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A randomized controlled clinical study to evaluate the efficacy of *Yastimadhu* Hydrogel in *Parikartika* vis-a-vis Fissure-in-Ano

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ABSTRACT

Parikartika, commonly known as Fissure-in-Ano, ranks among the prevalent anorectal disorders and represents a painful affliction affecting the anal region. Its clinical presentation bears a striking resemblance to the description of *Parikartika* in Ayurvedic texts. Contemporary therapeutic approaches involve the application of local soothing agents, oral analgesics, and stool softeners during the initial stages. Surgical interventions, including Lord's dilation, fissurectomy, and sphincterotomy, are considered in more advanced cases. Ayurveda, on the other hand, advocates the use of various drugs with distinct properties for treating this condition, with *Yashtimadhu* being recognized for its *Vrana Ropan*, *Mrudukara*, *Tvak Prasadana*, and *Pitta-Anila Hara* properties. Recognizing the regenerative potential of hydrogels on the skin, our study sought to evaluate and compare the local effects of *Yashtimadhu hydrogel* and *Yashtimadhu Ghrita* in the management of *Parikartika*. A randomized comparative study was conducted involving 60 patients with Fissure-in-Ano, divided into two groups. The trial group (n=30) received *Yashtimadhu* hydrogel through local application for a period of 3 weeks, while the control group (n=30) underwent treatment with *Yashtimadhu Ghrita* during the same duration. Assessment of symptoms such as Pain, Bleeding, Constipation, Itching, Discharge, and the size of anal fissure, along with observations on the anal fissure floor and granulation tissue, revealed promising results. Statistical analysis indicated the effectiveness of both *Yashtimadhu* hydrogel and *Yashtimadhu Ghrita* in the conservative management of *Parikartika*. Notably, *Yashtimadhu Ghrita* emerged as a more potent remedy in the management of anal fissure when compared to *Yashtimadhu* hydrogel.

Key words: *Parikartika*, *Fissure-in-Ano*, *Yashtimadhu*, *Hydrogel*, *Ghrita*, *Conservative Management*, *Randomized Clinical Study*.

INTRODUCTION

In the present era of changing lifestyle, irregularity in diet, sedentary lifestyle and increased stress all these causes disturbance in digestive system which results into many diseases, amongst them ano-rectal disorder

constitutes an important group out of which anal fissure is the commonest one. Ana fissure is an elongated ulcer in the long axis of the anal canal.^[1] *Parikartika* is a similar condition explained in ayurveda in which patients experience excruciating cutting pain in the anus.^[2] The incidence of anal fissures is around 1 in 350 adults. They occur equally in men and women and most often occur in adults aged from 15 to 40 years^[3] and also condition is more common in women. 90% of anal fissure occurs in the midline posteriorly and only 10% occur at the midline anteriorly.^[4] The pain of an anal fissure is so severe that usually the patient demands immediate relief. In modern science anal dilation, lateral sphincterotomy and anal advancement flap are the main treatment for anal fissure. In Ayurveda, *Parikartika* is treated with local applications formulated by using *Madhura*, *Sheeta* and *Snigdha Dravyas*. *Yastimadhu* has *Madhura Rasa*,

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Sheeta Veerya, Snigdha Guna, Vedanasthapana, Sothahara and Vranaropana properties.^[5] Acharya Susrutha has recommended *Yastimadhu Gritha* to subside the post operative pain.^[6] Previous researches proved that *Yastimadhu Gritha* is effective in management of *Parikartika*.^[7] Gel is one of the new dosage formulations with few chemicals and can be used as base to prepare different formulation. Hydrogels are the three dimensional, hydrophilic, polymeric networks capable of absorbing larger amount of water or biological fluids.^[8] Hydrogels have the ability to hold water and drug in them due to their cross linked structure. Due to their water holding ability they can hold and retain wound exudates.^[9] Hydrogels have capability of stimulating the regeneration of skin. It can be loaded with drugs which are responsible for the treatment of wound.^[10]

OBJECTIVES

1. To study the efficacy of *Yastimadhu* hydrogel in *Parikartika*
2. To study the efficacy of *Yastimadhu Gritha* in *Parikartika*
3. To compare the efficacy of *Yastimadhu* hydrogel with *Yastimadhu Gritha* in *Parikartika*

