

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

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In Ayurveda

Submitted by
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Under the Guidance of
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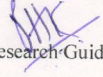
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CERTIFICATE

This is to certify that the thesis entitled “**Comparative Study of efficacy of Jatyadi ghrta Pichu and Yasthimadhu ghrta Pichu in the management of Parikartika (Fissure-in-Ano)**” which is being submitted herewith for the award of degree of Vidyavachaspati (Ph.D.) in the Late Vd. P. G. Nanal Department of Ayurveda, Tilak Maharashtra Vidyapeeth, Pune is a result of original research work completed by **Vd. Meda Mruthyumjaya Rao** under my supervision and guidance. To the best of my knowledge and belief, the work incorporated in this thesis has not formed the basis for the award of any degree or other similar title of this or any other Vidyapeeth or examining body upon him.

Place: Jaipur

Date: 23.07.2016


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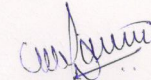
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DECLARATION

I hereby declare that the thesis entitled "**Comparative Study of efficacy of Jatyadi ghrita Pichu and Yasthimadhu ghrita Pichu in the management of Parikartika (Fissure- in-Ano)**" completed and written by me has not previous been formed as the basis for the award of any degree or other similar title of this or any other Vidyapeeth or examining body.

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Contents

Title		Page Number
Acknowledgements		i-ii
Contents		iii-v
List of Tables		vi-vii
List of Graphs		viii-ix
List of Plates & Symbols used in the master chart		x
Abbreviations		xi
Abstract		xii-xvii
Chapter 1	Introduction	3-7
	1.1. Present Modalities of treatment - Problems and Challenges	3-4
	1.2. Need for appropriate Ayurvedic Therapeutic approaches	4
	1.3. Rational of selection of trial intervention	4
	1.4. Pichu -unique drug delivery system of Ayurveda	5
	1.5. Mode of Action of Pichu	5
	1.6. Aim	5
	1.7. Objectives	5
	1.8. Plan of study	5
	1.9. References	6-7
Chapter 2	Review of Ayurvedic Literature	8 - 25
	2.1 Anatomical Aspects of Guda	8-14
	2.2 Physiological Concept of Guda	14-15
	2.3 Vascular supply to Guda:	15-16
	2.4 Gudosta Snayus in relation to Guda	16
	2.5 Description of Parikartika	16-17
	2.6 Nidana	17-19
	2.7 Rupa	20
	2.8 Samprapti	20-21
	2.9 Bheda	21
	2.10 Sadhya Asadhyata	21-22
	2.11 Chikitsa of Parikartika	22-25
Chapter 3	Review of Modern Literature	26 - 35
	3.1 Anatomy of Ano-Rectal Region	26
	3.2 Rectum	26-28

List of Tables

	3.3	The Anal Canal	28-31
	3.4	Blood Supply	32-33
	3.5	Nerve Supply	34
	3.6	Physiology of the Rectum and Anus	34
	3.7	References	35
Chapter 4	Drug Review		36 - 77
	4.1	Details of the Drugs used in the Trial Formulations (Drug Profile)	36-55
	4.2	Standardization and Quality Control parameters of Trial drugs	56-67
	4.3	The quality control parameters of Jatyadi Ghrita	67
	4.4	Establishment of quality control parameters of Yasthimadhu Ghrita	68-71
	4.5	Standard Operative Procedures (SOPs) for preparation of Trial Drugs	72-75
	4.6	References	76-77
Chapter 5	Materials and Methods		78 - 84
	5.1	Study Plan	79
	5.2	Interventions	79
	5.3	Application of Pichu	79-80
	5.4	Inclusion criteria	80
	5.5	Exclusion Criteria	80
	5.6	Withdrawal Criteria	80
	5.7	Outcome measures	81
	5.8	Assessment Criteria	82-84
Chapter 6	Observations and Results		85 - 114
	6.1	Observations	85-101
	6.2	Results	101-114
Chapter 7	Discussion		115 - 124
	7.1	Significant clinical observations	117-119
	7.2	Effect of jatyadi ghrita (Group-I) and Yasthimadhu ghrita (Group-II)	119-122
	7.3	Probable Mode of Action of Trial Drugs	122-124
Chapter 8	Conclusion and Summary		125 - 127

List of Tables

	8.1	Conclusion	125-126
	8.2	Summary	126-127
Chapter 9	Bibliography		128 - 135
Chapter 10	Appendix		136 - 149
	10.1	Study Schedule	136
	10.2	Prakruti assessment Proforma	137-143
	10.3	Case Record Format & Assessment Record	144
	10.4	Patient Information Sheet	145-147
	10.5	Consent Form	148
	10.6	Institutional Ethics Committee's Certificate	149
Published Articles			
	1	Comparative Study of Efficacy of Jatyadi Ghrita Pichu and Yasthimadhu Ghrita Pichu in the management of Parikartika (Fissure- in-Ano)	Published
	2	Establishment of Quality Control Parameters of Panchasakara Churna - A Classical Ayurvedic Formulation	Published
	3	Establishment of Quality Control Parameters of Madhuyashti Ghrita - A Classical Ayurvedic Formulation	Accepted

List of Tables

Table No.	Title of the table	Page No.
1.	Distribution of patients according to age	86
2.	Distribution of patients according to Gender	87
3.	Distribution of patients according to marital Status	87
4.	Distribution of patients according to Religion	88
5.	Distribution of patients according to Habitat of Patients	89
6.	Distribution of patients based on the food habits	89
7.	Distribution of cases based on the bowel habits	90
8.	Distribution of patients according to Prakruti	90
9.	Distribution of cases based on the chronicity of the disease	91
10.	Distribution of cases based on the onset of the disease	92
11.	Distribution of cases based on the severity of Pain	93
12.	Distribution of cases based on previous history of treatment	94
13.	Distribution of cases based on type of fissure	95
14.	Distribution of cases based on history of any associated diseases	95
15.	Distribution of cases based on nature of pain	96
16.	Distribution of cases based on the type of bleeding	97
17.	Distribution of cases based on Pruritis (Itching ani)	98
18.	Distribution of cases based on Position of Fissure-in-ano	99
19.	Distribution of cases based on Sphincter tone	100
20.	Distribution of cases based on tenderness	100
21.	Effect on Pain (Guda shoola) on VAS	102

List of Tables

22.	Effect on Bleeding	103
23.	Effect on Constipation	104
24.	Effect on Sphincteric spasm	104
25.	Effect on Size of Ulcer	106
26.	Effect on Healing of Ulcer	107
27.	Overall response of the therapy in respect to the Pain	108
28.	Overall response of the therapy in respect to the Bleeding	109
29.	Overall response of the therapy in respect to Sphincteric Spasm	110
30.	Overall response of the therapy in respect to Size of Ulcer	111
31.	Overall response of the therapy in respect to Healing of Ulcer	112
32.	Overall Clinical Assessment of the therapy	113

List of Graphs

Graph No.	Title of the Graph	Page No.
1.	Distribution of patients according to Age	86
2.	Distribution of Patients according to Sex	87
3.	Distribution of Patients according to Marital status	88
4.	Distribution of Patients according to Religion	88
5.	Distribution of Patients according to Habitat	89
6.	Distribution of Patients according to Food habits	90
7.	Distribution of Patients according to Prakruti	91
8.	Distribution of Patients based on the Chronicity of the disease	92
9.	Distribution of Patients based on the Onset of Fissure	93
10.	Distribution of Patients based on the Severity of Pain	93
11.	Distribution of Patients based on Previous history of treatment	94
12.	Distribution of Patients type of Fissure	95
13.	Distribution of Patients based on history of any associated diseases	96
14.	Distribution of Patients based on the Nature of pain	97
15.	Distribution of Patients based on type of bleeding	98
16.	Distribution of Patients based on Pruritis	98
17.	Distribution of Patients based on the Position (O ^o) of the fissure	99
18.	Distribution of Patients according to Sphincteric tone	100
19.	Distribution of Patients based on tenderness	101
20.	Overall response of the therapy in respect to Pain	102

List of Graphs

21.	Overall response of the therapy in respect to Bleeding	103
22.	Overall response of the therapy in respect to the Sphincteric Spasm	105
23.	Overall response of the therapy in respect to the Size of Ulcer	106
24.	Overall response of the therapy in respect to the Healing of Ulcer	107
25.	Overall Clinical Assessment of the therapy	114

List of Plates

Plate No.	Title of the Plate	Page No.
1.	Photographs of powder microscopic of Panchasakara churna	61
2.	Photographs of Microbiological limit test in Panchasakara churna	64
3.	Photographs of TLC plates of Panchasakara Churna and individual ingredients at 254 nm and 366 nm before derivatization	67
4.	Photographs of TLC plates of Madhuyashti Ghrita and Madhuyashtikalpa at 254 nm and 366 nm before derivatization	70
5.	Photographs of Microbiological limit test in Madhuyashti Ghrita	71

Symbols used in the master chart

BT	Before treatment
AT	After treatment
P	Probability
S.D	Standard deviation
S.E	Standard error
T	T test
>	More than
<	Less than
%	Percentage
0,1,2,3,	Grades of severity

Abbreviations

A.H.	Astanga Hridaya
A.S.	Asthanga Sangraha
B.A.	Bhagandara Adhikara
B.Ni.	Bhagandara Nidana
B.P	Bhava Prakasha
B.P. Ni.	Bhava Prakasha Nidana
B.R.	Bhaishajya Ratnavali
C.D.	Chakra Datta
C.S	Charaka Samhita
G.Nig.	Gada Nigraha
K.Nig.	Kayadeva Nighantu
M.Kh.	Madhyama Khanda
M.Ni.	Madhava Nidana
Ni.	Nidana Sthana
Ni.Sang	Nibandha Sangraha
Nya.Ch.	Nyaya Chandrika
Pr.Kh.	Pradama Khanda
Pr.Sh.	Pratyaksha Shareera
Ra.Nig.	Raja Nighantu
R.T.	Rasa Tarangini
R.R.S.	Rasa Ratna Samucchaya
Sa.	Shareera Sthana
Sh.S.	Sharangadhara Samhita
Sho.Nig.	Shodala Nighantu
Si.B.M.	Sidha Bhaishajya Manimala
S.K.D.	Shabdakalpadruma
Su.	Sutra Sthana
Su.S	Sushruta Samhita
Chi.	Chikitsa Sthana
Ni.	Nidana Sthana
Sh.	Shareera Sthana
Ck.	Chakrapani
Da.	Dlahana
Ha.	Harita Samhita
M.N.	Madhava Nidana
S.Su	Sushruta Sutrasthana
S.Sha	Sarangadhara Samhita
Ut.	Uttara Tantra
Y.R.	Yoga Ratnakara

Abbreviations

Abstract

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 acute fissure is a superficial splitting of the anoderm and may heal with conservative management. Once the fissure is recurrent or chronic, operation is required for a permanent cure. The chronic fissure is recognized by the presence of transverse fibres of the internal sphincter in its floor.

The incidence of anal fissures is around 1 in 350 adults and they occur equally commonly in men and women and most often occur in adults aged 15 to 40. 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 practices in young children.

Non-surgical treatments like topical nitroglycerin or calcium channel blockers or injection of botulinum toxin into the anal sphincter and Surgical treatments like Lateral sphincterotomy (LIS), Anal dilation or stretching of the anal canal (Lord's operation) are recommended for acute and chronic anal fissures however most of the therapeutic / surgical procedures are expensive and associated with more or less side effects including problems with incision site healing and incontinence to flatus and faeces.

Contrary to modern therapeutic modalities, Ayurveda offers safe, effective and cost effective therapeutic modalities in the management of Fissure-in-ano (Parikartika). 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.

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.

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.

With the aims and objectives of Evaluation of clinical efficacy of Pichu application of Jatyadi Grihta and Yasthimadhu Grihta in the management of Fissure- in-ano (Parikartika); Providing of easy, affordable, effective and accessible treatment for the disease Parikartika i.e. fissure-in-ano, the present research work has been planned out in three phases; viz. Conceptual, Analytical, Clinical study.

