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Note

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A randomised controlled clinical study to evaluate the role of Nirvapana Upakrama with Durva ointment in the management of Pittaja Dushta Vrana with special reference to fissure-in-ano

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ABSTRACT

Introduction: Fissure-in-ano is an ulcer in the longitudinal axis of lower anal canal. It is having prevalence of about 17.91%. By seeing the signs and symptoms we can consider it as one among the six varieties of Dushta Vrana i.e., Pittaja Dustavrana. Due to busy life schedules people don't prefer hospitalization and other operative procedures. So, there is a need to find out a new and simpler medicament which enables easy and better storage, preservation and mode of application. Here an attempt was made to study the effect of Nirvapana Upakrama in the management of fissure in ano is taken. This Upakrama is used for the treatment of Vrana accompanied with Daha, Paka, Jwara and having Pitta Kopa and Raktena Abhibhuta. Since fissure is having the similar symptoms this treatment can be adopted for the management of the same. **Methodology:** A randomized controlled clinical study was conducted over 30 subjects in two groups. Fifteen subjects were advised to apply Diltiazem gel and 15 subjects were advised to apply Durva ointment twice daily for a period of 14 days, **Results:** Rapid reduction in pain, burning sensation and length of ulcer was observed in the subjects who were given Durva ointment. Discussion: Durva ointment having Madura Rasa, Snigdha Guna and Sheeta Virya does Vatapitta Shamana and pacifies vitiated Rakta. Kashaya rasa of Durva does Vrana Ropana and Rakta Sthambana which amplifies in ulcer healing and relaxation of the sphincter.

Key words: Fissure-in-ano, Pittaja Dushta Vrana, Durva Ghrita

INTRODUCTION

Human being suffered various health disorders since ages. Anorectal disorders are one among such ailment attributed to change in lifestyle and food habits. In the present era about 30-40% of the population are suffering from anorectal disorders.[1] Among them

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fissure-in-ano is one of the commonest having prevalence about 17.91%.^[2] It is an ulcer in the longitudinal axis of lower anal canal, commonly occurs in midline posteriorly. It is more common in females. [3] In men 95% of anal fissure are posterior where as in females it constitutes 80%. "Parikarthika"- which literally means "Karthanavat Shoola" has been explained as a symptom in Virechana Vyapat having Vata Pitta predominance along with other symptoms like Gudadaha and Anilasanga. This has close similarity with "fissure-in-ano", which has symptoms like pain, constipation, bleeding, and itching and canoe type ulcer formation.[3] When we analyse these signs and symptoms, we can find similarity with Pittaja Dustavrana i.e., Daha, Paka etc.[4]

Contemporary science offers both conservative as well as surgical management for fissure. Conservative treatments include stretching of anal sphincter, lord's anal dilatation, use of laxatives, topical nitro glyceride

application, and diltiazem 2% application. Surgical management like dorsal fissurectomy, lateral anal sphincterotomy, anal advancement flap etc. are also practiced. The major drawback seen in those are prolonged convalescent period, continuous mucous discharge, hematoma formation, recurrent ulcer formation, risk of damage to the underlying sphincter.[3] When we look for a solution in Ayurvedic perspective, Shashti Upakrama mentioned in Susrutha Chikitsa comes to lime light. Here 60 modalities starting from Apatharpana to Rakshavidhana Vidhi are explained in details for the management of Vrana. Each of this *Upakrama* has an important role in management of various stages of Vrana. [6] Nirvapana is one among Shashti Upakrama explained for the treatment of Vrana accompanied with Daha, Paka, Jwara and having Pitta Kopa and Raktena Abhibhuta. Considering the similarity with fissure-in-ano in terms of symptoms, here an attempt to study the effect of Nirvapana Upakrama in the management of fissure was made. Here Acharya mentioned to use Seetha Guna Dravyas macerated in Ksheera added with Ghee as a Lepa^[7] over the Vrana. Commenting on the Sheeta Guna Dravyas in the context, Acharya Dalhana mentioned about Yoga Durvadi, which includes Durva, Nalamoola, Madhuka, Chandana etc.

As *Durva* is mentioned first and having properties like *Kashaya Rasa*, *Seetha Virya*, *Kapha-Pittahara*, *Raktapitta Samaka* and *Daha Samana*, it was taken here. [8] Ointment form, ensures easy application, better storage along with preservation makes it user friendly.

Thus, here an attempt to re-introduce and validate *Nirvapana Upakrama* one among *Shashti Upakrama* in an ointment form, which enables acceptance of *Nirvapana Upakrama*.

