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A Study on Nagaradhya Ghrita Matra Basti and Yastimadhu Ghrita Matra Basti in the Management of Parikartika (Acute Fissure-in-Ano) - An Open Label Randomised Comparative Clinical Trail.

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ABSTRACT

Parikartika (Fissure - in - ano) is the commonest condition seen in day-to-day clinical practice and considered as one of the most painful ano-rectal conditions affecting majority of the population. The presentday sedentary life style, intake of less fibrous and spicier food has led to an increase in the incidence of constipation in the population, thus leading to increased incidence of *Parikartika*. In this condition *Vibanda* and *Mandagni* are the prime causative factor. Treatment modalities mentioned in modern science include pain killers, application of local anaesthetics, sphincterotomy etc. Keeping in mind the complications of above said treatment modalities, So an attempt is made to find out an effective treatment for *Parikartika*, which brings about quick healing and also prevent the reoccurrence. Hence study is made to compare the effect of *Nagaradhya Ghrita Matra Basti* with *Yastimadhu Ghrita Matra Basti*. *Nagaradhya Ghrita* and *Yastimadhu Ghrita* is known for *Vata-hara*, *Pitta Shamaka* and *Vrana Ropaka* Properties where both, its base is *Ghrita*, which itself is having *Samkara Anuvarti* and healing properties.

Keywords: Parikartika; Fissure-in-Ano; Nagaradhya Ghrita; Yastimadhu Ghrita; Matra Basti.

INTRODUCTION

The earliest reference of 'Parikartika' is available from Sushruta Samhita (1500 B.C). Description about Parikartika is also available in all Brihatrayees and later classics. Parikartika is referred in Brihatrayees not as an independent disease but as a complication of Basti Karma and Virechana (Vyapad). In Parikartika due to Nidana, aggravated Vata attains upward movement and repelled by Udanavayu, reaches Guda and obstructs the passage of faeces producing severe Ruja, Gudadaha, etc which is very much suggestive of clinical features of Fissure-in-ano as per Modern science when it is limited to anal region.

Sushruta, the pioneer of surgery; in spite of his excellent surgical skills have given equal importance to medical management. By the descriptions of Sushruta, it is evident that unnecessary surgeries should be avoided and hence Shastra Karma was adopted as a last in the management. Hence even today instead of surgical intervention, medical management has a role to play in some surgical diseases. One such condition where surgery can be avoided is fissure in-ano.

Parikartika is a common painful condition among Anorectal diseases.¹ The word *Parikartika* derived from root '*Parikrt*' which denotes, to cut around (*Pari* = cut around, *Kartanam* = act of cutting).² The literal meaning of the word *Parikartika* is '*Paritah Kartanavat Vedana*'. Which means cutting type of pain around the anus.³ Acharya Dalhana has described the term *Parikartika* as a condition of *Guda* in which there is cutting and tearing pain. Similarly *Jejjata* and *Todara* have clearly described *Parikartika* as a condition which causes cutting pain in anorectum.

Acharyas have explained it as one among the Vamana- Virechana Vyapad and Basti Vyapad. It is caused due to 'Sthanasamshraya of Vata & Pitta dosha' in Gudapradesha. Exhibits symptoms like Kartanavat Ruja, Daha, Vatasanga and Vibanda. Acharya Charaka and Vagbhata used two words, "Vikartika" as well as "Parikartika" for denoting the condition. Chakrapani also opines the same. The factors responsible for causation of Parikartika are found in various texts as Vamana -Virechana Vyapad, Bastikarma Vyapad, Atisara, Grahani, Arsha, and Udavarta.

Later Acharya Kashyapa has described it in three types viz.

- Vataja.
- Pittaja.

• Kaphaja.

As per classical description of signs and symptoms, the disease Parikartika can be co-related with Fissure-in-Ano in modern.

