



Research Article

COMPARATIVE STUDY OF EFFICACY OF *JATYADI GHRITA PICHU* AND *YASTHIMADHU GHRITA PICHU* IN THE MANAGEMENT OF *PARIKARTIKA* (FISSURE- IN-ANO)

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ABSTRACT

The condition *Parikartika* has been mentioned in the Ayurvedic literature as one of the fifteen kinds of disorders which may result from an injudicious use of purgatives owing to the ignorance of the physician or of the patient. The acute fissure is a superficial splitting of the anoderm characterized by severe pain, sometimes associated with bleeding per rectum during/after defecation.

Application of local anesthetics, anal dilatation, sphincterotomy, and fissurectomy (chronic fissure) are usually in practice. But these procedures have sometimes associated with some complications like post operative anal stenosis, sphincter incontinence etc. To overcome such problems and to provide cheap, simple, ambulatory and effective treatment, a combined therapy has been kept on trial on the basis of the treatment mentioned in the ancient literature in the management. **Aim and objectives:** Evaluation of clinical efficacy of *Pichu* application of *Jatyadi Ghrita* and *Yasthimadhu Ghrita* in the management of Fissure-in-ano (*Parikartika*). **Materials & Methods:** Taking this view in to consideration, a modified regimen with *Jatyadi Ghrita* and *Yasthimadhu ghrita* in *Pichu* form in two different groups along with *Panchasakara churna* have been kept on trial on 100 patients in each group in the Ano-Rectal Clinic of the Institute.

Results and Conclusion: The results were assessed and compared and it was found that both the medicines were equally effective without any complications in the management of Fissure-in-ano.

KEYWORDS: Fissure-in-ano, *Parikartika*, *Pichu*, *Jatyadi ghrita*, *Yasthimadhu ghrita*, *Panchasakara churna*.

INTRODUCTION

An anal fissure or rectal fissure, commonly known as *Parikartika* in Ayurveda, is a split in the skin of the distal anal canal due to stretching of the anal mucosa beyond its capability. The incidence of anal fissures is around 1 in 350 adults. The true prevalence of Anal fissures is unknown, but it is estimated that they account for 5% of Proctology referrals. They occur equally commonly in men and women and most often occur in adults aged 15 to 40. If acute they may cause pain after defecation but with chronic fissures pain intensity is often less. They will generally self-heal within a couple of weeks but some anal fissures become chronic and deep and will not heal. The most common cause of non-healing is spasm of the internal anal sphincter muscle which results in impaired blood supply to the anal mucosa. The result is a non-healing ulcer, which may become infected by fecal bacteria.

In adults, fissures may be caused by constipation, or by prolonged diarrhoea. In older adults, may be caused by decreased blood flow to the area. Fissures may also be caused by tuberculosis, occult abscesses, leukemic infiltrates, carcinoma, Acquired Immunodeficiency Syndrome (AIDS) or Inflammatory Bowel Disease, Sexually Transmitted Infections (syphilis, herpes, chlamydia and human papilloma virus). Other common causes of anal fissures include: childbirth trauma in women, Crohn's

disease, Ulcerative colitis and poor toileting in young children.

As per the Ayurvedic classics, on the basis of symptoms, the disease fissure-in-ano can be compared to the disease *Parikartika* where there is excruciating, cutting pain in the *Basti* and surrounding areas.

"Parisarvato bhavena krintateeva chhinatteeva bastyadeeni iti Parikartika"

Acharya Dalhana has described the term *Parikartika* as a condition of *Guda* in which there is cutting pain and tearing pain. According to Kasyapa the *Parikartika* is the one having cutting and tearing pain in *Guda pradesha*.^[1] Similarly Jejjata and Todara have clearly described *Parikartika* as a condition which causes cutting pain in anorectum. The factors responsible for causation of *Parikartika* as found in various texts are *Vamana-Virechana-Vyapat*, *Bastikarma Vyapat*, *Atisara*, *Grahani*, *Arsha*, *Udavarta* etc. In the similar manner it has been described of three types viz. *Vata*, *Pitta* and *Kapha*. Sushruta while describing the symptoms of the disease speaks of the features like; cutting or burning pain in anus, penis, umbilical region and neck of urinary bladder with cessation of flatus. Sushruta has mentioned *Parikartika* as a *Vasti vyapat* which is due to the administration of *Ruksha vasti* containing of *Teekshna* and *Lavana dravyas* in heavy doses.^[2] According to him, it is due to *Vasti netra vyapat* which is due to inappropriate administration of

defective *Vasti netra* resulting in to cutting type of pain. [3] Whereas Charaka has described the features like: pricking pain in groins and sacral area, scanty constipated stools and frothy bleeding per rectum. *Parikartika* has been mentioned as *Purva rupa* of *Arsha* in *Susruta samhita*[4] and *Astanga Sangraha*. [5]

