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RESEARCH ARTICLE

A STUDY ON COMPARISON OF TRIMACINOLONE ACETONIDE 0.1% ORAL GEL AND JATIPATRA(JASMINUM GRANDIFLORUM LINN) LOCALLY ON MUKHAPAK WITH SPECIAL REFERENCE TO STOMATITIS

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ABSTRACT

In Ayurveda there is brief description of In Ayurveda there is brief description of 64 mukharoga mentioned by Acharya Charak, Sushrut, Acharya Bhoj, Madhavinda and Acharya Vagbhata. Mukhapak occurs all over oral cavity, Acharya charak has described it as mukhapak, while Acharya Sushrut and Acharya Vagbhata have described as 'Sarvsar'. The symptoms of mukhapak can be correlated with stomatitis. The word stomatitis means inflammation of mucosal membrane of mouth. It affects 20% of general population and characterised by recurrent small round or ovoid ulcers with circumscribed margins, erythematous halos and yellow or gray floor. Minor apthous ulcer are less than 5mm in diameter the major apthe are larger less common heal slowly over weeks to month and are associated with scarring. The inflammation can be caused by conditions in the mouth itself, such as poor oral hygiene, inflection, nutritional deficiencies, allergic reaction or conditions that affect whole body such as medications poorly fitted dentures, bad oral hygiene is very common in poor and uneducated class. The principal treatment of stomatitis is based on the problems causing it. Local cleansing and good oral hygiene are basic things. Recently low power treatment with Co2Laser has been found to relieve the discomfort of recurrent stomatitis Majority of cases are treated with antibiotics and local corticosteroids which gives symptomatic relief by cooling, soothing effect. In modern medicine there is no specific treatment for stomatitis combination of antibacterial, anti inflammatory and corticosteroids in form of paste, gel and gargles are used. Topical cortiosteroids remains the main stay of treatment. Topical cortiosteroids reduce painful symptoms but not the rate of recurrent. There are more in price with some side effects. Considering all above mentioned facts it is necessary to have effective, cost free treatment which does not have any side effects. The Jatipatra (Jasminum grandiflorumlinn) is having properties like Ras, Kashay-tikta, Virya-shit, Vipak-katu, Doshgnta-kaph-pittahara. Due to these properties pain excessive salivation, ulcerhealing may occur very effectively.

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INTRODUCTION

The name of Ayurveda originates from two Indian words Ayu- means life and Veda means knowledge .In a broad sense it means knowledge concerning the maintainance of life. Ayurveda is a ancient science of life from 5000 years. According to Ayurveda there are 64 types of mukhroga mentioned by Acharya Charak, while sushrut, Acharya Vagbhata have mentioned 67 type of mukhrog. The treatment of mukhapak mentioned by Bhavprakash in Nighantu Adarsha is....

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Mukhapak occurs all over oral cavity, Acharya Charak has described it as mukhpak, while Acharya Sushrut and Acharya Vagbhata have described as sarvasar. The symptoms of mukhpaka can be correlated with stomatitis. The word stomatitis means inflammation of mucosal membrane of mouth. It affects 20% of general population and characterized by recurrent small round or ovoid ulcer with circumscribed margins, erythmatous halos and yellow or grey floor. Minor apthous ulcer are less than 5mm in diameter, the major apthe are larger, less common, heal slowly over weeks to month and are associated with scarring. It is found more in pitta pradhan dosha, pitta pradhan prakruti and pittaj kala. It is more found in India because peoples are more prone to have pitta prakopak Aahar, oily spicy food, smoking, drinking, tobacco chewing, improper timing of food, vihar like late night sleeping. Due to

such habits ulcer and inflammation over affected area is seen in mukha. The inflammation can be caused by condition in the mouth itself, such as poor oral hygiene, infection, nutritional deficiencies, allergic reaction or condition that affect whole body such as medication, poorly fitted denture, bad oral hygiene is very common in poor and uneducated class. In some instance recurrent mouth ulcer may be a manifestation of an allergic reaction. Possible allergens include certain food example chocolates, coffee, eggs, nuts, tomatoes, cheese, citrus fruits, highly acidic food. The principle treatment of stomatitis is based on the problems causing it. Local cleansing and good oral hygiene are basic things. Recently low power treatment with CO₂ laser has been found to relieve the discomfort of recurrent stomatitis. Majority of cases are related with antibiotics and local corticosteroids which gives symptomatic relief by cooling, soothing effect. In modern medicine there is no specific treatment for stomatitis, combination of antibacterial, anti-inflammatory and corticosteroids in form of paste, gel, and gargles are used. Topical corticosteroids (TCS) remains the mainstay of treatment. Topical corticosteroids reduce painful symptoms but not the rate of recurrence. They are more in price with some side effects.

