



# Research Article

# EFFECT OF YASHTIMADHU SUPPOSITORY WITH COCOA BUTTER BASE IN THE PAIN MANAGEMENT OF PARIKARTIKA

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# ABSTRACT

Parikartika is one of the common ano-rectal anomalies observed in clinical practise. In Avurveda Samhitas, this condition is mostly mentioned as an Upadrava of Grahani, Atisara, Arshas and as Vamanavirechanavyapat. 'Kartanavatvedhana' is described as predominant symptom of *Parikartika* which means cutting type of pain in the anus. As per the description of signs and symptoms, Parikartika can be co-related to fissure-in ano in modern contexts. Yashtimadhu is the most widely used drug for Parikartika. Acharya Susruta has mentioned the drug *Yashtimadhu* in *Trividhakarma Adhyaya* in post-operative pain management and in treatment for Parikartika in Vamana virechana vyapat. Yashtimadhu in the form of Thaila and Ghrita are commonly used. Here, Yashtimadhuchurna was used to prepare a suppository with cocoa butter as its base for the management of *Parikartika*. **Objectives:** The objective of the clinical study is to evaluate any difference in the efficacy of Yashtimadhu suppository in treating *Parikartika*. Materials and Methods: The study was conducted as an open labelled, randomized, single arm clinical study. 40 Patients who are fulfilling the inclusion, exclusion, diagnostic criteria and complying with the informed consent was selected from OPD and IPD of Sri Jayendra Saraswathi Ayurveda College and Hospital [IEC NO- IEC/ SJSACH/ 09/2021, CTRI NO- CTRI/2021/07/035252]. Case proforma was prepared with all the appropriate details of the patient along with history and physical, rectal examination was done to diagnose Parikartika. Relevant laboratory investigations were performed. Yashtimadhu suppository was given twice per day for about 14 days to 40 patients along with 4 follow-ups once a week for one month after the treatment i.e., 7th, 14th, 21st, 28th day. The subjective parameter was pain and objective parameter were ulceration, sphincter tone. Grading was done according to the specified assessment criteria and was statistically analysed. Results: On completion of the study, statistical analysis was done on the data collected. The intervention, Yashtimadhu suppository showed significant difference in the outcome.

# **INTRODUCTION**

Ayurveda is the 'science of life' which gives eternal health and longevity. There are eight branches of Ayurveda. According to *Acharya Susrutha, Shalya Tantra* is the vital part that deals with the removal of all types of *Shalya* or pain causing factors from the body.

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Parikartika is the very painful ano-rectal condition which is not mentioned as a separate entity, but it is mentioned as complication, signs and symptoms of certain conditions. Parikartika is derived from root word "Parikrit" which means to cut around whereas Pari means all around and Kartanam means the act of cutting.<sup>[1]</sup> The associated symptoms are burning sensation, bleeding while defecating.

Pain is the most troublesome discomfort in day to day life. *Parikartika* can be co-related to fissure-in ano, as the name indicates there will be crack in the mucosa of anus lining that affects majority of the population irrespective of the age and gender. Anal fissure is the mere modern terminology for *Parikartika*. In anal fissure there will be crack in the mucosal lining of the anus associated with cutting type