According to Ayurvedic literature, there are several methods of treatment i.e. *Bhaishaja - Kshara - Agni - Shastra Karma* etc. Among them *Bhaishaja Karma* - medicinal treatment is the first line of treatment. However the *Kshara, Agni & Sastra karmas* have certain limitations and draw backs. Application of *Kshara* on the fissure lesion (Chronic) requires special equipment, skill and the procedure takes, a minimum period of 10-20 minutes with a meticulous handling. Otherwise, the spillage on the normal tissue can cause damage to the healthy tissues. Excessive penetration can lead for perianal abscess and fistula formation. Probably this requires surgical intervention. During the process of *Agni karma*, the accidental penetration deepens into the normal tissues amounts for infection poisoning and hematoma formation. This procedure is usually preceded by anal stretch. This leaves a large and rather uncomfortable external wound, which takes a long time to heal.

Besides *Basti prayoga* with different preparations [6-13], many authors have advocated local treatments like *Nadi sweda*, luke warm water sitz bath, *Parisheka* with cold water, milk and drugs having *Kashaya* and *Sheetal guna* which are aiming at *Vedana shaman* and *Vrana ropana* in the management of *Parikartika*. [14-15]

Need for appropriate Ayurvedic Therapeutic approaches: Owing to the above challenges and limitation of different conventional approaches viz. Non-surgical treatments like topical nitroglycerin or calcium channel blockers, or injection of botulinum toxin into the anal sphincter, topical anesthetics etc. and Surgical treatments like Lateral sphincterotomy (LIS), Anal dilation or stretching of the anal canal (Lord's operation) etc., it is at

MAERIALS AND METHODS

this juncture that the need for drugs/measures that could effectively tackle Fissure-in-ano. A vast number of indigenous drugs approaches coupled with innumerable claims of their varied uses in alleviating ano rectal diseases calls for scientific validation for their attributes and principles. Various scientific studies to substantiate the efficacy of Ayurvedic approaches in the management of fissure-in-ano conducted at different Academic and Research Institutes including Central Council for Research in Ayurvedic Sciences viz. Local application of *Jatyadi ghrita, Jatyadi taila, Anu taila, Prabhakara ghrita, Kasisadi Taila, Nimbadi taila, Vranaropana taila, Doorvadi ghrita, Vedanantaka Malahara* and internal administration of *Abhyarishta, Kutjarista, Triphala Churna* etc. have proven an edge over the conventional therapies in managing the symptoms viz. pain, bleeding besides healing of ulcer. Adding to this the achievement of bowel regulation is significantly observed in all these studies indicating the uniqueness of Ayurvedic approaches.

Rational of selection of trial intervention: A thorough review of scientific study to validate the Ayurvedic approaches in fissure-in-ano revealed that the *Pichu* application has not been given the emphasis. *Pichu* being a modality of drug delivery that certainly enhances the tissue contact time of the drug and improving the bio availability in comparison to conventional local application of drugs. Better therapeutic response over the conventional simple local application of drugs could be expected through this modality of *Pichu* application.

AIM AND OBJECTIVES

1. Evaluation of clinical efficacy of *Pichu* application of *Jatyadi Ghrita* and *Yasthimadhu Ghrita* in the management of Fissure- in-ano (*Parikartika*).
2. Comparative analytical study of unique drug delivery system - *Pichu* application with historical controls of simple local application of Ayurvedic drugs from published literatures.

Table 1 : Study Plan

Study Type	:	Interventional
Purpose	:	Treatment
Masking	:	Open label
Timing	:	Prospective
End Point	:	Efficacy
No. of Groups	:	Two
Sample size	:	200 (Group – I : 100 ; Group – II : 100)
Duration of the treatment	:	Seven weeks. (Duration of the Study Period) <ul style="list-style-type: none"> • 21 days (Three weeks) with treatment • One Month without treatment follow-up
Centre	:	National Research Institute of Ayurveda Drug Development, Bhubaneswar, Odisha, India,

Interventions

Panchasakara Churna (Siddha Yoga Sangraha); *Jatyadi Ghrita* (Astang Hridaya, Uttara sthana); *Madhuyashti Ghrita* (Bhaishajya Ratnavali Chapter 48). The formulations are manufactured as per the Standard Ayurvedic classical text in the Pharmacy section of the Institute.

