



## A CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF JATYADI GHRITA SUPPOSITORY IN THE POST OPERATIVE PAIN MANAGEMENT IN ANORECTAL DISORDERS – A CASE SERIES

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### ABSTRACT

According to international association for the study of pain, "pain is an unpleasant sensory and emotional experience associated with acute or potential tissue damage."<sup>[1]</sup> In *Ayurvedic* classics *vedana* is considered as an important diagnostic as well as prognostic factor. Management of any diseases is to primarily aimed at relieving the *vedana*. The study was conducted on 40 randomly assigned patients at SJGAUH Hospital, Bengaluru by dividing them into 2 groups -Group A and Group B. These groups were treated with *Jatyadi ghrita* rectal suppository 1gm and Diclofenac rectal suppository 50mg respectively. Assessment of pain, burning sensation, tenderness, and reliving sphincter spasm in Group A showed 86%, 92.5%, 75%, and 60% improvement and Group B showed 98%, 87%, 87.5%, and 37.5% improvement respectively. Both the groups *Jatyadi ghrita* suppository i.e. group A and Diclofenac suppository i.e. group B has been able to reduce Pain, burning sensation and Tenderness with results showing statistically highly significant at p value <0.001.

**KEYWORDS:** Post-operative pain; Ano rectal disorders; *Ayurvedic* management; *Jatyadi ghrita* suppository; Diclofenac suppository.

### INTRODUCTION

Ano rectal disorders are one of the common reasons for visits to both primary care physicians and proctologists, these include fissure-in-ano, hemorrhoids and fistula-in-ano, which in advanced condition requires surgery. Pain is the commonest post-operative manifestation experienced by the patients after ano-rectal surgical procedure.

Pain management after ano-rectal surgery becomes important since it could hamper day to day activities, disturb sleep, alter appetite and bowel evacuations and hamper quality of life of the patient. Hence the post-operative pain management plays a vital role in surgical practice. Suppositories are one such dosage form that can be used in post-operative pain especially in anorectal surgeries. Sodium diclofenac suppository is of NSAID category which has been shown to have analgesic effects. Though diclofenac rectal suppository is widely used it is associated with warnings like headache, dizziness, light headedness, drowsiness, loss of appetite, local rectal irritation, ringing in the ears and rectal bleeding.<sup>[2]</sup>

Lack of effective analgesics in *Ayurvedic* medicine is the major disadvantage for surgeons and this is one amongst

the various causes of downfall of *Ayurvedic* surgery. Hence there is constant quest for an ideal quick acting *Ayurvedic* analgesic procedure. Any type of *shastra karma* induces *vedana* (pain) due to aggravation of *vata* and *pitta doshas*. So any drug /procedure, which pacifies *vata* and *pitta*, will act as a potent *vedana sthapanaya*.

In *Ayurveda*, *Matrabasti* and *Sneha vartis* are used to relieve post operative pain. *Matrabasti* usually requires assistance and the level of comfort is comparatively less because of possibility of oozing out of administered taila.

Contemplating on this, here an attempt will be made for post operative pain management through *Jatyadi Ghrita* suppository.

*Jatyadi Ghrita* contains dravyas having *Shulahara*, *Angamarda prasamana*, *Daha prasamana*, *Vatanashaka*, *Vrana sodhana* and *Ropana* properties and it is indicated in *Marmashrita vrana*, *Gambhira vrana*, *Nadi vrana* and *Vedanayukta vrana*.<sup>[3]</sup>

Hence, *Jatyadi ghrita* is chosen for the present study, which will be modified into simple, cost effective,

patients friendly 'Suppository' form. The results obtained from the clinical study will be compared with the results obtained from the standard group which will be treated with Diclofenac suppositories.

### AIM

To evaluate the efficacy of *Jatyadi ghrita* suppository and diclofenac suppository in the post operative pain management in anorectal disorders.

### OBJECTIVES

1. To evaluate the effect of *Jatyadi ghrita* suppository in the post-operative pain management in anorectal disorders.
2. To evaluate the effect of diclofenac suppository in the post-operative pain management in anorectal disorders.
3. To study the comparative effect in both the groups.

### Null Hypothesis

1. *Jatyadi ghrita* suppository is not effective in the post-operative pain management of anorectal disorders.
2. Diclofenac suppository is not effective in the post-operative pain management of anorectal disorders.
3. There is no difference between the effect of *Jatyadi ghrita* suppository and Diclofenac suppository in the post-operative pain management of anorectal disorders.

### Alternate Hypothesis

1. *Jatyadi ghrita* suppository is effective in the post-operative pain management of anorectal disorders.
2. Diclofenac suppository is effective in the post-operative pain management of anorectal disorders.
3. There is significant difference between the effect of *Jatyadi ghrita* suppository and Diclofenac suppository in the post-operative pain management of anorectal disorders.

