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Preliminary clinical study to evaluate *jatyadi ghrita* suppository in the management of *parikartika* with special reference to fissure-in-ano.

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ABSTRACT

The earliest reference of *Parikartika* was available in *Acharya Charaka, Sushruta and Kashyap Samhita*. In modern point of view, it can be correlated with Fissure-In-Ano. Now a day, in Modern technological era, due to changing life style, consumption of fast foods, improper sleep habits may ultimately results into irregular bowel movements and constipation leads to the passage of hard stool and finally it causes erosion and deep tear through the skin of the anal margin extending into anal canal, which named as *Parikartika* i.e. Fissure-In-Ano.

In this study total 10 patients of *Parikartika* having signs and symptoms of same, selected from Arogyashala Rugnalaya OPD of Shalyatantra Department. The patients were treated with self-made "*Jatyadi Ghrita* Suppository" per anus for 10 days daily.

Assessment was done on the basis of criteria such as burning sensation, pain, spasm, and itching.

The better result was observed in reduction of burning sensation, pain, spasm and itching after treatment.

Key words: *Parikartika, Jatyadi Ghrita, Suppository, Fissure-In-Ano*

INTRODUCTION

In the quest to find a good life in 21st century, we often unknowingly host a number of diseases. Over the years, the unmarkable change in our food habits has made certain pathological conditions overwhelmingly common to us. One such painful disease of this group is the *Parikartika* i.e. Fissure-In-Ano.

A Fissure simply means a crack or an opening or a furrow or a tear on the normal smooth surface. This when a tear

occurs near the anus, it is called as Fissure-In-Ano. Most commonly it occurs at the midline of the posterior wall of anus ⁽¹⁾, sometimes at the anterior wall and exceptionally at other site too.

Fissure-In-Ano is a very painful condition. The *kartanvat Vedna* ⁽²⁾ or cutting like pain takes a huge toll of daily normal living especially if you have a sitting or desk job. A minor trauma to the inner anal lining along with hard and dry bowel (also loose and diarrheal bowel) is enough for an acute Fissure-In-Ano. If neglected or improperly or incompletely treated, it becomes chronic or develops a hook like tag called Sentinel piles.

Stool softeners, local anesthetics, sitz bath and dietary changes do help in treating the Fissure-In-Ano. Surgical interventions are also not required in majority of fissures because of some demerits like incontinence, infection, and recurrence, etc. but the '*Guda*' ⁽³⁾ one of the *Sadyapranahara marma*, must be treated holistically to averse any future complications.

Hence "*Jatyadi Ghrita Suppository*" was chosen for the study. *Jatyadi Ghrita* is made up of *Ghee* and several drugs with various properties including *Nimb*, *Japa*, *Patola*, *Manjishta*, *Haridra*, *Daru-haridra*, *Anantamula*, *Haritaki*, *Yashtimadhu*, *Kutaki* acts as *Vatanashaka* and *Vranaropana* properties and used to cure *Marmapradeshi vrana* described by *Acharya Vagbhat* as below ⁽⁴⁾

जातीनिम्बपटोलपत्रकटुकादावीनिशासारीवा-
मंजिष्ठाभयसिक्थतुत्थमधुकैर्नक्ताह्वीजान्वितैः।
सर्पिः साध्यमनेनसूक्ष्मवदनामर्माश्रिताः क्लेदिनो
गम्भीराः सरुजोव्रणासगतयः शुद्ध्यन्तिरोहन्ति च॥
अ.ह.उ. २५/६७

Hence an effort has been made to evaluate "*Jatyadi Ghrita Suppository*" in the management of *Parikartika* with special reference to Fissure-In-Ano.

AIMS AND OBJECTIVES

To study the efficacy of *Jatyadi Ghrita* Suppository in the management of *Parikartika* with special reference to Fissure-In-Ano.

MATERIALS AND METHODS

Total 10 patients of *Parikartika* were selected from OPD and IPD of *Shalyatantra* Department with informed written consent of each patient. All the patients had completed the course of treatment with *Jatyadi ghrita* suppository per anus daily for 10 days. All the symptoms like burning sensation, pain, spasm, itching recorded daily in the proforma designed especially for this study.

