RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF PERUKA CHURNA PRATISARANA IN MANAGEMENT OF MUKHAPAKA IN CHILDREN

Dr. Deepthi B Rao[1], Dr. Narayan Pai B[2], Dr. Jithesh Chowta[3], Dr. Avinash Katti[4], Dr. Syamily Raj K[5]

[1]PG Scholar, Dept. of PG Studies in Kaumarabhritya, Alva's Ayurveda Medical College, Moodubidri

[2]Professor, Dept. of PG Studies in Kaumarabhritya, Alva's Ayurveda Medical College, Moodubidri

[3]Associate Professor, Dept. of PG Studies in Kaumarabhritya, Alva's Ayurveda Medical College, Moodubidri

[4]PG Scholar, Dept. of PG Studies in Kaumarabhritya, Alva's Ayurveda Medical College, Moodubidri

[5]PG Scholar, Dept. of PG Studies in Kaumarabhritya, Alva's Ayurveda Medical College, Moodubidri

ABSTRACT

Mukhapaka is one of the commonest diseases of oral mucosa found in India as well as all over the world. According to modern science it can be corelated to stomatitis or mouth ulcer. The estimated point prevalence of oral ulcers worldwide is 4%, with apthus ulcer being the most common, affecting as many as 25% of population worldwide[1]. Males and females are affected in equal ratio, peak age of occurrence being 10-19 years[2]. It is considered important because it interferes with normal activities by affecting eating and swallowing[3] which might lead to malnourishment in children. Hence in view of its incidence and its tendency to disturb day to day activities *Mukhapaka* is taken up for study.

Keywords: *Mukhapaka*, Stomatitis, *Prathisarana*

INTRODUCTION

Oral health is a multifaceted function of persons' abilities to eat, speak, and perform expressions confidently. Paediatricians should be aware of the prevention of early onset oral disease as they often represent the first point of contact for a kid with a healthcare setting. Children with recurrent stomatitis may restrict their oral food and fluid intake due to the associated pain, resulting in dehydration; thus, prompt therapy for the lesions may be necessary. Stomatitis is swelling (inflammation) inside the mouth and on the lips. It can cause open sores (canker sores), redness, and pain. It occurs on the inside of the cheeks or on the tongue, lips, or gums. Stomatitis is more common in children. But it can occur at any age.[4] Despite their high prevalence,

etiopathogenesis remains unclear. These present as recurrent, multiple, small, round or ovoid ulcers, with circumscribed margins, having yellow or grey floors and are surrounded by erythematous haloes, present first in childhood or adolescence[5]. The primary treatment objectives are to reduce ulcer duration, relieve pain, and lengthen disease-free intervals; additional objectives include reducing recurrence frequency and severity. *Mukhapaka* is mainly a *pitta-kapha* dominant disorder. To break the *samprapti pittadoshahara, vranashodaka, vranaropaka chikitsa* is essential. Here *Khadira Churna* is taken as control drug which is proven already in management of *Mukhapaka*. In folklore practice, *Peruka* Patra is used for *Mukhapaka*[6,7]. Hence a randomized controlled clinical study to evaluate the efficacy of *Peruka Churna Pratisarana* in management of *Mukhapaka* in children.

OBJECTIVES OF STUDY

1. To evaluate the efficacy of *Peruka Churna Pratisarana* in *Mukhapaka*.

2. To compare the efficacy of *Peruka* and *Khadira Churna Pratisarana* in *Mukhapaka*.

HYPOTHESIS:

H0 –There is neither statistically significant difference between the effect of *Peruka Churna* and *Khadira Churna Pratisarana* with *Madhu*, nor *Peruka Churna* is better than *Khadira Churna* in management of *Mukhapaka* in children.

H1- There is statistically significant difference between the effect of *Peruka Churna* and *Khadira Churna Pratisarana* with *Madhu* with *Peruka Churna* better than *Khadira Churna* in management of *Mukhapaka* in children.

Materials and Methods:

Sample size: A minimum of 60 subjects fulfilling the Diagnostic and Inclusion criteria were selected and allotted into Groups A and B with 30 subjects each.