MATERIALS AND METHODS

Study Design: An Open labeled, randomized, comparative, interventional clinical study

Source

- **Literary source:** All Ayurvedic and allied science text books journals, internet source about the disease and procedure will be reviewed and documented for the intended study.
- **Clinical source:** The study is strictly confined to the cases of anal fissure; hence patients will be selected as per inclusion and exclusion criteria from the outpatient department and in patient department of Muniyal Institute of Ayurveda Medical Sciences, Manipal.
- **Drug source:** Raw drug for the preparation of *Yastimadhu* hydrogel will be obtained from known

source. It will be prepared in Bhaishajya Kalpaana laboratory of Muniyal Institute of Ayurveda Medical Sciences, Manipal.

Table 1: Showing ingredients for preparation of *Yastimadhu* hydrogel

Drug	Quantity
<i>Yastimadhu</i> root drug Extract water	Quantity sufficient
Sodium Benzoate	1.5%
Carbomer9405	2.5 %
Polyethylene Glycol 400	2%
Triethanolamine Solution	1.5%

Table 2: Showing ingredients for preparation of *Yastimadhu Gritha*

Drug	Quantity
<i>Kalka Dravyas</i>	1 part
<i>Snehana Dravya</i>	<i>Murcchita Ghrita</i> - 1 part
<i>Drava Dravya</i>	<i>Jala</i> - 4 parts.

Method of collection of data

This is a clinical comparative study of study group and control group. Minimum 60 patients suffering from *Parikartika* were selected as per inclusion and exclusion criteria. The patients enrolled in the study were divided into 2 groups:-

Group A: Study group were treated by *Yastimadhu* hydrogel local application over fissure in ano.

Group B: Control group were treated by *Yastimadhu Gritha* local application over fissure in ano.

Each group comprising of 30 patients. All the parameters as per the assessment criteria mentioned were observed and the results of two groups were compared, analyzed statistically.

Inclusion and exclusion criteria

Inclusion criteria

1. Clinically diagnosed cases of fissure in ano are taken for the study.
2. Patients irrespective of sex, religion, occupation & economic status.
3. Patients of both the sexes in between the age group of 18 to 60 years.

Exclusion criteria

1. Patients having fissure-in ano secondary to ulcerative colitis, syphilis, crohn’s disease, tuberculosis and malignancy of rectum and anal canal.
2. Patients with fissure in ano associated with conditions like hemorrhoids and fistula-in- ano.

Investigations

In patients of systemic pathology if necessary

- Hb
- TC, DC
- ESR
- CT
- BT
- HbsAg
- HIV
- VDRL
- RBS

Intervention

Study Group: Yastimadhu hydrogel was applied to cotton gauze then it was kept locally on fissure in ano for 3 hours, once in day for period of three weeks. Yastimadhu hydrogel was applied after warm water sitz bath for 15 minutes.

Control Group: Yastimadhu Gritha was applied to cotton gauze then it was kept locally on the fissure in ano for 3 hours, once in a day for period of three weeks. Yastimadhu Gritha was applied after warm water sitz bath for 15 minutes.

Assessment Criteria

Pain: According to VAS

Table 3: Grading of pain

VAS Grading
0 - No Pain
1
2
3
4
5 - Moderate Pain
6
7
8
9
10 - Worst possible pain

Itching

Table 4: Grading of itching

Grading	Itching
0	No itching
1	Mild (less than 5 min)
2	Moderate (for 5 - 10mins)
3	Severe (more than 10 mins)

Constipation

Table 5: Grading of constipation

Grading	Constipation
0	No constipation
1	Passing stools regularly with difficulty

2	Passing hard stools irregularly with difficulty
3	Passes pellet like stool once in week with difficulty

Bleeding

Table 6: Grading of bleeding

Grading	Bleeding
0	No bleeding.
1	Blood streak over the stool
2	Drop wise bleeding about 0-10 drops
3	bleeding about 10-20 drops
4	Profuse bleeding more than 20 drops.

