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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF PANCHATIKTA GHRITA ALONG WITH PANCHATIKTA GHRITA GUGGULU IN PARIKARTIKA W.S.R. TO FISSURE-IN-ANO

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ABSTRACT

Parikartika is a very general and hurting condition of the anorectum. It is frequently encountered on a daily basis practise. However, in *Ayurvedic* texts, it is not described as an independent disease. The factors responsible for *Parikartika* are found in various *Ayurvedic* texts such as *vamana-virechana vyapad*, *basti karma vyapad*, and *up-drava of atisara, grahani, arsha, udavarta*, etc. The disease '*Parikartika'* can be compared to the 'Fissure-in-ano' on the basis of symptoms. These symptoms are pain, bleeding from the anal region, swelling, pruritis, and a burning sensation. In modern texts, Fissure-in-ano is described as an ulcer in the longitudinal axis of the lower anal canal. There are medical as well as surgical treatments available for it with some complications. This research work was planned with the aim to provide relief to the patients and evaluate the efficacy of the Local Application of *Panchtikta Ghrita* and *Panchtikta Ghrita Guggulu* orally in the treatment of *Parikartika*. In this trial, a randomized clinical study was performed on 30 patients diagnosed with *Parikartika* (Fissure-in-ano). The assessment was done before and after treatment by subjective parameters like pain, burning sensation, constipation, and bleeding from the anal region. In this study, significant relief was found in pain and constipation while in burning sensation

and bleeding highly significant relief was observed in the patients of *Parikartika*. On the basis of clinical observations, **i**t is concluded that local application of *Panchtikta Ghrita* and oral use of *Panchtikta Ghrita Guggulu* are effective and economical treatment modalities in the management of *Parikartika* (Fissure-in-ano). No complication was observed in this trial.

Keywords: : *Parikartika*, Fissure-in-ano, *Panchtikta Ghrita, Panchtikta Ghrita Guggulu.*

INTRODUCTION

Parikartika is derived from *the Sanskṛit* word '*Pari'* which denotes 'all around' and '*Kartanam'* means the act of cutting off. It means that excessive cutting pain around the anus is seen in *Parikartika*.

Appropriately classified documentation of *nidana*, *Samprapti* & *Rupa*, etc. of *Parikartika* is not found in any one place, they are present in scattered texts. Even then lots of *nidana* that may directly or indirectly cause *Parikartika* are coined by *Acharyas*. *Acharya Kashyap* has mentioned that *Parikartika* is of 3 types due to the prevalence of *doshas* and their treatment is to be done according to the *doshas*.

In *Ayurvedic Samhita*, the disease *Parikartika* is not mentioned as a separate disease it is described at different places as a complication of some procedures and states such as *vamana-virechana vyapad*, *basti karma vyapad*, and *garbhini vyapad*. According to *Acharya Sushruta*, it is a condition in which there is cutting and burning pain in the anus, penis, and umbilical region. In modern it can be correlated with Fissure-in-ano.

Fissure-in-Ano has been described as an acute superficial break in the continuity of the anoderm (anal skin) usually in the posterior midline of the anal margin. Fissure-in-ano is one of the commonest causes of severe pain in the anal region during, and especially after defecation. It lasts from several minutes to a few hours and it

may or may not be associated with bleeding. It can occur at any age and have equal gender distribution.

The factors which are considered for the selection of drugs are their properties of *vata- pitta shamak* and *vrana shodana* and *vrana ropana*. Considering the *Parikartika* as an ulcer, an attempt is made to evaluate the effect of ***Panchatikta Ghrita* locally** and ***Panchatikta Ghrita Guggulu* orally** in the management of ***Parikartika*** w.s.r. to **fissure- in-ano**. The selected drugs are well described in *Ayurvedic* texts for the treatment of *Parkartika* to improve the healing of the *Vrana*, to reduce the pain and burning sensation, to relieve constipation, and to the promotion of *Agni*.