Design of study: Randomised controlled clinical study.

The assessment was done on BT (0th), on the 3th and 7th day of treatment. ▪ Follow up was done on the 14th day. ▪ Total duration was 14 Days.

DIAGNOSTIC CRITERIA:

The symptoms of *Mukhapaka* mentioned in classical texts, in addition to the signs and symptoms mentioned in contemporary texts.

- *Vrana* (ulcers)
- *Lala srava atyartha* (Excessive salivation)

With or without

- *Vyatha* (pain)
- *Daha* (burning sensation)

INCLUSION CRITERIA:

1. Patients of either gender aged between 10 to 16 years.

2. Patient fulfilling the diagnostic criteria of *Mukhapaka* will be selected.

EXCLUSION CRITERIA

1. Children with congenital anomalies

2. Children with other systemic illness.

3. Traumatic ulcers and infective stomatitis are excluded.

INTERVENTIONS:

Table no:1

| Group	Medicine	Mode of usage	Dose	Anupana	Duration
Group A [Trial Group]	*Peruka churna*	*Prathisarana*	2 g/ thrice a day	Honey	7 days
Group B Control Group]	*Khadira churna*	*Prathisarana*	2g/thrice a day	Honey	7 days

ASSESSMENT:

The effect of the treatment was assessed as follows:

- Within the group comparison was done by using RM ANOVA on rank test.

- Between the group analysis was done by the Mann-Whitney test.

ASSESSMENT GRADINGS:

1.VAS scale for pain
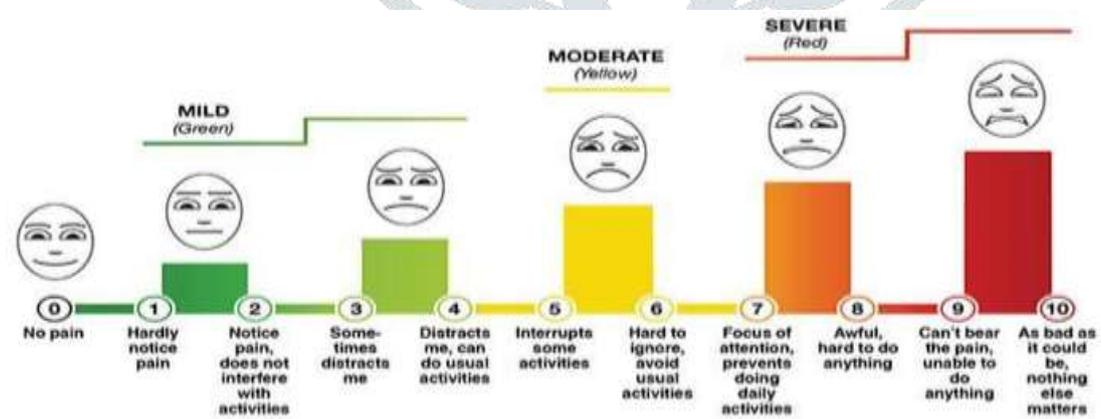
2.*DAHA*

Grade	Burning sensation
0	No burning sensation
1	Mild-tolerable, no need of external cooling agents
2	Moderate-intolerable, gets relief by cooling agents
3	Severe-intolerable, no relief by cooling agents

3.*LALASRAVA*

Grade	Excessive Salivation
0	Absent
1	Present

4.Size of the ulcer was measured in mm with the periodontal probe

5.Number of ulcers were counted.