Considering all above mentioned facts it is necessary to have effective, cost free treatment which does not have any side effects. The jatipatra (*Jasminum grandiflorum* Linn) is having properties like Ras kashay-tikta, virya –ushana, vipak-katu, Doshanghata –kapha-pittahara. Due to these properties pain, excessive salivation, ulcer healing occurs very effectively.

Aim

To compare the action of trimacinolone acetone 0.1% locally and jatipatra (*Jasminum grandiflorum* Linn) on mukhpak with special reference to stomatitis.

Objective

- To study the role of jatipatra (*Jasminum grandiflorum* Linn) on mukhpak.
- To study which local application acts better jatipatra (*Jasminum grandiflorum* Linn) or trimacinolone acetone 0.1%.

MATERIAL AND METHODS

The whole work was divided into

- Conceptual Study
- Standardisation
- Analytical Study
- Clinical Study

Conceptual Study: Review of Literature: The conceptual reference of Jatipatra and Mukhpak were studied from the Bruhatrayee including Ashtanga Sangraha and Nighantus.

Standardisation: Authentication and standardization of drug was done from collage and aligned institute.

Analytical Study

Physicochemical and phytochemical analysis of jatipatra was done in laboratory.

Clinical Study

Patient's selection was done irrespective of age, sex, religion, race, occupation etc. fulfilling the criteria of selection and eligibility for the study.

Sampling

Random sampling method was adopted for the selection of patients.

Eligibility Criteria

Patients presenting with sign and symptoms of Mukhpak as per Ayurved and Modern science.

Inclusion Criteria

- Age above 10 years-
- Patients having ulcers in oral cavity.
- Patients willing for oral trial.

Exclusion Criteria

- Patients below 10 years.
- Patients not willing for trials.
- Any congenital abnormality of oral cavity.
- Ulcer formed due to malignancy.
- Immunosuppressive disorders.

Withdrawal Criteria

- Patient refuse to continue treatment.
- No relief in symptoms or aggravation of symptoms.

Study Design

Randomised clinical Trials.

Sample Size: 60 Patients were selected.

MATERIALS

- Patients
- Drug

Patients: Total 60 patients were selected according to inclusion and exclusion criteria.

Grouping: Out of 60 patients, 30 patients were shifted to group A, And 30 to group B, by Random sampling method

Group A: 30 Patients treated with Triamcinolone acetone 0.1% Locally.

Group B: 30 Patients treated with Jatipatra (*Jasminum grandiflorum* Linn) locally.

Drug: Immature leaves of Jatipatra (*Jasminum grandiflorum* Linn) were collected from botanical garden of our collage.

Methods

Informed Consent: Written informed consent of each patient was taken prior to commencement of the clinical trial.

Case Record Form: Cases were recorded on specially prepared case record form.

Follow Up: Follow up on 20th and 30th days.

Observation were carried out during each follow up and Data collected at the end of Research work; subjected to Stastical Analysis.

Group wise distribution

Drugs	Dosages	Route of Administration	Duration
Group A- Triamcinolone acetone 0.1%	0.1% Twice a day, for 3-5 min	Local	7 days
	0.1% Once a day, for 3 -5 min	Local	Next 7 days
Group B- leaves of jatipatra (jasminum grandiflorum linn)	One karsh, according to bala of patient, Twice a day	Charvan-Local route- Charvan of leaves upto salivation, then split out	7 days
	Once a day	Local route -Charvan of leaves upto salivation, then split out	Next 7 days

