

A CLINICAL STUDY ON EFFECT OF KSHEERABALA TAILA MATRAVASTI IN PARIKARTIKA W.S.R. TO CHRONIC ANAL FISSURE

*Dr. Naresh Dhaked ** Dr. B. Swapna

* M.S. Scholar Dept. of Shalya Tantra NIA Jaipur

** Assistant Professor Dept. of Shalya Tantra Jaipur

Address for Correspondence – Dr. Naresh Dhaked MS scholar Department of Shalya Tantra National Institute of Ayurveda Jaipur
(Rajasthan) 302002

ABSTRACT

In the era of fast food, there is change or irregularity in diet and diet timings and also sedentary life style. These causes disturb in digestive system which many diseases amongst them ano-rectal disorder constitute an important group. Anal fissure is second most common condition seen in a rectal clinic and by far the most common cause of anal ulceration. *Parikartika* denotes cutting or cutting pain all around. In *Ayurveda*, many treatments are quoted for the treatment of *Parikartika* and *Vasti* karma is one among them. As vitiated vata is the main contributing factor for the spasm of the anal sphincter and will be relieved effectively by *matravasti*. Total 15 subjects randomly selected for the study, with ages ranging from 15 yrs. to 60 yrs. Study design was Randomized, Controlled, Prospective, Open trial study and the duration of clinical trial was 8 weeks including follow up. The test of significance showed that the efficacy of *ksheerabala taila matravasti* in *parikartika* w.s.r. to chronic anal fissure. It was observed that *Matra Basti* had shown better result in all subjective and objective parameters in a period of eight weeks trial.

Keywords:- *Ksheerbala Taila Matravasti, Parikartika*

INTRODUCTION

Ayurveda is the science which deals human being for their physical, mental & spiritual health. *Ayurveda* is the natural healing system of medicine to maintain health of a healthy person and cure the ailments of ailing person.

In the era of fast food, there is change or irregularity in diet and diet timings and also sedentary life style. In addition to change in diet and life style, one is always under tremendous mental stress. All these causes disturb in digestive system which many diseases amongst them ano-rectal disorder constitute an important group.

Anal fissure is second most common condition seen in a rectal clinic and by far the most common cause of anal ulceration. Acute Fissure in ano is a simple linear ulcer in the anal canal and in chronic stage ulcer may become deeper with indurated and thickened edges, sentinel tag at the distal end and hypertrophied anal papilla at proximal end of fissure.¹ Chronic anal fissure is characterized by severe pain after defaecation and often fresh anal bleeding.

Fissure in ano occurs most commonly in midline posteriorly. In male, fissures usually occur in the midline posteriorly – 90% and much less commonly anteriorly – 10%. In female, fissures on the midline posteriorly – 60% are slightly commoner than anteriorly – 40%, more common in women than men².

Parikartika denotes cutting or cutting pain all around. The word Parikartika is derived from root “Parikri” which denotes to surround to uphold, to cut around, clip, cut off or cutting up to. (Pari = all around, Kartanam=cutting). But according to Dalhana, the commentator of Sushruta Samhita, “There is cutting and tearing pain everywhere” i.e

Most Fissure in ano can be compared with Parikartika in Ayurvedic classics. Parikartika is mentioned in Susruta chikitsa Sthana³. As one of the complications of *Virechana* therapy and improper usage of Vasti. While in Charaka Siddhi Sthana⁴, it is mentioned as Atisara vyapad and in Kashyapa Samhita⁵, the similar condition is mentioned in pregnant women and classified as Vataja, Pittaja and Kaphaja on the basis of Doshic predominance, while Acharya Susruta described the condition as Vata & Pitta Dosha predominance⁶.

