

EFFECTIVENESS OF DWIHARIDRA RASAKRIYA PICHU IN CHRONIC FISSURE - IN-ANO - A SINGLE GROUP CLINICAL STUDY

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ABSTRACT

Fissure-in-ano is an elongated ulcer in the long axis of the lower anal canal. One in every ten people is affected by anal fissure in their lifetime. It occurs equally in both sexes and is mostly seen between 30-50 years of age. Sometimes it occurs in children also. Constipation is the primary and sole cause of initiation of a fissure-in-ano. Passage of hard stool, irregularity of diet, consumption of spicy and pungent food, faulty bowel habits, and lack of local hygiene can contribute to initiation of the pathology. Fissure-in-ano is of two types, acute and chronic. If a fissure is present for more than six weeks, it is termed a chronic fissure. In Ayurveda it may be correlated with *Parikarṭhika*. *Pichu dhārana* was found to be effective in chronic fissure-in-ano. The aim of this study is to find out the effectiveness of *Dwiharidra rasakriya pichu* in the management of chronic fissure-in ano.

Keywords: Fissure-in-ano, *Parikarṭhika*, *Dwiharidra rasakriya pichu*

INTRODUCTION

Anorectal diseases have become increasingly prevalent in the present era. It is due to various factors like sedentary lifestyle, unhealthy diets, obesity and genetics. Unhealthy dietary habits, often characterized by low fibre processed foods and inadequate hydra-

tion, lead to chronic constipation and straining during bowel movements, elevating the risk of anorectal diseases. The widespread use of technology has also led to increased sitting time, which can impede proper blood circulation to the anal area, fostering conditions

like Haemorrhoids and anal fissures. Inadequate hygiene practices, pregnancy, aging, stress and certain medical conditions further compound the problem. Fissure-in-ano is a canoe shaped longitudinal ulcer in the squamous epithelium of anal canal, located just below the muco-cutaneous junction. It extends from anal verge to the dentate line.¹ One in every ten people is affected with anal fissure in their lifetime. It occurs equally in both sexes and is mostly seen between 30-50 years of age. Sometimes it occurs in children also.² Constipation is the primary and sole cause of initiation of a fissure-in-ano and is commonly occurs in the midline posteriorly (90%), occasionally it occurs in the midline anteriorly (10%) and exceptionally found elsewhere on the circumference of the anus.³ Anal fissure may be classified as acute and chronic. Acute fissures heal spontaneously, usually within 6 weeks. If the symptoms persist more than 6 weeks it is considered as a chronic fissure.⁴ Pain during and after defecation, which is burning in nature, bright red bleeding or drop of blood or streaks of fresh blood on stool, perianal swelling, occasional mucous discharge and itching around anus are the common clinical features of anal fissure. There are many operative and non-operative procedures for the management of fissure-in-ano. Medical treatment includes oral analgesics, stool softeners, soothing ointment and self-dilatation. Surgical management includes Lord's dilatation, sphincterotomy, Fissurectomy, anal advancement flap. All these methods have one or another drawback.^{3,5} Fissure-in-ano may be correlated with the condition *Parikarthika* mentioned in Ayurveda. It is described as a *vyāpath* of *virechana* and *vasthi karma* by *acharya Susruta*⁶ and *Charaka*⁷ and also as a complication of various diseases like *atisara*, *udavartha* etc. *Acharya Kasyapa* described it as a *garbhini vyāpath* and classified the condition into three, based on dosha predominance.⁸ *Acharya sarangadhara* also included it under one among 76 complications of *vasthi*. Local therapies like *anuvāsana vasthi*, *taila pūrana*, *lepa* and *pichu dhārana* are given prime importance in the treatment of *Parikarthika*. There is no reference regarding the surgical management of *Parikarthika* in any of the

samhithas, so it indicates that conservative management is sufficient for *Parikartika*. But when local and medical treatment get failed, then parasurgical and surgical procedures can be adopted. In this study *Dwiharidra rasakriya pichu* has been selected to evaluate the effectiveness in chronic fissure-in-ano. *Dwiharidra rasakriya* is mentioned by *Acharya Suśruta* in *chikitsa sthāna*, *Dwivraneeya adyāya*. He mentioned that it is ideal for the healing of both *sud-dha vrana* and *Dushtavrana*. The ingredients of *Dwiharidra rasakriya* are *haridra* and *daruharidra*, *siktha taila* is used as a medium of application.

Objective of the study

1. To evaluate the effectiveness of *Dwiharidra rasakriya pichu* in the management of chronic fissure-in-ano.

MATERIALS AND METHODS

Study setting: OPD and IPD of V.P.S.V. Ayurveda College Hospital, Kottakkal

Study population: Participants satisfying the inclusion and exclusion criteria.