Subjective gradation of parameters

Sr	Parameters	Gradation			
		0	1	2	3
01	Pain at affected area (shool)	No complaint of pain	pain on touch	pain without touch	pain felt throughout day
02	Burning sensation (Daha)	No complaint of burning	Burning sensation on touch	Burning sensation on eating spicy and salty food	Burning sensation felt throughout day without any aggravated factor and normal food
03	Extensive salivation (Lalastrav)	No complaint of extensive salivation	Patient complaint excessive salivation	Patient has to split saliva	Dribbling Saliva
04	Dysphagia (GilanKashatta)	Patient Swallow easily	Difficulty in Swallowing solid	Patient can only eat liquid easily	Patient cannot chew or swallow solid as well as liquid
05	Ulceration (Vrana)	No Ulceration	Less than two ulcer	2-4 ulcers are there	More than 4 ulcers
06	Redness (Lalima)	No redness	Pink or red coloured mucous	cherry or fiery red coloured	Reddish purple

Symptoms gradation

Sr	Observation	Normal	Score	Borderline	Score	Abnormal	Score
01	Pain at affected area (Shool)	No complaint of burning	0	Pain on touch	1	Pain without touch	2
						Pain felt throughout day	3
02	Burning Sensation (Daha)	No complaint of burning	0	Burning Sensation on touch	1	Burning Sensation on eating spicy and salty food	2
						Burning sensation felt throughout day without any aggravated factor with normal food	3
03	Extensive Salivation (LalaStrav)	No complaint of extensive salivation	0	Patient is compling of extensive salivation	1	Patient has to splits saliva	2
						Dribbling saliva	3
04	Dysphagia (GilanKashat ta)	Patient can swallow easily	0	Difficulty in swallowing solid	1	Patient can only take liquid easily	2
						Patient can not chew solid as well as liquid	3
05	Ulceration(Vrana)	No ulceration	0	Less than two ulcer	1	2 to 4 ulcers are there	2
						more than 4 ulcers	3
06	Redness Lalima ()	No redness	0	Pink or Red colouredm ucosa	1	Cherry or fiery red coloured	2
						Reddish Purple	3

DIET

Patients were advised to take their routine diet, except some dietary constituents which can provoke the condition as mentioned in samhitas. Patients are advised to maintain good oral hygiene. Patients are advised to follow all the 'Pathyapathya' regarding to Mukhpak.

Criteria for Dignosis

For diagnostic purpose the classical sign and symptoms described in different Samhitas have been taken up, alongwith modern science.

Criteria For Assessment: Following scoring pattern was adopted for the study to observe the relief in sign and symptoms, of the disease.

Assesment of the total effect of therapy

The observation of sign and symptoms and other clinical parameters were recorded before and after the treatment.

Assesment of the total effect of therapy made by analyzing the data stastically as follows.

Assessment criteria

Subjective

Dropouts: Tha patients who didn't continue for total duration are considerd dropout, newer patients are filled in such case.

Presentation of data: The data collected from clinical trials was sorted out and processed further by subjection to various stastical methods and presented with graphical form.Result of the study evaluated on the basis of improvement of sign and symptoms.

Assessment criteria

Subjective

Sr	Parameters	Gradation			
		0	1	2	3
01	Pain at affected area (shool)	No Complaint of pain	Pain on touch	Pain without touch	Pain felt throughout day
02	Burning sensation (Daha)	No complaint of burning	Burning sensation on touch	Burning sensation on eating spicy and salty food	Burning sensation felt throughout day without any aggravated factor and normal food
03	Extensive salivation (Lalastrav)	No complaint of extensive salivation	Patient complaint of excessive salivation	Patient has to spit saliva	Dribbling Saliva
04	Dysphagia (GilanKashatta)	Patient can swallow easily	Difficulty in swallowing solid	Patient only eat liquid easily	Patient cannot chew or swallow solid as well as liquid
05	Ulceration (Vrana)	No Ulceration	Less than two ulcer	2-4 ulcers are there	More than 4 ulcer
06	Redness (Lalima)	No redness	Pink or red coloured ucous	Cherry or fiery red coloured	Reddish purple

Observation Group – A (Oral Gel (TRIAMCINOLONE ACETONIDE 0.1%))

Sr.	Criteria	Score	On 1 st Day	On 3 rd day	On 6 th day	On 10 th Day	On 14 th day	On 20 th day	On 30 th day
01.	Pain affected Area (Shool)		3	2	2	2	1	1	1
02	Burning sensation (Daha)		3	2	2	1	1	1	0
03	Extensive salivation (LalaStrav)		3	3	3	2	2	1	1
04	Dysphagia (Gilan Kashatta)		3	3	2	2	1	1	1
05	Ulceration (Vrana)		3	3	2	2	2	1	1
06	Redness (Lalima)		3	3	3	3	2	2	1