Patients with chronic anal fissure have a high resting anal canal pressure, which impairs blood flow through the anal sphincters to the anal mucosa and prevents healing. In *Ayurveda*, many treatments are quoted for the treatment of *Parikartika* and *Vasti karma* is one among them. As vitiated *Vata* is the main contributing factor for the spasm of the anal sphincter and will be relieved effectively by *Matravasti*. The primary aim of treatment for anal fissure is to reduce pressure generated by the anal sphincter mechanism, to improve blood flow and allow mucosal healing.

.AIMS & OBJECTIVE:

- To study aetiopathogenesis of fissure in Ano and to explore the clinical consequences.
- To evaluate the effect of the *Ksheerabala taila* in fissure in Ano.

MATERIALS AND METHODS:

SAMPLE SIZE:

Total 15 subjects randomly selected for the study, with ages ranging from 15 yrs. to 60 yrs., irrespective of sex, religion etc.

SOURCE OF SUBJECTS:

OPD or IPD, Department of Shalya-Tantra, National Institute of *Ayurveda*, Jaipur.

SELECTION CRITERIA:**INCLUSION CRITERIA:**

- Ages ranging from 15 yrs. to 60 yrs
- Patients having clinical features of chronic fissure in ano will be included.
- Those ready to give written informed consent

EXCLUSION CRITERIA:

- Who are not ready to give written informed consent
- Who are with acute fissure in ano
- Fissure in ano which developed because of some systemic diseases like IBD, Leukemia etc.
- Other active anorectal diseases like internal hemorrhoids, Fistula in ano, anorectal abscess, rectal prolapse and carcinoma
- Blood Dyscrasias
- Uncontrolled Diabetes Mellitus, HIV, HBsAg Positive patients
- Feacal Incontinence yrs
- Mentally ill patients
- Pregnant women

WITHDRAWAL CRITERIA:

- If the subject withdraws consent for any reason
- If the subject is lost to follow-up
- If the subject fails to adhere to the protocol requirements
- If the subject's clinical condition worsens in spite of currently prescribed medications

LAB INVESTIGATIONS Routine Inv. (Hb gm%, TLC, DLC, BT, CT, ESR, RBS, HIV & HBsAg, CUE, CXR, ECG)

STUDY TYPE: Interventional.

STUDY DESIGN: Allocation: Randomized, Controlled, Prospective, Open trial

DURATION OF CLINICAL TRIAL: 8 weeks including follow up

ASSESSMENT CRITERIA

Effect of therapy was evaluated before, during & after the course of treatment by using parameters as stated below with standard grading.

A). Primary Outcome Measures:

(a) Subjective Parameters

• **Bleeding**

Grade	Explanation
0	No Bleeding
1	Bleeding in the form of streak
2	Bleeding in the form of drop
3	Bleeding in the form of splash in the pan
4	Bleeding in the form of stream

• **Burning sensation**

Grade	Explanation
0	No complain of burning sensation
1	Negligible burning sensation

2	Occasional and tolerable to burning sensation
3	Constant and tolerable to burning sensation
4	Intolerable burning sensation makes the patient uncomfortable and makes the patient to rush for medical Help

- **Discharge**

Grade	Explanation
0	None
1	Small
2	Moderate
3	Large(copious)

(b) Objective Parameters

- **Sphincter spasm**

Grade	Explanation
0	Normal
1	spasmodic
2	relax

Wound healing

Grade	Explanation
0	Complete healed wound
1	Partially healed wound with healthy granulation tissue
2	Wound with healthy granulation tissue
3	Unhealthy granulation tissue without infected tissue bed

Wexner Continence Score

SCORE

0-perfect
20- Completely Incontinence

A Frequency Assessment Tool

Type of Incontinence	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wear Pad	0	1	2	3	4
Lifestyle Altered	0	1	2	3	4

- Never – 0
- Rarely - Less than once a month
- Sometimes - Less than once a week or once a month,
- Usually - Once a day or once a week
- Always – Once a day or more

Secondary Outcome Measures:

- Parental/patient satisfaction

Not Satisfied	0
Somewhat Satisfied	1
Extremely Satisfied	2

- Time to return to work
- Length of Hospital Stay

DATA ANALYSIS:

The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation and Standard error (SE). In Stat Graph Pad 3 software (Trial version), Wilcoxon matched-pairs signed ranks test was used for nonparametric data and results calculated. Paired t test was carried out at $p < 0.05$, $p < 0.01$, $p < 0.001$, $p < 0.0001$.