■ Inclusive criteria

1. Patient of both sexes.
2. Patients of age group 16 to 70yrs.
3. Patient diagnosed as *Parikartika* with sign and symptoms like- Pain in anal verge, burning sensation, itching, spasm, H/o- constipation, rectal bleeding.

■ Exclusive Criteria

1. Patient who is not willing to participate in clinical trial.
2. Patient who were suffering from CA of ano rectum, congenital anal stricture, congenital anal stenosis.

WITHDRAWAL CRITERIA FOR STUDY

- 1) Patient willing to discontinuous treatment.
- 2) Patient lost for two consecutive follow ups during treatment.
- 3) If any adverse effects are noted while conducting clinical criteria, such patients are excluded from study. Subsequent replacement of the patient was done which are not fulfilling the selection criteria.

▪ **Materials**

a) **Formulation composition⁽⁵⁾**

Sr. no.	Ingredients (Sanskrit Name)	Ingredients (Latin Name)
1	<i>Jati patra</i>	<i>Jasminum officinale</i> var. <i>grandiflorum</i>
2	<i>Nimba patra</i>	<i>Azadirachta indica</i>
3	<i>Patola patra</i>	<i>Trichosanthes dioica</i>
4	<i>katuka</i>	<i>Picrorhiza kurroa</i>
5	<i>Daru haridra</i>	<i>Berberis aristata</i>
6	<i>Haridra</i>	<i>Curcuma longa</i>
7	<i>Sariva</i>	<i>Hemidesmus indicus</i>
8	<i>Manjishta</i>	<i>Rubia cordifolia</i>
9	<i>Abhaya</i>	<i>Vetiveria zizanioides</i>
10	<i>Siktha</i>	Bees wax
11	<i>Tuttha</i>	Copper sulphate
12	<i>Madhuka</i>	<i>Glycyrrhiza glabra</i>
13	<i>Karanja</i>	<i>Pongamia pinnata</i>
14	<i>Sarpi</i>	Clarified butter from cow's milk
15	<i>Jala</i>	Water

b) **Method of Preparation⁽⁶⁾**

- Taken all the ingredients of pharmacopoeial quantity.
- Washed green leaves of ingredients 1 to 3 of the formulation composition were taken in and *kalka* was prepared.
- Decoction was prepared according to *Sharangdhara Samhita's* by using clean, dry powdered of ingredients 4 to 9 and 12 to 13 transferred to the wet grinder with paste of ingredients number 1 to 3 and 11. These ingredients then grind with enough quantity of water to prepare a homogeneous blend (*kalka*).

▪ **Ghrita Paka-**

Murcchita ghrita was taken in a stainless-steel vessel and heat it mildly. Then above prepared *kalka* were added in the *ghrita* and stir thoroughly while adding water in the ratio of 1:4. *Ghrita* was prepared on *mandagni* for about 3 hours with constant stirring maintaining the temperature between 50° and 90° during the first hour of heating. Stopped heating and allowed to stand overnight. Started heating on next day, observed the boiling mixture for subsidence of froth and *Ghrita siddha lakshna* was checked. *Ghrita* then filtered using muslin cloth and small pieces of *Siktha* were added.

The *Ghrita* was measured and packed it in tightly closed glass containers to protect from light and moisture.

c) **Preparation of Suppository**

Jatyadi ghrita suppositories are prepared by molding method. These are made up of *Jatyadi ghrita* and cocoa

butter in the proportion of 1:3. Cocoa butter and *ghrita* were melted at 40°C and mixture then poured into the chilled molds. After solidification in fridge the bullet shaped suppositories are formed. These suppositories are packed and kept in fridge to maintain its shape.

Investigation

Following investigation were carried out for patients treated with the proposed study.