Fissure-in-ano is very commonly encountered in current day to day practice. About 30-40% of the population suffers from proctologic pathologies at least once in their life. Anal fissure comprises of 18% of ano-rectal disorders. Fissure-in-ano is small longitudinal ulcer in the long axis of the lower anal canal.⁴ It is very common and painful condition, fissure occurs most commonly in the midline posteriorly. In males fissure usually occur in the midline posteriorly-90% and much less commonly anterior-10% (90:10). In case of females fissures on the midline posteriorly-60% and are slightly common than anterior-40% (60:40).⁵ Predominant cause has been explained as posterior angulation of the anal canal, relative fixation of the anal canal posteriorly, divergence of the fibers of the external sphincter muscles posteriorly and the elliptical shape of the anal canal. In addition to it, the other contributed factors are constipation, spasm of the internal sphincter, surgical catastrophe during operation of haemorrhoids followed by anal stenosis which may ultimately result into anal fissure.

Similarly secondary causes are ulcerative colitis, crohn's disease, syphilis, and tuberculosis have also been held responsible for the formation of the disease fissure-in -ano and is characterized by excruciating pain during and after defecation, bleeding per anum with spasm of anal sphincter. Pain may be so severe that patient may avoid defecation for days together until it becomes inevitable. This leads to hardening of the stools which further tear the anoderm during defecation setting a vicious cycle.

On the basis of clinical symptoms the disease fissure-in -ano has been classified into two varieties, viz

1) Acute Fissure-in ano

2) Chronic Fissure-in-ano

Either acute or chronic, pain and bleeding are the two main symptoms of this condition, pain is sometimes intolerable. In long standing cases it may be associated with haemorrhoids or a sentinel tag. Pruritis ani may be another symptom of this condition.

Fissure-in-ano is a medico- surgical condition. Medical management is said to be conservative and surgical intervention is the ultimate choice in the chronic ulcers. Medical treatment for acute Fissure-in-ano is supplementation of oral pain killers in the form of NSAID'S, stool softeners, soothing ointment, topical anaesthetics and self-dilatation (using anal dilators) on medical advice. Surgical management includes Lord's dilatation, sphincterotomy, fissurectomy, anal advancement flap. All these treatment procedures of modern science have drawbacks.

- Prolonged administration of NSAID may suppress the symptom but causes gastric irritation.
- Application of soothing ointment produces sufficient relaxation of the sphincter, but causes significant delay in fissure healing and recurrence rate is 50% in this particular method of management.
- Topical anaesthetics and steroids reduce blood flow to the area thus interfere with wound healing. Often the creams are combined with a
 small amount of steroids to reduce inflammation. The prolonged use of which result in thinning of anoderm (atrophy), which makes it more
 susceptible to trauma.

The Ayurvedic principles of managing this condition aims at Agni-deepana, Vatashamana, Vatanulomana, Vranaropana. Taking these factors into consideration and to avoid surgical intervention, the present study is planned to evolve an effective treatment by Ayurvedic approach. The present clinical study has been undertaken to assess comparative efficacy of of Nagaradhya Ghrita Matra Basti with Yastimadhu Ghrita Matra Basti which is already proven as standard in the management of Parikartika.

The assessment of clinical study was done on subjective parameter like Pain, Constipation, Streak of blood with stool, Burning sensation and objective parameter i.e. Sphincter tone and Tenderness. The findings were compared and subjected to statistical analysis to draw the conclusions.

Objectives:

To compare the effect of Nagaradhya Ghrita Matra Basti with Yastimadhu Ghrita Matra Basti in the management of Parikartika (Acute Fissure-in-Ano).

MATERIALS AND METHODS:

Source of Data:

a) Literary Source: Literary aspect of study was collected from Library of S.J.G.A.M.C Koppal, Classical Ayurvedic texts, modern texts, recent journals and e-medical journal, related websites about the disease and the drug.

b) Sample Source: 40 diagnosed patients with clinical features of *Parikartika* (Fissure-in-Ano) coming under the inclusion criteria approaching the *Shalya Tantra* OPD of S.J.G. Ayurvedic Medical College, Hospital and Research Centre, Koppal.

c) Drug Source: The required raw drugs were purchased from approved vendors and post purchase of the raw drugs was authenticated by the faculty of *Dravya Guna* department and prepared under the guidance of *Rasashastra* and *Baishajya Kalpana* department in SJGAMC and Hospital, Pharmacy, Koppal.

METHOD OF PREPARATION:

Nagaradhya Ghrita⁶:

Kalka Dravya: Nagara, Pippalimoola, Chitrakamoola, Gajapippali, Svadamstra, Pippali, Dhanyaka, Bilva, Patha, Yavanika (each drug equal quantity) Changeri Svarasa- 1Part.

