STUDY ON MRUDVIKADI PRATISARNA IN CHILDREN WITH MUKHPA-KA-APHTHOUS ULCERS

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ABSTRACT

Introduction - Mukhpaka is most common disease of oral cavity. It is considered as the most prevalent disease worldwide characterized by redness, ulceration with burning sensation in oral cavity. Aim - Study was aimed to study the efficacy of herbal drug named as Mrudvikadi Pratisarna in the management of Mukhpaka. The objectives of the study were to assess the efficacy of trial drug on Mukhpaka and its subjective and objective parameters. Materials and methods - The study was a single group interventional study. It is conducted on 30 Mukhpaka patients with complaint of ulceration, burning sensation, pain, excess salivation in mouth treated with 4 times application of semisolid paste of drugs like Mrudvika, Triphaladi for 7 days. The subjective parameters were as per the clinical features of Mukhpaka. Their grading was done as per their intensity. Observation and Results - In the study, 10-15 year’s age group was more likely to suffer from the Mukhpaka and female children were more. Study demonstrated that local application of Mrudvikadi Pratisarna was having rapid absorption, fast action, and good palatability. Also, it is economical and effective formulation in the management of aphthous ulcers. Conclusion - There was significant improvement (p<0.001) in both subjective and objective parameters. However, as it was conducted in limited samples, further large sample multi-centre studies would be preferable. Developing pharmaceutical standards would also be a newer area of research.

Keywords: Mukhpaka, Ayurveda, Pratisarna, Mrudvika, Aphthous ulcer, ulceration, children

INTRODUCTION

Ayurveda is an ancient traditional system of medicine that serves mankind. Kaumarbhritya is one of the most important and leading amongst all 8 branches of Ayurveda by Acharya Kashyapa1. Mukha (oral cavity), it works as the reflector of health. It acts as the gateway of the alimentary canal and thus, it is considered as one of the main parts of Urdhwajatru. Mukhpaka is a disease that is commonly caused due to Pitta Dosha. It is found in India because people are more prone to have Pitta Prakopak Ahara and Vihara like late night sleeping, improper time of meals. Due to the Paka process, ulcers and inflammation over affected areas seen in Mukha.2 According to Acharya Kashyapa Lakshana of Mukhpaka are Lasrava, Dughda Dwesha, Glani, Vyatha, Grasita and Dugdha Chhardana.3 Mukhapaka can be correlated with Aphthous ulcers. These are recurrent superficial ulceration of the mucous membrane of the oral cavity. It has a multitude of different causes.4 Etiology is unknown. The
common causes include infections, nutritional deficiencies, and allergic reactions\(^5\), \(^6\). The symptoms range from the presence of mouth ulcers, redness, and erosion of labial, buccal, or lingual, sublingual palatal or gingival mucosa. Three forms of Recurrent aphthous stomatitis exist minor (more than 70% of cases), major (10%), and herpetiform H (10%). Major aphthous ulcers are >10mm in diameter and take 10-30 days to heal.\(^7\) RAS accounts for 25% of recurrent ulcers in adults and 40% in children\(^8\). Figure of patients are rising day to day in relatively low socioeconomic countries like India\(^9\). In India, patients presented with an oral ulceration of 21.7% while 56.3% female were more commonly affected than 43.7% male. Prevalence of oral ulceration in the age group (1-10) years was 9.8%. The prevalence of oral ulceration in the age group of (11-20) years was 12.9% in India\(^{10}\). Modern medications can cause side effects like harsh allergic reactions, diarrhoea, vomiting, etc., so we may come across with some limitations for the management of the disease. There are different treatment modalities such as \(Nasya\), \(Gandoosha\), \(Pratisarna\), \(Kavala\), \(Pralepa\) are advocated. Among these \(Pratisarna\) has been selected in the study. \(Mrudvikadi Pratisarna\) a semi-solid paste was taken on fingertips and applied over the ulcers. It is a topical application that is rapid in absorption, quick in efficacy, easy to apply. \(Mrudvikadi\) drugs and \(Madhu\) did not show any allergic reaction in this study. \(Mrudvikadi Pratisarna\) is affordable to all income groups of patients as cost effective.