Group - I

Application of *Jatyadi ghrita pichu* preceded by sitz bath with luke warm water for three weeks along with internal administration of *Panchsakara churna* 5 gm at bed time with luke warm water for the same period.

Group - II -Application of *Yastimadhughrita Pichu* daily preceded by sitz bath with luke warm water for three

weeks and internal administration of *Panchsakara churna* 5 gm at bed time with luke warm water for the same period.

Follow up: Four follow up observation at an interval of seven days, three during drug intervention followed by last follow up after completion of drug intervention.

Application of Pichu (A tampon / sterile gauze soaked in the *Jatyadi ghrita* / *Yashstimadhu ghrita* is placed at anus or anal canal **Gudapichu**): Initially per rectal examination is done while the patient is in Lithotomy position, to confirm the number and position of the Fissure. The sphincter tone is assessed with the digital examination. After giving warm water sitz bath for a period of 2 minutes, either *Jatyadi ghrita* or *Yastimadhu ghrita pichu* is kept and advised the patient to keep it for 2-3 hours. A "T" bandage will be applied so that the *Pichu* will be retained in situ till the desired duration. The *Pichu* is applied on daily basis for 21days (Three weeks) or till the complete healing of the ulcer whichever is earlier (at OPD / IPD level) and thereafter, asked to visit the Ano-rectal clinic at the interval of 7 days for four weeks.

Inclusion criteria

1. Patients clinically diagnosed / confirmed by inspection as having *Parikartika* (Fissure in Ano)
2. Patients of either sex aged between 21 and 60 years
3. Patients of fissure-in-Ano with systemic diseases like Diabetes (FBS < 126 mg% / PP < 200 mg% / HbSag < 6.5) and Hypertension (Systolic < 150 mm Hg / Diastolic < 100 mm Hg) which are well under control.
4. Willing and able to participate in the study for 04 weeks.

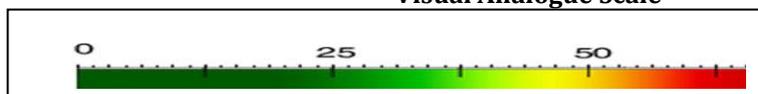
Exclusion Criteria

1. Patients having *Parikartika* (Fissure-in-Ano) secondary to Ulcerative colitis, Chron's disease,

Assessment Parameters

(1) Clinical Parameters

Visual Analogue Scale



Parameters Visual analogue Scale Score

- a) Pain
- b) Bleeding
- c) Itching

Criteria of assessment

Table 2: Relief of Symptoms before and after treatment

S.No.	Relief/Withdrawal	Description
1	Complete Relief	Above 75 % Complete disappearance of known symptoms and absence of complications and Recurrence
2	Marked Relief	Above 50% to 75% disappearance of known symptoms and absence of complications and Recurrence
3	Moderate Relief	Above 50 % relief in presenting symptoms and some recurrence of fissure
4	Mild Relief	25 % and above relief in presenting symptoms with negligible change in the ulceration of fissure
5	No Relief	No relief in presenting symptoms and no change in the ulceration of fissure
6	Withdrawal / Drop out	<ol style="list-style-type: none"> 1. Discontinuation of the treatment during the trial 2. Development of any complications 3. Aggravation of disease symptoms and 4. Any side effect of the trial drugs

Syphilis and Tuberculosis will be excluded.

2. Patients with uncontrolled systemic disease as like Diabetes (FBS > 126 mg% / PP > 200 mg% / HbSag > 6.5) and Hypertension (Systolic > 150 mm Hg / Diastolic > 100 mm Hg) will be excluded.
3. Patients with infectious diseases like HIV and HbsAg will be excluded.
4. Any other condition which the Investigator thinks may jeopardize the study.

Withdrawal Criteria

- The participant may be withdrawn from the trial if – during the course of the trial treatment, if any serious condition develops/ symptoms aggravate, which requires urgent treatment, necessitating the institution of new modalities of treatment.

OR

- Non-compliance of the treatment regimen (minimum 80% compliance is essential to continue in the study).