Before initiating the clinical trial the raw drugs used in the trial formulations were collected from local market of Bhubaneswar and Cuttack of Odisha State and were properly identified and authenticated as per the standard protocols. All the ingredients of the trial drugs were analysed and standardized as per the Quality Control Parameters set for the Ayurvedic Drugs. The trial drug – Jatyadi ghrita has already been established for its standards, the results were analysed and compared with the available standards and ensured the standards were complying with the established standards of the Jatyadi ghrita. The other trial drugs were analysed and their standards were established as there were no quality control parameters available. Thereafter the formulations were prepared as per the SOPs prescribed in API & AFI. The quality control parameters for Panchsakara 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.

Taking this view in to consideration, a clinical trial was kept on 200 patients of established cases of fissure-in-ano in two groups with 100 patients in each group with two different drug regimen viz: 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 Yasthimadhu ghrita 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. The Pichu was applied on daily basis for 21 days (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 for follow-up.

The patients were admitted for the clinical study from the Ano-Rectal Clinic of the Institute after getting due approval of the Institutional Ethical Committee of National Research Institute of Ayurvedic Drug Development, Bhubaneswar.

All the patients informed about the clinical trial and supplied a copy of Patient information sheet that was translated in to the regional language and written consent was obtained from the patients and their attendants also prior to the initiation of the study. All the standard guidelines were followed strictly which are laid down for the clinical study.

Significant clinical observations recorded in the study were as follow:

The youngest patient has been of 21 years while the eldest patient has been of 60 years. In the study it was observed that the incidence of fissure was highest (46%) in the age group of 31-40 yrs. More than the half of the patients belonged to the middle age. The current study revealed that the incidence of fissure was little higher in males (60%) compared to females (40%). Male to female ratio was 1.5:1. This data suggest that the disease is predominantly common in males. While discussing the nature of diet, it was observed in the study that a greater percentage of patients (90.5%) habituated to a non-vegetarian diet suffered from the disease compared to the patients following a vegetarian (9.5%) diet. It was observed that majority of the patients (98.5%) suffered from constipation and few of the patients (1.5%) had regular bowel habits. This results in long hours of straining and ineffective evacuation of bowels. The study revealed that maximum number (38%) of cases reported with acute type of fissures. Most of the patients reported for early intervention because of the intensity of the pain. Analysis shows that maximum number of (92.5%) patients had the hypertonic sphincter, this is because of the hypersensitivity in the ulcer area. It was observed in the study that the rate of the disease was highest in patients who are leading a sedentary life cycle. Business men and those doing office jobs need to sit constantly in the same posture over the perianal area, lack of exercise, eventually lead to constipation and culminates the causation of fissure-in-ano. The current study revealed that a large portion of the cases have a chronicity of one year, 47.5 percent of the patients of fissure in ano reported a chronicity of less than one year. Majority of the patients (62%) of fissure in ano had attended the OPD as fresh cases while 29 percent of cases had undergone medical treatment for the same purpose hence it revealed that repeated incidences even after

taking modern therapy for the fissures. Fissures were commonly found (56%) at 6 O' clock position with indurated edges. About 52 percent of fissure patients had itching ani.

The effect of both the trial formulations on both subjective and objective parameters were recorded and recorded that the effectiveness of the treatment on Pain, Bleeding, Sphincteric spasm, on Size of Ulcer and Healing of Ulcer in both the groups was statistically Highly significant with 'p' value <0.0001. As regards to the Overall Clinical Assessment of the therapy: 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.

Probable Mode of Action of local action of Pichu is based on cellular absorption of medicine, acts as snehana, lekahana 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. 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.

It is the amount of inflammation and spasm which is responsible for producing the agonizing pain in cases of fissure-in-ano. These preparations probably is able to

counteract these two factors more efficiently than the other drugs. The relief of severe pain within 24 hours is something remarkable about the drug although the ulcer takes as many as three to four weeks for complete healing.

It appears that the Panchasakara churna improve Agni, will reduce bacterial load in the stool, will check the gati of vata by virtue of anulomana effect, It reduces the purisha gadhata, Kosta shodhana will reduce congestion in haemorrhoidal vessels thus minimizing pressure on anal mucosa.

The jala used for Avagaha sweda is Luke warm. Heating the tissues increases metabolic activity, increases blood flow in turn improves the venous return and stimulates neural receptors. Heat appears to produce definite sedative effects and muscle relaxation. Because of these factors Avagaha sweda relieves Vedana and also acts as wound cleaning process.

Comparison of the effect obtained in both the groups showed the local application of Pichu of Jatyadi Ghrita provided significantly better relief in Guda Shoola, Bleeding per rectum, healing the ulcer and to increase the sphincter tone in comparison to the application of Paichu dipper in Yasthimadhu Ghrita.

On analyzing the results from the study, it can be summarized that Jatyadi Ghrita can be good for relieving cardinal symptoms, general symptoms and quick healing of ulcer in the patients of Parikartika (fissure-in-ano) and even economical also to the patients than Yasthimadhu ghrita that were applied on patients in Pichu form along with Panchasakara Chtracturna and Hot Sitz bath in both the groups.

Chapter 1 : 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. Examination of the lower half of the anal canal by separation of the buttocks to open up the peri-anal region will reveal the presence of any simple anal fissure as it is located below the dentate line and is always confined to the anoderm in the mid-posterior position (90 per cent) or the mid-anterior position (10 per cent). The anoderm is that part of the anal skin which lies between the dentate line and the anal verge and is the squamous lining of the anal canal. The acute fissure is a superficial splitting of the anoderm and may heal with conservative management. Once the fissure is recurrent or chronic, operation is required for a permanent cure. The chronic fissure is recognized by the presence of transverse fibres of the internal sphincter in its floor.

The incidence of anal fissures is around 1 in 350 adults and they occur equally commonly in men and women and most often occur in adults aged 15 to 40¹. If acute they may cause pain after defecation but with chronic fissures pain intensity is often less². 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 spasming 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)³ or Inflammatory Bowel Disease, Sexually Transmitted Infections (Syphilis, Herpes, Chlamydia and Human Papilloma Virus). Other common causes of anal fissures include: Childbirth trauma in women⁴, Crohn's disease⁴, Ulcerative colitis and Poor toileting practices in young children.

A well-developed idiopathic anal fissure rests directly over the internal sphincter and the circular fibres of this sphincter are visible on the floor of the fissure on naked eye inspection. The internal sphincter undergoes a perpetual state of spasm due to irritation and hypertrophies.

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*”

Acharaya Dalhana has described the term *Parikartika* as a condition of Guda in which there is cutting pain and tearing pain. 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*. Acharaya Sushrutha 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. Whereas Acharaya Charaka has described the features like: pricking pain in groins and sacral area, scanty constipated stools and frothy bleeding per rectum.

The references for *Parikartika* are found in the following Samhitas:

- 1) Siddhi Sthana of the Charaka Samhita and Bhela Samhita.
- 2) Chikitsa Sthana and Uttara Tantra of the Sushrutha Samhita.
- 3) Nidana Sthana of the Sushrutha Samhita and Astanga Sangraha
- 4) Sootra Sthana of the Astanga Sangraha.

According to the Sushrutha Samhita, in a debilitated person or in a subject of mridu kosta or mandagni, the ingestion of ati-rooksha / ati-teekshna / atyushna / atilavana or ati-rooksha ahara or the ingestion of virechana-oushada causes the dooshana of Pitta and Anila and causes *Parikartika*. At the end of the same chapter, the Acharya states that *Parikartika* is a vyapath of virechana karma, whereas kanta-kshanana is a vyapath of vama karma. Further ahead in the Chikitsa Sthana, when explaining the Basti-karma and its vyapath, *Parikartika* has been listed.

According to Charaka, if a strong Virechana oushadha is given in a snigdha-kaya, guru-kosta, in saamavastha, in a debilitated person or in mridu-kosta, in an exhausted or weak individual, it can cause a highly painful condition called *Parikartika*.

In Astanga Sangraha *Parikartika* has been mentioned either as vyapath of Virechana or Basti karmas or as poorva roopa of Arshoroga. In addition, Parikarta has also been considered a lakshana of Kaphaja arshas.

Apart from the Brihathrayees, the only other book to mention *Parikartika* is the Bhela Samhita. In the Siddhi Sthana of the Bhela Samhita, *Parikartika* has been mentioned as a vyapath of both Virechana and Basti karmas.

1.1. Present Modalities of treatment - Problems and challenges:

1.1.1 Non-surgical treatments are recommended initially for acute and chronic anal fissures. These include topical nitroglycerin^{6,7,8} or calcium channel blockers^{9,10} or injection of botulinum toxin into the anal sphincter. Other measures include warm sitz baths, topical anesthetics, high-fiber diet and stool softeners.

1.1.2 Surgical treatments:

Lateral sphincterotomy (LIS) is the Gold Standard for curing this affliction. Combination of medical therapies may offer up to 98% cure rates^{11,12}. LIS does, however, have a number of potential side effects including problems with incision site healing and incontinence to flatus and faeces.

Anal dilation or stretching of the anal canal (Lord's operation) has high incidence of fecal¹³ incontinence and flatus incontinence.¹⁴ Most of the therapeutic / surgical procedures are expensive and associated with more or less side effects. Contrary to modern therapeutic modalities, Ayurveda offers safe, effective and cost effective therapeutic modalities in the management of Fissure-in-ano (*Parikartika*).

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.

1.2. 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 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.

1.3. 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.

1.4. *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” (su.ut)

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.

1.5. Mode of Action of *Pichu*:

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.

1.6. Aim

Evaluation of clinical efficacy of *Pichu* application of *Jatyadi Grihta* and *Yasthimadhu Grihta* in the management of Fissure- in-ano (*Parikartika*)

1.7. Objectives:

Providing of easy, affordable, effective and accessible treatment for the disease Parikartika i.e. fissure-in-ano.

1.8. Plan of study:

The present research work has been planned out in three phases; viz. Conceptual, Analytical, Clinical study.

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Chapter 2 : Review of Ayurvedic Literature

2.1 Anatomical Aspects of Guda

It is clear from previous description that the *Parikartika* is the disease of anal region. It is, therefore, necessary to have a sound knowledge about this part both in anatomical and physiological aspects. For proper understanding of the disease as a whole, it is essential to have a clear knowledge of its site of manifestation and its relationship with surrounding structures, physiological aspects beforehand. Thus understanding the anatomical structure and physiology of guda assumes prime importance. Different authors have given different descriptions regarding the anatomy of the guda as detailed description regarding guda is not available at one place. *Guda* has been referred at several places in connection with organs and other topics. Most of the authors have mentioned guda as one of the three parts of the Bhaga.

According to Vijaya-Rakshita and Shrikantha Dutta, Bhaga is the collection of three structures namely, Bhaga (vagina), Basti (Urinary bladder), and Guda (Ano-rectal canal). The actual meaning which is important in view of disease is described in Sushrut Samhita :

ते तु भगगुदबस्ति प्रदेशदारणाच्च भगन्दरा इत्युच्यते । (सु०नि० 4/3)

Bhaga is a word which means all the structures around the guda including Yoni and Basti.

2.1.1 Nirukti (Definition): “*Guda Kridayam tag u malotsarge*”

The word *Guda* derived from root “*Gu*” which means the organ of pleasure and organ of excretion of *pureesha mala*.¹

Guda also means: Anus.²

2.1.2 Embryological Aspects of Guda

The source of formation of foetal organs according to Ayurveda is mainly from Matruja, Pitruja, Rasaja, Atmaja and Satvaja bhavas.