Observation Group – B (Jatipatra (Jasminum grandiflorum linn))

Sr.	Criteria	Score	On 1 st Day	On 3 rd day	On 6 th day	On 10 th day	On 14 th day	On 20 th day	On 30 th day
01	Pain affected Area (Shool)		3	2	2	1	0	0	0
02	Burning Sensation (Daha)		3	2	1	0	0	0	0
03	Extensive Salivation (LalaStrav)		3	2	1	0	0	0	0
04	Dysphagia (GilanKashatta)		3	2	1	0	0	0	0
05	Ulceration (Vrana)		3	2	1	0	0	0	0
06	Redness (Lalima)		3	2	2	1	0	0	0

Overall assessment criteria – Observation are according to sign and symptoms

Sr.	Observation	Normal	Score	Borderline	Score	Abnormal	Score
01.	Pain at affected area (Shool)	No complaint of pain	0	Pain on touch	1	Pain without touch	2
						Pain felt through out day	3
02	Burning Sensation (Daha)	No complaint of burning	0	Burning Sensation on touch	1	Burning Sensation on eating spicy and salty food	2
						Burning sensation felt through out day without any aggravated factor with normal food	3
03	Extensive Salivation (LalaStrav)	No complaint of extensive salivation	0	Patient is compling of extensive salivation	1	Patient has to splits saliva	2
						Dribbling saliva	3
04	Dysphagia (GilanKashatta)	Patient can swallow easily	0	Difficulty in swallowing solid	1	Patient can only take liquid easily	2
						2 to 4 ulcers are there	2
05	Ulceration(Vrana)	No ulceration	0	Less than two ulcer	1	more than 4 ulcers	3
						Cherry or fiery red coloured	2
06	Redness (Lalima)	No redness	0	Pink or Red colouredm ucosa	1	Reddish Purple	3

Severity of signs & symptoms before treatment

Sr no	Signs & symptoms	Gr 0		Gr 1		Gr 2		Gr 3	
		A	B	A	B	A	B	A	B
01	Pain[shool]	-	-	07	06	13	14	10	10
02	Burning [daah]	-	-	09	10	12	13	09	07
03	Salvation [lalastrav]	01	01	06	05	15	17	08	07
04	Dysphagia [gilankashatta]	02	02	05	05	10	11	13	12
05	Vrana [ulcer]	-	-	11	12	11	10	08	08
06	Lalima [redness]	01	01	16	13	09	11	04	05

Improvement of patient of group A

Sr.	Criteria	Gr	pt	On 1 st day	On 3 rd day	On 6 th day	On 10 th day	On 14 th day	On 20 th day	On 30 th day
01.	Pain affected ares (school)	0	00	-	-	-	-	-	-	-
		1	07	1	1	1	0	0	0	0
		2	13	2	2	2	1	1	1	0
		3	10	3	3	3	2	2	1	1
02.	Burning sensation (Daha)	0	00	-	-	-	-	-	-	-
		1	09	1	1	1	0	0	0	0
		2	12	2	2	2	1	1	0	0
		3	09	3	3	2	2	1	1	0
03.	Extensive salivation (Lalastrav)	0	00	-	-	0	0	0	0	0
		1	09	1	1	1	0	0	0	0
		2	12	2	2	1	1	0	0	0
		3	09	3	3	2	2	1	1	0
04.	Dysphagia (GilanKashatta)	0	02	0	0	0	0	0	0	0
		1	05	1	1	1	1	0	0	0
		2	10	2	2	2	1	1	0	0
		3	13	3	3	3	2	2	1	1
05.	Ulceration (Vrana)	0	00	-	-	-	-	-	-	-
		1	11	1	1	1	0	0	0	0
		2	11	2	2	2	1	1	0	0
		3	08	3	3	2	2	1	0	0
06.	Redness (lalima)	0	01	0	0	0	0	0	0	0
		1	16	1	1	1	0	0	0	0

