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A COMPARITIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF MADHUYASTI GHRITA GUDAVARTI AND JATYADI GHRITA GUDAVARTI IN MANAGEMENT OF PARIKARTIKA VIS-À-VIS FISSURE-IN-ANO

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ABSTRACT

Parikartika (Fissure-in-ano) is a commonly encountered ano-rectal disease in clinical practice. An anal fissure is a longitudinal split in the anoderm of the distal anal canal which extends from the anal verge proximally towards, but not beyond, the dentate line. The anal fissures are quite common, with around 1 in every 10 people affected at some point in their life. As a treatment, surgery remains the preferred option when there is intense pain, or recurrence in spite of prior conservative treatments but complications like wound infection, hematoma and abscess formation may occur. Hence conservative management of the fissure is more preferred. In this study, 40 patients suffering from Parikartika (Fissure-in-ano) were selected randomly from SDM Ayurveda Hospital, Udupi. 20 patients were treated with Madhuyasti Ghrita Gudavarti and 20 patients were treated with

Jatyadi Ghrita Gudavarti. The patients were demonstrated the method of inserting it into the anus and the intervention was given for a period of 10 days. The study reveals that both Madhuyasti Ghrita Gudavarti and Jatyadi Ghrita Gudavarti are helpful in controlling constipation, relieving pain, bleeding and pruritus thus helping in proper healing of the anal

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fissure.

KEYWORDS: Parikartika, Fissure-In-Ano, Madhuyasti Ghrita, Jatyadi Ghrita, Gudavarti.

AIM AND OBJECTIVE

To evaluate and compare the effect of Madhuyasti Ghrita Gudavarti and Jatyadi Ghrita Gudavarti in the management of Parikartika vis-à-vis fissure-in-ano.

INTRODUCTION

Unhealthy lifestyle and irregular dietary habits of the present era causes disturbances in the digestive tract. The biological clock is hampered leading to irregular bowel habits which in turn causes ano-rectal pathologies. One among the ano-rectal disease with pain as the main symptom is Parikartika (Fissure-in-ano) which is the second most common condition seen in an ano-rectal clinic. It occurs in adults aged 15- 40 years. [3] Anal fissures may be noticed by bright red anal bleeding on toilet paper and under garments, or sometimes in toilet. [4]

On the basis of symptoms, the disease Fissure-in-Ano can be compared to Parikartika mentioned in Ayurveda. Sushruta explains the symptoms of Parikartika as Kartanavat Cutting or burning sensation in the Guda (anus) region, Medra (penis), Bastishirasi (neck of urinary bladder) Anilasanga with cessation of flatus. [5] According to Acharya Sushruta, the pathognomonic feature of *Parikartika* is *Kshanana*^[6] (injury) of Guda causing the typical cutting pain. Similar injury occurs in the anoderm in anal fissures causing excruciating pain during after defecation.

The conservative managements includes oral pain killers to be taken before anticipated bowel movement, soothing ointments or stool softeners may be used to make the stool soft enough, weak bulk laxative are the best. [7] As a treatment, Fissurectomy or Sphincterotomy remains the preferred option when there is intense pain, or recurrence in spite of prior conservative treatments. But these surgeries are associated with complications like bleeding, wound infection, impaired control of bowel movements or gas, hematoma formation and abscess formation. [8] Parikartika has a high incidence as an independent disease with severity of pain demanding newer, more convenient and more effective modalities of management. So an alternative treatment which is least invasive, cost effective, easy to administer and having a healing effect on the wound of fissure was necessary.

Sushruta has directly mentioned the usage of *Madhuyasti Taila* administered in the form of *Picchabasti* as the prime treatment for *Parikartika*.^[9] The primary pathology of an anal fissure is a wound (*Vrana*). As a *Vrana Ropana Chikitsa* measure, *Varti* was considered.^[10] Here *Guda-varti* was prepared out of both the *Madhuyasti* Ghrita^[11] and *Jatyadi* Ghrita^[12] taking *Madhucchista*^[13] as base. In this work, an attempt has been made to retain the medicine in the form of *Guda-varti* in *Guda Pradesha* for a longer duration of time. *Madhuyasti Ghrita* which was chosen as it possesses the property of *Vedana Shamana*, *Vrana Ropana* and *Sandhana*. *Jatyadi Ghrita* has properties like *Vrana Ropana* and has *Pitta Shamaka* and *Vata Shamaka* properties. Hence a comparative clinical study was done to find the effect of *Madhuyasti Ghrita Guda Varti* and *Jatyadi Ghrita Gudavarti* in *Parikartika* vis-à-vis Fissure-in-Ano.