मृद्वत्र मातृजं रक्तमांसमज्जगुदादिकम् । (अ०ह०शा० 3/4)
मांसशोणितमेदोमज्जहृन्नाभियकृत्प्लीहान्त्रगुदप्रभृतीनि मृदुनि मातृजानि ॥ (सु.शा.3/33)

Embryologically, Guda is supposed to be originated from Matrija Bhavas of Garbha due to its soft and smooth consistency.

असृजः श्लेष्मणश्चापि यः प्रसादः परो मतः।

तं पच्यमानं पित्तेन वायुश्चापि अनुधावति॥२६॥

ततोअस्यान्त्राणि जायन्ते गुदं बस्तिश्च देहिनः॥ (सु०शा० ४/२७)

Antra (intestines), Basti (bladder) and Guda (anal canal) of the fetus are formed out of the essence of Rakta and Kapha. Pitta and Vayu are helping this entire process³. It takes its origin from Matruja bhava.

2.1.3 Synonyms :

Apana, Guda, Payu, Bughna, Braghna

अपानयति मलादिनिःसारणेन जीवयति इति अपानम्॥ (प्र०शा०)

The structure that collects and expels the waste products (faeces) and thus helps in the maintenance of life is Apana.

गूयतेअनेनेति गुदं तु पुरीषोत्सर्गे। (प्र०शा०)

गुदं क्रीडायाम्॥ (प्र०शा०)

That structure which is filled with dirt / excreta and helps in its removal is guda. It also acts as an organ of sexual pleasure.

पातिमलनिःसारणेन, पिबति बस्त्यैषधं पायतिशोषयति तैलं इति वा पायुः॥ (प्र०शा०)

The structure which causes the expulsion of faeces, drinks (or receives) the medicaments (and helps in its absorption) is termed payu.

ब्रध्नो गुदः॥ (प्र०शा०)

Braghna is also denoting guda.

2.1.4 Length of Guda :

अर्धपञ्चाङ्गुल गुदमाहुः॥

(सु.नि.2/5)

The length of guda is 4 ½ angula.

2.1.5 Location of Guda

तत्र स्थूलान्त्र प्रतिबद्धमर्द्धपञ्चाङ्गुलं गुदमाहुः॥

(S.S.Ni.2/5)

It is a structure, which is related to the *sthula antra* (large intestine)

नाभिपृष्ठकटीमुष्कगुदवंक्षक्षणशेफसाम् ।

एकद्वारस्तनुत्वक्को मध्ये बस्तिरधोमुखः ॥

वस्तिर्बस्तिशिरश्चैव पौरुषौ वृषणौ गुदः ।

एकसंबन्धिनो ह्येते गुदस्थि विवराश्रिताः ॥

(सु.नि.3/18-19)

In the context of anatomy of Vasti, Sushruta has mentioned that the Vasti is having close relation with Guda and both are situated in ‘Gudasthi-vivara’ (pelvic cavity).

2.1.6 Relations

ततः स्नेहाभक्ते क्लृप्तनखे वामहस्तप्रदेशिनीमध्यमे अंगुल्यौ

पायौ प्रणीधानानुसेवनीमासाद्य प्रयत्नबलाभ्यां पायुमेद्वान्तरमानीय (सु0चि0 7/3)

.... स्त्रीणां तु बस्ति पार्श्वगतो गर्भाशयः सन्निकृष्ट

(सु0चि0 7/33)

In the context of operation of the Ashmari (vesical calculus), Sushruta has instructed that surgeon should introduce his finger into the Guda and fix the Ashmari to make a prominence in perianal region⁴. It suggests that Guda has very close relation with Vasti.

पंचदशकोष्ठांगानि तद्यथा- नाभिश्च, हृदयं च क्लोम च

यकृत च प्लीहा च वृक्कौ च बस्तिश्च पुरीषाधारश्च, आमाशयश्च, पक्वाशयश्च,

उत्तरगुदं च, अधरगुदं च, क्षुद्रान्त्रं च स्थूलान्त्रं च वपावहन चेति । (च0शा0 7/10)

उत्तरगुदो यत्त पुरीषामवतिष्ठते, येन तु पुरीषा
निष्क्रमयति तदधर-गुदम् । (च०शा० 7/12)

Charaka regarded that the Guda is one of the fifteen Kostangas. And he divided Guda into two parts ^{5, 6} Uttara guda - the part in which pureesha is collected and Adhara guda – through which pureesha is excreted out, for proximal and distal parts of guda, respectively.

2.1.7 Extent of Guda

अर्धपंचांगुलमिति अर्धपंचमंगुलं यस्मिन् तत्तथा एतेन
सार्थं चतुरंगुलप्रमाणं गुदमित्यर्थः । (डल्हण, सु०नि० 2/5)

Regarding the extent of Guda, Sushruta and Vagbhata ^{7, 8} clarified that the total length of Guda is 4 ½ Angulas (fingers). Dalhana on commentating the length of the finger, advised to consider the maximum width of thumb for an Angula. One Angula has the breadth of about 1.5-2 cm and length 6-9 cm. It is well known that maximum length of anal canal is 3 cms. Thus the extent of Guda consist the length of anal canal plus lower 3-6 cms of rectum which gives roughly the inferior Houston Valve. Whatever be the measurement of a finger, Guda i.e. 4 ½ fingers, will always all short of the recto-sigmoid junction. So, it can be inferred that the Guda described by Sushruta and Vagbhata⁸ includes the anal canal and lower part of the rectum.

2.1.8 Importance:

तत्र तलहृदयेन्द्रबस्तिगुद स्तनरोहितानि मासं मर्माणि॥
दश प्राणायतनानि मूर्धाजिह्वाबन्धन कण्ठोहृदयं नाभिर्बस्तिर्गुदः शुक्रमोजो रक्तं च॥
(सु०शा० 6/7)

Guda is one of the mamsa marma, injury to which causes immediate death. As prana resides in such vital sites, guda has been included under one of the “Pranayatana”.

2.1.9 Muscles of Guda:

Acharya Sushruta has mentioned the presence of three muscles in the guda region⁹.

2.1.10 Guda as a Marma:

According to Sushruta, Guda is one among the Sadyapranahara marma which is situated in the terminal part of Sthulantra and categorized under Mamsa marma¹⁰. Vagbhata has mentioned guda as Dhamani marma¹¹ and mentioned that it is attached to Sthulantra and functions as evacuator of faeces and flatus and injury to this would lead to immediate death¹².

2.1.11 Parts of guda:

1. Uttara guda
2. Adhara guda
3. Gudoshta

उत्तरगुदः यत्र पुरीषमवतिष्ठते॥

येन तु पुरीषं निष्क्रामति तदधरगुदम्॥

रोमान्तेभ्यो यवाध्यकर्धो गुदौष्ठः परिकीर्तितः॥ {{(Chakrapani) च०शा० 7/10}}

Uttara guda is that part which faeces is stored or collected. Adhara guda is that part which helps in expulsion of the faeces. Gudoshta is the terminal portion of guda, 1 angula inside the hairy region in buttock.

From this we can infer that -

Sthula guda	Uttara guda	Upper portion of rectum and sigmoid colon
	Adhara guda	Lower portion of rectum and anal canal
	Gudoshta	Anal orifice

2.1.12 Description of Vali ¹³

तस्मिन् वलयस्तिस्रोअध्यर्धागुलान्तरसम्भूताः प्रवाहणी विसर्जनी संवरणी चेति॥

सर्वास्तिर्यगेकाङ्गुलोच्छ्रिताः॥

शङ्खावर्तनिभश्चापि उपर्युपरि सस्थिताः।

गजतालुनिभाश्चापि वर्णतः सम्प्रकीर्तिताः॥

प्रथमा तु गुदौष्ठादङ्गुलमात्रे॥ (सु.नि.2/5)

वल्यः प्रवाहिणी तासामन्तर्मध्ये विसर्जनि।

बाह्व संवरणी तस्या गुदौष्ठो बहिरङ्गुलो॥ (अ०ह नि० 7/4-5)

प्रवाहयतीति प्रवाहणी विसृजतीति विसर्जनी, संवृणोति इति संवरणी॥

(सु०नि०.2/6 Ni. Sang Teeka)

While describing the interior aspect of guda, Sushruta mentioned that there are three valis¹⁴ in the wall arranged one upon the other in a spiral way resembling the palate of an elephant. Each vali is situated at a distance of one and half finger from each other. Gudaustha (anal orifice) is situated at a distance of 1 ½ Yava (half finger) in length from hair margin, and the first vali is at a distance of one finger from anal orifice. The above three Valis are called Pravahini Visarjini and Samvarani.

Vagbhata accompanied Sushruta in the above description, further specified that the proximal Vali is Pravahini (1 1/2 angula in length) , and the distal most vali is Samvarani (1 angula); and Vararjini Vali lies in between to them (1 ½ angula).

Most of the Ayurvedic Scholars consider that the above three Valis are nothing but the valves of Houston, which lie in the rectum. But if we try to understand the description of Sushruta deeply, the above concept slips from the logic.

Sushruta's description in this regard is not merely structural but is also functional. The valves of Houston situated at a high level and they never fit for the

above concept. While describing the Piles, Sushruta regarded these valves are seat for piles. But the Houston's valves are nowhere concerned with piles.

According to Sushruta, the distal most vali Samvarani lies 3 cm from anal margin i.e. near the Dentate line which can be felt on digital examination as an ano-rectal junction a constricting action. Therefore, this can be taken as Samvarani Vali. Similarly, at a distance of 9 cm from anal margin, there lies the middle Houston Valve, which is prominent and constantly seen through Arshoyantra. This is the most suitable for the proximal vali Pravahini. Halfway inbetween to these Valis, where columns of Morgagni extends from the lower margin and end about the halfway appearing like a line, this will fulfil for the middle Vali, Visarjini.

2.1.13 Terminologies related to guda:

- Guda mukha = Gudoshta = Anal orifice
- Guda marga = Anal canal
- Guda mandala = Area around guda (Ischio-rectal fossa)
- Guda parshva kshetra = Ischio-rectal area
- Gudaposhta desha = Area between anus and genitalia (Perinium)
- Paymedhrantara = Perinium
- Payu randhra = Anal orifice

2.2 Physiological Concept of Guda

हस्तौ पादौ गुदोपस्थं वाग्निन्द्रियमथापि च ।

कर्मान्द्रियाणि पंचैव पादौ गमनकर्मणि ॥

(चि० शा०

1/25)

Guda or Payu is described as one of the Pancha Karmendriyas, and its function is to excrete the mala from the body.

श्रवणनयनवदनघ्राणगुदमेद्राणि नव स्रोतांसि नराणां बहिर्मुखानि (सु०शा० 5/10)

शृंगाटकान्यधिपतिः शंखौ कण्ठसिरा गुदम् ।

हृदयं वस्तिनाभ्यौ च घ्नन्ति सद्योहतानि तु ॥

(सु०शा० 6/9)

Guda has also been considered as Bahya Srotas and Sadyopranahara marma. He also regards the Guda and Pakwasaya are the seats of Apana-Vayu. The Apana-Vayu helps in expulsion of Vata, Mutra, Pureesha, Shukra and Garbha.

पक्वाधानालयोऽपानः अपानः काले कर्षति चाप्यधः ।
समीरणः शकृन्मूत्रं शुक्रगर्भातवानि च ॥
कृद्धश्च्य कुरुते रोगान् घोरान् वस्तिगुदाश्रयान् । (सु०नि० 1/19-20)

In case this Vayu is vitiated the diseases of Basti and Guda said to occur.

In Ayurveda, the excretory mechanism is described in lucid manner. According to an eminent scholar Mahopadhyaya Gananathsen, the proximal vali, Prarvahini helps in compression and pushing the stool downwards, Visarjini, the second Vali relaxes during this process and allows stool to pass further down.