The results were calculated as-

- No significant : $P > 0.05$
- Significant : $P < 0.05$
- Highly significant: $P < 0.01$, $P < 0.001$, $P < 0.0001$.
- The parameters were subjected to Wilcoxon matched-pairs signed ranks test to bring out the level of significance i.e. p value
- Other post procedure complications were compared with Chi- Square test.

CRITERIA FOR TOTAL ASSESSMENT OF PROCEDURE

Good response: complete relief in presenting signs and symptoms of the disease.

Fair response: 75% and above relief of signs & symptoms.

Poor response: 50% to 74% relief of signs & symptoms.

No response: No response in presenting signs & symptoms of the disease

List of contents in Ksheerabala Taila

- 1 Sida cordifolia Bala Moola twak 5 parts(5 pala)
- 2 Sesamum indicum Tila Taila Seeds 16 parts(1 prastha)
3. Goksheera 64 parts(4 prastha)

Method of preparation of Ksheerabala Taila Matravasti:

60 ml of Ksheer Bala Taila was taken in a small container made lukewarm by keeping it in a hot water. Then Saindhava Lavana (2 grams) and shatapushpa (2 grams) added and mixed with the help of mortar till a homogenous mixture was obtained. Once again Basti Dravya made into luke warm, filled in to enema syringe fitted with rubber catheter (no .08).

Method of administration of Matravasti

1. Poorvakarma:

- The patient was advised to have a light meal on the day of treatment. Before administration of Basti, Abhyanaga (massage) with Tila Taila was done.
- Thereafter, Nadi Sweda (sudation) was performed.

2. Pradhana karma:

- After recording the vitals patient was advised to lie down in the left lateral position with the left lower extremity extended and the right lower extremity flexed at the knees and hips.
- Then 60 ml of lukewarm Ksheerabala taila was loaded in an enema syringe. A rubber catheter oiled with oil was attached to the enema syringe. □ After any air in the enema syringe had been expelled, the rubber catheter was passed through the anus of the patient up to a length of 4 Angula and the drug was administered. The patient was asked to take deep breaths during the passage of the catheter and the administration of the drug.
- The entire oil in the syringe was not administered in order to avoid entrance of Vayu into the Pakvashaya as it may produce pain.

3. Pashchath karma:

- After the administration of Basti, the patient was advised assume the supine position. While in this position, the patient's buttocks were gently tapped and the legs were raised for a few minutes so as to raise the waist. These measures were intended to prevent the administered fluid from flowing out too soon.
- After a short time the patient was allowed to get up from the table, and was then advised to rest in bed for at least ½ an hour.
- Diet and Restriction: In general advised to take luke warm water, avoid heavy and oily food stuffs and suppression of natural urges, excess of travelling, exercise, excessive speech, sitting and lying in improper posture, exposure to wind, cold, heat
And dust.

OBSERVATION AND RESULT

TABLE No 1. Shows the pattern of clinical recovery in various „Subjective Parameters“ of *parikartika* (chronic fissure in ano) in 15 patients treated with “Following tag excision under L.A, *Ksheerbala Taila Matravasti* (60 ml *Ksheerbala Taila*, 2 grams *Saindhav lavan*, 2 grams *Shatapushpa*) were given per rectally for seven days from the first post- operative day” – by Wilcoxon matched-pairs signed-ranks test

S No	Symptoms	Mean		Dif.	% of Relief	SD	SE	P	Results
		BT	AT						
1.	Burning sensation	2.067	0.06667	2.000	96.75%	1.363	0.3519	0.0005	H.S.
2.	Pain	2.067	0.2000	1.867	90.00%	0.5164	0.1333	0.0001	H.S.
3.	Bleeding	1.333	0.2000	1.133	84.99%	0.5936	0.1919	0.0005	H.S.