**Aim**- Study on Mrudvikadi \(Pratisarna\) in Children with \(Mukhpaka\) (Aphthous ulcers).

**Objectives**-

1. To study the efficacy of \(Mrudvikadi Pratisarna\) on Pain of oral cavity.
2. To study the efficacy of \(Mrudvikadi Pratisarna\) on ulceration of oral cavity.
3. To study the efficacy of \(Mrudvikadi Pratisarna\) on salivation of oral cavity.
4. To study the efficacy of \(Mrudvikadi Pratisarna\) on burning sensation of oral cavity.

**MATERIALS AND METHODS**

**Source the drug**-

The trial drug \(Mrudvikadi Pratisarna\) the poly herbal formulation was taken from Ayurveda classic\(^{11}\) prepared at a \(Ras-shastra\) department attached to college as per the classical method of \(Raskriya and ghan\a preparation.\)
Table no. 1- properties of Mridvikadi yoga ingredients\(^{12}\).

<table>
<thead>
<tr>
<th>Dravya</th>
<th>Rasa</th>
<th>Guna</th>
<th>Virya</th>
<th>Vipaka</th>
<th>Doshghanta</th>
<th>Karma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mrudvikka</td>
<td>Madhura</td>
<td>Snighda</td>
<td>shita</td>
<td>Madhur</td>
<td>Vaatpita shamak</td>
<td>Raktaprasadana Kaphanisaraka</td>
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<td>Guru</td>
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<td>Sandhankara</td>
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<td>Patha</td>
<td>Tikta</td>
<td>Laghu</td>
<td>Ushana</td>
<td>Katu</td>
<td>Vaatkaphasamak</td>
<td>Jwaraghana Krimighana</td>
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<td>Tikshana</td>
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<td>Jati</td>
<td>Tikta</td>
<td>Laghu</td>
<td>Ushana</td>
<td>Katu</td>
<td>Tridosghana</td>
<td>Raktaprasadana Kusthaghana</td>
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<td></td>
<td>Kashaya</td>
<td>Snighda</td>
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<td>Kandughana</td>
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<td>Vibhitaka</td>
<td>Kashaya</td>
<td>Ruksha</td>
<td>Ushana</td>
<td>Madhura</td>
<td>Tridoshara</td>
<td>Sothagara Vedanasthapaka</td>
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<td></td>
<td></td>
<td>Laghu</td>
<td></td>
<td></td>
<td></td>
<td>Raktasthambahaka Jwaraghana</td>
</tr>
<tr>
<td>Haritk</td>
<td>Panchrasa</td>
<td>Laghu</td>
<td>Ushana</td>
<td>Madhura</td>
<td>Tridoshara</td>
<td>Dipana Anulomana Pachana</td>
</tr>
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<td>Lavaranarha-</td>
<td>Ruksha</td>
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<td>Amlaki</td>
<td>Panchrasa</td>
<td>Guru</td>
<td>Shita</td>
<td>Madhura</td>
<td>Tridoshara</td>
<td>Chakshushya Medhya Anulomana</td>
</tr>
<tr>
<td></td>
<td>Lavanrahita</td>
<td>Ruksha</td>
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<td></td>
<td>Shita</td>
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<td>Madhu</td>
<td>Madhura</td>
<td>Laghu</td>
<td>Ushna</td>
<td>Katu</td>
<td>Tridosaghna</td>
<td>Vilekhana, Yogvahi, Agnidi-</td>
</tr>
<tr>
<td></td>
<td>Kashaya</td>
<td>Ruksha</td>
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</tbody>
</table>

**Study design**

The study was planned as a single-arm interventional study for the efficacy of *Mrudvikadi Pratisarna* in the management of *Mukhpaka*. Patients were selected randomly. Data was recorded in special research proforma by personal interview and examination. Institutional ethics committee approval has been obtained with the I.E.C no. DMIMS (DU)/IEC/2017-18/7244 and the trial has been registered in CTRI with reference no. CTRI/2019/10/021640.