OBSERVATIONS:

Table no:2

OBSERVATION	PREDOMINANCE	%	Interpretation
AGE	14-16 Years	58.33 %	Stress, anxiety and the food habits in this age group
GENDER	MALE	70 %	Due to maximum subjects enrolled in my study were males
RELIGION	HINDU	70%	The fact may be the area were the study conducted was having predominance of Hindu religion.
DIET	MIXED	81.66 %	various *Nidanas* mentioned for *MukhaRoga* excessive consumption of *Anoopa Mamsa* and *Matya* is highlighted.
BOWEL	Irregular	63.33%	Due to *vishamagni*

SLEEP	DISTURBED	60%	The disturbed sleep that may be due to stress and anxiety
PRAKRUTHI	Vata-pitta	45%	Generally, *Mukhapaka* is a *Raktapradoshaja* and *Pittaja Nanatmaja Vyadhi* and can occur in all persons but *Pitta Prakriti* persons may be more prone to the disease as the observation suggests.
KOSHTA	MADHYAMA	62.5%	Majority is having *Madhyama Koshta*
AGNI	VISHAMAGNI	40%	As the *aharaja nidanas* and the stress, anxiety leading to *vishamagni*
AGGREVATING FACTORS	Hot/Spicy/salty food	30.95%	Since it is a *pittaja nanatmaja vyadhi*
ASSOSIATED COMPLAINTS	SHIRORUJA	44.83%	Due to disturbed sleep, stress and anxiety

RESULTS:

1.Pain

Table no:3 Within the group analysis

	Group A		Group B	
Comparison	q	P<0.05	q	P<0.05
BT vs DT	2.546	No	3.394	No
BT vs AT	9.192	Yes	5.020	Yes
BT vs FU	9.758	Yes	6.010	Yes
DT vs AT	6.647	Yes	1.626	NO
DT vs FU	7.212	Yes	2.616	No
AT vs FU	0.566	No	0.990	NO

Within the group analysis shows statistically significant results in both the groups at p< 0.05.

Table no:4 Between the Group analysis

GROUP	MEAN		T VALUE	P VALUE	REMARKS
	A	B			
BT-DT	1.267	1.800	979.000	0.347	NO
BT-AT	4.467	2.467	703.000	0.002	YES
BT-FU	4.667	2.800	737.500	0.009	YES
DT-AT	3.200	0.667	566.000	<0.001	YES
DT-FU	3.400	1.000	589.500	<0.001	YES
AT-FU	0.200	0.333	941.500	0.700	NO

There was statistically significant difference between group A and group B analysis on Pain. By comparing mean value of group, A and group B from BT-AT, BT-FU, DT-AT, DT-AF group A is better than group B.

2. NO. OF ULCER

Table no:5 Within the group analysis

	q	P<0.05	q	P<0.05
BT VS DT	2.970	No	2.546	No
BT VS AT	8.839	Yes	9.192	Yes
BT VS FU	9.122	Yes	9.758	Yes
DT VS AT	5.869	Yes	6.647	Yes
DT VS FU	6.152	Yes	7.212	Yes
AT VS FU	0.283	No	0.566	No

Within the group analysis shows statistically significant results in both the groups at p< 0.05.

Table no:6 Between the group analysis

	MEAN		T VALUE	P VALUE	REMARKS
	A	B			
BT-DT	0.567	0.867	780.000	0.046	**YES**
BT-AT	1.567	1.433	967.000	0.446	**NO**
BT-FU	1.667	1.567	949.000	0.620	**NO**
DT-AT	1.000	0.567	1077.500	0.016	**YES**
DT-FU	1.100	0.700	1052.500	0.043	**YES**
AT-FU	0.1000	0.133	900.000	0.830	**NO**

There was statistically significant difference between group A and group B analysis on Number of Ulcers. By comparing mean value of group, A and group B for BT-DT, DT-AT, DT-AF group A is better than group B.

3. DAHA

Table no:7 Within the group analysis

Comparison	q	P<0.05	q	P<0.05
BT vs DT	3.960	Yes	3.394	No
BT vs AT	7.920	Yes	6.647	Yes
BT vs FU	7.920	Yes	6.647	Yes
DT vs AT	3.960	Yes	3.253	NO
DT vs FU	3.960	Yes	3.253	No
AT vs FU	0.000	No	0.000	NO

Within the group analysis shows statistically significant results in both the groups at p< 0.05.