### METHODOLOGY

The study was conducted during the period of September 2022 to August 2023. Source of data Operated cases of fissurectomy, hemorrhoidectomy, fistulotomy at S.G.A.U.H Bengaluru & K.C.G Hospital Bengaluru were selected for the study.

### Method of Collection of Data

A total of 40 patients undergoing elective fissurectomy, hemorrhoidectomy, fistulotomy at S.G.A.U.H Bengaluru & K.C.G Hospital Bengaluru were selected randomly for the study using method of simple random sampling.

### Inclusion Criteria

- 1) Patients underwent fissurectomy, hemorrhoidectomy, fistulotomy.

2) Patients between the age group of 20 to 60 years were included in the study.

### Exclusion Criteria

1. Fissure/haemorrhoid/fistula in ano with Inflammatory Bowel Disease and Crohn's disease.
2. Patients suffering from systemic diseases like DM, Tuberculosis, Rheumatoid arthritis.
3. Positive cases for Human Immunodeficiency Virus (HIV), Venereal Disease Research Laboratory (VDRL) and Hepatitis-B.
4. The post-operative cases with complications like severe bleeding, Wound sepsis.

### Study Design

40 patients selected for the study were divided into 2 groups: group A and group B, each consisting of 20 patients.

### Materials Required

- 1) *Jatyadi ghrita* Rectal Suppository - Group A.
- 2) Diclofenac Sodium Rectal Suppository - Group B.
- 3) Sterile gloves.

### Procedure followed

#### Operative Procedure

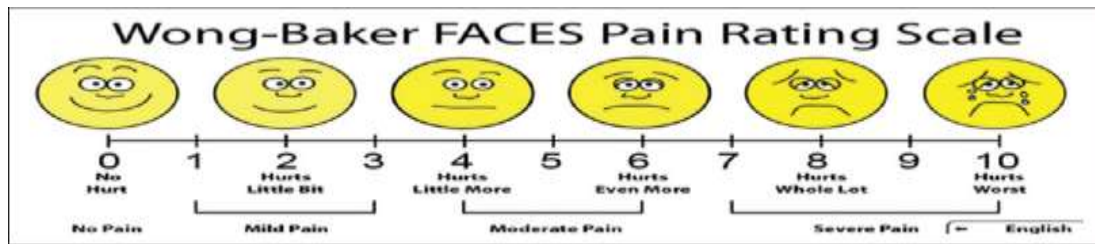
Fissurectomy/Fistulotomy/ Haemorrhoidectomy was done as per the diagnosis with complete sterile and aseptic precautions. After achieving haemostasis, the operated area was cleaned with betadine. 1gm *Jatyadi ghrita* suppositories was inserted into the rectum in Group A and 50 mg Diclofenac suppository was inserted into the rectum in Group B. Anal pack was placed and pressure bandage applied.

#### Post-Operative Procedure

- a) Patient was advised to remove anal pack after 6hours of procedure.
- b) Post operatively, 1gm *Jatyadi ghrita* rectal suppository was inserted every 12th hourly for post-operative 5days in Group A.
- c) Post operatively, 50mg Diclofenac Sodium rectal suppository was inserted every 12th hourly for post-operative 5days.
- d) The operative wound was dressed with Betadine daily for post-operative 5days.
- e) Antibiotic therapy and sitz bath during the post-operative period to prevent infection.
- f) *Sonamukhi choorna*, 6grams advised with sufficient quantity of hot water at bed time.

### Assessment Criteria

The effect of the treatment was assessed and noted on the basis of pain, burning sensation, tenderness, sphincter tone, in scoring pattern in a specific proforma.



### Subjective Parameters

#### 1. Pain

Grade (0)- VAS Score 0: No pain.

Grade (1)- VAS Score 1-3: Mild pain.

Grade (2)- VAS Score 4-6: Moderate pain.

Grade (3)- VAS Score 7-10: Severe Pain.

As per the Visual Analogue Scale.

#### 2. Burning sensation

Grade 0 - burning sensation Absent

Grade 1 - Mild burning sensation that can easily be ignored

Grade 2 - Moderate burning sensation after defecation, that cannot be ignored

Grade 3 - Severe burning not relieved easily and last for more than 3 hours.

### Objective Parameters

#### 1. Tenderness.

a. Grade 0 - No Tenderness.

b. Grade 1- Mild tenderness to palpation.

c. Grade 2- Mild tenderness with grimace and flinch to palpation.

d. Grade 3 - Severe tenderness on withdrawal.

e. Grade 4 - Severe tenderness on withdrawal from noxious stimuli.