**Method of preparation of Mrudvikadi Pratisarna**: Thick lotion of the drugs was prepared. Firstly each drug was taken 250gms. Ingredients were cleaned properly to remove the impurities. Each ingredient was taken in *Yavakuta* form, then boiled with 10 liters of water under low heat and reduced to 500ml and filtered, further reduced it to 350ml, then equal amount of honey by weight was added to it. In the end, sodium benzoate, 0.002% (w/w) was added as a preservative. At the end semisolid lotion was formed.
Source of Data

Children aged 5-15 years with common signs and symptoms of Mukhpaka were selected from O.P.D and I.P.D of Kaumarbhriya, and Health Camps of near periphery and Specialty Camps.

Method of study

After taking the informed consent from the parents /guardian, 35 subjects were enrolled as per the inclusion criteria. The trial drug was administered for a period of 7 days during which assessment of both subjective and objective parameters and other observations were recorded on 0th, 3rd and 7th in a specially prepared research proforma which were performed before and after trial. Follow up was for a period of 14 days post trial.

Treatment period- The trial drug, Mrudvikadi Pratisarna was administered in the following dosage for 7 days.

Follow up period-: follow up during treatment 2 follow up after treatment one follow up (1st, 4th, 7th & 14th).

Inclusion criteria-

1. With classical signs symptoms of Mukhpaka such as pain, irritability, ulceration, excessive salivation.
2. Both male and female sex.
3. Age group 5 to 15 years.
4. Only those patients who are enrolled with consent.

Exclusion criteria-

1. Systemic illness.
2. Oral, throat, tongue malignancies.
3. Non healing ulcers like syphilis etc.

Posology-

- **Pratisarna** – 1 drop each ulcer **Frequency**- Four times a day, before meal.
- **Mode of administration**- Local **Anupana**- **Madhu**.
- **Duration**– 7 days.

Criteria for Assessment

Assessment of the clinical trial was done based upon the changes in both subjective and objective parameters. Initial assessment was done before the study, followed by an assessment
of only subjective parameters on the 4th day of the study. Final assessment was done after the course of the trial i.e. on 7th day and follow up at 14th day after completion of treatment.

**Subjective Parameters:**

- Excess salivation
- Pain
- Burning sensation

**Objective parameter-**

- Ulceration

<table>
<thead>
<tr>
<th>Grading of excess salivation</th>
<th>Grading of pain.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade</td>
<td>Assessment</td>
</tr>
<tr>
<td>0</td>
<td>Absent</td>
</tr>
<tr>
<td>1</td>
<td>Present</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Grading of Burning sensation</th>
<th>Grading of ulceration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade</td>
<td>Assessment</td>
</tr>
<tr>
<td>0</td>
<td>Absent</td>
</tr>
<tr>
<td>1</td>
<td>Present</td>
</tr>
</tbody>
</table>

The obtained data was analyzed statistically. McNemar’s test was used to test the hypothesis of the study. P-value of < 0.05 was considered as statistically significant and p-value < 0.01 and were considered as highly significant. The level of significance was noted and interpreted accordingly. Overall assessment of the study was done by calculating complete improvement (100%) of parameters.

**Results-**

**Showing details on objective criteria-**

**Graph no. 1: Effect on ulceration-**
Before treatment, 30 patients were present with ulceration, after treatment there was 28 patients were cured. The improvement after treatment was 93.33%, 2 patients (6.67%) were having no relief in symptoms.