MATERIALS AND METHODS

Source of subjects

40 patients diagnosed as a case of *Parikartika* (fissure-in-ano) in the age group of 15-65 of either sex full filling the inclusion criteria were selected from Outpatient and Inpatient Department of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udupi.

Study Design

It is an open labelled randomized comparative clinical study with pre-test and post-test design. A detailed history was obtained and the observations were recorded based on subjective parameters in a proforma designed specifically for this study. The 40 patients were divided randomly into 2 groups A or B. Group A was treated with *Madhuyasti Ghrita Gudavarti* and Group B was treated with *Jatyadi Ghrita Gudavarti*. Prior to the *Gudavarti* insertion, patient was advised to do sitz bath in warm water for 10 minutes. The intervention was given for a period of 10 days. The patient was observed and data was recorded on 5th day and 10th day, followed by 17th and 24th day. Results obtained were recorded and statistically analyzed with Wilcoxon Signed Rank Test and Mann-Whitney U Test.

Materials Required

Following materials were required for this study.

- ➤ Madhuyasti Ghrita
- > Jatyadi Ghrita
- Madhucchista

Method of Preparation of Madhuyasti/ Jatyadi Ghrita Gudavarti

2 parts of Madhuyasti / Jatyadi Ghrita was taken in a vessel and heated in mild flame for about 4-5 minutes. To the heated Ghrita, 1 part of Madhucchista which was cut into small pieces was added little by little and was stirred slowly until it got melted completely. Then the vessel was removed from the fire and the contents stirred well, allowed to cool and solidify. After cooling, the mixture acquired a semi-solid form. Then the mixture was made into Varti form and was dried under room temperature for about half an hour. Then the Madhuyasti Ghrita Gudavarti and the Jatyati Ghrita Gudavarti were separately packed & sealed in zip-lock plastic covers.



Fig.1: Addition of Madhucchista to the heated Ghrita.



Fig.2: Semisolid Form after Cooling.



Fig 3: Prepared Gudavarti Packed and Sealed in Zip lock Plastic Covers.

INTERVENTION (Method of Insertion of Gudavarti)

The patients were provided with prepared Gudavarti for a period of 10 days. The method was explained and demonstrated to the patient on the first sitting.

Purvakarma

The patient was asked to do the same procedure, once daily, for 10 days after passing the bowel and sitz bath in warm water for 10 minutes.

Pradhanakarma

The patient was asked to do the same procedure, once daily, for 10 days after passing the bowel and sitz bath in warm water for 10 minutes. The patient was advised to self-insert the varti into the anus and retain the *Guda-varti* as long as possible.

Duration of Treatment

The procedure was carried out for a period of 10 days.

Observation

The patients were observed before treatment, on 5th day and 10th day.

Follow-Up: The patient's follow-up was done on 17th day and 24th day.

Inclusion Criteria: Patients with clinical signs and symptoms of anal fissure were selected in the age group of 15-65 years.

Exclusion Criteria: Patients suffering from systemic diseases like Hepatitis, Tuberculosis, HIV, Uncontrolled DM. Patients with associated ano-rectal diseases like Fistula-in-ano, Hemorrhoids, Polyp, Malignancy, Crohn's disease and Ulcerative colitis.

Assessment Criteria: For easy assessment of the condition of fissure-in-ano, the findings were thoroughly noted before treatment and after treatment. The signs and symptoms of *Parikartika* mentioned in Ayurvedic text and that of fissure-in-ano in modern text was combined and was put forth. The grading was considered after assessing the complaints and findings in the subject.

Parameters

1. Pain

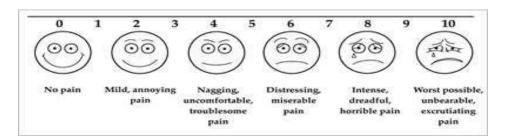


Fig.4 The Visual Analogue Scale was used for assessment of pain.