#### 2. Sphincter Tone

a. Grade 0 – Sphincter tone normal.

b. Grade 1 – Sphincter tone spastic.

### Follow up and observational period

All the assessment parameters were observed on the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, and 5<sup>th</sup> day of surgery. The same was

recorded in the proforma of case sheets prepared for the study.

A general follow up was done 15days after surgery.

### Overall assessment of result

The results were evaluated by subjective and objective parameters mainly based on clinical observation by grading method.

Assessment of responses were done in four groups as poor response, moderate response, good response and excellent response.

### RESULTS

\*Poor response - <24% reduction in subjective and objective parameters.

\*Moderate response - 25-49% reduction in subjective and objective parameters.

\*Good response - 50-74% reduction in subjective and objective parameters.

\*Excellent response - 75-100% reduction in subjective and objective parameters.

### OBSERVATIONS AND RESULTS

Total 40 patients were randomly allotted into 2 groups. Observations were recorded and necessary charts and graphs were made. maximum number of patients i.e., 70 % were in the age group 31 -50 years. 67.5% were male patients and 32.5% were female. Maximum patients' Socio-Economic Status was Middle Class i.e., 80%. 45% were diagnosed as haemorrhoids. Maximum people i.e., 11 members were house wives.

1) Pain.

**Table 1: Post Hoc Comparisons – Pain (Group-A).**

Pain	Pain	Mean Difference	SE	df	t	pbonferroni
Baseline	-D1	0.000	0.0000	19.0	NaN	NaN
	-D2	0.450	0.1141	19.0	3.94	0.018
	-D3	1.000	0.0725	19.0	13.78	< .001
	-D4	1.400	0.1124	19.0	12.46	< .001
	-D5	2.100	0.1235	19.0	17.00	< .001
	Post-intervention	2.100	0.1235	19.0	17.00	< .001
D1	-D2	0.450	0.1141	19.0	3.94	0.018
	-D3	1.000	0.0725	19.0	13.78	< .001
	-D4	1.400	0.1124	19.0	12.46	< .001
	-D5	2.100	0.1235	19.0	17.00	< .001
	Post-intervention	2.100	0.1235	19.0	17.00	< .001
D2	-D3	0.550	0.1141	19.0	4.82	0.003

	-D4	0.950	0.1141	19.0	8.32	< .001
	-D5	1.650	0.1094	19.0	15.08	< .001
	Post-intervention	1.650	0.1094	19.0	15.08	< .001
D3	-D4	0.400	0.1124	19.0	3.56	0.044
	-D5	1.100	0.1000	19.0	11.00	< .001
	Post-intervention	1.100	0.1000	19.0	11.00	< .001
D4	-D5	0.700	0.1051	19.0	6.66	< .001
	post-intervention	0.700	0.1051	19.0	6.66	< .001
D5	Post-intervention	0.000	0.0000	19.0	NaN	NaN

When the pain was compared between baseline and post intervention shows a significant difference with  $p < 0.001$ . This shows that there was an average of 86% improvement in pain was observed in Group-A.

**Table 2: Post Hoc Comparisons – Pain (Group-B).**

Pain	Pain	Mean Difference	SE	df	t	pbonferroni
Baseline	D1	0.000	0.0000	19.0	NaN	NaN
	D2	0.500	0.1357	19.0	3.68	0.033
	D3	1.000	0.0725	19.0	13.78	< .001
	D4	1.650	0.1094	19.0	15.08	< .001
	D5	2.350	0.1313	19.0	17.90	< .001
	Post-intervention	2.350	0.1313	19.0	17.90	< .001
D1	D2	0.500	0.1357	19.0	3.68	0.033
	D3	1.000	0.0725	19.0	13.78	< .001
	D4	1.650	0.1094	19.0	15.08	< .001
	D5	2.350	0.1313	19.0	17.90	< .001
	Post-intervention	2.350	0.1313	19.0	17.90	< .001
D2	D3	0.500	0.1147	19.0	4.36	0.007
	D4	1.150	0.1094	19.0	10.51	< .001
	D5	1.850	0.1094	19.0	16.91	< .001
	Post-intervention	1.850	0.1094	19.0	16.91	< .001
D3	D4	0.650	0.1094	19.0	5.94	< .001
	D5	1.350	0.1313	19.0	10.28	< .001
	Post-intervention	1.350	0.1313	19.0	10.28	< .001
D4	D5	0.700	0.1051	19.0	6.66	< .001
	Post-intervention	0.700	0.1051	19.0	6.66	< .001
D5	Post-intervention	0.000	0.0000	19.0	NaN	NaN

When the pain was compared between baseline and post intervention shows a significant difference with  $p < 0.001$ . It concludes that there was an average improvement of 98% in pain among Group-B.