Objective Parameters

Size of the Anal Fissure

Table 7: Grading of size of anal fissure

Grading	Size
0	No fissure
1	1 - 4 mm
2	4.1 - 8 mm
3	8.1 - 12 mm
4	12.1 - 16 mm

Discharge

Table 8: Grading of discharge

Grading	Discharge
0	No discharge
1	Spotting
2	One layer of gauze is wet

3	Two layer of gauze are wet
4	Need change of dressing more than once a day

Floor and granulation tissue of the wound

Table 9: Grading of floor and granulation tissue of the wound

Grading	Floor
0	Skin intact partially covers the wound
1	Bright beefy red 75%-100% wound filled
2	Bright red <75% and >25% of wound is filled
3	Pink or dull dusky red and fills <25%
4	Unhealthy granulation tissue

Tenderness

Table 10: Grading of tenderness

Grading	Tenderness
0	No tenderness
1	Pain on deep palpation
2	Pain tenderness on light pressure
3	Pain on touch
4	Patient does not allow palpation due to pain even on touching of under clothes and difficulty in sitting

Duration of the study: 28 Days

Follow up

Patient will be followed up on 7th day, 14th day, 21st day and 28th day. During each visit patient was questioned regarding all clinical features listed in the assessment criteria and the same documented.

Adjuvant Therapy

Avipattika Churna 3gm with luke warm milk at bed time.

Statistical analysis

Data collected are tabulated and scores are analyzed statistically in the form of mean score B.T (Before Treatment), A.T. (after Treatment), Difference of mean (B.T. - A.T), S.D (Standard Deviation). Friedman test was carried out for within the groups and Mann Whitney U test for between the groups. The results were considered Significant or Insignificant depending upon P value.

Table 11: Significance chart

Extremely significant	p<0.0001
Highly (Very) significant	p<0.001
Significant	p<0.05
Not significant	P>0.05

Table 12: Grading of results

Improvement	Scale
Minimum	0-25%
Mild	26-50%
Moderate	51-75%
Maximum	76-100%

RESULTS

Pain

Effect of treatment on pain in group A: In Group A mean score observed before the treatment was 4.27, after Treatment value reduced to 2.57, the effect of treatment showed 39.81% improvement in pain score which is statistically significant. After Follow-up mean score value reduced to 1.27.

Effect of treatment on pain in group B: In Group B mean score observed before the treatment was 4.07 After Treatment value reduced to 2.27, the effect of

treatment showed 44.22% improvement in pain score which is statistically significant. After Follow up value reduced mean score value to 0.97

Constipation

Effect of treatment on constipation in group A: In Group A mean score observed before the treatment was 1.46, after Treatment value reduced to 1.1, the effect of treatment showed 24% improvement in constipation score which is statistically significant After Follow-up mean score value reduced to 0.8.

Effect of treatment on constipation in group B: In Group B mean score observed before the treatment was 1.3, after Treatment value reduced to 0.67, the effect of treatment showed 53% improvement in pain score which is statistically significant. After Follow-up value reduced to 0.37

Itching

Effect of treatment on itching in group A: In Group A mean score observed before the treatment was 1, after Treatment value reduced to 0.5, the effect of treatment showed 50% improvement in itching score which is statistically significant. After Follow-up mean score value reduced to 0.4

Effect of treatment on itching in group B: In Group B mean score observed before the treatment was 1.16, after Treatment value reduced to 0.54, the effect of treatment showed 53.44% improvement in itching score which is statistically extremely significant. After Follow-up value reduced to 0.4.

Bleeding

Effect of treatment on bleeding in group A: In Group A mean score observed before the treatment was 0.73. After Treatment value reduced to 0.23, the effect of treatment showed 68% improvement in bleeding score which is statistically significant. After Follow-up mean score value increased to 0.27.

Effect of treatment on itching in group B: In Group B mean score observed before the treatment was 0.97. After Treatment value reduced to 0.3, the effect of treatment showed 69% improvement in bleeding score

which is statistically extremely significant. After Follow-up value reduced to 0.23.