AIMS AND OBJECTIVES:

1. To assess the efficacy of local application of *PANCHATIKTA GHRITA* and *PANCHATIKTA GHRITA GUGGULU* (Orally) in *Parikartika.*
2. To explore literature about the *Parikartika* in *Ayurvedic* classics and fissure-in-ano in the modern medical literature.
3. To provide cost-effective therapy and minimize complications.
4. To cure disease in less time.
5. To explore the literature about the properties of *Panchatikta Ghrita Guggulu* and *Panchtikta Ghrita.*

MATERIAL AND METHODS:

The objective of this study was to assess the effectiveness of the age-old remedies for the ailment *Parikartika* w.s.r.to Fissure-in-ano on the basis of fundamental principles of *Ayurveda* as well as the modern system of medicine utilizing the recent development in medical science.

1. **Study Design:** Randomized Controlled Clinical Trial

2. **Sample Size**: 30

3. **Duration of study**: 90 days

4. Selection of drug: *Panchatikta Ghrita* for local application and *Panchatikta Ghrita Guggulu* for oral use.

5. Selection of Patients: Patients with classical features of the *Parikartika* were selected from the OPD & IPD of Shalya Tantra, Department of Patanjali Bhartiya Ayurvigyan Evam Anusandhan Sansthan,

irrespective of sex, religion, and occupation. Mostly patients were registered as OPD patients. A detailed Performa is prepared for the study on the basis of the *Ayurvedic* text and allied sciences. The patients fulfilling the inclusion and exclusion criteria were registered on this Performa.

i. Inclusion Criteria:

• Patients willing to undergo trial and ready to give informed and written consent.

• Patients of ages between 18 to 60 years and both sexes irrespective of religion, socioeconomic status, and occupation will be taken with the clinical features of *Parikartika*.

• Patients having fissure-in-ano without tag.

ii. Exclusion Criteria:

- Patients are not willing to undergo a trial or not ready to give informed & written consent.
- Patients of either sex, age less than 18 and more than 60 years.
- Patients with uncontrolled systemic disorders like–Diabetes mellitus, uncontrolled hypertension, tuberculosis, ischemic heart disease, and renal disease.
- Patients with any type of endocrinal disorders.
- HIV and Hepatitis B/C positive patients.
- Patient with evidence of malignancy.
- Patient with any other ano-rectal diseases.

Investigations:

- Routine blood investigations like CBC, CT, BT, ESR, FBS/ RBS, HIV, HBsAg, and HCV did in every patient.
- Specific Investigation: if required LFT, KFT, Lipid profile, Urine R/M, X-RAY chest PA view, ECG, Tuberculin test, Colonoscopy, Biopsy.

Drugs selected- *Panchatikta Ghrita* and *Panchatikta Ghrita Guggulu*.

Method of preparation of *Panchatikta Ghrita Guggulu:* *Kwath* was prepared by reducing *kwath dravyas* to one-eighth by boiling. Then by using *kalka dravyas*, the *kalka* was prepared and mixed with *goghrita* followed by *kwath* taken in a stainless-steel vessel. After that, it was cooked on mild heat till it remained the quantity of *goghrita* was. After cooling, it was filtered and stored in wide-mouth glass bottles.

Method of Administration: *Panchtikta Ghrita Guggulu* is administered in two *Vati* twice daily doses with lukewarm water, after a meal after crushing.

Method of preparation of *Panchatikta Ghrita:* *Kwath* was prepared by using *kwath dravyas* and reduced to a quarter by boiling. And then rests of the ingredients were taken in a stainless-steel vessel. After that, it was cooked on mild heat till it remains the quantity of *goghrita*. After cooling, it was stored in glass bottles.

Method of Administration: Local Application

Methodology :

It is a randomized controlled clinical trial. Patients' complaints and history were taken in chronological order. General and systemic examination of every patient was done carefully. All the details related to the trial were given to the patients as well as their attendants. Informed written consent from each and every patient was taken before the treatment. For the clinical trial, 30 patients were selected.

Study design: It is a randomized controlled clinical trial.

Duration of study- 90 days.