Outcome measures: The following outcome measures will be recorded an interval of seven days for four weeks.

Primary Outcome Measure

- Change in the Clinical Parameters.

Secondary Outcome Measures

- Change in the bowel habit
- Clinical safety

Assessment Criteria

1. Pain assessed by visual analogs scale.
2. Status of Bleeding assessed by Examination and interrogation.
3. Status of itching ani assessed by Examination and interrogation.
4. Healing status of fissure assessed by physical examination with photographic evidence.

Table 3: Healing status of Ulcer

No change in Ulcer	No Relief
Partial healing	Moderate Relief
Complete healing	Complete Relief

Table 4: Gradation: Subjective Parameters

S. No.	Symptoms	Before Treatment	After Treatment
1	Pain	Excruciating - 5; Horrible - 4; Distressing- 3; Discomforting - 2; Mild - 1; No Pain - 0	Excruciating - 5; Horrible - 4; Distressing- 3; Discomforting - 2; Mild - 1; No Pain - 0
2.	Bleeding	Severe - 3; Moderate - 2; Mild-1; No - 0	Severe - 3; Moderate - 2; Mild - 1; No - 0
3.	Constipation	Severe - 3; Moderate - 2; Mild -1; No - 0	Severe - 3; Moderate - 2; Mild -1; No - 0

Table 5: Gradation: Objective Parameters

S. No.	Symptoms	Before Treatment	After Treatment
1	Sphincter tone assessment	Tightly contracted -2 Spasmodic -1; Normal-0.	Tightly contracted -2 Spasmodic -1; Normal-0.
2.	Size of Ulcer	Big - 3; Medium - 2; Small - 1	Big - 3; Medium - 2; Small - 1; No ulcer- 0
3.	Healing	-	Not Healing -2; Healing - 1; Completely Healed- 0

Descriptions of the grading of the parameters

A. Gradation of Subjective parameters

1. Bleeding

- ◆ Nil : No bleeding
- ◆ Mild : Along with stool
- ◆ Moderate : Drop wise 6-8 drops
- ◆ Severe : About 2-3 ml

2. Vibandha (Constipation)

- ◆ No : Passes stools regularly without difficulty
- ◆ Mild : Passes stools regularly with difficulty
- ◆ Moderate : Passes hard stools irregularly with difficulty
- ◆ Severe : Passes pellet like stool once in a week with difficulty

B. Gradation of Objective parameters:

1. Size of Ulcer

- ◆ Nil : No ulcer
- ◆ Small : 1mm to 4mm
- ◆ Medium : 5mm to 8mm
- ◆ Big : 9mm to 12mm

2. Sphincter tone

- ◆ Normal
- ◆ Spasmodic
- ◆ Tightly contracted

3. Healing of Ulcer

- ◆ Not Healing
- ◆ Healing
- ◆ Completely Healed

OBSERVATIONS AND RESULTS

Table 6: Condition of Patients on Admission

Incidence o Condition	No. of Patients	Percentage (%)
A. Age Groups (in Years):		
Age (in years)		
21-30	36	18
31-40	92	46
41-50	50	25
51-60	22	11
B. Sex		
Male	120	60
Female	80	40
C. Marital Status		

Married	172	86
Unmarried	28	14
Widow	0	0
Divorcee	0	0
D. Religion		
Hindu	199	99.5
Muslim	01	0.5
E. Habitat		
Rural	32	16
Urban	168	84
F. Food Habits		
Non-vegetarian	181	90.5
Vegetarian	19	9.5
G. Bowel Habits		
Regular	03	1.5
Constipated	197	98.5
H. Prakruti		
Vata	50	25
Pitta	72	36
Kapha	78	39

Out of 200 patients admitted for the clinical trial, 60 percent were males while 40 were females. Maximum of 46 percent of cases fall under the age group of 31-40 yrs. while minimum of 11percent in the age up of 51-60 yrs. Among them about 39 percent were of *Kapha prakriti* followed by *Pitta prakiriti* with the incidence of 36 percent and *Vata prakruti* with 25 percent. Maximum no. of patients (98.5%) had constipated bowel habits and almost all patients were recorded as non-vegetarians (90.5 %). Married patients were reported with maximum number (86 %) and almost were belong to the Hindu faith. Maximum of 84 % were from the Urban area.