Diagnostic criteria

- On the basis of history.
- Inspection - Elongated ulcer with or without sentinel tag.

Inclusion criteria

- Participants who fulfill the diagnostic criteria.
- Participants with chronic fissure-in-ano
- Age: 21 – 50 years.
- Participants with informed written consent.

Exclusion criteria

- Participants with other systemic and autoimmune illness like diabetes, ulcerative colitis, Crohn's disease
- All kind of malignancies
- High sphincter spasm.
- Participants suffering from anal fissure associated with anorectal conditions like fistula-in-ano, Haemorrhoids and perianal abscess.

Method of data collection: From the participants with symptoms of fissure-in-ano visited in *Shalyatantra* OPD/IPD, VPSV Ayurveda college hospital, Kottakkal, 16 participants satisfying the inclusion and exclusion criteria were selected for the study. They

were treated with *Dwiharidra rasakriya pichu* 2 hours daily for 14 days irrespective of sex, occupation and socioeconomic status.

Intervention

Drugs for the preparation of Dwiharidra rasakriya

SI No.	Sanskrit name	Botanical name	Parts used
1.	<i>Haridra</i>	<i>Curcuma longa L.</i>	Rhizome
2.	<i>Daruharidra</i>	<i>Berberis aristate DC.</i>	Stem bark, stem
3.	<i>Siktha taila (tila taila & bee wax)</i>		Used as a medium of application

- Dwiharidra rasakriya was procured from a GMP certified company.

Procedure for pichu dhārana

Purva karma

- Materials required: sterile dish, sterile cotton, betadine solution, sponge holding forceps, sterile gauze pad, gloves, *siktha taila*, *Dwiharidra rasakriya*.
- An informed consent was obtained from the participants and was assessed based on the diagnostic criteria.
- The participants were given *Avipathi churna* 20gm with lukewarm water the previous night for *virechana*.
- The participants were advised to do sitz bath with lukewarm water for 10 minutes.
- The perianal area was shaved well.

Pradhāna karma

- *Dwiharidra rasakriya* was made into a paste with the help of *siktha taila*
- Participant were made to lie down in lithotomy position.
- Peri anal region were cleaned with betadine solution prior to the procedure.
- *Dwiharidra rasakriya pichu* were applied.

Paschat karma

- Participants were moved to an observation room and were observed for two hours.
- Participants were advised to take sitz bath with lukewarm water for 10 minutes.

Investigations

Blood routine, FBS, PPBS, HIV, HBsAG

- They were advised to take *Gandharvahasthādi kashāya* -15ml + 45ml lukewarm water, twice daily before food for 2 weeks.

- They were also advised to take *Eranda taila* – 5ml with *kashāya*, morning for 2 weeks.

Outcome measurements

- Subjective assessment

Pain assessment:	Visual analogue scale
1 2 3	- Mild
4 5 6	- Moderate
7 8 9	- Severe
10	- Excruciating
Tenderness	:Present / Absent
Itching	: Present / Absent

- Objective assessment

Length of fissure	
1mm	- grade 1
2mm	- grade 2
3mm	- grade 3
4mm	- grade 4
5mm	- grade 5
>5mm	- grade 6

Duration and follow up.

Period of study – 28 days

Assessment – on 0th, 7th and 14th day

Follow up – on 28th day.

RESULT

Statistical analysis: The collected data was entered into an excel sheet and then it was entered in.

SPSS Version: 23

Table 1: Effect of treatment on Pain on defecation

Group Statistics					
GROUP		N	Mean	Std. Deviation	Std. Error Mean
PAIN_DAY0		16	8.31	1.352	.338
PAIN_DAY7		16	4.50	1.317	.329
PAIN_DAY14		16	.69	1.195	.299
PAIN_DAY 28		16	.06	.250	.063

Table 2: Effect of treatment on Tenderness

					Test Statistics	
		N	Mean Rank	Sum of Ranks	Z	Asymp. Sig. (2-tailed)
TENDERNESS_DAY7	Negative Ranks	4 ^j	2.50	10.00	-2.000 ^b	.046
	Positive Ranks	0 ^k	0.00	0.00		
	Ties	12 ^l				
	Total	16				
TENDERNESS_DAY14	Negative Ranks	15 ^m	8.00	120.00	-3.873 ^b	.000
	Positive Ranks	0 ⁿ	0.00	0.00		
	Ties	1 ^o				
	Total	16				
TENDERNESS_DAY28	Negative Ranks	16 ^p	8.50	136.00	-4.000 ^b	.000
	Positive Ranks	0 ^q	0.00	0.00		
	Ties	0 ^r				
	Total	16				