Assessment criteria: The result of therapy was assessed on the basis of changes in local as well as general signs and symptoms. The assessment was made on the following parameters:

SUBJECTIVE PARAMETERS: Pain: It was assessed on MRC (medical research council) scale

Pain	Grade
Absence of pain /no pain	0
Mild pain that can easily be ignored	1
Moderate pain that cannot be ignored, interferes with function, needs treatment from time to time	2
Severe pain that is present most of the time demanding constant attention	3

CONSTIPATION:

Constipation	Grade
Absent- no constipation	0
Mild constipation occurs occasionally and evacuation of the bowel after straining	1
Moderate Constipation and hard stool irregularity of bowel on and off	2
Severe Constant irregularity of bowel frequently and consistency of bowel after laxative	3

BURNING SENSATION IN THE ANAL REGION:

Burning Sensation	Grade
Absent – No burning sensation	0
Mild Burning sensation during defecation	1
Moderate Burning sensation persists upto 6 hrs after defecation	2
Severe Constant burning sensation	3

ASSESSMENT OF BLEEDING:

Bleeding	Grade
No bleeding	0
Mild bleeding (Streaks on the stool)	1
Moderate bleeding (10-15 drops)	2
Severe (more than 15 drops)	3

Assessment for Overall Effect of the Therapy: Overall effect of the therapy was assessed in terms of Complete Relief, Marked Relief, Moderate Relief, Mild Relief, and unchanged by adopting the following criteria.

Sr. No.	Result	Criteria
1.	Complete Relief	80% to 100% relief in signs and symptoms
2.	Marked Relief	61% to 80% relief in signs and symptoms
3.	Moderate Relief	41% to 60% relief in signs and symptoms
4.	Mild Relief	21% to 40 % relief in signs and symptoms
5.	Unchanged	0% to 20 No relief in signs and symptoms

Assessment of the effect of treatment was done on the basis of the above-given assessment criteria before and after the treatment schedule.

Statistical Analysis

OBSERVATIONS

- The demographic profile shows that a maximum number of patients i.e 56.67% were of the age group of 20 – 30 years.
- A maximum of 60% of patients were male.
- More of the patients belonged to the Hindu religion i.e 96.67%.
- A maximum of 63.33% of patients were married.
- A maximum number of patients i.e 30% were students.
- A maximum number of patients i.e 73.33% were from the higher middle class.
- The maximum number of patients belonged to urban areas i.e 73.33%
- Maximum i.e., 60% of patients were found addicted to tea/ coffee.
- Maximum i.e., 73.33% of patients were having a vegetarian diet.
- Maximum patients i.e 86.67% were having < 1year chronicity.

- A maximum number of patients i.e 53.33% were with irregular bowel habits.
- A maximum of 70% of patients were reported to pass hard stools during defaecation.
- Maximum patients (60%) were having posterior fissure

s.

- A maximum of 70% of patients were observed with Krura Kostha.
- A maximum of 66% of patients belonged to Vata-pitta Prakriti.
- 73.33% of patients were of Madhyam Samhana and 73.33 % were of Madhyam Pramana.
- The maximum number of patients in this study was 50% consuming Katu-Tikta Rasa dominant Ahara.
- A maximum of 76.66% were of Madhyam Satva.
- 60% of patients were having Madhyama Abhyavaharaṇa shakti and maximum of 80 % of patients were having Madhyama Jaraṇa Shakti
- Maximum of 70% of patients were having Madhyama Vyayama Shakti
- The majority of the patients i.e., 100% were suffering from pain, 60% from burning sensation, 88% patients had constipation, and 80% patients had bleeding per rectum.