## 2) Burning sensation

**Table 3: Post Hoc Comparisons - burning sensation (Group A).**

Burning sensation	Burning sensation	Mean Difference	SE	df	t	pbonferroni
Baseline	-D1	0.0500	0.0500	19.0	1.00	1.000
	-D2	0.5000	0.1147	19.0	4.36	0.007
	-D3	1.0000	0.0725	19.0	13.78	< .001
	-D4	1.4500	0.1141	19.0	12.70	< .001
	-D5	1.8500	0.0819	19.0	22.58	< .001
	post-intervention	1.8500	0.0819	19.0	22.58	< .001
D1	-D2	0.4500	0.1141	19.0	3.94	0.018
	-D3	0.9500	0.0500	19.0	19.00	< .001
	-D4	1.4000	0.1124	19.0	12.46	< .001
	-D5	1.8000	0.0918	19.0	19.62	< .001
	Post-intervention	1.8000	0.0918	19.0	19.62	< .001
D2	-D3	0.5000	0.1147	19.0	4.36	0.007
	-D4	0.9500	0.1141	19.0	8.32	< .001
	-D5	1.3500	0.1313	19.0	10.28	< .001
	Post-intervention	1.3500	0.1313	19.0	10.28	< .001

D3	-D4	0.4500	0.1141	19.0	3.94	0.018
	-D5	0.8500	0.0819	19.0	10.38	< .001
	Post-intervention	0.8500	0.0819	19.0	10.38	< .001
D4	-D5	0.4000	0.1124	19.0	3.56	0.044
	Post-intervention	0.4000	0.1124	19.0	3.56	0.044
D5	Post-intervention	0.0000	0.0000	19.0	NaN	NaN

When the burning sensation was compared between baseline and post-intervention shows a significant difference with  $p < 0.001$ .

This concludes that an average improvement of 92.5% in burning sensation was observed in Group-A.

**Table 4: Post Hoc Comparisons - burning sensation (Group B)**

Burning sensation	Burning sensation	Mean Difference	SE	df	t	pbonferroni
Baseline	-D1	0.0000	0.0000	19.0	NaN	NaN
	-D2	0.0500	0.0500	19.0	1.000	1.000
	-D3	0.8000	0.0918	19.0	8.718	< .001
	-D4	1.1500	0.0819	19.0	14.038	< .001
	-D5	1.6500	0.1094	19.0	15.079	< .001
	post-intervention	1.6500	0.1094	19.0	15.079	< .001
D1	-D2	0.0500	0.0500	19.0	1.000	1.000
	-D3	0.8000	0.0918	19.0	8.718	< .001
	-D4	1.1500	0.0819	19.0	14.038	< .001
	-D5	1.6500	0.1094	19.0	15.079	< .001
	Post-intervention	1.6500	0.1094	19.0	15.079	< .001
D2	-D3	0.7500	0.0993	19.0	7.550	< .001
	-D4	1.1000	0.0688	19.0	15.983	< .001
	-D5	1.6000	0.1124	19.0	14.236	< .001
	post-intervention	1.6000	0.1124	19.0	14.236	< .001
D3	-D4	0.3500	0.1094	19.0	3.199	0.099
	-D5	0.8500	0.1094	19.0	7.768	< .001
	post-intervention	0.8500	0.1094	19.0	7.768	< .001
D4	-D5	0.5000	0.1147	19.0	4.359	0.007
	Post-intervention	0.5000	0.1147	19.0	4.359	0.007
D5	Post-intervention	0.0000	0.0000	19.0	NaN	NaN

When the burning sensation was compared with baseline and post-intervention shows a significant difference with  $p < 0.001$ .

It concludes that there was an average improvement of 87% after intervention in burning sensation in Group-B.

### 3) Tenderness

**Table 5: Post Hoc Comparisons – Tenderness in Group A.**

Tenderness	Tenderness	Mean Difference	SE	df	t	Pbonferroni
Baseline	-D1	0.1000	0.0688	19.0	1.45	1.000
	-D2	0.4500	0.1141	19.0	3.94	0.018
	-D3	0.9500	0.0881	19.0	10.78	< .001
	-D4	1.0500	0.0500	19.0	21.00	< .001
	-D5	1.6500	0.1094	19.0	15.08	< .001
	Post-intervention	1.6500	0.1094	19.0	15.08	< .001
D1	-D2	0.3500	0.1094	19.0	3.20	0.099
	-D3	0.8500	0.0819	19.0	10.38	< .001
	-D4	0.9500	0.0500	19.0	19.00	< .001
	-D5	1.5500	0.1141	19.0	13.58	< .001
	Post-intervention	1.5500	0.1141	19.0	13.58	< .001
D2	-D3	0.5000	0.1147	19.0	4.36	0.007
	-D4	0.6000	0.1124	19.0	5.34	< .001
	-D5	1.2000	0.1376	19.0	8.72	< .001
	Post-intervention	1.2000	0.1376	19.0	8.72	< .001
D3	-D4	0.1000	0.0688	19.0	1.45	1.000