Table 3: Effect of treatment on Itching

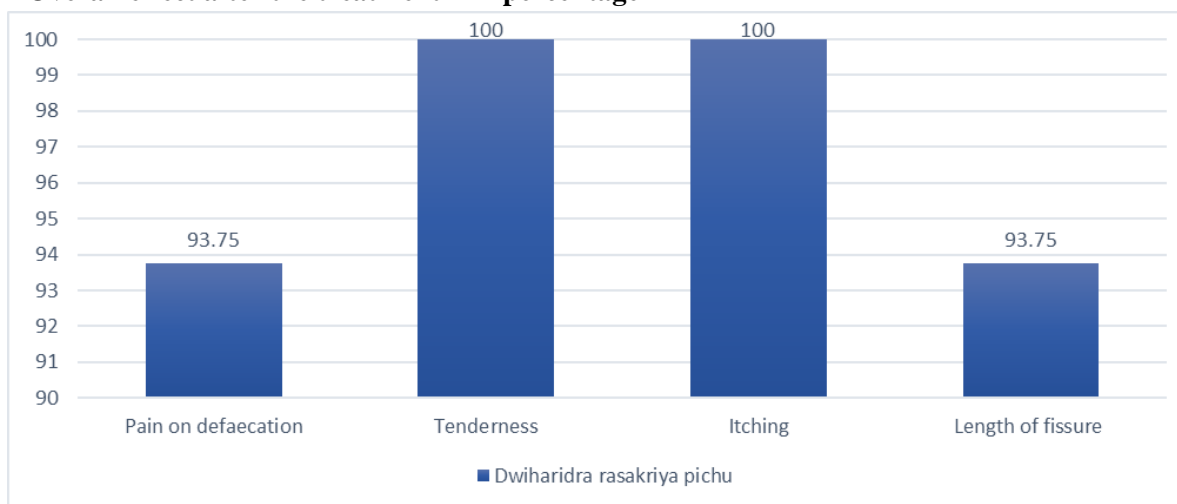
					Test Statistics	
		N	Mean Rank	Sum of Ranks	Z	Asymp. Sig. (2-tailed)
ITCHING_DAY 7	Negative Ranks	8 ^a	4.50	36.00	-2.828 ^b	.005
	Positive Ranks	0 ^b	0.00	0.00		
	Ties	8 ^c				
	Total	16				
ITCHING_DAY14	Negative Ranks	11 ^d	6.00	66.00	-3.317 ^b	.001
	Positive Ranks	0 ^e	0.00	0.00		
	Ties	5 ^f				
	Total	16				
ITCHING_DAY28	Negative Ranks	11 ^g	6.00	66.00	-3.317 ^b	.001

	Positive Ranks	0 ^h	0.00	0.00	
	Ties	5 ⁱ			
	Total	16			

Table 4: Effect of treatment on Length of fissure

Group Statistics					
		N	Mean	Std. Deviation	Std. Error Mean
LENGTH OF FISSURE_DAY0		16	5.81	.403	.101
LENGTH OF FISSURE_DAY 7		16	4.31	1.352	.338
LENGTH OF FISSURE_DAY 14		16	1.56	1.672	.418
LENGTH OF FISSURE_DAY 28		16	.13	.500	.125

Fig: 1 - Overall effect after the treatment – in percentage



DISCUSSION

Discussion on variables

Pain : In this present study out of 16 participants, 15 participants (93.75) got complete relief in pain on defecation by day 28. It shows *Dwiharidra rasakriya* is highly effective in reducing the pain on defecation. Out of 16 participants, 4 participants experience excruciating pain on defecation and 3 participants (75%) report complete relief by applying *Dwiharidra rasakriya pichu* by day 28, 10 participants experience severe pain on defecation and 9 participants (90%) got complete relief by day 14 and 2 participants experience moderate pain on defecation and both the participants got 100% relief by day 14. The spasmolytic

activity of curcuminoids present in *curcuma longa* helps in reducing the spasm of the internal anal sphincter, thereby reducing the pain during defecation. A study by Gupta et. al on superficial big burn wounds state that curcumin present in *curcuma longa* is capable to reduce the pain by its analgesic property.⁹

Tenderness: Out of 16 participants all the participants got 100% relief in tenderness by day 28. 93.75% participants got relief in tenderness by day 14 itself.

Itching

In the present study, 68.75 % of participants had itching, 31.25% had mild mucus discharge also. 50% of participants got complete relief by 7th day itself,

and the remaining 18.75% got relief by 14th day. It shows that *Dwiharidra rasakriya pichu* is effective in reducing the itching associated with mild mucus discharge.

The trapped Fecal matter and growth of bacteria in the anal region due to excessive moisture and poor hygiene may lead to irritation and itching. Inflammation and excessive dryness of the surrounding skin may also contribute to itching in chronic fissure-in-ano. The *kandughna*, *krimighna* and *kledopasoshana* properties of *haridra* and *dharu haridra* help in reducing the itching and discharge.