Sneha dravya : Moorchita Go Ghritha - 4 parts.

Drava dravya : Dadhi -16 parts.

PREPARATION⁸

Moorchita Ghrita was taken in a clean wide mouthed stainlesssteel vessel. The vessel was placed over Mandgni. When fumes started apeearing in Ghrita, then kalka dravya added to that followed by Drava dravya (Dadhi). Boiling was continued with frequent stirring until 'Sneha siddhi lakshsana's, are attained. Later the Ghrita is filtered through a clean cloth and preserved in wide mouthed container for further therapeutic use.

Yastimadhu Ghrita⁷

- Kalka Dravya: Yastimadhu 1 Part
- Sneha dravya : Moorchita Go Ghritha 4 parts.
- Drava dravya : Jala -16 parts.

PREPARATION⁸

Moorchita Ghrita was taken in a clean wide mouthed stainlesssteel vessel. The vessel was placed over Mandgni. When fumes started apeearing in Ghrita, then kalka dravya added to that followed by Drava dravya (Jala).

Boiling was continued with frequent stirring until 'Sneha siddhi lakshsana's, are attained. Later the Ghrita is filtered through a clean cloth and preserved in wide mouthed container for further therapeutic use.

PROCEDURE (MATRABASTI).9

For group A - Nagaradhya Ghrita.

For Group B - Yastimadhu Ghrita

Poorva Karma

Procedure was explained to the patient in his/her own language and informed consent taken. Required materials were kept ready. The patient was asked to lie comfortably in left lateral position on examination table. The left leg of the patient should be stretched straight and the right leg flexed at knee and hip joints & the head should be supported by left hand, with the right hand resting on the right leg. The part was cleansed with sterile gauze dipped in warm water and then mopped with a dry sterile gauze.

Pradhana karma:

1½ Pala (72ml) of warm *Ghrita* was taken in a sterile kidney tray and then loaded into the enema syringe A sterile red rubber catheter was fixed to the nozzle of the loaded syringe and air bubbles were evacuated from it. Tip of the catheter and Anal canal was lubricated with the same *Ghrita* and gently inserted into the anal canal of the patient upto 3 Angula. Entire 72 ml of *Ghrita* was then pushed inside slowly. The catheter was gently withdrawn and a sterile gauze was kept in place.

Paschat karma:

After administration of the Nagaradhya Ghrita, patient was asked to lie in supine position. There after both legs were raised and slightly flexed at knee joint for few times, and gently tapped over the hips. After 10 minutes patient was advised to get up from the table.

The same procedure was carried out daily for 7 days.

TABLE 1 : Nagaradhya Ghrita

Drugs	Rasa	Guna	Veerya	Vipaka	Effect on Dosha	Karma
Nagara	Katu.	Guru, Ruksha,	Ushna.	Madhura	Kaphavata	Vatanulomana,

		Tikshna			Shamaka	Dahaprasamana, Vranaropana,
Pippalimoola	Katu	Laghu, Ruksa	Ushna	Katu	Kapha-vatahara	Dipana, Pacana
Chitrakamoola	Katu.	Laghu, Rūkṣa,Teekshna	Uṣṇa	Katu	Vata-kapha hara.	Dipana-Pacana
Gajapippali	Katu	Laghu, Snigdha, Tikṣṇa (Ardra- Guru)	Ushna. (Ardra- Sita)	Madhura	Vata-pitta hara, śleşmahara (Ardra-Kapha vardhaka)	Dipana
Svadamstra	Madhura.	Guru, Snigdha	Sita.	Katu.	Vata-pitta hara	Dipana, Shulahara
Pippali	Katu	Laghu, Snigdha, Tikṣṇa (Ardra- Guru)	Ushna. (Ardra- Sita)	Madhura.	Vata-pitta hara, Sleshmahara (Ardra-Kapha vardhaka)	Dipana, Shulahara
Dhanyaka	Kasyhaya, Tikta.	Laghu, Snigdha	Ushna	Madhura.	Tridosahara,	Dipana- pacana
Bilva	Kashaa, Tikta.	Laghu, Ruksa	Uṣṇa	Katu	Vata-kapha hara,	Grahi, Deepana- Pachana
Patha	Tikta.	Laghu, Tikshna.	Ushna.	Katu	Vata-Kaphahara,	Shulahara
Yavanika,	Katu.	Laghu,, Rooksha Tikshna.	Ushna.	Katu	Kapha-vata hara	Dipanapacana Shulahara
Changeri	Amla, Kaṣāya.	Laghu,, Rooksha.	Ushna	Amla	Tridoshashamaka.	
Dadhi	MadhuraAmla, Atyamla Anurasa is Kashaya.	Sniigdha, Guru, Grahi	Ushna.	Amla.	Vata kaphanashaka	