	-D5	0.7000	0.1051	19.0	6.66	< .001
	Post-intervention	0.7000	0.1051	19.0	6.66	< .001
D4	-D5	0.6000	0.1124	19.0	5.34	< .001
	Post-intervention	0.6000	0.1124	19.0	5.34	< .001
D5	Post-intervention	0.0000	0.0000	19.0	NaN	NaN

When the tenderness was compared between baseline and post-intervention shows a significant difference with  $p < 0.001$

It concludes that there was an average change of 75% in tenderness after post-intervention in the Group-A.

**Table 6: Post Hoc Comparisons – Tenderness in Group B.**

Tenderness	Tenderness	Mean Difference	SE	df	t	pbonferroni
Baseline	-D1	0.000	0.0000	19.0	NaN	NaN
	-D2	0.300	0.1051	19.0	2.85	0.213
	-D3	0.850	0.0819	19.0	10.38	< .001
	-D4	1.050	0.0500	19.0	21.00	< .001
	-D5	1.750	0.0993	19.0	17.62	< .001
	Post-intervention	1.750	0.0993	19.0	17.62	< .001
D1	-D2	0.300	0.1051	19.0	2.85	0.213
	-D3	0.850	0.0819	19.0	10.38	< .001
	-D4	1.050	0.0500	19.0	21.00	< .001
	-D5	1.750	0.0993	19.0	17.62	< .001
	Post-intervention	1.750	0.0993	19.0	17.62	< .001
D2	-D3	0.550	0.1141	19.0	4.82	0.003
	-D4	0.750	0.0993	19.0	7.55	< .001
	-D5	1.450	0.1535	19.0	9.45	< .001
	Post-intervention	1.450	0.1535	19.0	9.45	< .001
D3	-D4	0.200	0.0918	19.0	2.18	0.884
	-D5	0.900	0.1235	19.0	7.28	< .001
	Post-intervention	0.900	0.1235	19.0	7.28	< .001
D4	-D5	0.700	0.1051	19.0	6.66	< .001
	Post-intervention	0.700	0.1051	19.0	6.66	< .001
D5	Post-intervention	0.000	0.0000	19.0	NaN	NaN

When the tenderness was compared between baseline and post-intervention shows a significant difference with  $p < 0.001$ .

It concludes that there was an average improvement of 87.5% after the intervention in Group-B.

#### 4) Reliving sphincter spasm

**Table 7: Post Hoc Comparisons - sphincter tone in Group A.**

Sphincter tone	Sphincter tone	Mean Difference	SE	df	t	pbonferroni
Baseline	-D1	0.0000	0.0000	19.0	NaN	NaN
	-D2	-0.1500	0.0819	19.0	-1.831	1.000
	-D3	-0.0500	0.1352	19.0	-0.370	1.000
	-D4	0.0500	0.1352	19.0	0.370	1.000
	-D5	0.1500	0.1094	19.0	1.371	1.000
	Post-intervention	0.1500	0.1094	19.0	1.371	1.000
D1	-D2	-0.1500	0.0819	19.0	-1.831	1.000
	-D3	-0.0500	0.1352	19.0	-0.370	1.000
	-D4	0.0500	0.1352	19.0	0.370	1.000
	-D5	0.1500	0.1094	19.0	1.371	1.000
	Post-intervention	0.1500	0.1094	19.0	1.371	1.000
D2	-D3	0.1000	0.1000	19.0	1.000	1.000
	-D4	0.2000	0.1376	19.0	1.453	1.000
	-D5	0.3000	0.1277	19.0	2.349	0.626
	Post-intervention	0.3000	0.1277	19.0	2.349	0.626
D3	-D4	0.1000	0.1000	19.0	1.000	1.000
	-D5	0.2000	0.1170	19.0	1.710	1.000

	Post-intervention	0.2000	0.1170	19.0	1.710	1.000
D4	-D5	0.1000	0.0688	19.0	1.453	1.000
	Post-intervention	0.1000	0.0688	19.0	1.453	1.000
D5	Post-intervention	0.0000	0.0000	19.0	NaN	NaN

When the sphincter tone was compared between baseline and post-intervention shows no significant difference with  $p = 0.23$ .