of pain, burning sensation and bleeding, elongated ulcer. 95% of anal fissures in men are posterior, 5% are anterior. 85% of anal fissures in females are posterior, 20% are anterior. Anterior anal fissures are common in females.<sup>[2]</sup> Fissure-in ano is classified into two based on severity- Acute and Chronic which occurs due to several etiological factors like constipation, passing hard stools. Acute fissure is a deep tear in the anal canal with surrounding oedema and inflammatory induration. It is associated with spasm of the anal sphincters. Acute fissure in later stage, lead to chronic fissure, it will gradually develop into a deep undermined ulcer with continuing infection and oedema. This ulcer stops above at the pectinate line. Below, there will be hypertrophied anal papilla and skin tag known as sentinel pile. This is a longitudinal ulcer in the anal canal posteriorly situated in majority of cases.[3] Patients who are suffering from *Parikartika* will suffer severe cutting type of pain in the anus which affects their day to day routine. The people affected have to endure severe pain, burning sensation, on and off bleeding while passing stools, slight difficulty along with pain in sitting posture, feeling like as if they are passing 'shards of glass or razor blades'[4]. This ano-rectal disease can affect all the age group irrespective of gender. In Ayurveda Parikartika is not mentioned as a separate entity but mentioned in different contexts. *Parikartika* is mentioned as *Upadrava* of *Vatikapakwaatisara*,[5] Arshas<sup>[6]</sup> and Udavarta.<sup>[7]</sup> The condition is also stated in Arshapurvarupa<sup>[8]</sup> and Vamanavirechanavvapat.[9] Acharva Dalhana mentioned it as cutting and tearing pain.[10] According to Acharya Charaka, Parikartika is the sharp cutting or sawing pain with bloody mucosal discharge along with discomfort in peri-anal region. The pain will persist before and after defecation as per Acharva Susruta. classified Acharva Kashyapa Parikartika into three types – Vataja, Pittaja, Kaphaja. The pain is classified according to the Doshik predominance<sup>[11]</sup>. Various treatment modalities have been mentioned for *Parikartika* in both Avurvedic and allopathic system of medicine. In Allopathic practice, common treatments of fissure-in ano are oral pain medication, laxatives, local anaesthetic agents which may cause side effects if used continuously. Surgical procedures mentioned are Lord's anal dilatation, fissurectomy, sphincterotomy for fissure-in ano<sup>[12]</sup>. As pain killers have its own complications like side effects. reoccurrence and most of the surgeries lead to postoperative pain, Ayurvedic treatment for Parikartika is beneficial and more effective. The cutting pain and burning pain are the cardinal symptom of *Parikartika*. Hence the involvement of Vata and Pitta Dosha is evident. So, formulations which are having the potency of Vata Pitta Shamaka, Vrana Ropaka can be used locally for better relief. According to Ayurvedic treatment modalities, Acharya Susruta has mentioned

the drug Yashtimadhu in Trividhakarma Adhyaya in post-operative pain management<sup>[13]</sup> and in treatment for *Parikartika* in *Vamanavirechanavyapat*<sup>[14]</sup>. Many research works are done in managing Parikartika using Yashtimadhu as Taila and Ghrita along with other ingredients like Dhatri, Tila and Ksheera. Yashtimadhu having its properties such as Vedanasthapana, Shonithsthapana. Rasavana, Vranashodhana Ropanagunas<sup>[15]</sup> will be helpful to alleviate the pain in Parikartika. This study is mainly concentrated in the pain management of Parikartika. No study has been conducted by using Yashtimadhu churna as a single drug in suppository form with cocoa butter as its base. Anal suppository is a small capsule like formulation designed for insertion into anus, where it will get melted and absorbed. Suppositories are the simple formulation which is easy to administer, easy to prepare, cost effective. This study is to determine the effect of Yashtimadhu churna as a suppository form which Vedhanasthapana, Shonithsthapana, has Vranashodhana, Ropana, Vranashothahara properties in the pain management of *Parikartika*.

# **AIMS AND OBJECTIVES**

- To review the available literature of *Parikartika* in Ayurvedic contexts.
- To review the available literature of fissure-in ano in modern view.
- To evaluate the effect of Yashtimadhu Churna with cocoa butter as a suppository in management of pain in Parikartika.
- H<sub>0</sub> *Yashtimadhu* suppository will not be effective in the management of pain in *Parkartika*.
- H<sub>1</sub> *Yashtimadhu* suppository will be effective in the management of pain in *Parikartika*.

# **MATERIALS AND METHODS**

#### Study Design

A randomized open labelled single arm clinical study.

#### Source of Data

Information was collected from Ayurvedic classic literatures– *Bruhtrayees, Laghutrayees,* other Ayurvedic available texts. Modern literatures, relevant contemporary literature along with the pertinent, past and present research works.

# Source of Drug

Yastimadhu Churna was procured and prepared from the SJSACH pharmacy. Drug authentication was obtained from Department of Dravya Guna before starting the clinical trial. Raw cocoa butter was purchased at local vendor.