अथ तासां – तिसृणां, अर्थानुगतानि नामान्याह – तत्र
मलप्रवाहणादन्तः – अन्तरेस्थितावली, प्रवाहिणीति कथ्यते ।
मध्ये – मध्यस्थितावली, मलस्य प्रवहतो बहिर्विसर्जनात्
विसर्जनीति भण्यते । गुदस्य बाहये स्थिता मलस्य
संवरणात् संवरणीत्युच्यते । (अरुणदत्त अ०ह नि० 7/4-5)

The distal most Vali, Samvarani which expels the stool out and constricts immediately, so that the continuity of the stool will cut out and falls down. This description is most suitable for the concept of ancient Ayurvedic scholars who laid them and indicated briefly by the terminology of valis. Simultaneously, this concept is very much similar to the modern physiological concept of defaecation what we know today.

2.3 Vascular supply to Guda:

विशेषतस्तु कोष्ठे चतुस्त्रिंशत् तासां गुदमेद्राश्रिताः श्रोण्यकमष्टौ। (च०शा० 7/7)
अधोगमास्तु वातमूत्रपुरीषशुक्रार्तवादीन्यधो वहन्ति। (च०शा० 7/7)

Sira carry rakta pitta, kapha etc. There are 34 sira in the region of koshta of which 8 sira are responsible for carrying vata and maintenance of its normal functions. These are situated in guda, medhra and shroni.

Dhamani which move downwards carry apana vata, mutra, purisha, shukra and artava to their respective seats or organs like pakvasaya, kati, guda, basti and medhra. They also control defaecation process.

2.4 Gudosta Snayus in relation to Guda¹⁵:

There are 10 Snayus in Vamkshana (groin) and 60 in Kati

Peshi of Guda¹⁶: There are three Peshi in the Guda bhaga (anal region).

Sira¹⁷: Eight Siras are present in the vankshana pradesha, which carries Vata, Pitta and Rakta.

Dhamani¹⁸: Two adhogami dhamanis named as Purishavahi dhamani are connected with guda.

Asthi¹⁹: The bones, which form Shroni, are Guda Asthi, Bhaga Asthi, and Nitamba Asthi and Trika Asthi.

Sandhi²⁰: There are three Sandhi. The Guda, bhaga, nitamba are connected to each other by samudga sandhi.

Seevani²¹: One Seevani is present in relation to Guda. Sushruta has considered guda as a moola of pureesha vaha srotas and bahya srotas means having opening to the exterior. According to Charak Vagbhata it is amongst 'Dashapranayatana'²² and Vagbhata considered it also as 'Jeevitadhama'²³.

2.5 Description of Parikartika

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.

2.5.1 Definition:

The term Parikartika is derived from Sanskrit word 'Parikr, which denotes 'all around'' 'all over' or 'whole' or 'every entity' or 'every aspect' and 'Kartanam' or

Kartika is derived from “Krita” verb, which means to cut. It means that excessive cutting pain in and around the anus is seen in Parikartika.

2.5.2 Synonyms:

Following are the terms used in different context, which denotes similar condition.

- Parkartika
- Guda vidara
- Guda Kshata
- Kasta Guda
- Kasta payu
- Vyakta Mala

Pain is the most important clinical symptoms in this disease.

2.5.3 Nirukti:

It refers to a condition in which patient experiences a sensation of pain as if the Guda is being cut around with scissor. The disease is characterized by excessive cutting pain around the anus.

Kashyapa says that Parikartika is the one having cutting and tearing pain in guda pradesha²⁴. Jejjata has anticipated this condition and explained pin pointedly. According to him in Parikartika a specific pain i.e. a cutting and tearing pain around the anal region²⁵. Dalhana also gives the similar opinion.

2.6 Nidana:

Proper descriptions about Nidana, Smaprapti and Rupa etc. are not available in any of the classical literatures at place under the heading Parikartika as the Acharyas have not given much emphasis to the condition as a separate disease condition. That might be the reason we don't find any direct references / descriptions about the aetiopathogenesis of the Pariakrtika. However one can find the nidana that produce condition Parikartika in scattered manner. As described in the Sarvaroga Nidana Adhyaya²⁶, those doshas that are in the Sanchaya avastha get to Prakopa avastha in presence of aetiological factors and produce the disease.

In Parikartika, Vata is the primary Dosha, as the Guda is the seat of Vata especially Apana Vayu. The vitiating factors Vata are Tikta, Ushna, Kashaya, Alpa Bhojana, Vegadharana, Udirana, excessive Shodhana therapy; diurnal and seasonal variations²⁷. The second predominant Dosha is Pitta and the factors vitiating²⁸ it are Katu, Amla, Lavana, Ahara, Krodha; diurnal and seasonal variations. Kapha Dosha, thought not predominantly present for triggering the condition, but still it plays a role many ways and its vitiating factors are Swadu, Amla, Lavana, Adhyasana, Sita, Guru Bhojana, Divaswapna and diurnal and seasonal variations.²⁹ Besides these three Doshas, Acharya Sushruta has mentioned the Rakta is the 4th Dosha. He also says that as Vayu unites with blood Vrana is formed. In Parikartika, Vrana produced is mostly Nija in origin and Acharya Charaka in Chikitasasthana Dwivraneeya Adhyaya³⁰ has explained that when Doshas take site in Bahya Roga Marga, they produce Vrana likewise prakuptita Vata and Pitta especially are the causes of Parikartika. According to Acharya Sushruta, the Nidana of Parikartika can be divided into three types.

1. Nija Nidana (Endogenous).
2. Nidanarthakari Roga (Complications)
3. Agantuja Nidana (Exogenous).

2.6.1 Nija Nidana:

The causative factors (Nidana) that vitiate Apana Vayu, Rakta are the Nija Nidana.^{31,32} Adoption and excessive use of the causative factors for Apana Vikriti are Rukshaanna and Guru Anna, withholding the natural urges of maturation and defecation, too much of traveling by vehicles, traveling repeatedly at various places by walking are the nija nidanas. Sushruta has further explained few more reasons for Parikartika like - excessive accumulation of Mala in Pakvashaya, which obstructs the normal passage of Vayu and produces Vibandha with cutting like pain. Due to this the Snehamsha (unctuous portion) gets absorbed rapidly and eliminates dry faeces with pain.³³ By excessive intake of astringent, bitter, pungent and dry articles of diet, by the suppression of natural urge of Mala Pravrutti, by excessive indulgence in eating and sex, the Apana Vata is provoked in the colon; growing stronger it causes obstruction in the lower part of the alimentary tract and produces retention of faeces, flatus and urine and thus

produces very serious disorders of misperistalsis.³⁴ Acharya Sushruta has said that due to consumption of Kashaya, Tikata and Ushana and Ruksha substance Vayu enters into Koshta of a person and along with abstained urges of defecation, produces Atopa, Shula and Parikartika as sequel to Vitasanga.^{35,36}

2.6.2 Nidanarthkari Roga Nimittaja:

Nidanarthkari Roga Nimittaja are such disorders that are produced due to any pre-existing diseases.³⁷ The chief Roga is Udavarta that produces Parikartika.^{38,39,40} Acharya Charaka has described this condition as a lakshana of Atisara.^{41,42} According to Charaka and Vagbhata, Parikartika is a symptom in Vataja Atisara who has complaints of scanty, watery or hard rounded motions, soon develops Parikartika^{43,44}

Sushruta while explaining the prodromal features of Arsha, has mentioned about a very similar symptom,⁴⁵ i.e Guda 'Parikartanam' which means there is cut in the anus and cutting pain. The shape of the Vatika Arsha is like 'arrow' and is pointed which is similar to sentinel tag. Acharya Charaka has said that in Sahaja Arsha⁴⁶ there is severe pain in Gudavallaya. In vatika Arsha, the symptoms that he has described⁴⁷ very much similar to those found in Parikartika viz. pain in anus, penis, abdomen, umbilical region etc. and in Kaphaja Arsha he has said that there is Parikartika, nausea etc.^{48,49}

2.6.3 Vaidya Nimittaja:

Parikartika mentioned as a complication of Pancakarma procedures like Virechana, Basti and Vamana,⁵⁰

- **Virechana Vyapad:** According to Sushruta if patient ingests Tikshna, Ushna and Ruksha drugs for Virechana^{51,52} Parikartika will develop as a complication.
- **Basti Vyapada:** If Ruksha Basti containing Tikshna and Lavana drugs is administered in heavy dose; it may produce Parikartika.^{53,54}
- **Basti Netra Vyapada:** Due to inappropriate administration of Basti Netra and defect in Basti Netra it may cause this disease.⁵⁵
- **Excessive use of Yavana Basti:** It may lead to Parikartika along with other diseases⁵⁶

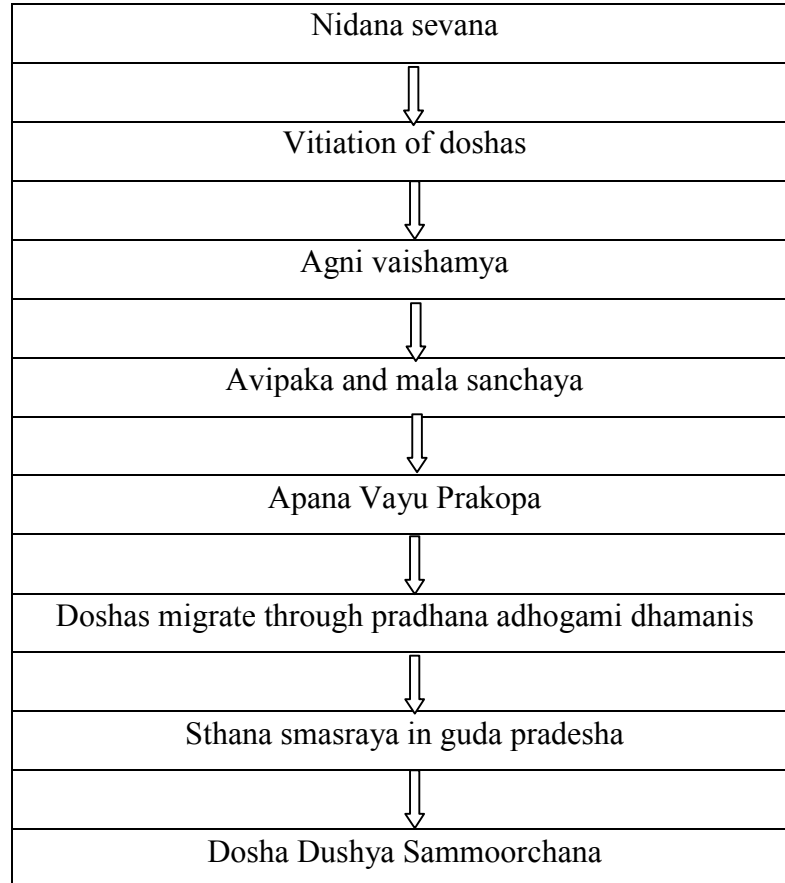
2.7 Rupa

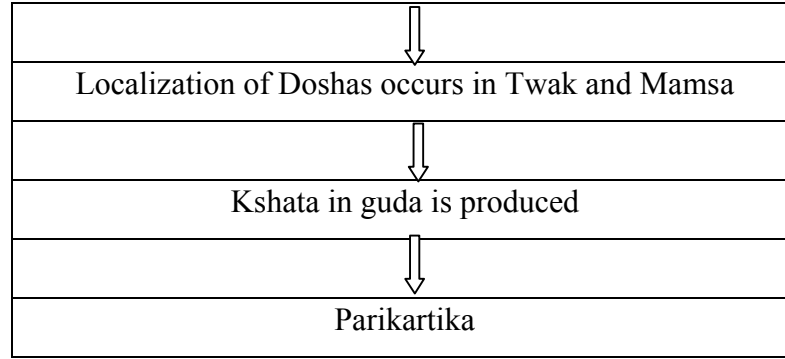
When Vikrita Vata gets localized in Guda⁵⁷ it produces retention of faeces, urine and flatus, colic pain and flatulence and Sarkara (fecolith)⁵⁸ and according to Sushruta there is a pain of sharp cutting nature in Guda⁵⁹ and due to this constipation develops.^{60,61} Acharya Vagbhatta has also described same signs and symptom as described by Acharya Charaka and Sushruta.⁶² Vrana is an essential symptom of Parikartika which is having Deeraghakruti shape or Triputakakruti⁶³ and there may be discharge⁶⁴ along with other features of Dusta Vrana.⁶⁵

2.8 Samprapti:

The causative factors of specified doshas will lead to vitiation of Vata and Pitta and they travel downwards to guda. These doshas will increase pressure in guda pradesha and produces Vikruti to Rakta and Mamsa which leads to kshata and thus produces kartanavat vedana in guda pradesha. This condition is called as Parikartika.^{66,67,68}

Flow Chart Describing Samprapti





2.9 Bheda

Acharya Charaka and Sushruta both have described two types of Doshas in Parikartika viz. Vata and Pitta. In almost all Ayurvedic texts, no detailed descriptions about classification of disease, its Samprapti and Symptomatology have been specified, but Acharya Kashyapa has described the involvement of all the three Doshas e.g. Vata, Pitta and Kapha in the Adhyaaya of Garbhini Chikitsa while giving the detailed Chikitsa of the disease Parikartika.⁶⁹

This classification is chiefly emphasized on the character of pain, shooting, cutting or pricking pain in Vata predominance, burning pain in pitta and dull ache type in kapha predominance. Since it is a known fact that Kashyapa Samhita is incomplete work and it might be possible that he might have considered the Nidana Panchaka of Parikartika in detail in some of lost portion over a period, but later on given a brief description of it in relation to a Gravid woman.

