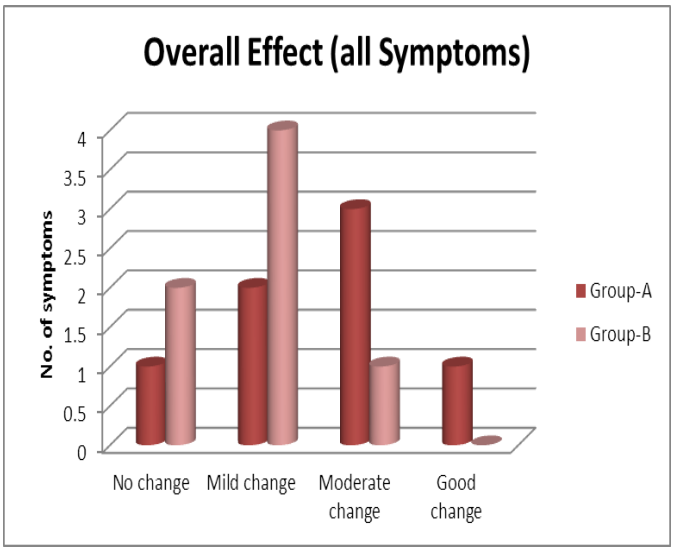
Grade	Group A	Percentage %	Group B	Percentage %
Grade 1:- (Excellent) Having no signs and symptoms and no lesion in oral cavity at the end of the treatment.	0	0	0	0
Grade 2:- (Good) No lesions remaining inside oral cavity but signs and symptoms.	0	0	0	0
Grade 3:- (Fair) Signs and symptoms decreased completely still the lesions are remaining in oral cavity.	3	10%	0	0
Grade 4:- (Poor) No improvement in signs and symptoms and lesions at the end of the treatment.	27	90%	30(100)	100%



Graph No: -1 Statistical result of subjective parameter according to percentage of relief in both groups.



Graph No: - 2 According to objective parameter effect after treatment/ change in lesion.



Graph No.3 Frequency distribution according to overall effect of the drugs on symptoms

Graph No. 4 Overall results after treatment in both groups:

DISCUSSION

The aims and objective of investigation is to reach up to a definite conclusion by understanding the concepts into their correct manner. Study of any concept under various heading gives it complete orientation, but correct understanding and proper interpretation of the concept helps to achieve the determined goal and it is possible only with the discussion.

1) **Table No 1, Graph No 1:-** The above results shows relief in percentage, in group A- Oshthachimchimayana 46.7%, Jivhamula gaurav 67%, Dantaharsha 47.8%, Hanustambha 15.9%, Mukhagat daha 66.9%, Atilalastrav 68.6%, Dantamool Shooth 82.5%. And in group B- Oshthachimchimayana 29.09%, Jivhamula gaurav 17%, Dantaharsha 35.6%, Hanustambha 4.8%, Mukhagat daha 39.2%, Atilalastrav 39.2%, Dantamool Shooth 69.7%.

2) **Table No 2, Graph No 2:-** Oral submucous fibrosis has highest incidence in both groups. Totally in group A 33 lesion are seen and mean of total surface area before treatment was 254.21 mm2. Decreased mean of total surface area after treatment was 246.36 mm2. In group B total lesion seen is 26. Mean of total surface area before treatment 178.90 mm2. And after treatment the mean of total surface area was 176.17 mm^2.

3) **Table No 4, Graph No 3:-** Group A there was only 1 symptom showed No changes (<25%), 2 symptoms showed mild changes (25%-49.9%), 3 symptoms showed moderate changes (50%-74.9 %), and only 1 symptom showed good changes (more than 75%). In Group B there was 2 symptoms showed No changes (<25%), 4 symptoms showed mild changes (25%-49.9%), only 1 symptom showed moderate changes (50%-74.9 %), and there was no single symptom showed good changes (more than 75%).

4) **Table No 5, Graph No 4:-** Total effect on therapy in control and experiment group shows poor to fair result. Group A shows fair result in 10 % and 90 % in poor grade. While group B shows 100 % poor result. It is due to the very short duration of clinical study and absence of internal medicine during treatment.

CONCLUSION

1. It is caused by the vitiation of Rakta and Pitaa due to Nidana sevana like addiction of tobacco chewing, improper oral hygiene, etc.

2. Vishagna effect of Shirisha helps to nullify the toxic effect of tobacco because alkaloids of Shirisha such as tannin and saponin have supportive action over Nicotine the main toxic alkaloid in tobacco.
3. The demographic data obtained from this clinical study suggests that tobacco chewing is more common in the middle age group and in the male worker class population.
4. The Trial drug (Shirisha beeja + Madhu) is statistically more effective in reducing the symptoms like Oshtachimchimayana, than the Control drug Madhu.
5. The Trial drug and the Control drug were equally effective in reducing the symptoms like Dantaharsha, Mukhagata Daha, Atilala Srava and Dantamoola Shotha produced due to tobacco chewing.
6. In Oral submucous fibrosis statistically significant results were obtained in both the groups. But clinically none of the patients got complete healing of the lesion.
7. No adverse drug reactions were noted with administration of the trial drug for 30 days of duration.
8. Based on the results of the current study, it can be concluded that the trial drug can be used in cases of Oral Tobacco Toxicity caused due to Tobacco chewing.