Table no:8 Between the group analysis

GROUP	MEAN		T VALUE	P VALUE	REMARKS
	A	B			
BT-DT	0.700	0.833	759.000	0.021	YES
BT-AT	1.333	1.500	724.000	0.005	YES
BT-FU	1.333	1.500	736.000	0.008	YES
DT-AT	0.633	0.667	792.500	0.071	NO
DT-FU	0.633	0.667	783.500	0.053	NO
AT-FU	0.000	0.000	855.000	0.377	NO

There is statistically significant difference between Group A and Group B analysis on Daha. By comparing mean value of group A and Group B at different time point BT group B is found better.

4. LALASRAVA

Table no:9 Within the group analysis

Comparison	q	P<0.05	q	P<0.05
BT VS DT	3.960	Yes	3.960	Yes
BT VS AT	5.940	Yes	7.920	Yes
BT VS FU	5.940	Yes	7.920	Yes
DT VS AT	1.980	NO	3.960	Yes
DT VS FU	1.980	No	3.960	Yes
AT VS FU	0.000	NO	0.000	No

Within the group analysis shows statistically significant results in both the groups at p< 0.05.

Table no:10 between the group analysis

GROUP	MEAN		T	P	REMARKS
	A	B	VALUE	VALUE	
BT-DT	0.700	0.267	1005.000	0.185	NO
BT-AT	0.700	0.667	930.000	0.830	NO
BT-FU	0.233	0.667	930.000	0.830	NO
DT-AT	0.233	0.400	840.000	0.269	NO
DT-FU	0.000	0.400	840.000	0.269	NO
AT-FU	0.700	0.000	915.000	0.994	NO

There is no statistically significant difference between Group A and Group B analysis on Excessive salivation.

5. SIZE OF ULCER

Table no:11 Within the group analysis

Comparison	q	P<0.05	q	P<0.05
BT vs DT	4.172	Yes	4.101	Yes
BT vs AT	10.041	Yes	9.617	Yes
BT vs FU	10.112	Yes	10.324	Yes
DT vs AT	5.869	Yes	5.515	Yes
DT vs FU	5.940	Yes	6.223	Yes
AT vs FU	0.0707	No	0.707	No

There is no statistically significant difference between Group A and Group B analysis on Excessive salivation.

Table no:12 Between the group analysis

GROUP	MEAN		T VALUE	P VALUE	REMARKS
	A	B			
BT-DT	1.067	0.900	977.500	0.03	NO
BT-AT	2.467	2.167	1004.000	0.190	NO
BT-FU	2.467	2.300	912.000	0.970	NO
DT-AT	1.400	1.267	963.000	0.482	NO
DT-FU	1.433	1.600	873.000	0.539	NO
AT-FU	0.0333	0.333	851.000	0.346	NO

There is no statistically significant difference between Group A and Group B analysis on Size of ulcer.

DISCUSSION ON RESULTS

Effect of treatment on PAIN:

Within the group analysis shows statistically significant results in both the groups at $p < 0.05$.

Between the group analysis shows statistically significant result with *Peruka Churna* better than *Khadira Choorna*.

Property of *Madura* rasa of decreasing *Vata* and *Kashaya rasa* ability to promote healing will work together to reduce pain.

Here catechin or epicatechin perform significant functions as an anti-inflammatory and antioxidant agent.[8]

Effect of treatment on NO. OF ULCER

Within the group analysis shows statistically significant results in both the groups at $p < 0.05$.

Between the group analysis shows statistically significant result with *Peruka Churna* better than *Khadira Choorna.*

Kashaya Rasa is *Vranaropaka* and *Sandhankara*, due to which they promotes healing of ulcers.[9]

The presence of high amounts of gallic acid- derived compounds is primarily responsible for the astringent, tanning, and antioxidant properties of the extracts.[10\]

Effect of treatment on DAHA:

Within the group analysis shows statistically significant results in both the groups at $p < 0.05$.

Between the group analysis shows statistically significant result with *Khadira Churna* better than *Peruka Choorna*

Khadira contains *Tikta-Kashaya rasa*. It's *Kashaya- Tikta rasa* act on vitiated *pitta* and help to reduces *Daha*.[11]

Effect of treatment on LALASRAVA

Within the group analysis shows statistically significant results in both the groups at $p < 0.05$

There is no statistically significant difference between Group A and Group B analysis on Excessive salivation. This shows that both groups are equally effective in reducing excessive *Lalasrava* in *Mukhapaka*.