It concludes that there was an average improvement of 60% in sphincter tone on Group-A.

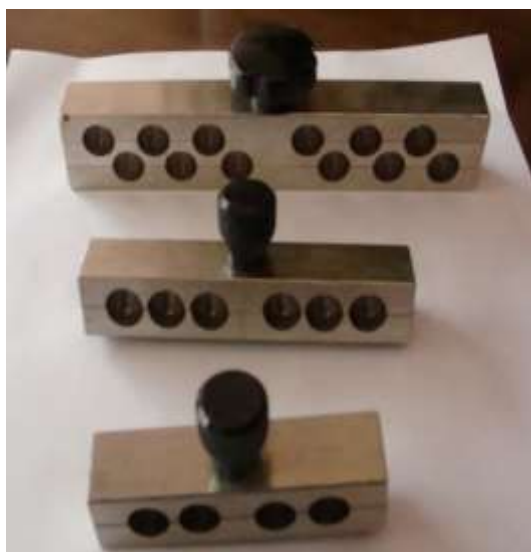
**Table 8: Post Hoc Comparisons - Sphincter tone in Group B.**

Sphincter tone	Sphincter tone	Mean Difference	SE	df	t	pbonferoni
Baseline	-D1	0.0000	0.0000	19.0	NaN	NaN
	-D2	-0.2000	0.0918	19.0	-2.18	0.884
	-D3	-0.3000	0.1051	19.0	-2.85	0.213
	-D4	-0.2500	0.0993	19.0	-2.52	0.441
	-D5	-0.2500	0.0993	19.0	-2.52	0.441
	Post-intervention	-0.2500	0.0993	19.0	-2.52	0.441
D1	-D2	-0.2000	0.0918	19.0	-2.18	0.884
	-D3	-0.3000	0.1051	19.0	-2.85	0.213
	-D4	-0.2500	0.0993	19.0	-2.52	0.441
	-D5	-0.2500	0.0993	19.0	-2.52	0.441
	Post-intervention	-0.2500	0.0993	19.0	-2.52	0.441
D2	-D3	-0.1000	0.0688	19.0	-1.45	1.000
	-D4	-0.0500	0.0500	19.0	-1.00	1.000
	-D5	-0.0500	0.0500	19.0	-1.00	1.000
	Post-intervention	-0.0500	0.0500	19.0	-1.00	1.000
D3	-D4	0.0500	0.0500	19.0	1.00	1.000
	-D5	0.0500	0.0500	19.0	1.00	1.000
	Post-intervention	0.0500	0.0500	19.0	1.00	1.000
D4	-D5	0.0000	0.0000	19.0	NaN	NaN
	Post-intervention	0.0000	0.0000	19.0	NaN	NaN
D5	Post-intervention	0.0000	0.0000	19.0	NaN	NaN

When the sphincter tone was compared between baseline and post-intervention shows a significant difference with  $p = 0.03$ .

It concludes that there was an average change of 37.5% after then intervention in sphincter tone among Group-B.

#### Figures.



**Fig no. 1: Moulds.**



**Fig no. 2: Jatyadi Grita Suppositories.**



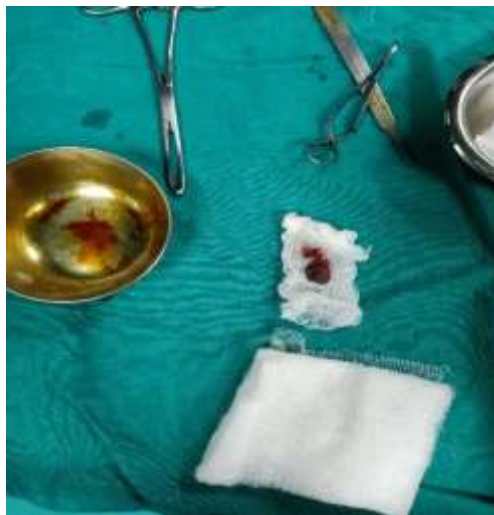
Fig no. 3: Fissurectomy.



Fig no. 4: Fistulotomy.



Fig no. 5: Haemorrhoidectomy.



## DISCUSSION

### Discussion on selection of drug

The inquisition includes comparison of currently available practice of use of the drug Diclofenac Sodium with proposed *Ayurvedic* formulation *Jatyadi ghrita* as rectal suppository.

The shortcomings of Diclofenac Sodium viz., headache, dizziness, loss of appetite, local rectal irritation, ringing in the ears and rectal bleeding were thought to be overcome by the use of an equally or more effective formulation having similar analgesic/ anti-inflammatory effect selected from the classical texts of *Ayurveda*.