TABLE 2 Yastimadhu Ghrita

Drugs	Rasa	Guna	Veerya	Vipaka	Effect on Dosha	Karma
Yastimadhu	Madhura.	Guru, Snigdha.	Sita.	Madhura.	Tridosahara,	VranaSodhana
						VranaRopana/
Go Ghrita	Madhura	Guru, Snigdha, Mrudu	Sita	Madhura	Vata-pittahara	Dipana-Pacana

METHOD OF COLLECTION OF DATA:

Study Design: An Open Label Randomised Comparitive Clinical Trial.

Sample Size: A total 40 cases of *Parikartika* after consideration of below mentioned criteria have be included for the study. These 40 cases were randomly allotted into 2 groups.

NAMELY - Group A-20 Patients

Group B-20 Patients

Selection Criteria:

A) Diagnostic Criteria:

Based on the Signs and Symptoms of Parikartika (Acute Fissure-in-Ano)

- Gudagata Shoola (Cutting type of Pain).
- > Gudagata Daha (Burning sensation at Anal verge).
- > Gudagata Raktasrava (Streak of blood with the Stool).
- Vibandha (Constipation).

B) Inclusion Criteria:

- > Patients of either sex.
- > Patients with age group between 18-40years.
- Patients presenting with complaints of Acute Fissure-in-ano like Constipation, Painful and Burning defecation and Bleeding per Anum (Streak).

C) Exclusion Criteria:

- > Patients diagnosed with Chronic Fissure-in-ano.
- > Fissure-in-ano Secondary to Ulcerative colitis, Crohn's disease, Malignancy and associated with Haemorrhoids and Fistula-in-ano.
- > Uncontrolled Systemic disorders like Diabetes and Hypertension.

Immunosuppresive disorders like Tuberculosis, HIV and HBsAG Positive.

D) Screening Criteria:

- ► CBC.
- > RBS.
- ≻ HIV 1&2, HBsAg.

STUDY GROUPS: TABLE 3

SERIAL NO	GROUP	INTERVENTION	DURATION
1	А	Matra Basti with Nagaradhya Ghrita	7 days
2	В	Matra Basti with Yastimadhu Ghrita	7 days

POSOLOGY:

Matra Basti is administered in the dose of 11/2 pala i.e, 72ml/day.10

ASSESSMENT CRITERIA

Subjective parameters before and after the treatment was compared and statistically analyzed.

a) Subjective Parameters:

i) Pain-Visual Analouge Scale.

Pain was graded according to visual analogue scale.

VAS	GRADE	PAIN
0	0	No pain
1-3	1	Mild pain
4-6	2	Moderate pain
7-9	3	Severe pain
10	4	Worst pain

ii) Constipation:

Graded according to severity.

Grade	Constipation
0	No constipation (Passing stool daily with normal consistency)

1 2	Mild constipation (Passing stool daily but with hard consistency) Moderate constipation (Passing stool on alternate day with hard consistency)			
3	Severe constipation (Passing stool on every 3 rd day with hard consistency)			

iii) Burning sensation:

Grading was done according to the presence and absence of same.

Absent - 0

Present - 1

iv) Bleeding per anum:

Bleeding was seen as streaks over the stools or few drops on toilet pan in some cases.

Grading was done depending on presence and absence of bleeding.

Absent - 0

Present-1

b) Objective Parameters:

i) Sphincter tone:

This feature was assessed and graded on digital rectal examination.

Normal - 0

Spastic - 1

ii) Tenderness:

Grading was done depending on presence and absence of tenderness on digital rectal examination.