AIM AND OBJECTIVES

Aim

To evaluate the role of *Nirvapana Upakrama* with *Durva* ointment in the management of *Pittaja Dushtavrana* with special reference to fissure-in-ano.

Objectives

- To evaluate the role of Nirvapana Upakrama with Durva ointment in the management of fissure-inano.
- 2. To re-evaluate the role of diltiazem 2% gel in the management of fissure-in-ano.
- To compare the role of *Durva* ointment and diltiazem 2% gel in the management of fissure-inano.

MATERIALS AND METHODS

In this study 30 diagnosed cases of fissure-in-ano who fulfilled the inclusion criteria were selected from Out Patient and In Patients Departments of Shalya Tantra, SSCAS&RH, Bengaluru.

Groups of study

Number of thirty subjects suffering from fissure-in-ano fulfilling the inclusion criteria were selected by simple randomization technique. They were divided into two groups of fifteen each. Each group was given sitz bath followed by *Triphala Choorna* (dose 5-10g) at bed time as constipation is the main factor for fissure-in-ano.

Study Design

A randomized controlled clinical trial in which 30 subjects were divided into 2 groups of 15 each.

Clinical Trial	Group A	Group B
Procedure	Diltiazem ointment was applied twice daily after sitz bath.	Durva ointment was applied twice daily after sitz bath.
Dose	Quantity sufficient to cover the ulcer.	Quantity sufficient to cover the ulcer.
Duration	Two weeks	Two weeks
Follow Up	Fourteen days (21st and 28th day to observe any recurrence)	Fourteen days (21st and 28th day to observe any recurrence)

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Diagnostic criteria

Subjects with classical symptoms of fissure-in-ano were selected for study such as *Guda Daha*, *Karthanavat Peeda*, *Anilasanga* and those having characteristics of *Pittaja Dushta Vrana*.

Inclusion criteria

- Clinically diagnosed cases of fissure-in-ano (Chronic Fissure-in-Ano were taken for the study.)
- Patient irrespective of sex, religion, occupation and economic status. Patients between 21-60 years of age irrespective of both sexes.
- Patients of fissure-in-ano with Diabetes and Hypertension which are under control, were also included in study.

Exclusion criteria

- Fissure-in-ano secondary to ulcerative colitis, tuberculosis, syphilis, crohn's disease, and other systemic diseases pertaining to colon were excluded from the study.
- Previously diagnosed cases of Ca rectum, Ca colon and fistula-in-ano.

Assessment criteria

Following subjective and objective parameters will be considered in the study.

1) Subjective parameters

- Gudagata Karthanavat Peeda (cutting and burning type of pain at anus.)
- Itching
- Bleeding
- Constipation
- Burning sensation
- Pain assessment VAS Scale

Itching^[9]

Grade 0 - Absent (no itching)

- Grade 1 Mild (Occasional itching)
- Grade 2 Moderate (Frequent itching)
- Grade 3 Severe (Continuous itching)

Burning sensation^[9]

- Grade 0 No burning sensation
- Grade 1 Mild burning sensation
- Grade 2 Moderate burning sensation
- Grade 3 Severe Burning sensation.

Bleeding^[1]

- Grade 0 No bleeding
- Grade 1 Bleeding per anum.

Constipation^[1]

- Grade 0 Easy evacuation / Normal consistency
- Grade 1 Hard stools passed once daily
- Grade 2 Hard stools passed once in 2-3 days
- Grade 3 Very hard stools passed once in 3-4 days

2) Objective parameters

(1) Length of ulcer[1]

After gently parting the gluteal region, the fissure will be visualized and the length of ulcer is measured with a cotton swab by keeping it over the ulcer. This is later measured in millimetre.

- (2) Sphincter spasm^[1] (by per rectal digital examination.)
- Grade 0 Normal
- Grade 1 Spastic

Method of preparation

Durva ointment was prepared under 3 stages

- 1. Preparation of Durva Ghrita.
- 2. Conversion of Durva Ghrita into Durva Sikta Ghrita
- 3. Making and packing of Durva ointment

1. Preparation of Durva Ghrita.

Equipment's

Vessels, measuring jar, gas stove, big spoons, wooden spatula, filters, tray, mixer grinder, weighing machine, cora cloth, tripod stand.

Ingredients

Durva Panchanga - quantity sufficient, Milk - 2 litre, Kalka - 250gm, Ghrita - 1 litre, Durva Swarasa - 2 litre, Madhuchista - quantity sufficient.

