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A clinical study to evaluate the role of *Kshara Karma* in oral mucocele with *Teekshna Pratisaraniya Apamarga Kshara*

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ABSTRACT

Introduction: Mucoceles are the most common benign lesions of the oral cavity developing as a result of retention or extravasation of mucus from the minor salivary glands. There are various treatment modalities which include excision, laser ablation, cryosurgery, sclerotherapy, micro marsupialization, and intra-lesional injection of sclerosing agent or corticosteroid. Although surgery is widely used, it has several disadvantages such as bleeding, lip disfigurement and damage to adjacent ducts with further development of satellite lesions. *Kshara* being an *Anusastra* possessing *Chedana, Bhedana, Lekhana, Pachana, Vilayana, Shodhana, Ropana, Shoshana* and *Stambhana Karmas* will address all the difficulties faced during conventional ways of treatments. The current study was undertaken to introduce, validate and standardise novel, minimally invasive, para surgical approach towards the treatment of oral mucocele. **Methodology:** *Teekshna Pratisaraniya Apamarga Kshara* was prepared. Clinical study was conducted on 30 subjects diagnosed with oral mucocele. *Ksharakarma* was done. For statistical analysis of parametric values, Repeated period ANOVA test within the group and for non-parametric values, Friedman's Test within the group were used. **Result:** The comprehensive analysis of all the results reveals that, all the parameters showed significant change both statistically and clinically with no side effects or complication. **Discussion:** *Ksharakarma* on oral mucocele acts by tissue necrosis, gradual sloughing off followed by healing of remnant ulcer with epithelialisation, which was found to be an effective, minimally invasive, para surgical management of oral mucocele without any complications.

Key words: *Oral Mucocele, Jalarbuda, Pratisaraniya Kshara, Kshara Karma.*

INTRODUCTION

Mucoceles are the most common benign lesions of the oral cavity developing as a result of retention or extravasation of mucus from the minor salivary glands.[1] The incidence of mucoceles is generally high which is 2.5 lesions per 1000 patients, frequently in the second decade of life.[2] They usually present as painless, smooth, round, or oval swellings containing fluid which is translucent and fluctuates. They may present as single or multiple swellings with size ranges from a few millimeters up to 2 cm, deeper once can be larger.[1] In Ayurveda, oral mucocele can be understood as *Kshataja Ostha Roga* or *Jalarbudha,* where *Kshara Pratisarana* is one among the treatments.[3]

There are various treatment modalities which include excision, laser ablation, cryosurgery, sclerotherapy, micro marsupialization, and intra-lesional injection of sclerosing agent or corticosteroid. Although surgery is widely used, it has several disadvantages such as bleeding due to high vascularity, lip disfigurement and damage to adjacent ducts with further development of satellite lesions.[1] Hence there is a need of minimally invasive, economic and more effective treatment

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modality in the management of oral mucocele. *Kshara* being an *Anusastra*[4] possessing *Chedana, Bhedana, Lekhana, Pachana, Vilayana, Shodhana, Ropana, Shoshana* and *Stambhana Karma,*[5] will address all the difficulties faced during conventional ways of treatments.

The current study "A clinical study to evaluate the role of *Kshara Karma* in oral mucocele with *Teekshna Pratisaraniya Apamarga Kshara*" was undertaken to introduce, validate and standardise novel, minimally invasive, para surgical approach towards the treatment of oral mucocele.

AIM AND OBJECTIVES

Research Question: Does *Teekshna Pratisaraniya Apamarga Kshara* have any role in the management of oral mucocele?

Aim

To evaluate the role of *Ksharakarma* with *Teekshna Pratisaraniya Apamarga Kshara* in oral mucocele.

Objectives

1. Primary Objective

To evaluate the role of *Ksharakarma* with *Teekshna Pratisaraniya Apamarga Kshara* in oral mucocele.

2. Secondary Objective

To do the literary review of oral mucocele and *Ksharakarma.*

Hypothesis

H_0 - *Teekshna Pratisaraniya Apamarga Kshara* does not have any significant role in the management of oral mucocele

H_1 - *Teekshna Pratisaraniya Apamarga Kshara* have significant role in the management of oral mucocele.

MATERIALS AND METHODS

Diagnostic criteria

One or more swellings in oral mucosa which are, Colorless to bluish, Transparent, Soft or hard, Associated with or without difficulty in speech and chewing.

Inclusion criteria

Subjects fulfilling the diagnostic criteria of oral mucocele, Age between 10 - 60 years.