## **Selection of Patients**

40 patients who are fulfilling the inclusion, exclusion, diagnostic criteria and complying with the informed consent was selected from OPD and IPD of Sri Jayendra Saraswathi Ayurveda College and Hospital.

# Drug Review Ingredients

• Yashtimadhu Sukshma Churnam

• Cocoa butter

Yashtimadhu<sup>[16]</sup>

Botanical Name: Glycyrrhiza glabra

Family Name: Fabaceae Classical name: *Madhuyasti* 

Sanskrit names: Madhuyasti, Yastimadhu-

Yastimadhuka, Madhuka, Klitaka-Klitanaka.

Charaka described two varieties of Yashti-Anupaja and Sthalaja. Charaka included Kleetaka under Phalini Varga. In Nighantu, Kleetanaka and Madhulika are the synonyms given for Jalaja-Yashti. Kaviraj Virajacharana opines that Yashti is the only one plant and according to its distribution people classified this into different varieties.

Chakrapani qotes the opinion of Sushruta according to which laxative property is attributed to fruit of *Yashti* though root is extensively used. *Charaka* attributes *Medhyarasayana* action to *Yashti-churna*. In Unani system of medicine *Yashtimadhu* is categorized under 3 varieties – *Misariya*, *Arabiya*, *Turushkiya*.

Table 1: Yashtimadhu Ingredients

Kula	Shimbikul		
Upakula	Aparajitha		
Upakula Gana	Khantya, Jivaniya, Sandhaniya, Varnya, Kanthya, Kandugna,		
Acharya Charaka	Mutravirechaniya, Shonithsthapana, Chardinigrahana, Snehopaga,		
	Vamanopaga, Asthapanopaga, Purishavirajaniya, Dahaprasamana		
Acharya Susrutha	Kakolyadi, Sarivadi, Anjanadi, Vachadi, Brihatyadi, Utpaladi,		
	Nyagrodhadi		
Rasa	Madhura		
Guna	Guru, Snigdha		
Virya	Sheeta muniliaprin a		
Vipaka	Madhura Madhura		
Dosa Karma	Vata Pitt Ahara		
Sthanika Karma	Doshasamaka Keshya, Vedhanasthapana, Shoth Ahara, Chedana,		
(Bahya)	Vranaropana		
Dhatu Karma	Balavarnakrit, Cakshushya, Vrishya, Rasayana, Raktapradhana		
Roga Karma	Chardi, Sosha, Trsna, <mark>Vrana</mark> shodana, Vatarakta, Sadhyovrana, Kshata		

# **Major Chemical Components**

Glycyrrhizin, Glycyrrhizic Acid, Glycyrrhetinic Acid, Liquirtin, Isoliquirtin, Neoisoliquirtin, Liquiritogenin, Isoliquiritogenin, Glabrine, Licuraside, Licochalcones A & B, Hispaglabrine A & B, Licoricidin, Glabrene, Liquiritic Acid, Glabrolide.

- Glycyrrhizin showed anti-arthritic and antiinflammatory effect on formaldehyde-induced ratpaw oedema in adrenalectimized rats. It was found to potentiate the anti-arthritic action of hydrocortisone in rats (Gujral et al., 1961a).
- The anti-inflammatory activity of glycyrretic acid and its diacetate was similar to that of hydrocortisone on formalin-induced arthritis in albino rats (Tangri et al., 1964).
- Glycyrrhetic acid protected guinea pig against bronchospasm induced by histamine or 5-HT. It significantly lowered plasma corticosterone concentration although adrenal weight remained unaltered (Tangri et al., 1968).
- The oral administration of powdered root in 5 cases of pemphigus, who had been kept free from bullae with prednisolone, could considerably reduce the

- dose of prednisolone without reappearance of the lesions (Saxena et al; 1965a).
- The anti-inflammatory response of G.glabra was found to be equivalent to that of oxyphenbutazone.
  It appeared to possess a more potent anti-pyretic and anti-exdative activity in comparison to oxyphenbutazone (Saxema et al; 1970).
- Glyayrrhizin showed a significant anti-diuretic effect in rats and rabbits on oral and parenteral administration (Gujral et al; 1961c).
- Glycyrrhetinic acid drops were found to be of definite therapeutic value on 32 cases of allergic conjunctivitis both in acute and chronic cases (Saxena et al; 1965b).
- Glycyrrhetic acid showed an antipyretic activity similar to that of sodium salicylate on rectal temperature of normal and pyretic rats (Saxena & Bhalla. 1968)

#### Cocoa Butter[17]

# **Synonyms**

Theobroma oil, cocoa butter, cocoa beans, semina theobromatis.