**Table no. 2: Showing result of Mrudvikadi Pratisarna on ulceration.**

<table>
<thead>
<tr>
<th>Effect on Ulceration</th>
<th>B/T</th>
<th>A/T</th>
<th>%Effect</th>
<th>p-value</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.of patients out of 30 in which ulceration was present</td>
<td>30</td>
<td>2</td>
<td>93.33%</td>
<td>0.000</td>
<td>Significant</td>
</tr>
<tr>
<td>No.of patients out of 30 ulceration was absent</td>
<td>0</td>
<td>28</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table shows, out of 30 patients 2 patients were uncured with ulceration after treatment and 28 patients were relieved with ulceration. On applying McNemar’s test, it showed statistically highly significant with p-value 0.000. The medicine was said to be highly significant in relieving ulceration.

**Showing details on subjective criteria in graph-**

**Graph 2- Showing effect on excess salivation--**
Before treatment 17 patients (56.67%) were present with excess salivation, and 13 patients were having an absence of excess 43.33% salivation. After treatment, 30 patients were having an absence of the symptom excess salivation. The improvement after treatment was found to be 100%.

**Table no. 3: Showing result of *Mrudvikadi Pratisarna* on salivation.**

<table>
<thead>
<tr>
<th>Effect on Salivation</th>
<th>B/T</th>
<th>A/T</th>
<th>%Effect</th>
<th>p-value</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Patients out of 30 Excess salivation presence</td>
<td>17</td>
<td>0</td>
<td>100%</td>
<td>0.001</td>
<td>Significant</td>
</tr>
<tr>
<td>No. of Patients out of 30 excessive salivation absence</td>
<td>13</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table shows, after treatment out of 30 patients, no patient was having symptoms of excessive salivation. On applying McNemar’s test it shows statistically highly significant with p-value 0.001. The medicine is said to be highly significant in relieving excessive salivation.

**Graph no. 3: Showing the effect on pain**

Before treatment among 30 patients (100%) all were present with excess salivation. After treatment, there were 26 patients found cured with the symptom of pain. The improvement after treatment was found to be 86.67%, 4 patients (13.33%) were found uncured after treatment.

**Table no. 4: Showing result of *Mrudvikadi Pratisarna* on pain.**
### Table showing effect on pain

<table>
<thead>
<tr>
<th>Effect on Pain</th>
<th>Before Treatment</th>
<th>After Treatment</th>
<th>%Effect</th>
<th>p-value</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Patients out of 30, Pain presence</td>
<td>30</td>
<td>4</td>
<td>86.67%</td>
<td>0.0000</td>
<td>Significant</td>
</tr>
<tr>
<td>No. of Patients out of 30, pain absence</td>
<td>0</td>
<td>26</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table shows after treatment Out of 30 patients 4 patients are uncured with pain and 26 patients were relieved with pain. On applying Mc-Nemar’s test it shows statistically highly significant with p-value 0.000. The medicine is said to be highly significant in relieving pain.

**Graph no. 4: Showing effect on burning sensation.**

![Graph showing effect on burning sensation](image)

Before treatment among 30 patients (100%) all were present with the symptom of burning sensation. After treatment, there were 28 patients found cured with the symptom of pain. The improvement after treatment was found to be 93.33%, 2 patients (6.67%) were found uncured after treatment.

**Table no.5: Showing result of Mrudvikadi Pratisarna on burning sensation.**

<table>
<thead>
<tr>
<th>Effect on Burning Sensation</th>
<th>B/T</th>
<th>A/T</th>
<th>p-value</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of Patients out of 30 Burning sensation presence</td>
<td>30</td>
<td>2</td>
<td>0.0000</td>
<td>Significant</td>
</tr>
<tr>
<td>No. of Patients out of 30 burning sensation absence</td>
<td>0</td>
<td>28</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table shows, after treatment out of 30 patients, 2 patients are uncured with pain, and 28 patients were relieved with symptom burning sensation. Burning sensation was assessed applying Mc Nemar's test results shows statistically highly significant with p-value 0.000. The medicine is said to be highly significant in relieving burning sensation.