Size of Anal Fissure

Effect of treatment on size of anal fissure in group A:

In Group A mean score observed before the treatment was 1.47 After Treatment value reduced to 1.07, the effect of treatment showed 27% improvement in size of fissure score which is statistically significant. After Follow-up value reduced to 0.67.

Effect of treatment on size of anal fissure in group B:

In Group B mean score observed before the treatment was 1.63, After Treatment value reduced to 0.97, the effect of treatment showed 40% improvement in size of fissure score which is statistically extremely significant. After Follow-up value reduced to 0.63.

Discharge

Effect of treatment on discharge in group A:

In Group A mean score observed before the treatment was 0.4, After Treatment value reduced to 0.17, the effect of treatment showed 57.5% improvement in discharge score which is statistically significant. After Follow-up mean score value increased to 0.2.

Effect of treatment on discharge in group B:

In Group B mean score observed before the treatment was 0.7, After Treatment value reduced to 0.2, the effect of treatment showed 70% improvement in discharge score which is statistically extremely significant. After Follow-up value reduced to 0.27.

Floor and Granulation Tissue

Effect of treatment on floor and granulation tissue in group A:

In Group A mean score observed before the treatment was 1.33 After Treatment value reduced to 0.8, the effect of treatment showed 39.84% improvement in floor and granulation tissue score which is statistically significant. After Follow-up mean score value increased to 0.6.

Effect of treatment on floor and granulation tissue in group B:

In Group B mean score observed before the treatment was 1.27, After Treatment value reduced to 0.77, the effect of treatment showed 39% improvement in floor and granulation tissue score

which is statistically significant. After Follow-up value reduced to 0.53.

Tenderness

Effect of treatment on tenderness in group A:

In Group A mean score observed before the treatment was 1.83 After Treatment value reduced to 0.8, the effect of treatment showed 56% improvement in tenderness score which is statistically significant. After Follow-up mean score value reduced to 0.4.

Effect of treatment on tenderness in group B:

In Group B mean score observed before the treatment was 1.73 After Treatment value reduced to 0.5, the effect of treatment showed 71% improvement in tenderness score which is statistically significant. After Follow-up mean score value reduced to 0.2.

Photo 1: Anal fissure before treatment (Group A)



Photo 2: Anal fissure after treatment (Group A)

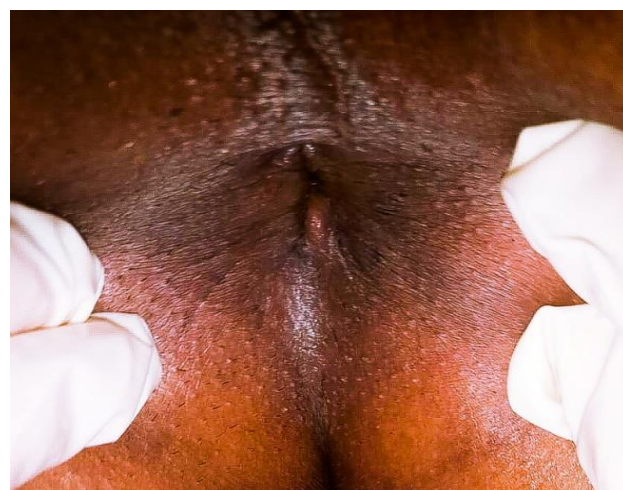


Table 13: Result summary of subjective parameters

Parameters	Mean score BT		Mean score AT				Mean score FU			
	A	B	A	%	B	%	A	%	B	%
Pain score	4.27	4.07	2.57	39.81%	2.22	44.77%	1.27	50.8%	0.97	57.26%
Constipation score	1.47	1.3	1.1	24%	0.67	53%	0.89	39.97%	0.73	38.33%
Itching score	1	1.17	0.57	50%	0.53	53.44%	0.47	17.4%	0.43	24.52%
Bleeding score	0.73	0.97	0.23	68%	0.33	69%	0.29	-	0.33	23.33%