4.	Discharge	0.2000	0.6667	0.1333	66.65%	0.3519	0.0908	0.5000	N.S.
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Highly significant results are shown on Burning sensation, pain, Bleeding. Non-Significant results obtained on Discharge.

INTRA GROUP COMPRISON

TABLE NO 2. Shows the pattern of clinical recovery in various „Objective Parameters“ of *parikartika* (chronic fissure in ano) in 15 patients treated with

“Following tag excision under L.A, *Ksheerbala Taila Matravasti* (60 ml *Ksheerbala Taila*, 2 grams *Saindhav lavan*, 2 grams *Shatapushpa*) were given per rectally for seven days from the first post- operative day” –by Paired t-test.

S No	Symptoms	Mean		Dif.	% of Relief	SD	SE	P	Results
		BT	AT						
1.	Wound healing	1.533	0.1333	1.400	91.32%	0.8338	0.9103	0.0001	H.S.
2.	Sphincter spasm	1.000	0.2000	0.8000	80.00%	0.4140	0.1069	0.0001	H.S.

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Highly significant results are shown on wound healing and sphincter spasm

Table No 3: Shows the Overall Percentage improvement of symptoms

S.NO.	PARAMETERS	RESULT IN PERCENTEDGE
1	Burning Sensation	96.75
2	Pain	90.00
3	Bleeding	84.99
4	Discharge	66.65
5	Wound Healing	91.32
6	Sphincter Spasm	80.00

DISSCUSION

Effect of Ksheerbala Taila Matravasti - :

- a. Burning sensation: It showed highly significant relief of 96.75% with p value (0.0005) in burning sensation.
- b. Pain: it showed highly significant relief of 90.00% with p value (0.0001).
- c. Bleeding: Observations for the data for bleeding showed highly significant relief with p value of 0.0005, percentage relief in group B was 84.99%.
- d. Discharge: Data for discharge showed non-significant results at the end of treatment, with p value of 0.5000 and percentage relief in group B was 66.65%
- e. Wound healing: It showed highly significant relief of 91.32% with p value (0.0001).
- f. Sphincter spasm: Observations for the data for sphincter spasm, showed highly significant relief (p value 0.0001), percentage relief in group B was 80.00%.

Probable Mode of Action Of Ksheerabala Taila

As mentioned earlier the healing of fissure is different from the healing of any other ulcer because in the former, there is constant contamination of the wound by faeces and its frequent friction with the mucosa while there is continuous spasm of the sphincteric muscle. They are the important factors which keep a fissure away from normal healing. In such situation a drug which produces a soothing effect, VataPittahara, Vedana Sthapana, Vrana Shodhana, Vrana Ropana and influences reduction of inflammation will be more suitable than drug which may act as the best healer of ulcer on other parts of the body. Those Tailas probably has these properties. But as far as main symptoms are concerned Pain and Burning may be relieved due to the action of Vedana Sthapana, Dahaprashamana and Vata Pittahara. Its well-known fact that the Vata and Pitta Doshas are predominant in pain as well as in fissure.

According to modern pharmacological action, this drug has a potent anti-inflammatory and steroidal activity. Due to the amount of inflammation and spasm which is responsible for producing the agonizing pain in cases of fissure-in-ano. Ksheerabala Taila probably is able to counteract these two factors more efficiently than Jatyadi Taila. The relief of severe pain within 24 hours is something remarkable about this drug although the ulcer takes as many as three to four weeks for complete healing.

CONCLUSION

Whereas among 15 subjects of Group B, 12 subjects got cured completely, 01 got marked relief, one subject got moderate relief (50%- 74%) and 3 subjects got mild relief.

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