Table no.6: Showing overall results for subjective and objective parameters (after follow up):

<table>
<thead>
<tr>
<th>Before Intervention</th>
<th>After follow up</th>
<th>Total Marginal</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0 (A)</td>
<td>25 (B)</td>
<td>30</td>
</tr>
<tr>
<td>0</td>
<td>0 (C)</td>
<td>0 (D)</td>
<td>0</td>
</tr>
<tr>
<td>Total Marginal</td>
<td>5</td>
<td>25</td>
<td>30</td>
</tr>
</tbody>
</table>

(A) 5 patients were uncured at both times, before intervention and after follow up.

(B) 25 patients were uncured before intervention but cured after follow up.

(C) 0 patients cured before intervention but uncured after follow up.

(D) 0 patients were cured at both times

On applying Mc Nemar, it showed highly significant results i.e. (0.00). That shows Mrudvikadi Pratisarna is effective in both the parameters. On applying Mc Nemar, it showed highly significant results i.e (0.00). That shows Mrudvikadi Pratisarna is effective in both the parameters.

Overall results of Mrudvikadi Pratisarna was assessed on the basis of cured (100%), Marked positive response more than 75%, Moderate 51-75%, Mild improvement less than 50%
DISCUSSION- Mrudvikadi Pratisarna contains Mrudvika, Triphala, Jatipatra, Patha, and Madhu. Mrudvika is Madhura Rasatmaka and Sheetavirya. Because of its Sheetavirya it is mainly having Pita shamak properties. So, it helps in reducing the symptoms like a burning sensation, redness. Amlaki is Panch Rasatmaka but due to its Madhura Rasa and Sheeta Virya it mainly pacifies Pitta. Amlaki is a rich source of Vitamin C and it helps in healing the wound. It is also a good source of iron and calcium. Jati and Vibhitaka are Tikta kshaya Rasa Pradhana Tridosha shamaka. Haritki is Panch Rasatmaka. It balances all three Doshas because of its Madhura and Tikta, Kshaya Rasa helpful in Pitta Shamana. It is Shoolhara (analgesic) and Krimihara (antimicrobial)\(^{13, 14, 15}\). Madhu is Madhura and Kshaya Rasa and it is the best Yogvahi substance. Studies reported that Triphla showed significant antimicrobial effects against *Streptococcus mutans*\(^{16}\). *Streptococcus mutans* are responsible for mucosal ulceration, dental caries, and gingivitis\(^{17}\). *Jasminum grandiflorum* has potential antiulcer activity\(^{18}\). Honey is anti-inflammatory\(^{19, 20}\) due to its anti-inflammatory properties it helps in healing the ulcers. Cumulatively this Mrudvikadi drugs showed the action of Tridosha Shamana, Rakta Prasadan, Vrana-Ropana, Shothhara which is accomplished to cure Mukhapa-ka.
Route of administration has its importance in the management of disease. Pratisarna comes under the external route of administration. It is a type of topical application. Mouth is a highly vascular area due to this it showed rapid absorption and response. These drugs cross the mucous membrane of the body and enter the bloodstream. The topical application and inhalation of drugs showed a faster effect than the oral route\textsuperscript{21}.