Improvement of patient of Group B

Sr.	Criteria	Gr	Pt	On 1 st Day	On 3 rd day	On 6 th day	On 10 th day	On 14 th day	On 20 th day	On 30 th day
01	Pain affected Area (Shool)	0	00	-	-	-	-	-	-	-
		1	06	1	1	0	0	0	0	0
		2	14	2	1	1	0	0	0	0
		3	10	3	2	2	1	0	0	0
02	Burning Sensation (Daha)	0	00	-	-	-	-	-	-	-
		1	10	1	1	0	0	0	0	0
		2	13	2	2	1	1	0	0	0
		3	07	3	3	2	1	0	0	0
03	Extensive Salivation (LalaStrav)	0	01	0	0	0	0	0	0	0
		1	05	1	1	0	0	0	0	0
		2	17	2	2	1	0	0	0	0
		3	07	3	3	2	1	1	0	0
04	Dysphagia (GilanKashatta)	0	02	0	0	0	0	0	0	0
		1	05	1	1	0	0	0	0	0
		2	11	2	2	1	0	0	0	0
		3	12	3	3	2	1	0	0	0
05	Ulceration (Vrana)	0	00	-	-	-	-	-	-	-
		1	12	1	1	0	0	0	0	0
		2	10	2	2	1	1	0	0	0
		3	08	3	3	2	2	1	0	0
06	Redness (Lalima)	0	01	0	0	0	0	0	0	0
		1	13	1	1	0	0	0	0	0
		2	09	2	2	1	0	0	0	0
		3	05	3	3	2	1	0	0	0

Symptoms relief percentage

Sr. No.	Symptom	BT	AT	Difference	Percentage of relief
1	Pain	63	10	53	84.12
2	Burning	63	7	56	88.83
3	Salivation	60	5	55	91.66
4	Dysphagia	64	8	56	87.5
5	Ulceration	57	8	49	85.96
6	Redness	46	5	41	89.13
	Total	350	43	307	87.71

All the values in following tables are calculated by using Mann-Whitney test for subjective criteria. Statistical analysis of every symptom is described separately in the following tables showing comparison between two groups with respect to symptoms score by "Mann-Whitney test". By applying Mann-Whitney test for comparison of both groups, it is observed that P value is more than significant level $\alpha = 0.05$, hence we should accept the null hypothesis H_0 and reject

the alternative hypothesis H_a for all symptoms. That means both groups are equally effective in relieving these symptoms. Table showing effect of treatment Triamcinolone acetonide 0.1% oral gel on symptoms score of 30 patients of "Mukhpak" in "Group A". Table showing effect of treatment Jatipatra on symptoms score of 30 patients of "Mukhpak" in "Group B".

Effect of Therapy on Symptoms score: It was observed that, over all percentage of relief was more in "Group B" (97.42%)

than „Group A“ (87.71%). Table showing total effect of therapy in 60 patients of „Mukhpak“. In Case of „Group A“ of Triamcinolone acetonide 0.1% oral gel out of 30 patients, 8 patients (26.66%) were Cured, 19 patients (63.33%) were Highly Improved, 3 patients (10%) were moderately improved.

Jatipatra with its Tikta, Kashay properties provides good remedial sign and symptoms. According to various Nighantus, Jati with its tikta, kashay ras, virya ushna and katu vipak. It is kaphpittnashak. According to Acharya Sushrut there are 3 types of mukhpak. Vataj, Pittaj, and Kaphaj mukhpak.

Effect of Therapy on Symptoms score

Sr. No.	Symptom	BT	AT	Difference	Percentage of relief
1	Pain	64	3	61	95.31
2	Burning	56	1	55	98.21
3	Salivation	60	1	59	98.33
4	Dysphagia	63	2	61	96.82
5	Ulceration	56	1	55	98.21
6	Redness	51	1	50	98.03
	Total	350	9	341	97.42

Total effect of therapy

Sr. No.	Total effect of therapy	Group A		Group B		Total	
		No. of pts.	%	No. of pts.	%	No. of pts.	%
1	Cure (100%)	8	26.66	21	70	29	48.33
2	High improvement (>75% relief)	19	63.33	9	30	28	46.66
3	Moderate improvement (>50-75% relief)	3	10	0	0	3	5
4	Mild improvement (>25-50% relief)	0	0	0	0	0	0
5	Unchanged (<25% relief)	0	0	0	0	0	0