Absent - 0

Present - 1

Assessment of Results

Subjective and objective parameters will be assessed on 1st day (Before treatment),

3rd day, 5th day and 8th day (After treatment), 21st day (Follow up). Final data will be compared and statistically analysed according to the data.

FOLLOW UP PERIOD

Follow up period was scheduled on 21st day to know the recurrence rate in which observations were recorded in the concerned proforma.

STATISTICAL TEST

Repeated Measures of ANOVA and Mann Whitney U test is used and analysed.

Result interpretation:

In Group A, patients were given *Nagaradhya Ghrita*, whereas in Group B, patients were treated with *Yashtimadhu Ghrita*. Data was collected at different stages on 1st day, 3rd day, 5th day, 8th day, 21st day.





Fig 1-Before Treatment

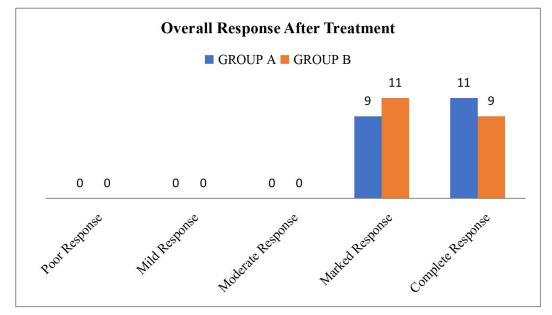
Fig 2- After Treatment

Table 3: Showing overall response after treatment.

Overall Response After Treatment							
	Response	GROUP A		GROUP B			
Response Grouping		No. Of Subjects	%	No. Of Subjects	%		
(0%-25%)	Poor Response	00	00%	00	00%		
(25%-50%)	Mild Response	00	00%	00	00%		
(50%-75%)	Moderate Response	00	00%	00	00%		
(75%-99%)	Marked Response	09	45%	11	55%		
(100%)	Complete Response	11	55%	09	45%		
Total		20	100%	20	100%		

The overall response of Nagaradhya Ghrita with marked response of 55% whereas Yastimadhu Ghrita is 45%.

GRAPH 1: Showing overall response after treatment



DISSCUSSION:

Relief in the cardinal symptoms:

Pain: 98 % of relief is seen in Group A and 94% relief is seen in Group B.

Constipation: 98 % of relief is seen in Group A and 91% relief is seen in Group B.

Bleeding per Anum: 100 % of relief is seen in Group A and 100% relief is seen in Group B.

Burning sensation: 85 % of relief is seen in Group A and 90% relief is seen in Group B.

Sphincter tone: 75 % of relief is seen in Group A and 75% relief is seen in Group B.

Tenderness: 95 % of relief is seen in Group A and 90% relief is seen in Group B.

Relief in the disease:

When percentage of relief in the disease is concerned, Group A was having complete response of 55%, Moderate response of 45%.

Group B, it was having complete response of 45%, Moderate response of 55%.

From these findings it is clear that Group A was having better effect over the curing of the disease than Group B.

Mode of action of Nagaradhya Ghrita

Ingredients of Nagaradhya Ghrita are Nagara, Pippalimoola, Chitrakamoola, Gajapippali, Svadamstra, Pippali, Dhanyaka, Bilva, Patha, Yavanika, Changeri Svarasa. Most of the ingredients of Nagaradhya Ghrita have Madhura, Tikta, kashaya, katu Rasa and possess Tridoshahara, Vedanahara, Dahaprashamana, Vrana Ropana properties. These properties might have helped in relieving pain, burning sensation, bleeding and constipation when it is administered in the form of Matrabasti thus reduces Doshik pathology.

Shoola in *Parikartika* is mainly due to *Vata Dosha* aggrevation and as per modern science, pain is due to inflammation and sphincter spasm. Hence *Rujahara, Vatanulomana,* analgesic, anti-inflammatory properties of *Nagaradhya Ghrita* helps in reducing the pain by decreasing the anal canal pressure and hypertonicity of sphincter muscles when it is administered in the form of *Matrabasti* and given in *Sukoshna* form, By this *Vata Dosha Shamana* occurs and there by pain decreases and *Pittahara* qualities reduces burning sensation and bleeding.