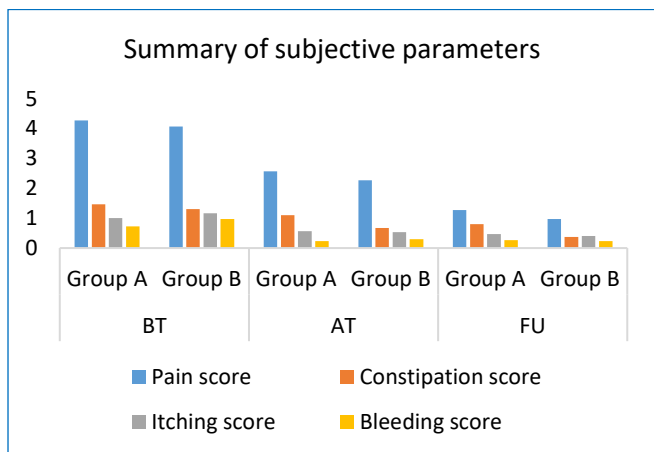
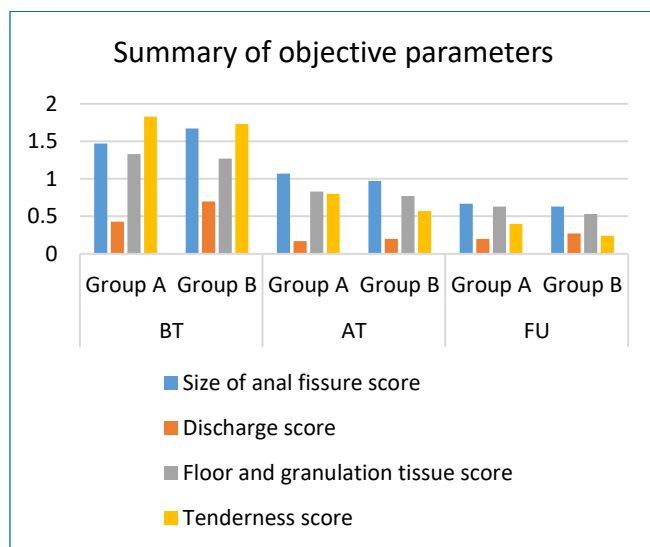


Table 14: Summary of objective parameters

Parameters	BT		AT				FU			
	A	B	A	%	B	%	A	%	B	%
Size of anal fissure score	1.47	1.3	1.1	24%	0.67	53%	0.89	39.97%	0.73	38.33%
Discharge score	0.47	0.3	0.1	24%	0.067	5.3%	0.089	3.997%	0.073	3.833%

Floor and granulation tissue score	1.33	1.27	0.83	30.8%	0.97	35.74%	0.73	27.0%	0.67	24.81%
Tenderness score	1.83	1.73	0.83	29.3%	0.97	35.74%	0.73	27.0%	0.67	24.81%



DISCUSSION

Effect of treatment on pain

In both the groups the main drug was Yastimadhu. Yastimadhu has *Madura Rasa, Guru Snigdha Guna, Sheeta Veerya, Vata-Pittahara, Vranaropana* and *Vranasodhana* property and thereby relieving pain developed in *Parikartika*. *Yashtimadhu* contains Glycyrrhizine and asparagine as active ingredients. Glycyrrhizine is widely used as an anti-inflammatory agent. *Vatapittahara* and *Soolahara* properties in *Ghritha* may have helped the *Yastimadhu Gritha* in alleviating pain. Sitz bath with luke warm water before treatment increases the blood circulation at perianal region thus reducing the pain.

Effect of treatment on constipation

Avipattikara churna consists of drugs like *Shunti, Maricha, Hartaki, Vidanga, Twak* and *Lavanga* which are *Deepana, Pachana* and *Vata anulomana* and *Trivrut* which is *Sukha Virechana* help in relieving Constipation and easy evacuation. The *Snigdha, Mrudu Guna* of

Yastimadhu Ghrita further helps to relieve the sphincteric spasm through *Vata Shamana* and there by contributing for easy passage of stool. Thus, we can conclude that the combined effect of *Yastimadhu Gritha* and *Avipattikara Churna* helped in easy passage of bowels.

Effect of treatment on itching

Yastimadhu has *Vrana Shodana*, *Vrana Vropana*, *Rakta Shodaka* property and there by contributing for relieving of itching.