Comparison between two groups by Chi – square test

Sr. No.	Group	Cure	Highly Improved	Moderately Improved	Total	Chi-square Value
1	Group A	O=8 E=14.5	O= 19 E= 14	O=3 E=1.5	30	12.399, P=0.002
2	Group B	O=21 E=14.5	O= 9 E=14	O=0 E=1.5	30	

In Case of „Group B“ of Jatipatra out of 30 patients, 21 patients (70%) were cured while remaining 9 patients (3%) were in highly improved category. Out of total 60 patients, 29 patients (48.33%) were cured, 28 patients (46.66%) were highly improved and 3 patients (5%) were in moderately improved category. All patients in this study were improved more than 50%. Comparison between two groups was statistically evaluated by chi- square test. The value 12.399 at 2 degrees of freedom, P=0.002 which is statistically significant which suggest that Group B was more effective than Group A.

RESULTS

Effect of the TRIAMCINOLONE ACETONIDE 0.1% ORAL GEL (Group A) and JATIPATRA (Group B) on symptoms observed in Mukhpak is statistically proved to be significant. Comparison between two groups by Mann-Whitney test, there is no significant differences found between two groups i.e. both groups are equally effective. Comparison by chi-square test shows Group B is More effective than Group A. From above statistical calculations it was observed that Jatipatra is more effective than Triamcinolone acetonide 0.1% oral gel treatment to relieve Mukhpak.

DISSUCSSION

Mukhpak affects an accountable population and involves whole oral cavity. No remedial measures for the prevention and care of this pathology. In modern treatment local applications have limitation. This challenge of time was accepted by Ayurveda. Chief complaints in Mukhpak are pain, ulceration, daha (burning sensation), dysphagia. Hence treatment with chewing jatipatra upto salivation is given.

According to Acharya Vagbhata Mukhpak is of 5 types. In Shargandharsamhita Mukhpak is described in 8 types. After going through various literature, the main sign and symptoms of Mukhpak are as follows.. Aruchi, Daha, Pain, Ulceration, Dysphagia, Kandu. It is as a result of raktadushti (ch.sutra.10/14). Also improper administration of vaman, virechan, dhumpān siravedh etc are considered as itraogenic cause of rakta and pitta dushti. Inadequate oral hygiene is also a prime cause. Excessive intake of anupmas, milk, yogurt give rise to kaphaprakop, pittaprakop, and these viated dosha cases mukhroga. Various treatments have been suggested for mukhpak by various Acharya, according to Charak, nasya, vaman, virechan, siravedh are mode of treatments. In local treatment kawal, gandush, pratisaran, charvan are there. Our study was divided in two groups, one group is receiving local application of triamcinolone acetonide 0.1% and other group is receiving Jatipatra for charvan uptill salivation and then spitting out. Here in this study, we had given jatipatra for chrvan upto salivation, and then spitting out, so probably it may complete its action by-

- Shodhan (cleaning)
- Stimulation of salivary glands
- Absorption

By shodhana- regaining oral hygiene- it may stimulate salivary gland and promotes the defence mechnisam by increased salivation at immune level.

Absorption: Tikta, kashay rasa, and phytochemical constituent of jatipatra get absorbed in epithelium, and promotes healthy oral cavity. As sign, symptoms appears

patients visited within a week or before 7 days are 80%, and 20% patients after 7 days of appearance of sign and symptom.

Frequency Analysis of Clinical Data

For the following attributes, data across following points : before treatment, 1st day, 3rd day, 6th day, 10th day, 14th day after treatment follow up on 20th and 30th day were collected and compared using test for repeated measures.

Statistical Analysis for Clinical Data

It was observed that there is improvement in the symptoms before and after the treatment in case of pain, burning, excessive salivation, dysphagia, ulceration, redness.

In group A out of 30 patients 8 cured (26.66%)

19 patients - highly improved (63.33%).

3 patients - moderately improved (10%).

In group B -21 patients cured (70%).

9 patients highly improved (30%).

Comparison between two groups was statistically evaluated by chi square test. The value 12.399 at 2 degree of freedom, P = 0.002 which is statistically significant, which suggests that Group B was more effective than Group A.

Conclusion

The data suggest that pain, burning sensation, dysphasia, ulceration, excessive salivation can be effectively countered by Jatipatra. Statistical test proves that Jatipatra is more effective than Triamcinolone acetonide 0.1% on Mukhpak.

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