- Durva Panchanga was collected. Cleaned and washed properly.
- From this Durva Swarasa 2L was prepared and Durva Kalka 250gm was prepared.
- 1L Ghrita was taken in a clean open vessel, to which prepared Kalka was added and boiled in Mandagni with constant stirring.
- Into that 2 litre of *Durva Swarasa* was added boiled in *Mandhagni* with constant stirring till *Ghrita Siddha Lakshana* were appreciated.
- After cooling down, Ghrita was filtered using a clean cloth and store in an air tight container.

2. Conversion of Durva Ghrita into Durva Sikta Ghrita

- Filtered liquefied Madhuchista was added to warm Durva Ghrita in 1:5 ratio respectively to make it a homogeneous mixture - Durva Sikta Ghrita.
- A sample of this batch was sent for analysis which are prescribed for Lepa/ Malahara/ Kalimbu/ Pasai/ Medicated wax/ Cream/ Poultice mentioned in "Laboratory guide for the analysis of Ayurveda & Siddha formulations", Central council for Research in Ayurveda & Siddha (CCRAS).

3. Making and packing of Durva ointment

- The Durva Sikta Ghrita was warmed at constant temperature with the help of electric warmer, to maintain the liquid state of the Ghrita throughout the process.
- 5ml of Durva Sikta Ghrita was poured into containers and allowed to cool down and packing done.



Durva Panchanga



Ghrita



Durva Kalka was added into Ghrita



Durva Swarasa was added



Mixture of Ghrita, Durva Kalka, Swarasa and milk



Phenashanti in Ghrita



End product



Durva Ointment

OBSERVATIONS AND RESULTS

Observation during preparation of Durva ointment

- Durva was difficult to pulverize to obtain Swarasa and Kalka.
- 4 kg Durva Panchanga was needed for getting 2L Swarasa and 250 g Kalka.
- Pleasant odour of the preparation was appreciated.

Observations during intervention

- Ointments are the soft semisolid preparations, used for external application to the skin or mucous membrane where medicaments dissolved or suspended or emulsified in the base. (non irritating, uniformly distributed throughout the base, melt at body temperature etc.)^[10]
- Durva ointment seemed to have all the qualities of an ideal ointment.
- Both interventions were easy to apply, nonirritant, maintained adequate moisture and showed no signs of infection.
- It was observed that there was early recurrence in control group.

Results - Analytical result



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Table 1: Between the group comparison (BT & AT) for pain.

P ai n	Cat ego ry	N	Mea n Rank	Sum of Ranks	Mann- Whitne y U	Wilco xon W	Z	р
B T	Gro up A	1 5	14.6	219	99	219	0. 63 8	0. 52 3
	Gro up B	1 5	16.4	246				
A T	Gro up A	1 5	18	270	75	195	2. 40 8	0. 01 6
	Gro up B	1 5	13	195				
F U	Gro up A	1 5	16	240	105	225	1	0. 31 7
	Gro up B	1 5	15	225				

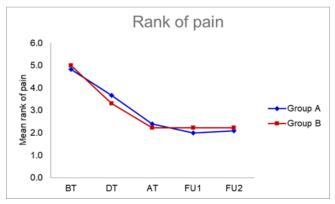


Table 2: Between the group comparison (BT & AT) for itching

Itc hin g	Cat ego ry	N	Mea n Rank	Sum of Ranks	Mann- Whitne y U	Wilc oxon W	Z	р
ВТ	Gro up A	1 5	15.1 7	227.5	107.5	227.5	0. 24 9	0. 80 4

	Gro up B	1 5	15.8 3	237.5				
АТ	Gro up A	1 5	17	255	90	210	1. 79 5	0. 07 3
	Gro up B	1 5	14	210				
FU	Gro up A	1 5	16	240	105	225	1	0. 31 7
	Gro up B	1 5	15	225				

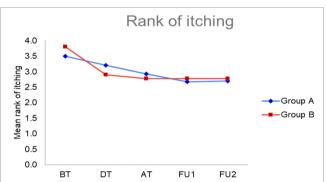


Table 3: Between the group comparison (BT & AT) for bleeding

Ble edi ng	Cat ego ry	N	Mea n Rank	Sum of Ranks	Mann- Whitne y U	Wilc oxon W	Z	р
ВТ	Gro up A	1 5	15	225	105	225	0. 39 2	0. 69 5
	Gro up B	1 5	16	240				
AT	Gro up A	1 5	15	225	105	225	1	0. 31 7
	Gro up B	1 5	16	240				

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	Rank of Burning sensation
<u>_</u> 6.0	
Mean rank of Burning sensation 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	K
9 5 6 4.0	
0.8 Burn	→ Group A
र्कु 2.0	Group B
0.1 au	
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FU	Gro up A	1 5	16.5	247.5	97.5	217.5	1. 43 9	0. 15
	Gro up B	1 5	14.5	217.5			-	