2.10 Sadhya Asadhyata

Sadhyasadhyata of a disease is decided by considering all the factors which are likely to influence the curability and incurability of a disease. It is essential to consider the Sadhyasadhyata before administering any forms of Chikitsa (treatment)⁷⁰ any type of Vrana can be cured easily, provided the patient is with good Satva, Mamsa Dhatu, and Agni and if he is in his younger age. Also⁷¹ Vrana occurs in Guda can be cured easily⁷² if a Vrana is left untreated, the Sadhyatva, as a consequence may lead to Yapyatva stage and finally leading to Asadhyatva stage.⁷³

Parikartika which affects the superficial layer of the Twak (Anal skin) is easily curable. Therefore it can be included in the Sadhyata group. If it affects the deeper

layers, it shows reluctance to heal. Therefore it can be included in Kricchrasadhya group. If it is associated with Kushta, Vishadushti and Srotasa, the healing of Vrana will be delayed. If parikartika is associated with Sanniruddha guda, it is considered as Yapya.

2.11 Chikitsa of Parikartika

Parikartika as a disease has been considered very briefly by Sushruta and other successive authors. They have described the treatment of Parikartika in most brief manner. Kashyapa has mentioned its management according to Doshika predominance, others have not considered as Doshika type classification, but it is a fact that none of them has described surgical management, thereby showing that there was no need of surgery as the disease was completely cured by the use of medicinal preparations only, and they were satisfied with management. According to route of administration the medicines are divided into two categories viz. 1) Local and 2) General.

2.11.1 Local Treatment:

This local treatment is nothing but only Basti Karma. Basti is prepared in Ghrita, Taila and milk with the help of other different drugs. Most of the drugs, which are used in Basti Karma, are VataShamaka, Varna Shodhan – Ropaka and Pittashamaka. There are three types of Bastis described by Sushruta and other Ayurvedic authors viz. Anuvasana Basti ii) Piccha Basti and iii) Sital Basti. Remedy consists in employing a piccha Basti with Yashtimadhu and Sesamum pasted together and dissolved in clarified butter and honey. And patient should be kept on Anuvasana Basti, (in cases of Pitta predominance) Basti should be employed with the cream of clarified butter and in case of Vata predominance with Taila cooked with Yashtimadhu⁷⁴ Charaka has also advocated both of medicines which have been advocated by the Sushruta. He says Sheeta Basti consisting of drugs having Madhura and Kashaya properties (Piccha and Anuvasana Basti) prepared by Madhuyasti powder and Kwatha should be used.⁷⁵ Kashyapa has also advised for the Anuvasana Basti. In this type of Basti the⁷⁶ base is milk, oil or Ghrita these are either VataShamaka or Pitta shamaka. In many compositions so many drugs have been used they have Vata and Pitta shamaka properties and Madhuyasti is many times used. Because it has

property of cooling, Vata- pitta-Rakta shamaka and widely it has been advocated by Sushruta for treatment of traumatic wounds, Pittaja Vrana, Fractures, Bhagandara, Upadansa and ulcer etc. Both the Acharya Charaka and Sushruta have advocated piccha Basti with Madhuyasti, Madhu and Taila for treatment of Parikartika.

2.11.2 General Treatment:

The oral preparation have many- fold objective some are used to correct the anorectal disorders other are used as laxative and few more as to correct the Agnidugti. They have advised drugs as the Tridosha shamaka. Sushruta has advised for cold water bath and milk for oral administration.⁷⁷

In this disease the main problem is that of constipation and pain only. If one corrects the constipation part of disease and alleviates the pain the disease may disappear to a great extent within few days. Pain due to Vata and Pitta vitiation and constipation due to two reasons 1) Habitual constipation and 2) Due to fear of pain patient does not go for the defaecation. Acharya Charaka has also written about the oral treatment in Parikartika and advised for only milk drinking.⁷⁸

Acharya Charaka has also advised to take Amla Dravya because it has the property of Vatashamaka and increases the digestive fire. According to Charaka, if there is Parikartika present with fever, patient should drink the gruel prepared with the heart shaped leaves of seed, fruits of Kokam, butter tree, sour jujube, then painted leaved ueria and yellow barred night shade mixed with Beal.⁷⁹ In Kashyapa Samhita the treatment has been given according to predominance of Dosha.

1. Vatika Parikartika:

Brihati, Beal and Ananta are used which all have the vatashamaka⁸⁰ property

2. Pattika Parikartika:

Such drugs like Madhuyasti, Hanaspatti, Madhu etc. are useful for Pittashamana and have also property to correct abdominal with its laxative effect⁸¹

3. Kaphaja Parikartika:

In this he has used the drugs which have the property of Kaphashamaka and Vatashamaka also as Kantakari, pippal, Gokshura and Salt.⁸² Further he has

given the treatment for Gravid stri who is suffering from Parikartika is milk prepared with drugs which have Madhura Rasa and mixed with Madhu, Sharkara, Taila and madhuyasti in this way, all the treatment is based on following factors.

1. To alleviate the Vata and Pitta.
2. To correct the abdominal trouble.

Most of the patients come with burning type of pain. So keeping these points in the mind all Ayurvedic authors have described only Vata and Pittashmaka management.⁸³

2.11.3 Details of different Chikitsa Yogas described in various classics of Ayurveda:

(a) Pichha basti :

i. Sushruta :

- The paste of Yasimadhu, Krishna Tila along with Madhu and Ghrita⁸⁴.
- Badara, Nagbala, Slesmataka, Salmali, Dhanvana, boiled in Dugdha and later added with Madhu and Rakta.⁸⁵

ii. Charaka : Salmali, Kusha, Bahupada, Kutaja, Utpala, Chandana mixed with Madhu Ghrita⁸⁶.

(b) Anuvasana basti:

i. Sushruta :

- Madhuyashti, Usira, Gambhari, Kutaki, Utpala, Chandan, Shyama, Padmaka, Jeemoota, Indrayava, Ativisha, Tail, Ghrata along with mild and decoction of Nyogradhadgana⁸⁷.

ii. Kashyapa:

- LaghuPanchamoola, Madanphala, Triphala, Bala, Rasna, Punarnava, Guduchi, Aragvadha, Daru, Palasa, Madhuka, Musta, Priyangu, Hapusa, Rasa gana, Pippali and Kutaja along with Madhu, Taila, Lavana, Gomootra, Mamsa rasa⁸⁸.

(c) Basti: Charak : Madhuyashti, Tila-Kalka along with Milk⁸⁹.

- (d) Peya: Charak : The Peya of raktasali made from decoction of Vrakshamala, Badara and Kantakari with powder of unripened fruit of Bilva⁹⁰.
- (e) Leha Yoga: Kashyapa: Madhura Dravyas along with Milk, Sugar, Madhu, Tila tail⁹¹.
- (f) Yusha (Vatika):
- Kashyapa: Bhrati, Bilva, Ananta moola⁹¹.
 - Khila Sthana: Madhuyasthi, Hanspadi, Dhanayaka, Madhu and Tandulodaka⁹¹.

Chapter 3 : Review of Modern Literature

3.1 Anatomy of Ano-Rectal Region

It is obvious that the sound knowledge in anatomical and physiological aspects of ano-rectal region not only helps in understanding the pathological aspect and diagnosis purposes, but also assists in the operative techniques ano-rectal diseases and fissure-in-ani in particular.

3.2 The Rectum

The rectal wall consists of mucosa, submucosa and two complete muscular layers, inner circular and outer longitudinal.

Extent: The rectum extends from the sigmoid colon to the anal canal following the curve of sacrum. It thus passes downwards and backwards and then downwards and finally downwards and forwards to become continuous with the anal canal by passing through the pelvic diaphragm. The ano-rectal junction is situated 2-3 cm in front of and slightly below the tip of the coccyx, from this level, which in the male the apex of the prostate starts.

The rectum is approximately 12 to 15 cm in length and in the upper part it has the same diameter (4 cm) as that of the sigmoid colon, but in the lower part it forms the widest part of the large gut called the Ampulla of the Rectum.

The Rectum contains three distinct curves, the proximal and distal curves are convex to right, whereas the middle is convex to the left.

3.2.1 Peritoneal Relations:

The anterior peritoneal reflexion is about 6-8 cm above the anus. The posterior peritoneal reflexion is usually 12 – 15 cm above the Anus. The upper third of the Rectum is covered by peritoneum on its anterior and lateral surfaces. The middle third of the Rectum is covered by peritoneum only on its anterior surface, and the lower third of the Rectum is below the peritoneal reflexion.

The proximal rectum is identified as the level at which the Taeniae coli of the colon coalesce to form a complete layer of longitudinal muscle at approximately the level of the sacral promontory.

3.2.2 Visceral Relations:

(a) **Anteriorly in males:** Upper 2/3 of the rectum is related to upper part of the base of the bladder, seminal Vesicals and rectovesical pouch with terminal coils of the ileum and lower 1/3 of the rectum is the lower part of the base of the bladder, seminal vesicles, vas deferens terminal parts of the ureters and the prostate.

In females, upper 2/3 of the rectum is related to the upper part of the vagina, the uterus, the recto-uterine pouch with terminal coils of the ileum and the sigmoid colon and lower 1/3 of rectum is related to the lower part of the vagina.

(b) **Posteriorly:** Posteriorly the rectum is related to sacrum, coccyx ano-coccygeal ligament ; pyriformis , coccygeus , levator ani, the Sacral plexus and the Sympathetic trunks.

3.2.3 Mucosal Folds : The mucous membrane of an empty rectum projects into the lumen as folds , which are of two types.

1. Longitudinal folds
2. Transverse or Horizontal folds

- 1. Longitudinal folds :** These are transitory and are present in the lower part of an empty and obliterated by distension.
- 2. Transverse or Horizontal folds (Valves of Houston (or) plicae transversatis)¹:** These mucosal infoldings present some difficulty for proctoscopic examination, but they are excellent targets for mucosal biopsy, since they do not contain all layers of the muscular rectal wall and the risk of perforation is therefore diminished. These are permanent and most marked when rectum is distended. These are three to four in number.

- i. The **upper fold** lies near the upper end of the rectum, projects from the right or the left wall. Sometimes it may encircle and partially constrict the lumen.
- ii. The **middle fold** is the largest fold and present most constantly. It lies at the upper end of the rectal ampulla and projects from the anterior and right walls. This middle valve of Houston roughly correlates with the level of the anterior peritoneal reflexion.
- iii. The **lower fold** lies 2.5 cm below the middle fold, projects from the left wall. This is an inconstant fold.
- iv. Sometimes a fourth fold may be present of the left wall, 2.5 cm above the middle fold.