The *Kashaya rasa* is present in both the drugs that is *Peruka churna* and *Khadira Churna*, that has contributed to reduce the excessive salivation.

Effect of treatment on SIZE OF ULCER

Within the group analysis shows statistically significant results in both the groups at $p < 0.05$.

There is no statistically significant difference between Group A and Group B analysis on Size of the ulcer. This shows that both groups are equally effective in reducing Size of Ulcer in *Mukhapaka*.

PROBABLE MODE OF ACTION OF PERUKA CHURNA PRATHISARANA

- *Peruka* has *Kashaya rasa, Sheeta veerya, Madhura vipaka* and its *Vata – Pitta shamaka.*

- *Kashaya Ra*sa is *vranaropaka* and *sandhankara*, due to which they promotes healing of ulcers by reducing the size.

- Due to its *Madhura Vipaka,* it decreases *Vata* and *Kashaya rasa* ability to promote healing will work together to reduce pain.

- Honey is having the *Yogavahi guna*, so it takes the goodness of the drug to the target organ.

- The main phenolic substances in guava leaves are catechin, gallic acid, and quercetin.

- Recent findings revealed that P. guajava is an excellent source of antioxidant phytochemicals.

- These antioxidant properties of the guajava leaf are associated with its phenolic compounds such as gallic acid, ellagic acid, ascorbic acid, quercetin, and resveratrol.

- Many studies revealed the beneficial effects of gallic acid in wound healing.

PROBABLE MODE OF ACTION OF KHADIRA CHURNA PRATHISARANA

- *Khadira* has *Tikta-Kashaya rasa*, *Laghu-Ruksha guna*, *Sheeta veerya* and *Katu vipaka*, *Pitta Kapha Shamaka*.

- It's *Kashaya- Tikta rasa* act on vitiated pitta and help to reduces *Daha*.

- It's *Katu vipaka*, *Ushna Virya* act on vitiated *Vata* and help to reduces pain in *Mukhapaka*. *Kashaya rasa* also help to reduces excessive salivation in oral cavity.

- The chief phytoconstituent are constituents of the Khadira are catechin and epicatechin. They perform significant functions as an anti-inflammatory and antioxidant agent.

- The presence of high amounts of gallic acid- derived compounds is primarily responsible for the astringent, tanning, and antioxidant properties of the extracts.[10]

- Steroids stimulate fibroblast collagen production, which accelerates wound healing.

- It has been proposed that flavonoids have anti-inflammatory properties that include inhibiting pro-inflammatory enzymes like lipoxygenase and cyclooxygenase-2 that aid in the healing process of wounds.

PROBABLE MODE OF ACTION OF *PRATISARANA*

- It has *Vrana shodana* (debridement) and *Ropana* (Healing) actions.

- *Pratisarana* produces a false inflammatory response. *Pratisarana* which acts as constant irritation to the oral mucosa, generates a pseudo inflammatory reaction on the tissue and causes altered permeability of the blood capillaries.

- Due to this altered permeability of the vessels, there will be a favorable atmosphere for the active principle of the drugs.

CONCLUSION

After completion of the study the following conclusions were drawn.

- This study proved that both *Peruka Churna Pratisarana* and *Khadira Churna Pratisarana* are highly significant in the management of *Mukhapaka* in children.
- During the end of follow up period also same result was found.
- The result of the study shows that, between the group analysis shows *Peruka Churna Prathisarana* having better result in reducing Pain and Numer of the ulcer, *Khadira Churna Prathisarana* showing better results on *Daha* and there is no statistically significant results on *Lalasrava* and size of the ulcer.
- So, here the null hypothesis is accepted that, there is no statistically significant difference between the effect of *Peruka Churna* and *Khadira Churna Pratisarana* in management of *Mukhapaka* in children.
- No side effects by medicine were observed during treatment.

ACKNOWLEDGEMENT

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