Table 7: Characteristics of Fissure-in-ano (*Parikartika*) on Admission

Incidence of Characteristics	No. of Patients	Percentage (%)
A. Duration of illness (in days)		
Up to 365	95	47.5
366 -730	45	22.5
731 & above	60	30
B. Onset of fissure		
Acute	135	67.5
Gradual	65	32.5
C. Severity of pain		
Mild	62	31
Moderate	98	49
Severe	40	20
D. Previous H/O treatment		
Fresh	124	62
Medical	58	29
Operation	18	9
E. Type of fissure		
Acute	73	36.5
Acute on Chronic	76	38
Chronic	51	25.5
F. History of any Associated diseases		
Present	13	6.5
Absent	187	93.5

About 47.5 percent of patients had the disease for at least one year and 67.5 percent patients had acute onset and 9 percent of patients had previous anal surgery. Previous history revealed that 62 percent of patients developed afresh and 29 percent were underwent medical treatment for the *Parikartika*. The type of fissure was Acute on Chronic in 38 percent of patients and most of the fissures (49 %) developed moderate pain. Only 6.5 percent of patients had the family history of the disease.

Table 8: Clinical features of Fissure-in-ano (*Parikartika*) on Admission:

Incidence of Clinical features	No. of Patients	Percentage (%)
A. Nature of pain		
Pricking	92	46
Cutting	29	14.5
Throbbing	01	0.5
Burning	78	39
Lehing	0	0
B. Type of Bleeding		
Persistent	0	0
During / Defecation	104	52
Mixed with Stool	96	48
Malena	0	0
C. Itching Ani (Pruritis)		
Present	105	52.5
Absent	95	47.5
D. Type of Edges		
Indurated	200	100
Undermined	0	0
A. Position (O-Clock) of Fissure-in-ano		
2	1	0.5
3	4	2
4	8	4
5	20	10
6	112	56
7	40	20
10	3	1.5
11	2	1
12	10	5
B. Sphincter tone		
Normal	15	7.5
Hypertonic	185	92.5
C. Tenderness		
Present	200	100
Absent	0	0

A maximum of 56 percent of fissures were positioned at 60 clock having indurated edges (100 %). All patients had Pain & bleeding per rectum during and after the defecation. Maximum of 39 percent had the pricking type of pain and 52 percent of patients had itching ani. Almost all patients had Hypertonic sphincter (92.5 %) and tenderness (100 %).

The overall assessment of the treatment in both the groups were analysed on Subjective and Objective parameters and the results were summarized in the following tables. The study revealed that in both the groups, all the patients were having 100 % relief from the clinical features i.e., in subjective and objective parameters. The effectiveness of the treatment in both trial groups reveals statistically extremely significant with the 'p' value of <0.0001 in both groups.

Table 9 : Result of the treatment in Group - I

Signs & Symptoms	Mean ±SE (BT)	Follow-up	Mean ±SE	't' value	P value	Effectiveness
A. Subjective Parameters						
1. Pain on VAS	2.556 ± 0.13	AT1	0.86 ± 0.14	19.16864	<0.0001	Extremely significant
		AT2	1.40 ± 0.14	9.658595	<0.0001	Extremely significant
		AT3	1.97 ± 0.15	13.30896	<0.0001	Extremely significant

2. Bleeding	1.63 ± 0.05	AT1	1.63 ± 0.06	10.9389	<0.0001	Extremely significant
		AT2	1.02 ± 0.08	12.69006	<0.0001	Extremely significant
		AT3	0.16 ± 0.06	25.49594	<0.0001	Extremely significant
3. Constipation	1.62 ± 0.04	AT1	0.82 ± 0.08	10.64365	<0.0001	Extremely significant
		AT2	0.97 ± 0.08	13.80036	<0.0001	Extremely significant
		AT3	1.45 ± 0.06	26.01735	<0.0001	Extremely significant
B. Objective Parameters						
4. Sphincter spasm	1.61 ± 0.05	AT1	0.68 ± 0.08	8.902519	<0.0001	Extremely significant
		AT2	1.01 ± 0.07	14.07332	<0.0001	Extremely significant
		AT3	1.39 ± 0.06	20.89993	<0.0001	Extremely significant
5. Size of Ulcer	1.63 ± 0.04	AT1	0.66 ± 0.06	9.636413	<0.0001	Extremely significant
		AT2	1.11 ± 0.07	15.05878	<0.0001	Extremely significant
		AT3	1.48 ± 0.05	27.36403	<0.0001	Extremely significant
6. Healing of Ulcer	1.62 ± 0.04	AT1	0.73 ± 0.05	12.51011	<0.0001	Extremely significant
		AT2	1.22 ± 0.06	17.67627	<0.0001	Extremely significant
		AT3	1.49 ± 0.05	27.53466	<0.0001	Extremely significant