### Discussion on demographic data

#### Sex

Out of 40 patients, 32.5% female and 67.5% male. The present study shows that men are more prone to ano-rectal disorders. It can be due to men are more exposed for etiological factors like prolonged sitting, continuous riding of vehicles, untimely diet, unhygiene.

#### Age

Out of total 40 patients in group A and group B, the mean age in Group-A was 40.6 years while the mean age of Group-B was 42.3 years. This shows that subjects of the age group between 35-50 years have approached for diagnosis and treatment. The reason for this may be attributed to an increased consumption of mixed type of dietary habit and sedentary lifestyle as indicated in the same study.

#### Occupation

Out of 40 patients taken for the study, the number of house wives were more, 4 in Group-A and 7 in Group-B were present. This can be attributed to untimely food habits and lifestyle practices.

#### Religion

Out of 40 patients taken for the study, maximum patients belonged to Hindu Religion. This shows the predominance of Hindus amongst the local population.



### Socio-economic status

Out of 40 patients taken for the study, maximum patients belonged to middle class indicating the prevalence of ano rectal disorders in this category which can be attributed to lack of awareness about early medical care and compromised dietary and life style practices.

### Diet

Out of 40 patients taken for the study, 65% of vegetarians, 35% of Mixed in Group-A and 70% of vegetarians and 30% of mixed diet patterns was present in Group-B. This may be because patient followed vegetarian diet in Post- op period.

### Operative Procedures

Out of 40 patients taken for the study, 45% of haemorrhoidectomy, 30% of fistulotomy and 25% of fissurectomy cases were present in both Group-A and Group B.

### Discussion on disease related statistics

#### Subjective parameters

##### Effect of treatment on Pain

In **Group A**, the treatment had a highly significant effect on Pain ( $p < 0.001$ ) with an average improvement of 86%. In **Group B**, the treatment had a highly significant effect on Pain ( $p < 0.001$ ) with an average improvement of 98%. The comparative analysis of the treatment's effect on Pain between Group A and Group B resulted in a p-value 0.04, suggesting a statistically significant difference. Hence the result in the effect of treatment on Pain in group B was better than group A.

*Jatyadi Gritha*, ingredients like *tuttha*, *haridra*, *daruharidra*, *katuki*, *karanja*, *jati* have *vrana shodhana* property. Anti-inflammatory action of these help to reduce Pain with reduction of inflammation.

*Yashtimadhu* one of the ingredient of *jatyadi ghritha* contains asparagine as active ingredients. Asparagine is a type of amino acid and which act as analgesic (natural painkiller) and anti - inflammatory.

Diclofenac inhibit cyclooxygenase (COX)-1 and-2 which are the enzyme responsible for producing prostaglandins (PGs). PGs contribute to inflammation and pain signalling.

##### Effect of treatment on Burning sensation

In **Group A**, the treatment had a highly significant effect on Burning sensation ( $p < 0.001$ ) with an average improvement of 92%. In **Group B**, the treatment had a highly significant effect on Burning sensation ( $p < 0.001$ ) with an average improvement of 87%. The comparative analysis of the treatment's effect on Burning sensation between Group A and Group B resulted in a p-value  $> 0.05$ , suggesting a statistically insignificant difference. Hence the result in the effect of treatment on Burning sensation in group A was comparatively better than group B.

The burning sensation is due to vitiated *pitta dosha*. As *Jatyadi ghritha* suppositories contains *Yashtimadhu* one of the ingredient which had soothing effect and most most of the *Jatyadi ghritha* ingredients having *sheeta veerya* properties. And *gritha* having *vata pitta hara*, *ropana* and *daha shamaka* properties thus helps in reducing burning sensation.

##### Effect of treatment on Tenderness

In **Group A**, the treatment had a highly significant effect on Tenderness ( $p < 0.001$ ) with an average improvement of 75%. In **Group B**, the treatment had a highly significant effect on Tenderness ( $p < 0.001$ ) with an average improvement of 87%. The comparative analysis of the treatment's effect on Tenderness between Group A and Group B resulted in a p-value  $> 0.05$ , suggesting a statistically insignificant difference. Hence the result in the effect of treatment on Tenderness in group B was comparatively better than group A.

The above observation indicated that *Jatyadi ghritha* possess analgesic and anti-inflammatory properties which makes it an effective formulation administered in the form of rectal suppository to considerably reduce tissue tenderness.

At the site of tissue damage prostaglandins were produced which contribute to inflammation and pain signalling. Diclofenac inhibit cyclooxygenase (COX)-1 and-2 enzymes which responsible for producing prostaglandins (PGs). Thus it reduces tenderness at the site of injury.