Table 1: Distribution of patients according to signs and symptoms-

Sr. no	Symptom	Number of patients	Percentage
1	Pain	30	100%
2	Constipation	27	90%
3	Burning sensation	08	26.67%
4	Bleeding per rectum	19	63.33%

Table no. 1 Shows the percentage of the most commonly seen features in Parikartika in all the patients. This study showed that a maximum of 100% of patients were suffering from pain. 90% of patients had Vibandha (constipation) which is the main causative factor of Parikartika. 26.67% of patients were found suffering from a burning sensation during and after defecation. Bleeding per rectum symptom was observed in 63.33% of patients

RESULT

The data were statistically analyzed by Friedman's test and Wilcoxon Signed Rank Test, at $p<0.05$, $p<0.01$, and $p<0.001$. The obtained results were interpreted as,

Non-significant: $p>0.05$,

Significant: $p<0.05$,

Highly significant: $p<0.01$.$p<0.001$

Table 2: Result after completion of treatment (90 days):

Parameters	Wilcoxon signed Rank W	P-value	% Effect	Result
Pain	-4.920	0.03	82.66%	Significant
Constipation	-4.667	0.02	68.67%	Significant
Burning sensation	-2.828	0.000	100%	Highly Significant
Bleeding	-3.923	0.000	100%	Highly Significant

Table no 2 shows the percentage of relief. In this study, we have used the Wilcoxon Signed Rank test to test the efficacy of the drug. Here are the observations made on the gradation score. From the above table we can find out that the P value for pain is 0.03,

the P value for constipation is 0.02 whereas the P value for burning sensation and bleeding per rectum is 0.00. Therefore, we can conclude that the effect observed is significant for pain and constipation, and highly significant for burning sensation and bleeding per rectum.

The overall effect of therapy

Table 3: Overall effect of the study

Sr. No.	EFFECT OF THERAPY	NO. OF PATIENTS(30)	PERCENTAGE
1	Complete relief	18	60%
2	Marked relief	11	36.67%
3	Moderate relief	1	3.33%
4	Mild relief	0	0%
5	Unchanged	0	0%

Based on the particular scoring pattern adopted, the total effect of therapy had been assessed. Out of 30 patients a maximum number of patients i.e. 18 (60%) showed Complete relief, 11 (36.67%) showed marked relief, and 1(3.33%) showed moderate relief.

DISCUSSION

Parikartika is a very common and painful anorectal disease. It becomes a chief problem in society. This is commonly found in pregnant women, the purpureal period, and youngsters. In this disease, an ulcerative lesion present in the anal region either in the anterior or posterior aspect inflicts severe spastic sort of excruciating and agonizing pain during the process of evacuation of the bowels. The recurrence rate is very high, and it is completely not cured by surgical intervention. Therefore, to avoid after-surgery complications and to provide an effective treatment this study was conducted on *Panchtikta Ghrita Guggulu* and *Panchtikta Ghrita* to reduce the pain, constipation, bleeding, and burning sensation and to prevent a recurrence.

MODE OF ACTION:

The probable mode of action of *Panchtikta Ghrita Guggulu* and *Panchtikta Ghrita* on the *Parikartika* is as follows-

Considering the *Parikartika* as an ulcer, an attempt is made to evaluate the effect of *Panchatikta Ghrita* locally and *Panchatikta Ghrita Guggulu* orally in the management of *Parikartika* w.s.r. to fissure-in-ano. The selected drugs are well described in *Ayurvedic* texts for the treatment of *Parkartika* to improve the healing of the *Vrana*, to reduce the pain and burning sensation, to relieve constipation, and to the promotion of *Agni*. The *Panchtikta Ghrita Guggulu* is used internally, and it has properties like *Vatashamaka, Vedanasthapaka Shothahara, Balya, Rasayana*, etc. The *Panchtikta Ghrita* is used externally as it has *Vata- Pitta hara, Vrana Sodhaka*, and *Ropaka* properties. Due to these properties, the trial drugs are used to alleviate *Dosha* and to help in the healing of *parikartika*.

CONCLUSION

In modern medical science, the disease *Parikartika* resembles fissure-in ano. Ayurveda has amazing results in anorectal diseases. In this clinical study, it was found that *Panchtikta Ghrita* and *Panchtikta Ghrita Guggulu* are effective and play an important role in alloying the cardinal symptoms of *Parikartika* and help in the fast healing of fissure-in-ano. During this treatment, there was no need to put the patients under general anaesthesia, hospitalization, or need to take time off from work. It was found that the treatment was not costly and has no adverse effects.

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