Effect of treatment on bleeding

Yastimadhu has *Madhura Rasa*, *Guru Snigda Guna*, *Sheetha Veerya*, *Rakta Shodaka* and *Vata Pitta Hara* property help in relieving bleeding from fissure in ano.

Effect of treatment on size of fissure

In both groups *Yastimadhu* has *Madhura Rasa*, *Sheeta Veerya*, *Madhur Vipaka* and has *Vata-Pitta Shamaka* property. *Yashimadhu* also has *Vrana Shodhana* and *Rrana Ropana* properties property in group B *Gritha* has *Snigda Guna*, *Mrudukara Tvak Prasadana*, *Pitta Anila Hara* property hence combined effect of *Yastimadhu* and *Gritha* helped in healing of fissure.

Yastimadhu proved to increase interleukin 2 which is essential for wound healing. In group B hydrogel has property of anal mucous layer regeneration hence helped in reducing the size of the fissure.

Effect of treatment on discharge

Yasthimadhu (*Glycyrrhiza glabra*) is culpable for its antioxidant activity by means of hydrogen-donating and significant free radical scavenging properties helps to prevent further infection and discharge. In group B due water holding capacity of hydrogel it can absorb and withhold wound exudates and discharge and helped in reducing discharge from fissure in ano.

Effect of treatment on floor and granulation tissue

Yastimadhu have been shown to have anti-ulcer activity. *Goghrita* also contains vit. A, D, E and K. Vitamin A and K are antioxidant and are helpful in preventing oxidation injury to the body. Vitamin K keeps epithelial tissue of the body instant which is very

useful of wound healing. Liolenic acid helps in granulation. *Go-Ghruta* has soothing property and form a thin film layer over them and that allows early epithelialization of wound.

Effect of treatment on tenderness

Yastimadhu contains Glycyrrhizine and asparagine as active ingredients. Glycyrrhizine widely used as an anti-inflammatory agent. Asparagine is a type of amino acid and act as analgesic (natural painkiller) and anti-inflammatory. *Yastmadhu* has *Madura Rasa*, *Guru Snigda Guna*, *Sheeta Veerya*, *Vata-Pittahara*, *Vrana Ropana*, property helped in relieving tenderness in both groups. In group B *Gritha* has *Snigda*, *Vatapitta Hara*, *Mrudukara* property hence *Yastimadhu Gritha* helped in relieving tenderness in *Parikartika*.

Overall Effect of treatment on Acute fissure in ano

Group B is showing better effect in reducing pain, constipation, bleeding, itching size of fissure, discharge, floor and granulation tissue and tenderness.

In both groups *Avipattikara Churna* was given at bed time which showed effectiveness in relieving constipation.

CONCLUSION

The disease *Parikartika* has similarity with the disease Fissure-in-Ano of Modern medical science. Majority of the patients were in the middle age group, males, poor class, non vegetarians (mixed), *Mandagni*, married, residing in rural areas. Sedentary life style and hard work and stressful life too, like businessman in modern era, is having key role in occurrence of disease *Parikarthika*. The present study, 60 patients of *Parikartika* were randomly assigned into two groups A and B. In Group A *Yastimadhu hydrogel* and in Group B *Yastimadhu Ghrita* were given for local application for 3 weeks. Majority of the patients had small Ulcer. Posterior midline position was the most common position. The effect of the treatment in both the groups has shown statistically significant results in subjective parameters like Pain, Constipation, Itching, Bleeding per rectum and also in objective parameter like size of anal fissure, Discharge, floor and granulation tissue and Tenderness. So, treatment was highly effective in both

the groups. The effect of treatment was statistically non-significant between the Groups A and B on Pain, Bleeding, Itching, Size of anal fissure, discharge, floor and granulation tissue and tenderness. Sitz bath with luke warm water after defecation also helped in reducing pain and tenderness. *Avipattikara Churna* administered internally facilitated easy bowel movement thus reducing pain during defecation. From the present study it can be concluded that both *Yastimadhu Gritha* and *Yastimadhu hydrogel* are effective in *Parikartika*. But *Yastimadhu Ghritha* showed better results than *Yastimadhu hydrogel*.

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