##### Effect of treatment on Sphincter tone

In **Group A**, the treatment had statistically insignificant effect on Sphincter tone ( $p > 0.05$ ) with an average improvement of 60%. In **Group B**, the treatment had statistically insignificant effect on Sphincter tone ( $p > 0.05$ ) with an average improvement of 37.5%. The comparative analysis of the treatment's effect on Sphincter tone between Group A and Group B resulted in a p-value 0.032, suggesting a statistically significant difference. Hence the result in the effect of treatment on Sphincter tone in group A was better than group B.

Sphincter tone assessment shows relief of spasm after the use of *Jatyadi ghritha* Rectal Suppository. This might be because of the formulation *Jatyadi ghritha* suppository being a *vata hara dravya* has positive therapeutic effect on sphincter spasm of both internal and external anal sphincter. *Gritha* reduces increased *Ruksha guna* of *Vayu* and maintain the normal tone of muscles.

### Discussion on overall result

Diclofenac suppository was more effective in the Post-operative pain management in ano-rectal disorders than *Jatyadi ghritha* suppository. However, when take into consideration of individual assessment parameters *Jatyadi ghritha* suppositories has better effect on reducing burning sensation and reliving sphincter spasm. While

Diclofenac suppositories has better effect on reducing pain and tenderness.

### Discussion on probable mode of action of *jatyadi ghrita* suppository

The suppository dissolves to release the drug once inside the body and travel to other parts of the body through the blood stream. Most of the ingredients of *jatyadi ghrita* act as *vatanashaka* and *vrana ropaka*. Its *Shodana* and *ropana* properties helps in reducing the inflammation of anal mucosa, discharge, and pain. The *Goghrita* used as content of *jatyadi ghrita* has “*Sanskar Anuvartana*” property, the *Yogavahi guna* of it carries the active principle of the drugs at the level of body tissue.

According to modern point of view lipophilic action of *ghrita* facilitates transportation to a target organ and finally delivery inside the cell because cell membrane also contains lipid.

- *Jati* is having *vrana shodana* and *ropana* properties which enhances wound healing and thus synergizes the analgesic effect.
- Drugs like *nimba*, *haridra*, *daru haridra*, *karanja*, has anti-inflammatory action thus it reduces the inflammation.
- Drugs like *madhuka* and *ushira* having *sheeta veerya* which helps in reducing the burning sensation.
- Drugs like *jati*, *manjista*, *sariva*, *karanja*, *patola*, *siktha* having *vrana shodana* and *ropana* properties which helps in healing the wound.
- *Yastimadhu* has soothing and healing action on skin lesions.
- In *Rasa tarangini* there is a reference which highlights that *tuttha* is effective in the management of *Shoola*, *Gudashoola*, *Arshas*, *Kandu*, *Krimi*.
- *Tuttha* i.e copper sulphate induces vascular endothelial growth factor appearance in the wound or ulcer.

### CONCLUSION

- Surgery suppresses the immune system and most patients who undergo surgical procedures experience acute post-operative pain. "Pain Relief is a Human Right." Pain, local irritation, bleeding, bowel irregularities, posture discomfort are inevitable sufferings in patients undergoing ano-rectal surgeries. *Jatyadi Ghrita* contains dravyas having analgesic, anti-inflammatory and also wound healing properties. Being antimicrobial checks infection of the post-operative wound site, being a wound healer enhances wound healing and thus synergizes the analgesic effect.
- In the present study, the effect of the treatment in both the groups has shown statistically highly significant results in the assessment parameters like Pain, Burning sensation, Tenderness (BT-AT).

- The average reduction in pain subjectively assessed in Group A is 86% by POD5 Where as in Group B it is 98%.
- The average reduction in burning sensation subjectively assessed in Group A is 92% by POD5 Where as in Group B it is 87%.
- The average reduction in tenderness objectively assessed in Group A is 75% by POD5 and in Group B is 87%.
- The average reduction in sphincter spasm assessed objectively in Group A is 60% by POD5 where as in Group B is 37.5%.
- No adverse effects were observed in both the groups during the course of the study.
- Based on observation and result, following Alternate hypothesis can be accepted
- There is significant effect of *Jatyadi ghrita* suppository in the post-operative pain management of ano rectal disorders.
- There is significant effect of Diclofenac suppository in the post-operative pain management of ano rectal disorders.
- Diclofenac suppository was more effective in the Post-operative pain management in ano-rectal disorders than *Jatyadi ghrita* suppository. However, when take into consideration of individual assessment parameters *Jatyadi ghrita* suppositories has better effect on reducing burning sensation and relieving sphincter spasm. While Diclofenac suppositories has better effect on reducing pain and tenderness.

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