The age-wise distribution showed that the maximum number of patients of Mukhpaka i.e., 20 patients (66.67\%) fell in the age group of 10-15 years. The possible assumption for the higher incidence of Mukhapaka in this age group of 10-15 years may be because of excessive intake of Katu, Madhura and Amla Rasa. According to Ayurveda, the age 10-15 is considered under Balya Avastha where Pitta and Kapha Doshas\textsuperscript{22, 23} are involved. Mukhpaka is Pitta Pradhana Vyadhi. The distribution based on gender indicates that among 30 patients, 21 patients were females (70\%). Maximum 60\% of the patients came below the poverty line, 23.33\% of the patients were of lower class. So, this can be due to the fact that the lower class people do not maintain their hygiene properly, may due to poor awareness. Among 30 patients, 16 patients (53.33\%) had poor appetite, 9 patients (30.00\%) had moderate appetite. Among 30 patients, 19 patients (63.33\%) had Sama sleep, 9 patients (30\%) had Alpa and 2 patients (6.67\%) had Ati Nidra. Nidra is one among Triupsthambha. So, improper sleep may disturb the body equilibrium. Alpanidra was due to the symptom of pain in this study. Among 30 patients, 13 patients (43.33\%) had the habit of eating spicy food, 10 patients (33.33\%) had the habit of eating junk and spicy food. The prevalence of Mukhapaka was higher in those who frequently ate spicy and junk food. The habit of acidic intake can lead to change the PH of mouth. Among 30 patients, the maximum no. of patients had proper hygiene i.e.; 18 patients (60\%) absence of dental unhygiene whereas 12 patients (40\%) had lack of oral hygiene. Large numbers of microorganisms are present in our mouth\textsuperscript{16}. Poor oral hygiene increases bacterial multiplication and can cause diseases like periodontitis, halitosis, mouth ulcers. Study reveals that maximum patients 17 i.e., 56.67\% were having red-colored ulcers, 7 patients (23.33\%) were having white-colored ulcers. Red-colored blisters were caused due to Pitta Dosha, and seen in Pitaja Mukhpaka.

All the signs and symptoms of Mukhpaka were relieved significantly with the use of Mrudvikadi drugs along with Madhu. Statistically, present clinical study showed significant reductions in mouth ulcerations, excessive salivation, pain and burning sensation as the value is <0.001 for all signs. Mrudvikadi drugs act locally as well as systematically. Madhu is pal-
atable and has healing properties so, it helps in healing the ulcers. In the present study we did not observe any side effect and adverse drug reaction after the application of Mrudvikadi Pratisarna. This treatment also convinces its effect on the ground of statistics as statistical tests applied to all the assessment criteria found extremely significant it can be strongly concluded that this treatment is useful in Mukhapaka. The percentage reduction in various parameters assessed under the proposed study revealed the fact that, Mrudvikadi Pratisarna showed a significant reduction in all the parameters viz. ulceration, excessive salivation, pain, burning sensation. Trial drugs showed significant results after treatment and after follow up. The overall effect of the treatment is 76.67% are completely cured, 3.33% were having moderate improvement, 10% were having mild improvement, 3.33% showed no improvement. Comparing the overall results, the percentage of fully cured children was far more as compared to moderate and mild relief children. Thus, we can claim that the trial drug is significantly efficacious in the treatment of Mukhapaka.3 patients were having a re-occurrence of ulceration after 14 day. The drugs in Mrudvikadi Pratisarna are mainly Tikta, Kashaya Rasatmak, having Vranaropaka and Shulhara action. Practicing Dantadhawan and Jivha Nirlekhana for the maintenance of good oral health should also be advisable to prevent the diseases of the oral cavity. Procedures like Gandusha, Kavala should be practiced daily and popularized among the population.

CONCLUSION:

Mrudvikadi Pratisarna has shown statistically highly significant results on symptoms like ulceration, pain, excess salivation, burning sensation. Drug has helped in the reduction of symptoms of disease and Vrana Ropana Karma. Mrudvikadi Pratisarna was easy to apply and helpful in the early reduction of symptoms and reduces the progression of disease by having Tikta Kashaya Rasa. Mrudvikadi Pratisarna is proved appropriate for the management of Mukhpaka in children because of good palatability, rapid absorption and fast action. Based on this study it can be concluded that Mrudvikadi Pratisarna showed significant results in reducing the sign and symptoms, also helpful in the recurrence of Mukhpaka. However, the study was conducted at a single centre, single group with small sample so, further study should be done multicentric in a large sample.

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