2. Bleeding

The presence of streaks of blood after a bowel movement is a common symptom in an anal fissure. This was graded depending upon the presence and absence of streaks of blood over the stool.

Table No: 1 Grading for bleeding.

| Present | 1 |
|---------|---|
| Absent | 0 |

3. Constipation

The grading of constipation was done depending on the frequency of bowel movement.

Table No 2: Grading for constipation.

| Constipation Grading | Score |
|--------------------------------------|-------|
| Passes bowels everyday | 0 |
| Passes bowels once in 2 days | 1 |
| Passes bowels once in 3 days | 2 |
| Passes bowels once in 4 days or more | 3 |

4. Pruritus

The degree of itching was totally dependent on the words of the patient.

Table No 3: Grading for Pruritus.

| Pruritus Grading | Score |
|-------------------|-------|
| No Pruritus | 0 |
| Mild Pruritus | 1 |
| Moderate Pruritus | 2 |
| Severe Pruritus | 3 |

Investigations

- HB%, TC, DC, RBS
- Any other investigation if required.
- Only those patients with normal reading were selected for the study.

RESULTS

The statistical tests were Wilcoxon Signed Rank Test which was used for analysis of data in between the group and Mann-Whitney U Test which was used for analysis of data within the group.

a. Pain in between the group.

Table No: 4 Mean score on effect of both treatment on Pain.

| Danamatana | Pain Mean | | | | | | |
|--|-----------|-------|------|--------------------|--------------------|--|--|
| Parameters | BT | Day 5 | AT | 1 st FU | 2 nd FU | | |
| Madhuyasti Ghrita Gudavarti – Group 1 | 2.80 | 1.55 | 0.00 | 0.00 | 0.00 | | |
| Jatyadi Ghrita Gudavarti - Group 2 | 2.85 | 1.80 | 0.3 | 0.1 | 0.1 | | |

b. Pain within the Group

➤ Between the group analysis of pain before treatment and Day 5,Madhuyasti Ghrita Gudavarti Group showed better result (MR=18.98 and p value = 0.345) which is statistically insignificant.

- ➤ Between the group analysis of pain before treatment and Day 10, Madhuyasti Ghrita Gudavarti Group showed better result (MR=18.80 and p value = 0.238) which is statistically insignificant.
- > Between the group analysis of pain before treatment and Day 17 and also before treatment and Day 24, Madhuyasti Ghrita Gudavarti Group showed better result (MR=20.00 and p value = 0.708) which is statistically insignificant.

2. Effect on Constipation

a. Constipation in between the group.

Table No: 5 Mean score on effect of both treatment on Constipation.

| Donomotona | Constipation Mean | | | | | | |
|--|-------------------|-------|------|--------------------|--------------------|--|--|
| Parameters | BT | Day 5 | AT | 1 st FU | 2 nd FU | | |
| Madhuyasti Ghrita Gudavarti - Group 1 | 1.29 | 0.58 | 0.00 | 0.00 | 0.00 | | |
| Jatyadi Ghrita Gudavarti - Group 2 | 1.29 | 0.11 | 0.00 | 0.00 | 0.00 | | |

b. Constipation within the Group

- Between the group analysis of constipation before treatment and Day 5 Madhuyasti Ghrita Gudavarti Group showed better result (MR=17.00 and p value = 0.676) which is statistically insignificant.
- ➤ Between the group analysis of constipation before treatment and Day 10, both Madhuyasti Ghrita Gudavarti Group and Jatyadi Ghrita Gudavarti Group showed no difference (MR = 17.50 and p value = 1.00) which is statistically insignificant.
- Between the group analysis of constipation before treatment and Day 17 and also before treatment and Day 24, both Madhuyasti Ghrita Gudavarti Group and Jatyadi Ghrita Gudavarti Group are same (MR = 17.50 and p value = 1.00) which is statistically insignificant.