3.2.4 Supports of the Rectum:

- i. **Waldeyer's fascia¹**: is a dense recto-sacral fascia, which begins at the level of the fourth sacral body and extends anteriorly to the rectum, covering the sacrum and overlaying the vessels and nerves.
- ii. **Denonvilliers' fascia**: is present anterior to the extra peritoneal rectum, which is the recto-vesical septum in men and rectovaginal septum in women.
- iii. **The lateral ligaments of Endopelvic fascia**: support the lower rectum but do not usually contain major blood vessels, as previously believed. Division of the lateral ligaments is thus, possible without impairing the blood supply to the rectum.
- iv. **The pelvic floor**: is a musculotendinous sheet formed by the levator ani muscle. The pubococcygeus, iliococcygeus and puborectalis muscles make up the levator ani muscle. These are paired muscles that intertwine and act as single unit. The line of decussation is called the ano-coccygeal raphe. The rectum, vagina, urethra and the dorsal vein of pubococcygeal portion of the levator ani. During defaecation, the puborectalis relaxes and the levator ani contracts, widening the levator hiatus.

3.3 The Anal Canal

The anal canal starts at the pelvic diaphragm and ends at the anal verge. It is approximately 4 cm long and normally exists as a collapsed antero-posterior slit. The

anatomical anal canal extends from the anal verge to dentate line. For practical purposes, however, surgeons usually define the surgical anal canal, extending from the anal verge to the anorectal ring, which is the circular upper border of the puborectalis that is palpable by digital rectal examination. The ano-rectal ring is 1 to 1.5 cm above the dentate line.

3.3.1 Interior of the Anal Canal

This can be divided into three parts:

(i) Upper part (Mucous): It starts from the Ano-rectal ring to the pectinate line. It is about 15 mm long and shows (a) **anal columns of Morgagni**, which consists of 8 to 14 longitudinal folds located just above the dentate line and forming the **anal crypts** at their distal end. Small rudimentary glands open into some of these crypts. The dentate line is a true muco-cutaneous junction, located 1-1.5 cm above the anal verge. Anal glands or the ducts are the extensions of the anal mucosa through the substance of the wall of the anal canal.^{3,4} They may provide an avenue of infection from the anal canal to the submucosa and intersphincteric spaces; they may also be the site of origin of an adenocarcinoma.⁵

(ii) Middle Part : It is above 15 mm long and extends from the **pectinate line** to **white line** of **Hilton** which is situated at the level of the interval between the subcutaneous part of the external anal sphincter and the lower border of internal sphincter. On digital examination an intersphincteric groove can be felt at this side. The sub-mucosa is a dense connective tissue fixes the pectin to the surrounding muscle coats.

(iii) Lower part (Cutaneous): It is about 8 mm long and is lined by true skin containing the sweat and sub-cutaneous glands.

3.3.2 Musculature of Anal Canal:

I. Anal Sphincters: The wall of anal canal is surrounded by a complex of muscular sphincters i.e. are internal and external sphincters, which together constitute the anal sphincter mechanism.

The internal sphincter is a specialized continuation of the inner circular smooth muscle of the rectum. It is an involuntary muscle and is normally contracted at rest. The inter-sphincteric plane represents the fibrous continuation of the longitudinal smooth muscle layer of the rectum. An additional layer of longitudinal fibres to which Fine and Laws first drew attention, is the one that lies on the inner aspect of the internal sphincter under the anal mucosa and skin and they named it the *musculus submucosae ani*.⁶

The external sphincter is a voluntary, striated muscle divided into three **U-shaped loops** (subcutaneous, superficial and deep)⁸ acting as a single functional unit. It is specialized continuation of the levator muscles of the pelvic floor, especially of the puborectalis muscle. Behind the anal canal, between the upper raphae of the levators and the lower one formed by the external sphincter, lays a space filled with fatty tissue-*retrosphincteric space of Courtney*.⁷ The puborectalis originates at the pubis and joins posterior to the rectum. It is normally contracted, causing 80° angulations or in a system of three loops, which according to *Shafik*⁸ facilitates the maintenance of continence of the anorectal junction.

The levator ani muscle⁹ is a broad, thin muscle, attached peripherally to the inner sides of the pelvis and united medially with its fellow of the opposite side to form the greater part of the floor of the pelvic cavity. It consists of iliococcygeus, pubococcygeus and puborectalis muscles.

II. Ano Rectal Ring¹⁰: Ano-rectal ring is 1-1.5 cm above the dentate line and is the circular upper border of the puborectalis that is palpable by digital rectal examination. Surgical division of this ring leads to rectal incontinence.

III. Hilton's white line in the Anal canal: Hilton defined this line with three distinct characteristics – that it is easily recognizable, white and marks the interval between the external and internal anal sphincters.¹¹

IV. Surgical Spaces: These are spaces actual or potential around the rectum and anal canal. These are the primary sites for accumulation of pus and formation of abscess, further leading to Fistula-in Ano. These spaces allow lines for drainage of pus, therefore, these are also termed as **Surgical spaces**. These are:

i. Ischio rectal space: These are bounded **medially** by pelvic diaphragm and anal wall, **laterally** by fascia of internal obturator muscle, **superiorly** by pelvic diaphragm, **inferiorly** by the intermittent of the buttocks. Apart from these, there is a thin band of tissue intervening between the ischio-rectal fossa posteriorly, which is still a weaker point and permits entry of pus from one fossa to the other, thereby producing a Horse shoe abscess in the posterior peri-anal region.

ii. Pelvi- rectal space : These are two in number – one on each side of the rectum. These are bounded medially by rectal wall, laterally and inferiorly by pelvic diaphragm, superiorly by peritoneum, posteriorly by lateral ligaments of the rectum, anteriorly by the bladder, seminal vesicles and prostate in males and in females by broad ligaments, and uterus. These spaces can hold good amount of pus.

iii. Retro- rectal space :It lies in the forward concavity of the sacrum. This is bounded anteriorly by rectal wall, posteriorly by prevertebral fascia of sacrum, superiorly by peritoneal reflection, inferiorly by pelvic diaphragm, laterally by lateral ligaments of rectum.

iv. Sub-mucus space: It is situated between the mucus membrane and internal sphincter and above the white line of the Hilton.

3.4 Blood Supply

3.4.1 Arterial Supply

- i) **Superior Rectal Artery:** The terminal branch of the inferior mesenteric artery becomes the superior rectal artery as it crosses the left common iliac artery. It descends in the sigmoid mesocolon and bifurcates at the level of the third sacral body. The left and right branches of the superior rectal artery supply the upper and middle rectum.
- ii) **Middle Rectal Artery:** It arises from the internal iliac arteries, run through Denovillievs fascia and enter the anteriolateral aspect of the rectal wall at the level of the ano-rectal ring. Collaterals exist between the middle and superior rectal arteries. Preservation of the middle rectal arteries is necessary to maintain viability of the remaining rectum after proximal ligation of the inferior mesenteric artery. The middle and inferior rectal arteries supply the lower two thirds of the rectum.
- iii) **Inferior Rectal Artery:** These are the branches of internal pudendal arteries. They traverse Alcock's canal and enter the posteriolateral aspect of the ischio-rectal fossa. They supply the internal and external sphincters and the lining of the anal canal and do not form collaterals with the other rectal arteries.
- iv) **The Middle Sacral Artery:** It arises just proximal to the aortic bifurcation and provides very little blood supply to the rectum.

3.4.2 Venous Drainage:

The venous drainage of the rectum parallels the arterial supply and empties in to both the portal and systemic (Caval) systems.

- i) **The Superior Rectal Vein :** The upper and middle rectum are drained by Superior rectal vein which enter the portal system via inferior mesenteric vein.
- ii) **The middle rectal veins:** drain the lower rectum and upper anal canal which empty into the internal iliac veins and then into canal system.
- iii) **The inferior rectal veins:** drain the lower anal canal and empty into the pudendal veins, which drain into the canal system via the internal iliac veins.

Low rectal tumors can thus metastasize through venous channels into both the portal and systemic venous systems.

iv) Internal Haemorrhoidal Complexes (I.H.C): These are three submucosal I.H.C. located above the dentate line.

- The left lateral,
- Right posterolateral, and
- Right anterolateral. Internal haemorrhoidal veins drain into Superior Rectal vein.

v) External Haemorrhoidal Veins: They are located below the dentate line and drain into the pudendal veins. These are communications between External and Internal plexi.

3.4.3 Lymphatic Drainage:

- a. Lymph from the upper and middle rectum drains into the inferior mesenteric nodes.
- b. The lower rectum primarily drained and enters the inferior mesenteric nodes. Lymph from the **lower rectum** can also flow **laterally** along the middle and inferior rectal arteries, **posteriorly** along the middle sacral artery, or **anteriorly** through channels in the rectovesical or rectovaginal septum. These channels in the rectovesical or rectovaginal septum. These channels drain to the iliac nodes and subsequently to periaortic lymph nodes.
- c. Lymphatics from the **anal canal above the dentate line** drain via the superior rectal lymphatics to the inferior mesenteric lymphnodes or laterally to the internal iliac lymphnodes.
- d. **Below the dentate line**, the lymphatics drain primarily to the inguinal nodes but can drain to the inferior or superior rectal lymphnodes as well.

The mode of the extension of cancer show that the main direction of spread from any growths in any part of the rectum is upwards along the superior hemorrhoidal vessels.¹² Metastases have been demonstrated in the internal iliac glands in some cases with growths in the extra peritoneal part of the rectum. It is well known that metastases occurs in the inguinal glands in cases of rectal or anal carcinoma only when the skin of the anal canal or perianal region is involved by the growth.¹³

3.5 Nerve Supply:

The innervation of the rectum is shared with the urogenital organs of the pelvis and consists of both **Sympathetic (L_{1,2})** and **Parasympathetic (S_{2,3,4})** nerves.

- (i) **Above the pectinate line:** The anal canal is supplied by autonomic nerves, both sympathetic (Inferior Hypogastric plexus L_{1,2}).
- (ii) **Below the pectinate line:** It is supplied by Somatic (Inferior rectal S_{3,4}) nerves.
- (iii) **Sphincters:** The internal sphincter contracts by Sympathetic nerves and relaxes by the parasympathetic nerves and relaxes by the parasympathetic nerves. The external sphincter is supplied by the inferior rectal and perineal of fourth nerve.

3.6 Physiology of the Rectum and Anus

The lower part of the Gastro-intestinal tract, i.e., Ano-rectal canal has merit to store and excrete the faeces.

According to **Paterson** (1912), rectum has an upper part, lies above the middle Houstons's valve and a **lower part**, lies below the valve and in normal conditions it will be empty. **Paterson** regards that the **upper part** is a reservoir for faeces, which can freely distend anteriorly. And **lower part** is so sensitive that its distension produces desire of defaecation. According to **O'Bierne** (1833) and **Hurst** (1919) the sigmoid colon is the faecal reservoir and the whole of the rectum is empty in normal individuals, being sensitive to distension, passage of faeces into the rectum therefore, causes desire to defaecate. There are **two reflexes** which initiates peristalsis.

- (i) **Orthocolic reflex:** This occurs when a person awakes from sleep assuming the erect position.
- (ii) **Gastrocolic reflex:** This occurs when a person is moving and taking food and liquid. The increased intra-rectal pressure causes the relaxation of anal sphincter which is counteracted by voluntary contraction of external sphincter permits the act to proceed. If the delay is prolonged, a temporary reduction in the intensity of the urge may occur.

3.7 References

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Chapter 4: Drug Review

According to Ayurveda, four pillars (*Pada chatustayam*) of treatment are physician, medicine, attendant, and patient. The wise physician starts treatment after thorough analysis of an ideal therapeutic procedure, thus he never commits mistake in administration of remedial measure.