1) Stool routine microscope (if required)

Follow up study

0th, 5th 10th day

- **Weight-** 1gm

- **Dose-** 2 suppositories at a time, kept after defecation in morning and before going to bed at night.
- **Route of Administration-** Per anus
- **Melting point-** 30-35°C ⁽⁷⁾
- **Images shown below-**

Fig-(a) represents: Materials required for preparation of suppository.

Fig-(b) represents: Chilled molds filled with mixture.

Fig-(c) represents: Prepared *Jatyadi ghrita* suppositories.



Fig-(a)

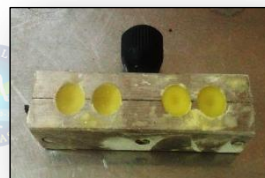


Fig-(b)



Fig-(c)

CRITERIA FOR ASSESSMENT

All the patients selected for the current study were assessed on following parameters during treatment.

Burning sensation

Grades	Features
0	No burning sensation
1	Burning sensation lasts for 1 hrs. after defecation
2	Burning sensation lasts for 4-5 hrs. after defecation
3	Unbearable burning sensation after and before defecation

Pain

Grades	Features
0	No pain
1	Pain for 1 hrs. after defecation
2	Pain for 4-5 hrs. after defecation
3	Unbearable and continuous pain

Spasm

Grades	Features
0	No spasm
1	Mild spasm
2	Moderate spasm
3	Severe spasm

- **Itching**

Grades	Features
0	Absent
1	Mild (occasionally in a day)
2	Moderate (intermittent itching)
3	Severe (continuous itching throughout the day)

RESULT AND OBSERVATION

In this preliminary clinical study total 10 patients were treated with *Jatyadi ghrita* suppository per anus daily for 10 days. All of them have regular follow up. A special case proforma made for clinical study. Separate criteria for assessment were prepared for them. The data collected observed, summarized and results were presented in the form of percentile relief. Following observations were made during the study:

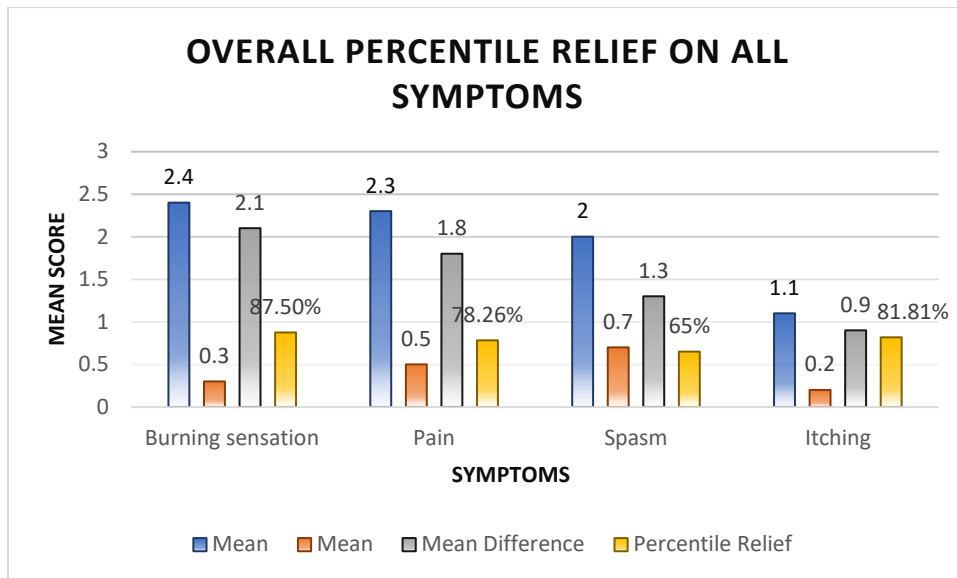
OVERALL PERCENTILE RELIEF ON ALL SYMPTOMS

Sr. No.	Symptoms	Mean		Mean Difference	Percentile Relief
		BT score	AT score		
1	Burning sensation	2.4	0.3	2.1	87.5%
2	Pain	2.3	0.5	1.8	78.26%
3	Spasm	2.0	0.7	1.3	65%
4	Itching	1.1	0.2	0.9	81.81%