# **Biological Source**

It is obtained from roasted seeds of Theobroma cacao Linn. belonging to family Sterculiaceae.

# **Geographical Source**

Cocoa is cultivated in Brazil, Sri Lanka, Philippines, Curacao, Mexico, West Africa (Ghana, Nigeria) and some parts of India.

# **Description**

Cocoa butter is the fat from the Theobroma cocoa. It may be obtained either by expressing the oil from the seeds or by the solvent extraction. Chemically, it is a mixture of triglycerides of saturated and unsaturated fatty acids, primarily stearic, palmitic, oleic, lauric, and linoleic. It is solid in room temperature but melts at the body temperature with the melting point of 31 degree to 34°C. The specific gravity of the melt is 0.858 to 0.864. Cocoa butter is non-irritant to sensitive membrane tissues. It is also an excellent emollient and is used alone or in topical skin products for this property. Cocoa butter has a solidification temperature 12°C to 13°C below its melting point. This makes it easy to pour suppositories before the base solidifies<sup>[18]</sup>. In many previous Research works in Ayurveda, cocoa butter has been used for the preparation of suppository.[19, 20]

# **Preparation**

- Cocoa seeds contain nearly 50% of cocoa butter.
- The seeds are separated from pods and are allowed to ferment.
- Fermentation process takes place at 30-40 degree Celsius in tubes, boxes or in the cavities made in the earth for three to six days and during fermentation the colour of the seeds changes from white to dark reddish brown due to enzymatic reaction.
- If the seeds are not subjected for the process of fermentation and dried in sun, then they are more astringent, bitter tasting and of less value.
- After fermentation, the seeds are roasted at 100-140 degree Celsius to remove acetic acid and water present in the seeds and facilitate removal of seed coat also.
- The seeds are cooled immediately and are fed into nibbling machine to remove the shells followed by winnowing.
- The kernels are then fed into hot rollers which yield a pasty mass containing cocoa butter.
- The pasty mass is further purified to give cocoa butter.

#### **Characteristics**

Cocoa butter is yellowish white solid and brittle below 25 degree Celsius. It has pleasant chocolate odour and taste. It is insoluble in water but soluble in chloroform, petroleum ether, ether and benzene. Specific gravity ranges from 0.858 to 0.864, melting point between 30 degree Celsius and 35 degree Celsius, refractive index varies from 1.4637 to 1.4578, saponification value is 188-195 and iodine value 35-40.

# **Chemical Constituents**

It consists of glycerides of stearic (34%), palmitic (25%), oleic acid (37%) acids, and small amount of linoleic acids and arachidic acid. Glyceride structure is responsible for non-greasiness of product.

#### Uses

It is used as an emollient, as a base of suppositories and ointments, manufacture of creams and toilet soaps. It reduces the formation of stretch marks during pregnancy by keeping the skin supple. It is used as an ingredient in lotion bars, lip balms, body butters, soaps and belly balms for expectant mothers.

# **Drug Preparation**

For the preparation of suppository, cocoa butter was melted by double boil method. Then *Yashtimadhu Churna* was added to it in the ratio 2:1. The formulation is then poured in the mould of anal suppository which is cone shaped and measures around 2-4cm length and refrigerated at 3 to 5 degree. Suppositories were stored in an aseptic environment. It was used whenever needed after bringing it to normal room temperature.

#### **Procedure Review**

- Patients who are under inclusion criteria, who signed in the consent form was selected
- The procedure that has to be done was explained to the patient
- Patient was made to lie in lithotomy position.
- Inspection, palpation was done
- Digital examination: It was done wearing disposable gloves. Patient was instructed to open his/her mouth and breathe in and out deeply.
- Patient's anus was cleaned with antiseptic solution.
- *Yashtimadhu* suppository was inserted into the anus after defecation and covered with cotton swab.