The present study is aimed towards providing easily, affordable, effective and accessible treatment for the disease Parikartika i.e. fissure-in-ano. The preparations used in this clinical study were Jatyadi Ghrita, Yastimadhu Ghrita, both drugs applied as Pichu and Panchasakara Churna.

Under the heading Drug Review, the following contents are discussed :

1. Details of the Drugs used in the Trial Formulations
2. Establishment of Quality Standard Parameters of the individual drugs and finished formulations
3. Standard Operative Procedures for preparation of Trial drugs namely: Churna and Ghrita.

4.1 Details of the Drugs used in the Trial Formulations (Drug Profile):

The raw drugs used in the trial formulations were collected from local market of Bhubaneswar and Cuttack of Odisha State and were properly been identified and authenticated as per the standard protocols. All the ingredients of the trial drugs were analysed and standardized as per the Quality Control Parameters set for the Ayurvedic Drugs. The trial drug – Jatyadi ghrita has already been established for its standards, the results were analysed and compared with the available standards and ensured the standards were complying with the established standards of the Jatyadi ghrita. The other trial drugs were analysed and their standards were established as there were no quality control parameters available.

4.1.1 Name of the Formulation : Panchasakara Churna (Siddha Yoga Sangraha)

1. Shunti⁹²:

Latin Name	: Gingiber officinalis (Fam Gingiberaceae)
Gana	: Truptighna, Arshoghna
Synonyms	: Mahaushadha, Vishwabheshaja
Assam.	: Adasuth, Aadar, Shunth
Beng.	: Suntha, Sunthi
Eng.	: Ginger root
Guj.	: Sunth
Hindi	: Sonth
Kan	: Shunthi
Kash.	: Shonth
Mal.	: Chukku
Mar.	: Sunth
Ori.	: Sunthi
Punj.	: Sund
Tam.	: Sukku
Tel.	: Sonthi
Urdu.	: Sonth
Habitat	: All over India hot and wet places
Morphology	: Annual shrub
Properties	: Rasa - Madhura : Guna- Guru, Ruksha, Teekshna : Vipaka- Katu : Virya - Ushna
Part used	: Moola kanda
Effect on dosha	: Kapha Vata Shamana
Karma	: Ama pachana, Deepana, Shotha hara
Chemical composition:	Gingiberin, gingerol, Oil of ginger, gingerone
Pharmacology	: Antiseptic, Anti bacterial

2. Misreya (API Part-1,Vol-1,Page-86)

Latin Name : Foeniculum vulgare Mill (Fam. Umbelliferae)

Synonyms-

Sansk.	: Misi, Misi, Madhurika
Assam.	: Guvamuri
Beng.	: Marui, Panmauri
Eng.	: Fannel Fruit
Guj.	: Variyali
Hindi	: Saunf
Kan.	: Badisompu, Doddasompu
Kash.	: Sanuf, Badnai
Mal.	: Kattusatakuppa, Parinjaeragum
Mar.	: Badishop
Ori.	: Panamadhuri
Punj.	: Saunf
Tam.	: Shombu
Tel.	: Sopu
Urdu.	: Saunf

Habitat : All over India

Morphology : Herb

Properties : Rasa- Madhura, Katu, Tikta

: Guna- Laghu, Ruksa

: Virya- Sita

: Vipaka- Madhura

Part used : Fruit

Effect of Dosa : Vata Pitta Shamaka

Karma : Dipana, Vatapittahara, Balya, Anulomana,
Amadosahara

Chemical composition : Essential oil and fixed oil

3. **Svarnapatri** (API Part-1, Vol-1, Page-105)

Latin Name	: <i>Cassia angustifolia</i> Vahl (Fam. Legummosae)
Synonyms	: Swarnpatri
Assam	: Sonamukhi
Beng.	: Svarnamukhi, Sonapatra
Eng.	: Indian, Senna, Tinnevelly Senna
Guj.	: Mindhiaval, Sonamukhi
Hindi	: Sanaya, Hindisana
Kan.	: Nelavarika, Sonamukhi, Nelaavare, Nelavarike, Nela Aavariake
Kash.	: Sna
Mal.	: Sunnamukhi, Nilavaka, Chinnukki, Adapatiyan
Mar.	: Sonamukhi
Ori.	: Sunamukhi
Punj.	: Sanapati, Sarnapatta, Sannamakhi
Tam.	: Nilapponnai, Avarai
Tel.	: Sunamukhi
Urdu.	: Sena, Barg-e-Sana
Habitat	: Southern India
Morphology	: Small shrub
Properties	: Rasa Katu, Tikta, Kasaya
Guna	: Laghu, Ruksa, Tiksna
Virya	: Usna
Vipaka	: Katu
Part used	: Leaf
Effect on dosha	: Pitta sodhaka and Vatanulomaka
Karma	: Recana
Chemical composition	: Anthraquinone, Glucoside, Steroids and resin, Flavonoids.

4. Haritaki⁹³:

Latin Name	: Terminalia Chebula
Family	: Combretaceae
Gana	: Taiphala (Su), Vayasthavana (Ch.)
Synonyms	: Abhaya, Pathya
Assam	: Shilikha,
Beng.	: Haritaki
Eng.	: Myrobalan
Guj.	: Hirdo, Himaja
Hindi	: Hare
Kan.	: Alalekai
Kash.	: Halela
Mal.	: Katukka
Mar.	: Hirda
Ori.	: Harida
Punj.	: Halela
Tam.	: Kadukkai
Tel.	: Karakla
Urdu.	: Halela
Habitat	: All over India, especially in West Bengal, Assam
Morphology	: A tree growing up to 50-80 Ft. in height
Properties	: Rasa – Pancharasa (Lavan varjita) Kashaya : Pradhana Guna- Laghu, Ruksha : Virya- Ushna : Vipaka- Madhura
Part used	: Tender Fruit
Effect of dosha	: Tridosha Shamaka
Karma	: Vrana-Sodhana & Ropana, Vedna- Sthapana
Chemical Composition	: Phala contains, Tannin 30 to 32%, Glucose Amino acids, Phosphoric acids, etc.
Pharmacological	: Laxative, Stomachic, Bleeding, Ulceration, Adhmana

5. Saindhava Lavana

It is a mineral which is obtained from Punjab mines. There are two varieties of Saindhava Lavana, they are White and Red. According to Charaka it is considered best among all the salts for internal use.

- English name : Chloride of Sodium
- Latin Name : Sodi chloridium

Physical Properties

- Appearance : Stony pieces
- Colour : Whitish red
- Consistency : Hard
- Solubility : Dissolves in water

Chemical Properties

- Sodium Chloride (NaCl) – 97.6 % w/w
- Sodium Bicarbonate (NaHCO₃) – 0.07 % w/w
- Insoluble matter – 0.031% w/w
- Also contains minor quantities of Magnesium Chloride, Calcium Chloride and Calcium Sulphate.

Pharmaco-Therapeutic Properties

1. Paryaya – Sindhu Lavana, Sindhutha, Sindhudeshaja, Shiva, Sita Shiva
2. Guna – Laghu, Snigdha, Tikshna
3. Karma – Agnideepana, Pachana, Ruchya, Netriya, Hridya, Vrishya
4. Veerya – Sheeta
5. Doshakarma – Tridoshashamaka
6. Amayika Proyoga – Sodhahara, Vibandaghna, Vranadoshahara

According to Charaka Sutrasthana 27th Chapter it is having tridoshahara, deepana, rochana, hrudya, chakshusya, vrishya, avidahi. It cures netra rogas, vranas and vibandha.

4.1.2 Name of the Formulation : Jatyadi Ghrita (Astang Hridaya, Uttarasthana)

The key ingredients of Jatyadi ghrita are

1. Jati
2. Nimba
3. Patola
4. Katuka
5. Daruharidra
6. Haridra
7. Sariva
8. Manjishta
9. Kushta
10. Siktha
11. Tutha
12. Madhuka (yastimadhu)
13. Karanjabeeja
14. Moorchita ghrita

1. Jati:⁹⁴

Latin Name	: Jasminum officinale
Family	: Oleaceae
Gana	: Kusthgnha
Synonyms	: Sumana, Chetaki, Soumanasyayani
Assam	: Yasmeen
Beng.	: Chamelee
Eng.	: Jasmine
Guj.	: Chamelee
Hindi	: Chamelee
Kan.	: Jati Maltiga, Sanna Jati Mallige
Kash.	:
Mal.	: Pichi
Mar.	:Chamelee

Ori.	:
Punj.	: Chamelee
Tam.	: Pichi, Jatimalli
Tel.	: Jati, Sannajati
Urdu.	: Chameli, Yasmeen
Habitat	: All over India
Morphology	: Creeper
Properties	: Rasa - Tikta, Kashaya. : Guna - Laghu, Snigdha, Mrudu : Vipaka - Katu : Virya - Ushna
Part used	: Patra
Effect on dosha	: Tridosha Shamana
Karma	: Kandughna, Vrunashodhana, Vrunaropana
Chemical composition:	Salicylic acid
Pharmacology	: Antibacterial, antiseptic

2. Nimba:⁹⁵

Latin Name	: Azadirachta Indica
Family	: Meliaceae
Gana	: Kandughna
Synonyms	: Pichumarda, Aristha, Hinguniryasa
Assam	:
Beng.	: Nim, Nimgaachh
Eng.	: Margosa tree, Neem Tree, Indian Lilac
Guj.	: Leemado
Hindi	: Neem
Kan.	: Turakbevu, Huchechabevu, Chikkabevu
Kash.	:
Mal.	: Veppu, Aryaveppu, Aaruveppu
Mar.	: Kadunimba, Nimb
Ori.	: Neemo, Nimba
Punj.	: Nimb, Nim

Tam.	: Vempu, Veppu
Tel.	: Vemu, Vepa
Urdu.	: Neem
Habitat	: All over India
Morphology	: Tree 40 to 50 ft. height.
Properties	: Rasa - Tikta, Kashaya : Guna - Laghu : Vipaka- Katu : Virya - Sheeta
Part used	: Patra
Effect on dosha	: Shamana
Karma	: Kandughna, Vrunashodhana, Vrunaropana
Chemical composition:	Nimbin, Nimbidin, Nimbinin
Pharmacology	: Anti-Bacterial, Wound healing, Antiseptic

3. Patola:⁹⁶

Latin Name	: Trichosanthes dioica
Family	: Cucurbitaceae
Gana	: Truptighna
Synonyms	: Kulaka, Rajifala, Beejagarbha
Beng.	: Patola
Eng.	: Pointed gourd
Guj.	: Parbal
Hindi	: Parbal
Kan.	: Kadu Padbal
Mal.	: Patolam
Mar.	: Parbal
Tam.	: Kambupudalai
Tel.	: Kombupotala
Habitat	: On the banks of river Ganga
Morphology	: Creeper
Properties	: Rasa - Tikta : Guna - Laghu, Ruksha

	: Vipaka- Katu
	: Virya - Ushna
Part used	: Patra
Effect on dosha	: Tridosha Shamana
Karma	: Vedanasthapana, Vrunashodhana, Vrunaropana
Chemical composition:	Protein, Carbohydrates, Oils
Pharmacology	: Antipyretic, Antiseptic, Anti-inflammatory

4. **Katuki**⁹⁷

Latin Name	: Picrorhiza kurroa
Family	: Scrophulariaceae
Gana	: Patoladi
Synonyms	: Katurohini, Tikta, Matsyashakala
Assam	: Katki, Kutki
Eng.	: Hellebore
Guj.	: Kadu, Katu
Hindi	: Kutki
Kan.	: Katuka rohini, katuka rohini
Mal.	: Kaduk rohini, Katuka
Mar.	: Kutki, Kali Kutki
Ori.	: Katuki
Punj.	: Karru, Kaur
Tam.	: Katuka rohini, Kadugurohini
Tel.	: KaruKarohini
Urdu.	: Kutki
Habitat	: Himalayas
Morphology	: Small perennial shrub
Properties	: Rasa - Tikta
	: Guna - Laghu, Ruksha
	: Vipaka- Katu
	: Virya - Sheeta
Part used	: Root
Effect on dosha	: Kapha Pitta Shamana

Karma : Kushtaghna
 Chemical composition: Picrorhizin, Kutkin
 Pharmacology : Antipyretic, Antiseptic

5. Daruharidra⁹⁸

Latin Name : Berberis aristata
 Family : Berberidaceae
 Gana : Kandughna, Lekhaniya, Arshanashaka (ca), Haridradi,
 Lakshadi (su.)
 Synonyms : Darvi, Iksura, Kokilaksi

Beng. : Daruharidra
 Eng. : Indian Barberry
 Guj. : Daruharidra
 Hindi : Daruhaladi
 Kan. : Maradarishana, Maradarishina
 Mal. : Maramannal, Maramanjnal
 Mar. : Daruhalad
 Ori. : Daruhaladi
 Punj. : Sumalu
 Tam. : Gangeti, Varatiu manjal
 Tel. : Manupasupu
 Urdu. : Darhald

Habitat : Himalayas, Nilgiri, Shri Lanka
 Morphology : Shrub 6 to 15 ft.