As *Nagaradhya Ghrita* is a *Sneha dravya*, made it warm and administered which lubricates the anal canal and provides a smooth evacuation of stools & resting pressure in the anal canal decreases by decreasing the hypertonicity of sphincter muscles. By warm liquids, relative ischemia is relieved and proper blood supply will help in proper nourishment of tissue thereby helps in healing.

After Basti, medicaments cover the ulcer surface with Snigdha dravya, by which the wound contamination with faecal matter is avoided and this may enhance healing process.

Mode of action:

Yastimadhu Ghrita has Pittavata Shamaka, Vranaropaka, Dahashamaka, and Vranashodhaka properties. Recent researches have shown that Yashtimadhu (Glyzirrhia glabra) has a potent anti-inflammatory and analgesic principle and is been

widely used. This anti-inflammatory and analgesic property might have helped in bringing down the pain.

Yastimadhu has Sheeta and Dahashamaka. This property might have helped in relieving burning sensation. Since it has Vranaropaka property the healing of fissure was possible. When Yastimadhu Ghrita given as Basti helps in easy expulsion of Pureesha and nourishes and cures disease caused by aggravated Vata and Pitta Dosha.

*The underlying pathology in *Parikartika* is constipation and spasm of the sphincter muscle which results slight narrowing of the anal canal. This triggers formation of fissure-in-ano. During the act of defecation, the anal canal is stretched and pain gets aggravated which will in turn cause spasm of the sphincter muscle. Thus the vicious cycle is continues. The treatment which is adopted will break this vicious cycle by correcting the constipation and sphincter spasm. The relaxed anal canal will reduce the sphincter spasm, which will in turn facilitates the fissure to heal.

CONCLUSION:

In this study, 40 patients of *Parikartika* w.s.r to Fissure-in-ano were randomly allotted and assigned into two groups of 20 Patients each. Group-A as Trial group was treated by administration of *Nagaradhya Ghrita Matra Basti* for 7 days and Group-B as standard group was treated with *Yastimadhu Ghrita Matra Basti* for same duration, through specific observations following conclusions were drawn:

- Parikartika defined as "Paritah kartanavat vedana" means cutting type of pain along with Burning sensation, Bleeding per anum.
- On the basis of location, nature of pathology and features, as mentioned in the *Samhitas* as a *Upadrava* of *Virechana* and *Basti*, condition *Parikartika* in *Guda Pradesh* can be correlated to Fissure-in-ano.
- The incidence is predominantly seen in middle age group precisely in the age between 18 40 years.
- Vata and Pitta have dominancy in the development of the disease Parikartika, but Vata is more predominant.
- Improper dietary regimen and stressful life is found to have influenced the high incidence observed today.

- *Vibandha* is the prime cause of tear in the lower anal canal which results in excruciating pain during and after defecation, the cardinal feature of Fissure-in-ano.
- Matrabasti carried out in this study was based on classical references.
- Matrabasti helps in relieving the sphincter spasm as there was retention of medicament, also its contact with the lesion was there for longer duration, this helped in healing of fissure. It lubricates the anal canal and provided easy evacuation of faeces and thus promotes healing of fissure.
- The therapy was well tolerated and there have been no untoward effects found in the study. *Nagaradhya Ghrita* can be easily prepared, the technique of administration is simple and can be done as an out-patient procedure.
- Nagaradhya Ghrita Matra Basti and Yastimadhu Ghrita Matra Basti was found effective in relieving Pain, Constipation, Burning sensation and Bleeding of Fissure-in ano.
- The effect of the treatment in both the groups has shown statistically highly significant results (*P* value <0.001) in subjective parameters like Pain, Constipation, Burning sensation, Bleeding per rectum and also in objective parameters like Sphincter tone and Tenderness. So treatment was highly effective in both the groups.
- The effect of treatment was statistically non-significant between the Group A and Group B (P value > 0.05) but based on ranks of sum of values and the Complete response obtained with Nagaradhya Ghrita Matra Basti (55%) and that of, Yashtimadhu Ghrita Matra Basti (45%). Thus it was observed that Nagaradhya Ghrita Matra Basti was more efficacious than Yashtimadhu Ghrita Matra Basti in the management of Parikartika.

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