3. Effect on Pruritus

a. Pruritus in between the group

Table No: 6 Mean score on effect of both treatment on Pruritus.

| Do wo ma ot one | Pruritus Mean | | | | | |
|---------------------------------------|---------------|-------|------|--------------------|--------------------|--|
| Parameters | BT | Day 5 | AT | 1 st FU | 2 nd FU | |
| Madhuyasti Ghrita Gudavarti – Group 1 | 1.29 | 0.58 | 0.00 | 0.00 | 0.00 | |
| Jatyadi Ghrita Gudavarti - Group 2 | 1.26 | 0.60 | 0.00 | 0.00 | 0.00 | |

b. Pruritus within the Group

- ➤ Between the group analysis of pruritus before treatment and Day 5 Madhuyasti Ghrita Gudavarti Group showed better result (MR=16.35 and p value = 0.911) which is statistically insignificant.
- ➤ Between the group analysis of before treatment and Day 10, pain before treatment and Day 17 & pain before treatment and Day 24, Madhuyasti Ghrita Gudavarti Group showed better result (MR=16.29 and p value = 0.865) which is statistically insignificant.

4. Effect on Bleeding

a. Bleeding in between the group.

Table No: 7 Mean score on effect of both treatment on Bleeding.

| Danamatana | Bleeding Mean | | | | | | |
|--|---------------|-------|------|--------------------|--------------------|--|--|
| Parameters | BT | Day 5 | AT | 1 st FU | 2 nd FU | | |
| Madhuyasti Ghrita Gudavarti – Group 1 | 1.00 | 0.55 | 0.00 | 0.00 | 0.00 | | |
| Jatyadi Ghrita Gudavarti - Group 2 | 1.00 | 0.50 | 0.00 | 0.00 | 0.00 | | |

b .Bleeding within the Group

- ➤ Between the group analysis of bleeding before treatment and Day 5, Jatyadi Ghrita Gudavarti Group showed better result (MR =18.00 and p value = 0.742) which is statistically insignificant.
- ➤ Between the group analysis of bleeding before treatment and Day 10 both groups, Madhuyasti Ghrita Gudavarti Group and Jatyadi Ghrita Gudavarti Group showed no difference (MR =18.50 and p value = 1.00) which is statistically insignificant.
- ➤ Between the group analysis of constipation before treatment and Day 17 and also before treatment and Day 24 showed in both Groups are same (MR = 18.50 and p value = 1.00) which is statistically insignificant.

DISCUSSION

Warm Sitz bath

Warm sitz bath which was adviced prior to insertion of *Gudavarti* helped in reducing the hyper tonicity of anal sphincter and thus relaxing the sphincters. When the muscles were relaxed, the pain also was relieved. It also helped in cleansing the area of wound and thus helping in wound healing. The warm sitz bath increased blood flow, in turn improved the venous return and helped in stimulating the neural receptors.

Madhuyasti Ghrita Gudavarti

Madhuyasti Ghrita indication is Sadhyovrana associated with Shoola which is typically seen in an acute anal fissure. The drugs like Haridra, Hareetaki and Amalaki have Tikta Rasa which has astringent action and helped stoppage of bleeding in anal fissures. The drugs like Madhuyasti, Amalaki and Mustaka have Sheeta Virya which helped in reducing the burning sensation in the Guda Pradesha. Most of the drugs have anti-inflammatory, anti-microbial and wound healing properties and thus helped to heal the ulcer. Most of the drugs are Tridoshahara in nature and possess Vedanastapaka, Kandughna, Vranashodhana and Vranaropana properties. Moreover Madhucchista which was used as the base for Gudavarti preparation has actions like Vranaropana, Vranashodana, Shothahara and Vedana-shamaka and thus relieves Vata, possess Mrudu and Snigdha properties thus added soothing effect to the anal mucosa. Bee wax is rich in Vitamin A and a natural exfoliator, helps in soothing and hydrating the skin and is ideal for sloughing away dead skin cells which helped in healing of anal fissures.

Jatyadi Ghrita Gudavarti

Jatyadi Ghrita indication is Saruja Vrana which is deep seated, which is also observed in anal fissures. All the drugs possess Tikta Rasa Pradhana which acted as haemostatic and helped in stoppage of bleeding in anal fissure. The drugs like Jati, Katuki, Ushira and Sariva are Sheeta Virya in nature which helped in reducing the burning sensation experienced by the patient. Most of the drugs are Kapha-Pitta Shamaka and possess Laghu-Ruksha property and Katu Vipaka which helped in ideal sloughing away of necrotic tissue in the Vrana and thus enhancing healing of the Vrana. The drugs in Jatyadi Ghrita have Anti-Microbial, Anthelmintic (Krimighna) and Anti-inflammatory properties along with Vranashodhaka and Vranaropaka properties. Madhucchista along with Jatyadi Ghrita has synergic effects on soothing the Vrana on one side as well as exfoliating the dead skin on the other side, thus helping in healing the anal ulcer.