Length of fissure-in-ano

In this study, out of 16 participants in each group, 12 participants report complete healing of fissure by day 14. In Chronic anal fissures, persistent trauma due to the passage of dry stool, poor blood supply and recurrent inflammation causes delayed wound healing. The compound curcumin and berberin present in *haridra* and *daru haridra* respectively have strong anti-inflammatory and antimicrobial properties, which may help to prevent secondary infections and thereby promote fast healing. Spasmolytic and vasodilatory activities of oxyacanthine and curcuminoids also promote fast healing. Out of 16 participants, 13 participants had a fissure with a length more than 5mm and 9 participants report complete healing of fissure by day 14. 3 participants in study group with length of fissure less than 5mm reports complete healing of the fissure by day 14. So, the present study shows that *Dwiharidra rasakriya pichu* is highly beneficial for ulcer healing.

Discussion on probable mode of action of drugs

Dwiharidra rasakriya pichu

The ingredients of *Dwiharidra rasakriya* are *haridra* and *daruharidra*. *haridra* has *kledopasoshana*, *kandughna*, *krimighna*, *raktashodhaka*, *vrana ropana* properties.¹⁰ *Laghu ruksha guna* of *haridra* possess *lekhana* property, so it helps in the irrigation of the local debris, make the wound *suddha* and promote healing. *Haridra* is *katu*, *tiktha* in *rasa*. *Katu rasa* having a property *srotamsi vivrnoti*, which may help in restoring the blood flow by dilating the vessels, thereby promote wound healing.¹¹ *Haridra* contain

active ingredients like curcumin, dimethoxy curcumin, bisdemethoxycurcumin and tetrahydro curcumin, polysaccharides etc, which exhibits anti-inflammatory, anti-oxidant and immunomodulatory activities.¹² A study conducted by Jamil & Iqbal on vasodilation & spasmolytic activities of curcuminoids from *curcuma longa* in guinea pigs states that all the curcuminoids – curcumin, demethoxycurcumin, bisdemethoxycurcumin and tetrahydro curcumin exhibited significant spasmolytic and vasodilator activity in smooth muscles.¹³ *Daruharidra* is the next ingredient of *Dwiharidra rasakriya*. It is *tikta* and *khashaya* in *rasa* & possess *laghu ruksha guna*.¹⁴ It is *kandughna*, *kledopasoshana*, *raktha sodhana*, and *vrana ropana*. *Kashaya rasa* & *laghu ruksha guna* poses *lekhana* property, so this drug also promote healing by making the *vrana suddha*.¹⁵ *Daruharidra* contain active ingredients like berberine, palmatine, magnoflorine etc. which exhibit anti-inflammatory, antioxidant and anti-microbial activities.¹⁶ The ingredient oxyacanthine exhibit vasodilator activity. In the study group *siktha taila* is used as a medium of application, it contains *tila taila* and beewax. Beewax is *mrudu* & *snigdha*. *Tila taila* is *Madura*, *tiktha*, and *eshat kashaya* in *rasa*, *madura vipaka*, *snigdha* and *vataghna*, which neutralize the *ushna veerya* of the drugs.¹⁷

CONCLUSION

Fissure-in-ano is a canoe shaped longitudinal ulcer in the squamous epithelium of anal canal located just below the muco-cutaneous junction. It may be correlate with *Parikarthika* in Ayurveda. A wide range of conventional treatments are available for fissure in ano, but many of them have their own limitations. In Ayurveda local therapies like *anuvāsana vasthi*, *lepa*, *pichu dhārana* etc. are given prime importance in the treatment of *Parikarthika*. The objective of the study was to find out the effectiveness of *Dwiharidra rasakriya pichu* in the management of fissure-in-ano. The aim of the study was to explore an effective Ayurvedic management for wound healing in chronic fissure-in-ano. The following conclusions were evolved

after conceptual compilation, critical review, clinical observation and discussion.

1. *Dwiharidra rasakriya pichu* is found to be effective in reducing the pain on defecation (93.75%).
2. *Dwiharidra rasakriya pichu* is found to be effective in reducing the length of fissure (93.75%).
3. *Dwiharidra rasakriya pichu* is found to be effective (100%) in reducing tenderness.
4. In Chronic fissure-in-ano with severe itching and discharge, *Dwiharidra rasakriya* was found to be effective.
5. During the follow up, no recurrence was noticed in any of the participants.

Limitations

- Convincing the patients to stay in hospital for 2 hours after the application of pichu was difficult.

Recommendations

- Effect of the procedure by altering the frequency and duration of application can be studied.
- Try to make the procedure in such a way that the patient can do it by himself and can reduce the hospital stay.
- A large sample size is needed for generalizing the study.
- Add on effect of regular diet and bowel pattern along with local application can be studied.
- The grading system of assessing the length of fissure may be improved.

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