# Diagnostic Criteria

Based on the history and per rectal examination findings, sign and symptoms—cutting type of pain, pain during defecation, passage of bright streaks of blood along with stool or seen in the tissue paper, tight sphincter tonicity, *Parikartika* was diagnosed.

# Plan of the Study

# **Inclusion Criteria**

- Patient diagnosed with Parikartika/fissure-in ano
- Irrespective of gender and age

#### **Exclusion criteria**

- · Crohn's disease
- Congenital anomalies of rectum, anal canal
- All malignancies, all sexually transmitted diseases
- AIDS, TB, Hepatitis B
- Uncontrolled diabetes mellitus, hypertension.

#### **Assessment Criteria**

- Pain
- Ulceration in anus
- Tight sphincter tone

# **Subjective Criteria**

Pain was assessed based on the following scoring pattern.  $^{[21]}$ 

- 0 No pain
- 1 Pain remains only during defecation
- 2 Pain remains 1-2 hours after defecation
- 3 Pain remains 4-6 hours after defecation
- - Pain remains 24 hours

# **Objective Criteria**

# **Ulceration in Anus**

• 0 – No tearing

- 1 Mucosal tearing less than 1cm
- 2 Mucosal tearing greater than 2cm
- 3 tearing upto pectinate line

# **Sphincter Tone**

During P/R examination,

- 0 Index finger insertion to anal canal without any pain or discomfort
- 1 able to admit index finger with tolerable pain
- 2 able to admit little finger with tolerable pain
- 3 Pain by touching perianal area. Not possible to perform examination<sup>[22]</sup>

# **Duration of the Study**

*Yashtimadhu* suppository was administered daily twice for a period of 14 days.

# Follow up

Follow up for once a week for one month–  $7^{th}$ ,  $14^{th}$ ,  $21^{st}$ ,  $28^{th}$  day.

# Investigation

- Hb %
- TC
- DC
- ESR
- HIV
- HbsAg

# Pain

Effect of Yashtimadhu Suppository on Subjective and Objective Parameters

Chi-Square **Mean Rank** P Value Pain day 1 7.95 Pain day 5 6.98 Pain day 10 5.63 Pain day 14 3.38 254.601 < 0.001 Pain 1st follow up 3.03 Pain 2nd follow up 3.03 Pain 3rd follow up 3.01 3.01 Pain 4th follow up

Table 2: Assessment on the Effect of Yashtimadhu Churna Suppository on Pain

There was a statistically significant difference in pain with treatment,  $\chi 2$  (2) = 254.601, p = <0.001. The mean rank has a steady fall from day1 to 4<sup>th</sup> follow up. Pain at day 14 indicating a 65% reduction in mean rank from day 1. **Ulceration** 

Table 3: Assessment on the Effect of Yashtimadhu Churna Suppository on Ulceration

	Mean Rank	Chi-Square	P Value
Day 1	7.89		
Day 5	6.79		
Day 10	5.69	240.007	
Day 14	3.56		ر د0 001
1st follow up	3.00	249.086	<0.001
2 <sup>nd</sup> follow up	3.08		
3 <sup>rd</sup> follow up	3.00		
4 <sup>th</sup> follow up	3.00		

There was a statistically significant difference in pain with treatment,  $\chi 2$  (2) = 249.086, p = <0.001. The mean rank has a steady fall from day 1 to day 14 then showing a slight increase from first follow up to  $2^{nd}$  and stabilizes at 3 points. AT indicating a 62.1% reduction in mean rank from day 1.