Table 10 : Result of the treatment in Group - II

Signs & Symptoms	Mean ±SE (BT)	Follow-up	Mean ±SE	't' value	P value	Effectiveness
C. Subjective Parameters						
1. Pain on VAS	2.6 ± 0.12	AT1	1.01 ± 0.10	9.212632	<0.0001	Extremely significant
		AT2	1.53 ± 0.12	12.23121	<0.0001	Extremely significant
		AT3	2.14 ± 0.133	16.04818	<0.0001	Extremely significant
2. Bleeding	1.68 ± 0.04	AT1	1.64 ± 0.06	10.19161	<0.0001	Extremely significant
		AT2	1.04 ± 0.07	14.37204	<0.0001	Extremely significant
		AT3	1.49 ± 0.05	26.63134	<0.0001	Extremely significant
3. Constipation	1.6 ± 0.04	AT1	0.68 ± 0.07	8.902519	<0.0001	Extremely significant
		AT2	1.01 ± 0.07	13.5518	<0.0001	Extremely significant
		AT3	1.45 ± 0.06	23.7989	<0.0001	Extremely significant
D. Objective Parameters						
4. Sphincter spasm	1.66 ± 0.04	AT1	0.75 ± 0.07	9.574271	<0.0001	Extremely significant
		AT2	1.08 ± 0.06	16.31912	<0.0001	Extremely significant
		AT3	1.45 ± 0.06	23.7989	<0.0001	Extremely significant
5. Size of Ulcer	1.6 ± 0.04	AT1	0.64 ± 0.06	9.940172	<0.0001	Extremely significant
		AT2	1.11 ± 0.06	15.97615	<0.0001	Extremely significant
		AT3	1.41 ± 0.05	25.53319	<0.0001	Extremely significant
6. Healing of Ulcer	1.68 ± 0.04	AT1	0.79 ± 0.05	13.36501	<0.0001	Extremely significant
		AT2	1.25 ± 0.06	18.19017	<0.0001	Extremely significant
		AT3	1.52 ± 0.05	29.12737	<0.0001	Extremely significant

Table 11 : Overall Clinical Assessment of the therapy

Study period	Group	No. of Patients	Overall response of the therapy									
			Complete Relief		Marked Relief		Moderate Relief		Mild Relief		No Relief	
			No. of Pts.	%	No. of Pts.	%	No. of Pts.	%	No. of Pts.	%	No. of Pts.	%
Before treatment	Group - I	100	0	0	0	0	0	0	0	0	0	0
	Group - II	100	0	0	0	0	0	0	0	0	0	0
7th Day of treatment	Group - I	100	71	71	21	21	8	8	0	0	0	0
	Group - II	100	68	68	27	27	5	5	0	0	0	0
14th Day of treatment	Group - I	100	85	85	15	15	0	0	0	0	0	0
	Group - II	100	79	79	18	18	3	3	0	0	0	0
21st Day of treatment	Group - I	100	100	100	0	0	0	0	0	0	0	0
	Group - II	100	100	100	0	0	0	0	0	0	0	0
Overall Response	Group - I	100	100	100	0	0	0	0	0	0	0	0
	Group - II	100	100	100	0	0	0	0	0	0	0	0

In Group - I, the study revealed that about 71 percent of the patients got Complete relief, 21 percent got marked relief while 8% got moderate relief during first week of the treatment i.e., by 7th day. By the end of 14th day 85 percent got complete relief and 15 percent got

marked relief. At the 21st day of the treatment 100 percent of patients got complete relief. No recurrence was reported during the follow-up period of four weeks after the completion of the treatment period of 21 days.

In Group – II, the study revealed that about 68 percent of the patients got Complete relief, 27 percent got marked relief while 5% got moderate relief during first week of the treatment i.e., by 7th day. By the end of 14th day 79 percent got complete relief and 18 percent got marked relief while 3 percent got moderate relief. At the end of 21st day of the treatment 100 percent of patients got complete relief. No recurrence was reported during the follow-up period of four weeks after the completion of the treatment period of 21 days.