Exclusion criteria

Swellings other than mucocele, Pregnant and Lactating woman, Patients diagnosed with HIV, HbsAg, Leprosy, Tuberculosis and Malignancy.

Assessment

Table 1: Assessment

Assessment	1st	2nd	3rd	4th	5th
Time	0th day BT	0th day AT	3rd day (F1)	7th day (F2)	14th day (F3)

Subjective criteria

1. Pain – VAS scale[6]

Table 2: Assessment of difficulty in speech and chewing

Assessment	1st	2nd	3rd	4th	5th
Difficulty in speech					
Difficulty in chewing					

*** Absent – 0, Present – 1**

Objective criteria

1. Size of swelling - measured in cm
2. Colour
3. Consistency: Soft/ Hard

- Duration of study - 14 Days
- Duration of treatment - 1DAY
- Follow up dates - 3rd day, 7th day and 14th day

Study Design

Clinical study with pre and post-test design. Thirty subjects presenting with oral mucocele, who fulfilled the inclusion criteria were selected and allotted to single group. During the course of treatment, subjects

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were allowed to continue with their regular medications which did not interfere with the study.

Intervention

Kshara Karma[7] with *Teekshna Pratisaraniya Apamarga Kshara.*

Purvakarma

- *Teekshna Pratisaraniya Apamarga Kshara* were prepared in classical method[8]
- Informed consent was taken from each subject.
- Under all aseptic conditions subjects were taken in to minor OT.
- The subjects were asked to rinse their mouth prior to the procedure with Normal Saline.
- Subjects were made to lie down in supine position.
- The mucocele was exposed.
- Draping was done.
- Topical anaesthesia (Xylocaine 12% spray) is sprayed over and around the swelling.

Pradhana Karma

- The mucosa over the swelling is wiped using sterile gauze.
- *Teekshna Pratisaraniya Apamarga Kshara* was applied uniformly all over the lesion with a spatula with at most care to avoid spillage.
- After *Shatamatra Kala* lesion was cleaned with buttermilk.

Paschat Karma

- Patient was advised to rinse their mouth properly.

Observations and Results

Observations during intervention

- It is observed that, majority of subjects experienced mild burning sensation on application of *Kshara* even after application of anaesthetic spray.
- The *Shikhari* guna of *Kshara* helped to prevent the injury to adjacent tissues.
- Colour of tissues in contact changed immediately to purplish black with in *Satamatrakala* of application of *Kshara*.
- Subjects did not experience any discomfort after treatment and during the follow ups.
- Six out of 30 subjects presented with a small ulcer within 3-7 days of *Kshara* application without any associated complaints, which is healed within 1-3 days of its appearance.

Results

Pain

In this study consisting 30 subjects of oral mucocele in order to analyse the effect of intervention on pain before to after treatment and during follow ups, Repeated ANOVA test was used. The test revealed the result as shown in the table 3.

Table 3: Assessment of pain with repeated ANOVA test

Assessments And Analysis		Mean	Mean Difference	Std. Error	P
1	2	1.00	0.000	.000	-
	3		0.750	.250	.577
	4		1.000	.000	-
	5		1.000	.000	-
2	1	1.00	.000	.000	-
	3		.750	.250	.577
	4		1.000	.000	-
	5		1.000	.000	-
3	1	0.25	-.750	.250	.577
	2		-.750	.250	.577
	4		.250	.250	1.000
	5		.250	.250	1.000
4	1	0.00	-1.000	.000	-
	2		-1.000	.000	-
	3		-.250.	.250	1.000

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	5		.000	.000	-
5	1	0.00	-1.000	.000	-
	2		-1.000	.000	-
	3		-.250	.250	1.000
	4		.000	.000	-

Difficulty in speech and chewing

In the current study effect of intervention on difficulty in speech and chewing was analysed using Friedman test before to after treatments and during follow ups, result of which is shown in the table 4.

Table 4: Friedman test for assessment of difficulty in speech and chewing

Assessments	N	Mean	Std. Deviation	Mean Rank	P
1st	5	1.00	.000	4.50	<0.001
2nd	5	1.00	.000	4.50	
3rd	5	.00	.000	2.00	
4th	5	.00	.000	2.00	
5th	5	.00	.000	2.00	

Assessment of objective parameters

Size of swelling

Here the effect of intervention on size of of swelling was analysed Repeated ANOVA test before and after treatments and during follow ups, result of which is as shown in the table 5 and figure 4.