Rank of Bleeding

5.0
4.5
94.0
93.5
93.5
93.0
0 2.5
1.5
94.0
0.5

FU1

FU2

Table 4: Between the group comparison (BT & AT) for burning sensation

Burnin g Sensati on	Cat ego ry	N	Mea n Ran k	Sum of Rank s	Mann- Whitn ey U	Wilc oxon W	Z	р
ВТ	Gro up A	1 5	16.4	246	99	219	0. 6 1 9	0. 5 3 6
	Gro up B	1 5	14.6	219			9	0
AT	Gro up A	1 5	18	270	75	195	2. 4 0 8	0. 0 1 6
	Gro up B	1 5	13	195			0	O
FU	Gro up A	1 5	16	240	105	225	1	0. 3 1 7
	Gro up B	1 5	15	225				,

Table 5: Between the group comparison (BT & AT) for constipation

FU1

FU2

Cons tipati on	Cat ego ry	N	Mea n Ran k	Sum of Rank s	Mann- Whitne y U	Wilc oxon W	Z	р
ВТ	Gro up A	1 5	15.9 3	239	106		0. 3 6	0. 7 1
	Gro up B	1 5	15.0 7	226			5	5
AT	Gro up A	1 5	15.5	232.5	112.5	232. 5	0	1
	Gro up B	1 5	15.5	232.5				
FU	Gro up A	1 5	15.5	232.5	112.5	232. 5	0	1
	Gro up B	1 5	15.5	232.5				

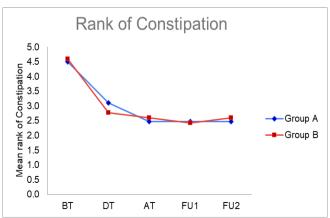


Table 6: Between the group comparison (BT & AT) for sphincter spasm

Sphinc ter Spasm	Cat ego ry	N	Mea n Ran k	Sum of Rank s	Mann- Whitn ey U	Wilc oxon W	Z	р
ВТ	Gro up A	1 5	16	240	105	225	0. 5 9	0 5
	Gro up B	1 5	15	225			8	5
AT	Gro up A	1 5	16	240	105	225	0. 5 9	0 5
	Gro up B	1 5	15	225			8	5
FU	Gro up A	1 5	15.5	232.5	112.5	232. 5	0	1
	Gro up B	1 5	15.5	232.5				

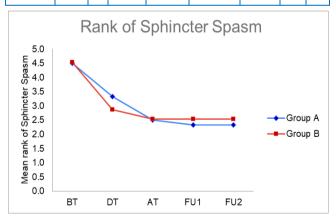


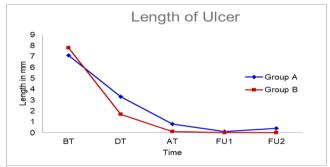
Table 7: Between the group comparison (BT & AT) for length of ulcer

Length of ulcer (mm)	Group (n=15)		Group B (n=15)		Unpaired t test	
	Mea n	Sd	Mea n	Sd	t	р
ВТ	7.1	2.0	7.8	2.0	- 0.92 1	0.36 5

DT	3.3	2.4	1.7	1.0	2.50 9	0.01 8
AT	0.8	1.5	0.1	0.5	1.65 4	0.10 9
FU1	0.1	0.3	0.0	0.0	1	0.32 6
FU2	0.4	1.1	0.0	0.0	1.38 2	0.17 8

Table 8: Between the group comparison (BT & AT) for length of ulcer

Change in Length of ulcer (mm)	Group A (n=15)		Group B (n=15)		Unpaired t test	
	Me an	Sd	Me an	Sd	t	р
BT - AT	2.0	0.0	2.0	0.0		
AT - FU2	0.7	0.9	0.1	0.5	1.9 91	0.0 56
BT – FU2	2.0	0.0	2.0	0.0		



There was a significant difference before and after the treatment between the groups with high clinical efficacy seen in Group B compared to Group A in respect to subjective and objective parameters.

Limitations

- The adoption of intervention by the subjects were not under the supervision of the principal investigator.
- Availability of fresh Durva during all seasons is difficult

Further Scope

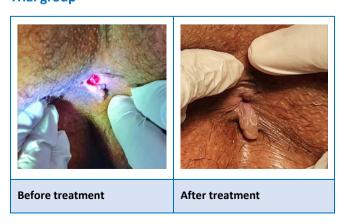
 This study is a part of Post Graduate research on small sample. So, it is recommended to be studied on large sample size to create more evidence based data.