DISCUSSION

The objective of the study was to Evaluation of clinical efficacy of *Pichu* application of *Jatyadi Ghrita* and *Yasthimadhu Ghrita* in the management of Fissure- in-ano (*Parikartika*) and Comparative analytical study of unique drug delivery system - *Pichu* application with historical controls of simple local application of Ayurvedic drugs from published literatures. In this study a total number of 200 patients were registered and were distributed in to two groups each containing of 100 patients each. The study revealed that in both the groups, all the patients were having 100 % relief from the clinical features i.e in subjective and objective parameters. The effectiveness of the treatment in both trial groups reveals statistically extremely significant with the 'p' value of <0.0001 in both groups. Maximum number of patients i.e., above 70 percent got complete relief in their clinical symptoms by 7th day of the treatment in both the groups which indicates that these *Ghrita* preparations are highly effective in the management of fissure-in-ano conditions.

Pichu -unique drug delivery system of Ayurveda:

Though the description about *Pichu* are not vividly available in Ayurvedic literatures, it is one of the important and effective modalities of drug delivery system having diversified applications in the management of various diseases /conditions viz. *Siro rogas*, *Yoni vyapat*, *Karna roga*, *Nasa roga*, *Guda rogas* owing to its unique nature of drug delivery and enhancing bio-availability.

"*Pichu sthoola kavalika*" - A thick swab or a cotton pad is called as *Pichu*. *Pichu Dharana* (placing of soaked linen) is a process in which a piece of cloth, gauze or linen is soaked in the medicated ghee or oil and placed in the desired position over the body or in the body parts according to the site of the treatment.

Mode of Action: Local action of *Pichu* is based on cellular absorption of medicine, acts as *Snehana*, *Lekahana* etc eg: *Vrana ropana*, effective in *Baghna*, *Nasa arsas* etc.

Exploration of Ayurvedic and contemporary literature endorse various therapeutic potential of the formulation viz. *Jatyadi ghrita*, *Yasthimadhu ghrita* and *Pancha sakara churna* and the ingredients embodied in these compound formulations attributed with analgesic anti- inflammatory, wound healing, anti- microbial, bowel regulating actions. These Pivotal principles are highly contributory for comprehensive management of fissure-in-ano and also to improve the quality of life. The combination of trial drugs in both the groups acts systemically as well as locally on fissure-in ano and help in the significant reduction of the clinical symptoms.

CONCLUSION

Based on the descriptions available from the ancient classical literatures and observations made during the clinical study on fissure-in-ano with two drug combinations in two different groups which was aimed at assessment of clinical efficacy, the following inferences or conclusions can be drawn.

- All the raw drugs used in the trial formulations were identified and authenticated as per the quality control parameters mentioned in the Ayurvedic Pharmacopoeia of India and manufactured as per the standard operative procedures laid down in Ayurvedic Formulary of India. The quality control parameters for *Panchasakara churna* and *Yasthimadhu ghrita* were established in association with Department of Pharmaceutical Analysis and Quality Assurance, School of Pharmaceutical Sciences, Siksha 'O' Anusandhan University, Bhubaneswar.
- Through the descriptions on the clinical features available in the literature the condition - *Parikartika* can be correlated with fissure-in-ano of modern medical science.
- Though the condition - *Parikartika* was not mentioned as a separate / independent disease, owing to its severity in clinical condition, the *Parikartika* can be taken as a separate / independent disease condition since many therapeutic procedures described in literature for its management.
- Majority of patients were of middle aged group having the constipated bowel habits which can be attributed to their sedentary and stressful life that play the key role in the occurrence of the *Parikartika*.
- Fissure-in-ano commonly exhibit in the midline of the lower quadrant of the peri-anal region and it was found in maximum number patients at 6 o' clock position.
- The hypertonic sphincteric spasm is commonly associates with acute fissure-in-ano can be relieved affectively by both the drug regimens.
- The most evident symptoms present i.e., pain and spasm can be relieved much earlier by the application of *Jatyadi ghrita* rather than *Yasthimadhu ghrita*.
- The longer the availability of the drug i.e bio-availability of the of the *Pichu* form in situ (on fissure site), the faster the healing of the ulcer.
- The patients treated with *Jatyadi ghrita* (first group) showed better results than *Yasthimadhu ghrita* as 71 percent of patients got complete relief and 21 percent got marked relief during the first week while in group two with *Yasthimadhu ghrita* the complete and marked relief were 68 and 27 percent respectively during first week i.e. by 7th day of the treatment.

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