# **Sphincter Tone**

Table 4: Assessment on the Effect of Yashtimadhu Churna Suppository on Sphincter Tone

	Mean Rank	Chi-Square	P Value
Day 1	7.79		
Day 5	6.41		
Day 10	5.39	222.520 <0	
Day 14	4.10		ر د0 001
1st follow up	3.78	222.520	<0.001
2 <sup>nd</sup> follow up	3.01		
3 <sup>rd</sup> follow up	2.76		
4 <sup>th</sup> follow up	2.76		

There was a statistically significant difference in sphincter tone with treatment,  $\chi 2$  (2) = 222.520, p = <0.001. The mean rank has a steady fall from day 1 to 4<sup>th</sup> follow up. Sphincter Tone at 4<sup>th</sup> follow-up indicating a 54.2% reduction in mean rank from day 1

#### Overall Assessment

**Table 5: Overall Assessments** 

Parameter	Effect of the Treatment
Pain	65%
Ulceration	62.1%
Sphincter tone Sphincter tone	54.2%

Pain was managed in 65%, ulceration was moderately healed in 62.1% and sphincter tone was moderately normalized in 54.2%.

#### RESULTS AND DISCUSSION

# **Effect on Pain**

There was a statistically significant difference in pain with treatment,  $\chi 2(2) = 254.601$ , p = <0.001. The mean rank has a steady fall from day 1 to 4<sup>th</sup> follow up. Pain at day 14 indicating a 65% reduction in mean rank from day 1.

A Wilcoxon signed-rank test showed that a treatment did elicit a statistically significant change in pain in individuals. All group comparisons from day 1 showed a statistically significant change. Pain values are found to decrease from G4 to G0 in all the patients, pain values remained a constant across all the follow ups.

# **Effect on Ulceration**

There was a statistically significant difference in ulceration with treatment,  $\chi 2(2) = 249.086$ , p = <0.001. The mean rank has a steady fall from day 1 to day 14 then showing a slight increase from first follow **Images of** *Yashtimadhu* **Suppository with Ingredients** 

up to 2<sup>nd</sup> and stabilizes at 3 points. AT indicating a 62.1% reduction in mean rank from day 1.

A Wilcoxon signed-rank test showed that a treatment did elicit a statistically significant change in ulceration in individuals. All group comparisons from Day 1 showed a statistically significant change. Ulceration values are found to decrease from G4 to G0 in all the patients, ulceration values almost remained a constant across all the follow ups.

# **Effect on Sphincter Tone**

There was a statistically significant difference in sphincter tone with treatment,  $\chi 2(2) = 222.520$ , p = <0.001. The mean rank has a steady fall from day 1 to 4th follow up. Sphincter Tone at 4th follow-up indicating a 54.2% reduction in mean rank from day 1.

A Wilcoxon signed-rank test showed that a treatment did elicit a statistically significant change in pain in individuals. All group comparisons from day 1 showed a statistically significant change. Sphincter Tone values is found to decrease from G4 to G0 in all the patients, values slightly increasing from day 14 to follow-up.



Figure 1: Yashtimadhu



Figure 2: Yashtimadhu churna and Cocoa butter



Figure no 3: Yashtimadhu Suppository



Figure no 4: Before treatment Figure no 5: After treatment

# **CONCLUSION**

In this clinical study, the efficacy of *Yashtimadhu* suppository in the management of pain in *Parikartika* (fissure-in ano) showed statistically significant result.

- *Yashtimadhu* suppository showed significant effect in *Parikartika* especially pain.
- The objective parameters are ulceration, sphincter tone. Sphincter tone of the patients in this study were found to be least improved. Since *Yashtimadhu* suppository mainly focuses on the pain, it doesn't showed much impact on the sphincter tone. So, along with *Yashtimadhu* suppository one should give *Anulomana* e.g., *Triphala choorna* which helps in relieving the constipation.
- Since it relieves pain in the *Parikartika*, it can be used in the other ano-rectal conditions i.e., post-operative pain management in haemorrhoidectomy or any after any other surgical conditions too.

- The recurrence of symptoms was found in most of the patients even after follow-ups showed the temporary effect of the *Yashtimadhu* suppository due to the recurrent nature of the *Parikartika* (fissure-in ano). So, *Anulomana chikitsa* also plays a significant role to relieve *Parikartika*.
- Rectal Suppositories are the simple formulation which is easy to administer, easy to prepare, cost effective.
- It can be carried easily if packed in aluminium foil sheet. The main focus of the suppository is the pain management and can be used whenever required.

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