BIBLIOGRAPHY

Ayurvedic text

1. AshtangaHridaya of Vagbhata edited by Prof. K.R.Srikantha Murthy. Published by ChaukhambhaOrientalia, Varanasi. 7th Edition, 2010.
2. AstangaHridaya of Vagbhata with Sarvanga-sundara commentary by Arundatta and Ayurveda rasayana commentary by Hemadri. Edited by HariSadasivaSastriParadakara. Published by ChaukhambaSurbharatiPrakashan, Varanasi. 2010.
3. Ayurvediya Kriyashareer, Vd.Ranjeet Ray Desai. Ed. 1999.
4. Bhavaprapashnighantu (Indian MateriaMedica) Written by Bhava Mishra, Commentary by K.C.Chunekar. Edited by G.S.Pandey. Published by ChaukhambaBharati Academy, Varanasi. 2010.
5. Basavarajiyam (Telegu translation of Basavarajiyam written by Basavaraj) Translated by PuvvadaGurunathRao. Published by Anandabharati Power Press, Chennai. 1934.
6. Bhaisajya Ratnavali of GovindaDasjiBhisagratna, Commented upon by VaidyaShriAmbikaDattaShashtri, English Translation by Dr.KanjivLochan (Vol-3). Published by Chaukhambha Sanskrit Sansthan, Varanasi. Reprint 2009.

7. Bhel Samhita (Text with English Translation, Commentary and Critical notes of Dr.K.H.Krishnamurthy Edited by Prof.PriyaVrat Sharma. Published by ChaukhambhaVishvabharati, Varanasi.First Edition 2000.
8. Charaka Samhita, Written by Agnivesha, Redacted by Caraka, compiled by Dridhabala, with Ayurveda Dipika commentary by Chakrapanidatta. Edited by YadavjiTrikamjiAcarya, Published by ChaukhambaSurbharatiPrakashan, Varanasi. 2009.
9. Classical uses of Medicinal Plants by Priyavrat Sharma. Published by ChaukhambhaVishvabharati, Varanasi. Reprint 2004.
10. Database on Medicinal Plants used in Ayurveda – CCRAS.
11. DravyagunaVijnana (Study of the essential medicinal plants in Ayurveda) Vol-2, by Dr. J. L. N.Sastry. Published by ChaukhambhaOrientalia, Varanasi. Reprint 2010.
12. Kaiyadev-Nighantu Edited by AcharyaPriyavrat Sharma AvemDr.Guruprasad Sharma. Published by ChaukhambhaOrientalia, Varanasi. First Edition 1979.
13. KashyapaSamhita or VriddhajivakiyaTantra, Preached by MaharshiMarichaKashyapa; summarized then written by his disciple AcharyaVriddhaJivaka; redacted by latter's descendant Vatsya (Text with English Translation and Commentary, Edited by Prof.(Km.) P. V. Tewari. Published by ChaukhambhaVishvabharati, Varanasi. Reprint 2002.
14. Madanapala-nighantu written by Madanapala. Edited by J.L.N.Sastry. Published by ChaukhambaOrientalia, Varanasi. 2010.
15. NighantuAdarsha (Vol-1 and 2) by Bapalala G. Vaidya. Published by ChaukhambhaBharati Academy, Varanasi. Third Edition 2002.
16. Raja-Nighantu of PanditNarahari, by Dr.IndradeoTripathi. Published by ChowkhambhaKrishnadas Academy, Varanasi. Third Edition 2003.
17. Rasa-ratnaSamuccaya written by Vagbhata. Hindi commentary by IndradevTripathi. Published by ChaukhambaSansthan, Varanasi. 2009.
18. Sachitra-Shalakyatantra- by Vd.DayalParmar, SaraswatiPustakBhandar, Ahmedabad. 1st edition 2005.
19. SarangadharaSamhita written by Sarangadhara with Dipika commentary by Adhamalla and Gudharthadipika commentary by Kasiram, Edited by ParasuramShastri. Published by ChaukhambaSurbhsratiPrakashan. Varanasi. 2006.
20. ShaligramAushadShabdasagarArthatAyurvediyaAushadhikosha. Published by KhemrajShrikrishnadasPrakashan, Mumbai. Reprint 1998.

21. SushrutaSamhita of Susruta with NibandhaSangraha Commentary by Dalhana, Edited by YadavjiTrikamjiAcharya, Published by ChaukhambaSurbharatiPrakashan, Varanasi. 1994.
22. SushrutaSamhita (Text, English Translation, Notes, Appendices and Index) Edited and Translated by Prof.K.R.Murthy, Published by ChaukhambhaOrientalia, Varanasi. Reprint 2008.
23. YogRatnakar, Commented by Vaidya Shree lakshmipatiShashtri, Chaukhambha Sanskrit Samsthan, Varanasi, Reprint 2004.

Modern text:-

1. Parikh's Textbook of medical jurisprudence, forensic medicine and toxicology by Dr C.K Papikh Publishers and distributors 2007.
2. Modi's Medical jurisprudence and toxicology by B.V. Subrahmanyam Leis Nexsis Butterworth 2002.
3. Textbook of forensic medicine and Toxicology V.V.PillyParas Medical publishers, New Delhi. 2010.
4. Modern Medical Toxicology by V.V. Pillay. JAYPEE Publishers (P) Ltd.Fourth edition (2013).
5. Textbook of oral Pathology (6th edition 2009) by Dr. William Shefer. Edited by Rajendran. Elsevier India Pvt. Ltd. Noida, Delhi.
6. Textbook of Oral and Maxillofacial Surgery (6th edition 2007) by Dr. S. M. Balaji Elsevier India Pvt. Ltd. Noida, Delhi.