Pain

In Madhuyasti Ghrita Gudavarti group, all the 20 patients suffered from pain before the treatment. The mean score was 2.80 before treatment and it reduced to 0.00 after treatment of 10 days. There was no recurrence of pain either in 1st follow-up or 2nd follow-up, which shows that *Madhuyasti Ghrita Gudavarti* is effective in managing the pain in anal fissures.

In *Jatyadi Ghrita Gudavarti* group, all the 20 patients suffered from pain before the treatment. The mean score was 2.85 before treatment and it reduced to 0.3 after treatment of 10 days. There was no recurrence of pain in either 1st follow-up or 2nd follow-up, which shows that *Jatyadi Ghrita Gudavarti* is effective in managing the pain in anal fissures.

Constipation

In *Madhuyasti Ghrita Gudavarti* group, 17 patients suffered from constipation before the treatment. The mean score was 1.29 before treatment and it reduced to 0.00 after treatment of 10 days. There was no recurrence of constipation either in 1st follow-up or 2nd follow-up.

In *Jatyadi Ghrita Gudavarti* group, 17 patients suffered from constipation before the treatment. The mean score was 1.29 before treatment and it reduced to 0.00 after treatment of 10 days. There was no recurrence of constipation in either 1st follow-up or 2nd follow-up.

Pruritus

In *Madhuyasti Ghrita Gudavarti* group, 17 patients suffered from pruritus before the treatment. The mean score was 1.29 before treatment and it reduced to 0.00 after treatment of 10 days. There was no recurrence of pruritus neither in 1st follow-up nor 2nd follow-up.

In *Jatyadi Ghrita Gudavarti* group, 15 patients suffered from pruritus before the treatment. The mean score was 1.26 before treatment and it reduced to 0.00 after treatment of 10 days. There was no recurrence of pruritus in neither 1st follow-up nor 2nd follow-up.

Bleeding

In *Madhuyasti Ghrita Gudavarti* group, 18 patients suffered from bleeding before the treatment. The mean score was 1.00 before treatment and it reduced to 0.00 after treatment of 10 days. There was no recurrence of bleeding neither in 1st follow-up nor 2nd follow-up.

In *Jatyadi Ghrita Gudavarti* group, 18 patients suffered from bleeding before the treatment. The mean score was 1.00 before treatment and it reduced to 0.00 after treatment of 10 days. There was no recurrence of bleeding in neither 1st follow-up nor 2nd follow-up.

Thus by the statistical group analysis of pain, constipation and pruritus from before treatment to Day 5, *Madhuyasti Ghrita Gudavarti* showed better results. By statistical group analysis of bleeding from before treatment to Day 5, *Jatyadi Ghrita Gudavarti* showed better result.

CONCLUSION

- The people indulging in more of spicy foods or who had non-vegetarian diet are more prone to develop anal fissures. The *Doshas* mainly involved are *Vata* and *Pitta Dosha* and also it is more seen in *Vata-Pittaja Prakruti* persons.
- 50% of patients were having presence of anal fissure in 6 O clock position, 27.5% of patients were having at 12 O clock position and 22.5% of patients were having fissure in both 6 O clock and 12 O clock positions. Pain is the most evident presenting symptom and then constipation and bleeding lies the next.
- The warm sitz bath helped in reducing the tightness of anal sphincters and relaxing the muscles.
- Most of the part of *Gudavarti* was absorbed and only small portion was eliminated while passing motion. The *Gudavarti* insertion didn't cause any feeling of foreign body sensation as it was semi-solid in nature.
- Majority of the patients got considerable relief within 5 days of treatment and were
 effective in managing pain, constipation, pruritus and bleeding. Both *Madhuyasti Ghrita*Gudavarti and Jatyadi Ghrita Gudavarti were effective in management of Parikartika
 (fissure-in-ano).

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