Table 5: Repeated ANOVA test for assessment of size of swelling

Analysis		Mean	Mean Difference	Std. Error	P
1	2	14.017	.000	.000	-
	3		11.667*	1.616	<0.00
	4		13.900*	1.990	<0.00
	5		14.017*	2.008	<0.00
2	1	14.017	.000	.000	-
	3		11.667*	1.616	<0.00
	4		13.900*	1.990	<0.00
	5		14.017*	2.008	<0.00
3	1	2.35	-11.667*	1.616	<0.00
	2		-11.667*	1.616	<0.00
	4		2.233*	.579	.006
	5		2.350*	.651	.011
4	1	0.117	-13.900*	1.990	.000
	2		-13.900*	1.990	<0.00
	3		-2.233*	.579	.006
	5		.117	.101	1.000
5	1	0	-14.017*	2.008	<0.00
	2		-14.017*	2.008	<0.00
	3		-2.350*	.651	.011
	4		-.117	.101	1.000

Colour of the swelling

In the current study effect of intervention on colour of swelling was analyzed by means of percentage, before, after and during follow ups. In 100% subjects of colour changed to black in 2nd assessment and to yellowish in 3rd assessment. And is presented in table 6.

Table 6: Assessment of colour of swelling with percentage

Assessment	Colour of swelling	Frequency	Percentage
1st	Pinkish red	25	83.33%
	Reddish brown	3	10%
	Bluish	2	06.66%
2nd	Black	30	100%
3rd	Yellowish	30	100%
4th	Yellowish	3	10%
	No Swelling	27	90%
5th	No swelling	30	100%

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Before Treatment

During Treatment

After Treatment

After Follow-up 1

After Follow-up 5

Steps of preparation of *Apamarga Kshara*

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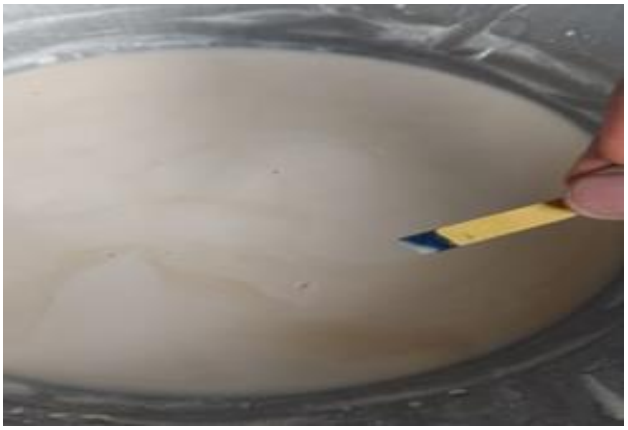

DISCUSSION

Mucoceles are the most common disease of minor salivary gland commonly seen over lips, cheeks, floor of the mouth and palate. They present as bluish, soft, fluctuant, often transillumination and well localized swelling. Thirty subjects suffering from oral mucocele, who fulfilled the inclusion criteria were selected and treated in a single group with pre and post-test design. Demographic data i.e., age, gender, socio-economic status, marital status etc. had found no significance in occurrence or pathology of oral mucocele. It is noted that the colour of mucocele changed to purplish black after intervention, then to pale yellow during follow ups with gradual sloughing off and healed with epithelialisation which reflected the action of *Pratisaraniya Kshara on* oral mucocele.

Pratisaraniya Kshara penetrates deep by its *Ushna,Teekshna,Anu and Sukhanirvapya Guna* does *Vilayana* of *Kapha, Anulomana* of *Vata* and *Pachana* of *Mamsa* and *Medas* in contact immediately and deeper tissues in due course, which further leads to *Bhedana,*

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Chedana and *Lekhana* followed by *Ropana* of mucocele. The alkalinity of *Pratisaraniya Kshara* (pH>12) causes liquefaction necrosis of surface epithelium and submucosa, creates saponification and liquefaction of proteins enabling deep penetration and target tissue damage leaving soft, brownish black gelatinous eschar, which sloughs off gradually with simultaneous/ early epithelisation.

LIMITATION

The outbreak of pandemic has prevented the population from voluntary approach for medical care for oral mucocele. Thus, had to depend on medical camps and advertisements. This might have interfered with the demographic data of studied sample. Even though there is no recurrence observed during the follow ups, long term observation is required to establish the fact.

Detailed cytological study is required to understand the Pharmacokinetics and pharmacodynamics of intervention on oral mucocele. Which was out of the scopes of current study.

CONCLUSION

In this trial all the parameters showed significant change both statistically and clinically with no side effects or complication ($p < 0.05$). Hence it can be concluded that *Teekshna Pratisaraniya Apamarga Kshara* have a significant, effective role in the management of oral mucocele.

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