- Along with *Durva* other drugs mentioned by Acharya for *Nirvapana Upakrama* can also be tried for proving the efficacy of *Vrana Chikitsa* in the management of fissure in ano.
- Not only Durva, combination of all those medicines mentioned in Misrakadyaya like Nalamoola, Madhuka, Chandana can be tried as a combination for further study.
- Present study was conducted on chronic fissure-inano, similar study can also be concentrated on acute fissure in ano.

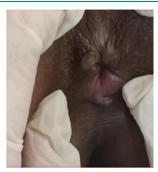
Control group



Trial group







Before treatment

After treatment

DISCUSSION

The pH was slightly acidic. As pH value within the wound milieu directly and indirectly influences all biochemical reactions taking place in the process of wound healing. It has been proven that the surface pH of a wound plays an important role in wound healing as it helps control infection and increase antimicrobial activity, oxygen release, angiogenesis, protease activity, and bacterial toxicity. Hence, pH of the drug may have influenced wound healing. [11] The presence of required spreadability, viscosity, thermal stability and the absence of rancidity, infers that Durva ointment contained right proportion of Madhuchista needed for an ointment. The sample was pathogen free and had negligible microbial load, suggestive of safe for therapeutic use.

Pain^[12]

Significant reduction in pain may be due to *Madura Rasa* of *Durva* along with, *Snigdha Guna* of *Goghruta*, *Ksheera* and *Madhuchista* which are the main ingredient of *Durva* ointment, having *Vatahara* property. Also, reduction in pain can be due to presence of Alkaloids, Flavonoids, Saponins and Tannins.

Itching

This may be due to *Kashaya Tikta Rasa* of *Durva* which is helping in the *Kaphahara* property. Bleeding *Raktasthambaka* property along with *Kashaya Rasa, Seetha Virya, Kapha - Pittahara, Raktapitta Samaka* properties of *Durva* helped in reduction of bleeding and also can be due to the presence of Tannins, Saponins, and Glycosides.

Burning sensation^[13]

Nirvapana Upakrama is used for the treatment of Vrana accompanied with Daha, Paka, Jwara and having Pitta Kopa and Raktena Abhibhuta. Here Acharya mention to give Seetha Guna Dravyas macerated in Ksheera added with Ghee to be applied as a Lepa. Properties of Durva like Kashaya Rasa, Seetha Virya, Kapha Pittahara, Raktapitta Samaka and Daha Samana property along with Madura Rasa, Snigdha Guna, Pittahara and Dahasamana properties of Ghrita and Payas helped in the reduction of burning sensation.

Wound healing^[14]

Vrana Ropana property of Madhuchista along with Kashaya Rasa, Seetha Virya, Kapha-Pittahara, Raktapitta Samaka property of Durva might have led to Vrana Ropana. The flavonoids present in Durva facilitate the healing process by increase in collagen and protein and decrease in lipid peroxide found during the inflammation.

Sphincter spasm^[12]

Ghrita helps in reduction of the Rookshata of Vata and maintains normal tone of muscles. Flavanoids which are present in Durva having wound healing and Vedanasthapana properties helps in relaxation of sphincter. Durva is also having Madura Rasa, Seetha Virya which also aids in the Vatashamana.

Summarizing all results

Contemplating all these findings, it can be inferred that *Durva* ointment delivered better results than diltiazem gel in the management of fissure-in-ano.

CONCLUSION

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. It is commonly seen in posterior bed due to direct pressure of stool and also due to less muscular support at the posterior aspect of the anus. In the classics we are not getting the apt correlation for fissure-in-ano as an individual disease; by seeing the signs and symptoms we can consider it as one among the six

varieties of Dushta Vrana i.e., Pittaja Dushtavrana.[5] Even though treatment modality includes both conservative and surgical techniques, prolonged convalescent period, continuous mucous discharge, hematoma formation, recurrent ulcer formation, risk of damage to the underlying sphincter and recurrence are the most common drawbacks seen in conventional treatment. Both the groups showed high statistical significance when compared within the group before and after treatment also during follow-up. Rapid reduction in pain, burning sensation and length of ulcer was observed in the subjects who were given trial drug comparing to the control drug. Overall clinical effect size with respect to majority of parameter is much higher in group B comparing to group A, clearly showing its superiority to Group A. Trial Group has shown better clinical and statistically significant result compared to control group. Therefore rejected null hypothesis and accepted alternate hypothesis [H1: The efficacy of Durva ointment in fissure-in-ano is better than the group receiving diltiazem gel 2%]

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