In this study it is found that the signs and symptoms reported by the patients showed significant reduction in Burning sensation (87.5%), Pain (78.26%), Spasm (65%), and Itching (81.81%). there was significant improvement observed in all the parameters like Burning sensation, pain, spasm, and itching

TOTAL EFFECT IN PERCENTAGE

Total effect of *Jatyadi ghrita* suppository therapy shows **78.14%** relief in all the symptoms of patients enrolled for preliminary study. This shows the effect of *Jatyadi ghrita* suppository in *Parikartika* with special reference to Fissure-In-Ano is better.



DISCUSSION

• Discussion on observation-

The objective of the study was to evaluation of *Jatyadi ghrta* suppository in the management of *Parikartika*. In this study total 10 patients were registered and treated with *Jatyadi ghrta* suppository per anus for daily 10 days. All the patients having better result from the clinical features i.e. mentioned in assessment criteria has been discuss as follows-

• Discussion on Total effect of therapy-

1) Burning sensation

After studying all data thoroughly, in 10 patients of- 87.5% relief was observed from burning sensation.

2) Pain

In these criteria, in 10 patients of- 78.26% relief was observed from pain.

3) Spasm

In these criteria, in 10 patients of- 65% relief was observed from spasm.

4) Itching

In these criteria, in 10 patients of- 81.82% relief was observed from itching.

5) Overall effect of therapy

In this study above all mentioned criteria it was observed that in 10 patients, 78.14% patients showed significantly better results of *Jatyadi ghrta* suppository in the management of *Parikartika* w.s.r. to Fissure-In-Ano.

• Discussion on probable mode of action of *Jatyadi ghrta* suppository-

The suppository dissolves to release the drug once inside the body and travel to other parts of the body through the bloodstream⁽⁸⁾. In these studies the most of the ingredients of *Jatyadi ghrta* are acts as *Vatanashaka* and *Vranaropana* properties⁽⁹⁾. It's *Shodhana* and *Ropana* properties help in reducing the inflammation of the anal mucosa, discharge and pain. The *Goghrta* used as content of *Jatyadi ghrta* has "Sanskar Anuvartana" property⁽¹⁰⁾, the *Yogavahi guna* of it carries the active principle of the drugs at the level of body tissue. According

to modern point of view lipophilic action of *ghrita* facilitates transportation to a target organ and finally delivery inside the cell because cell membrane also contains lipid ⁽¹¹⁾. As *Jatyadi ghrita* includes the ingredients like *Nimb*, *haridra*, *Daru haridra*, *Karanj* are *krimighna* by its *prabhava* and hence work as Anti-microbial property ⁽¹²⁾. *Manjishta*, *Sariva*, *Karanj* possesses *Vranashodhana* property. *Jati*, *Patola* and *Siktha* are having the *Vranaropana* action ⁽¹³⁾. *Yashtimadhu* has soothing and healing action on skin lesions typically. *Tuttha* i.e. copper sulphate induces vascular endothelial growth factor appearance in the wound or ulcer ⁽¹⁴⁾.

In the pathology of *Parikartika* i.e. Fissure-In-Ano already there is indulgence of various etiological factors leads to deep tear through the skin of the anal margin which later results into inflammation, induration or edema of its edges accompanying spasm of the anal sphincter muscle ⁽¹⁵⁾. Hence in *Parikartika*, it is found that the use of self-made ***Jatyadi Ghrita Suppository*** exerts localized effect over the anal mucosa. The melting of *Jatyadi ghrita* suppositories inside the bad passage lubricates and soften the faecal matter. The oily and sticky property of it keeps the ulcerated surface wet and thereby, facilitates healing by its best *Vranaropana* property.

CONCLUSION

As stated in the discussion part, after careful assessment the effect on individual parameters and overall response *Jatyadi ghrita* suppository

seems to be more effective, simple treatment modality for *Parikartika* i.e. Fissure-In-Ano without any adverse effects.

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