6. Haridra⁹⁹

Latin Name : Curcuma Longa
 Family : Gingeraceae
 Gana : Kusthaghna, Kandughna
 Synonyms : Nisha, Gouri

Assam : Haldhi
 Beng. : Halud

Eng.	: Turmeric
Guj.	: Haldar
Hindi	: Haldi
Kan.	: Arishina
Kash.	: Ledar
Mal.	: Manjal
Mar.	: Halad
Ori.	: Haladi
Punj.	: Haldi
Tam.	: Manjal
Tel.	: Pasupu
Urdu.	: Haldi
Habitat	: All over India
Morphology	: Annual shrub
Properties	: Rasa - Tikta, Katu : Guna - Laghu, ruksha : Vipaka- Katu : Virya - Ushna
Part used	: Moola kanda.
Effect on dosha	: Tridosha Shamana
Karma	: Kandughna, Vrunashodhana
Chemical composition:	Kusthaghna
Pharmacology	: Antiseptic, Anti bacterial

7. Sariva¹⁰⁰

Latin Name	: Hemidesmus indicus
Family	: Asclepidaceae
Gana	: Sthanya shodhana, dahaprashamana
Synonyms	: Gopavalli, Anantamula
Assam	: Vaga sariva
Beng.	: Anantamul
Eng.	: Indian Sarasa Parilla
Guj.	: Upalsari

Hindi	: Anantamul
Kan.	: Namada viru,sogadeberu
Kash.	: Ananta mool
Mal.	: Nannari
Mar.	: Upalsari
Ori.	: Ananta mula
Punj.	: Ushbah
Tam.	: Van nannari
Tel.	: Sugandhi pala
Urdu.	: Ushba hindi
Habitat	: All over India
Morphology	: Creeper 5 to 15ft.
Properties	: Rasa - Madhura, Tikta : Guna - Guru, Snigdha : Vipaka- Madhura : Virya - Sheeta
Part Used	: Moola
Effect on dosha	: Tridosha Shamana
Karma	: Rakta Shodhaka, Shotha hara
Chemical composition:	P-methoxy salicylic aldehyde
Pharmacology	: Anti inflammatory, Blood purifier

8. Manjishta¹⁰¹

Latin Name	: Rubia cordifolia
Family	: Rubeaceae
Gana	: Varnya
Synonyms	: Yojanavalli, vikasa
Assam	: Phuvva
Beng.	: Manjistha
Eng.	: Indian Maddar
Guj.	: Manjitha
Hindi	: Manjitha
Kan.	: Manjustha

Kash.	:
Mal.	: Manjatti
Mar.	: Manjihtha
Ori.	:
Punj.	: Manjistha
Tam.	: Manjatte
Tel.	: Manjistha
Urdu.	: Majeeth
Habitat	: All over India
Morphology	: Creeper
Properties	: Rasa - Tikta, Kashaya, Madhura
	: Guna - Guru, ruksha
	: Vipaka - Katu
	: Virya - Ushna
Part used	: Moola
Effect on dosha	: Kapha pitta Shamana
Karma	: Varnya, Vrunashodhana, Vrunaropana
Chemical composition:	Manjisthin, Purpurin
Pharmacology	: Pigmentation

9. Kushta¹⁰²

Latin Name	: Saussurea Lappa
Family	: Compositae
Gana	: Lekhaneeya
Synonyms	: Vapya, utpala
Assam	: Kud,Kur
Beng.	: Kudo
Eng.	: Costus
Guj.	: Upleta,Kath
Hindi	: Kutha
Kan.	: Changle Kustha
Kash.	: Kuth
Mal.	: Kottam

Mar.	: Kustha
Ori.	: Kudha
Punj.	: Kuth
Tam.	: Kottam
Tel.	: Changanva koshtu
Urdu.	: Qust
Habitat	: Himalayas
Morphology	: Shrub
Properties	: Rasa - Tikta, Madhura, Katu
	: Guna - Laghu, Ruksha, Teekshn
	: Vipaka- Katu
	: Virya - Ushna
Part used	: Moola
Effect on dosha	: Kapha Vata Shamana
Karma	: Jwaraghna, Kushtaghna
Chemical composition:	Sassurine, Reginoid, Tanin
Pharmacology	: Analgesic, Antiflatulant

10. Madhuka (Yastimadhu)¹⁰³

Latin Name	: Glycyrrhiza Glabra
Family	: Leguminosae
Gana	: Kanthya, Sandhaneeya, Jeevaneeya
Synonyms	: Yashimadhu, Klitaka
Assam	: Jesthimadhu
Beng.	: Yasthimadhu
Eng.	: Liquorice
Guj.	: Jethimadha
Hindi	: Mulethi
Kan.	: Jestamadu
Kash.	: Multhi
Mal.	: Irattimadhuram
Mar.	: Jesthamadh

Ori.	:Jasthimadhu
Punj.	: Mulathi
Tam.	:Athimadhurum
Tel.	:Atimadhuramu
Urdu.	: Mulethi
Habitat	: South Middle Asia
Morphology	:Perennial Shrub 6ft.
Properties	:Rasa - Madhura
	:Guna - Guru, Snigdha
	:Vipaka- Madhura
	:Virya - Sheeta

Part used	: Moola
Effect on dosha	:Vata Pitt Shamana
Karma	:Vedanasthapana, Shotha hara, Dahashamaka
Chemical composition:	Glycyrnizin, Liquiritin
Pharmacology	:Anti inflammatory, analgesic

11. Karanjabeeja¹⁰⁴

Latin Name	: Pongamia pinnata
Family	: Leguminosae
Gana	: Kandughna
Synonyms	: Naktamala, Gucchapuspaka
Assam	: Korach
Beng.	:Nata karanj
Eng.	:Smooth leaved pongamia
Guj.	:Kanaji
Hindi	: Karuaini
Kan.	: Honge
Kash.	:
Mal.	: Avittal
Mar.	:Karanja
Ori.	:Karanja

Punj.	: Karanj
Tam.	:Pungan
Tel.	:Lamiga
Urdu.	: Karanj
Habitat	: Himalayas
Morphology	: Tree 25 to 50ft.
Properties	: Rasa - Katu tikta kashya : Guna - Laghu, teekshna : Vipaka - Katu : Virya - Ushna
Part used	: Beeja
Effect on dosha	: Kapha vata Shamana
Karma	: Kusthaghna
Chemical composition:	Pongamin, Karanjin, Qurcetin
Pharmacology	: Anti inflammatory, blood purifier

12. Tutha¹⁰⁵

Chemical Name	: Copper sulphate
Gana	: Maharasa
Synonyms	: Sasyak, Mayuraka
Habitat	: India, Germany, Czechoslovakia
Morphology	: Crystalline Blue in color
Properties	: Rasa - Katu, Kashaya, Madhura : Guna - Laghu : Vipaka- Ushna : Virya - Katu
Effect on dosha	: Kapha vata Shamana
Karma	: Vruna shodhana, Ropana, Kriminashaka
Chemical composition	: Copper sulphate
Pharmacology	: Antibacterial, Antiseptic

13. Sikta (madhuchishta)¹⁰⁶

The wax obtained by processing the honey comb is called as sikta. There are many varieties depending upon the bee.

Synonyms	: Madhushesha, madhuchishta, Madhuja.
Properties	: Rasa - Madhura. Guna - Snigdha, pichila. Virya -Ushna. Vipaka - Madhura.
Effect on dosha Karma	: Vata Pitta Shamaka.
Chemical composition	: Myricine, Myricil palmitate, cerotic acid, melissic acid,
Pharmacological	: Anti bacterial, analgesic, anti inflammatory, smoothening.
Actions	: Vrana-sodhana, Ropana , Sothahara, Vedana shamaka, Bagna sandhanakara.

14. Go-Ghrita¹⁰⁷

Latin Name	: Butyrum departum
Gana	: Mahasneha (Su. Ca.)
Vernacular Names:	
Sanskrit	: Ghrita English: Clarified butter
Hindi	: Ghee Gujarati: Ghee
Synonyms	: Aajya, Havis, Snehotama, Varasneha, Sarpi
Pharmacodynamics:	
Rasa	: Madhura Guna: Guru, Singdha, Mridu
Virya	: Sheeta Vipaka: Madhura
Doshakarma	: Vata-Pittahara

Actions and Uses: Ghee is the clarified butter fats. It promotes Agni, Sukra and lengthens the life span. Attributes of Ghee i.e. unctuousness and coldness are antagonistic to those of Vata and Pitta like dryness, lusterless, roughness and heat respectively. Moreover, boiling with Kapha antagonist drugs (like

pungent, bitter taste), prepared medicated Ghee can inhibit the action of deranged Kapha due to its assimilating properties.

According to Bhavaprakasha, Sushruta, Charaka and almost all Acharya Go-Ghrita is also beneficial for visual acuity by oral as well as local use. It also improves Dhi, Dhrti and Smrti. It is good for complexion, voice and in Kshatakshina, Visarpa, toxins, Unmada etc. (A.H. Su. 5/37-39)

Chemical Constituents:

Go-Ghrita contains carotene in the amount of 3.2-7.4 g/g, Vitamin A in the amount of 19-34 I.U./g and Tocopherol (Vitamin E) in the amount of 26-48g in it. It also contains Vitamin D and K. (Source: Mild products of India by Srinivasan and Anantkrishnan)

The principal contents are triglycerides or neutral fats. Fatty acid contents in percentage by weight of different fatty acids is as follows: saturated- c14, below 3.0 palmitic (c10) 29, stearic (c18) 21, c20 and above 1.0; monounsaturated – palmitoleic (c16) 3, oleic (c18) 41; polyunsaturated; linoleic (c18:2) 2, arachidonic (c20:4) c22 and higher in trace. (Beaton G.H. McHenry W.E. 1964)

4.1.3 Name of the Formulation :**Madhuyashti Ghrita** (Astang Hridaya, Uttarasthana)

The key ingredients of Madhuyashti ghrita are

1. Madhuyashtikalpa
2. Ghrita (Go Ghrita)
3. Water

1. **Madhuka (Yastimadhu)**¹⁰³

Latin Name	: Glycyrrhiza Glabra
Family	: Leguminosae
Gana	: Kanthya, Sandhaneeya, Jeevaneeya
Synonyms	: Yashimadhu, Klitaka
Assam	: Jesthimadhu
Beng.	: Yasthimadhu

Eng.	: Liquorice
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Punj.	: Mulathi
Tam.	:Athimadhurum
Tel.	:Atimadhuramu
Urdu.	: Mulethi
Habitat	: South Middle Asia
Morphology	:Perennial Shrub 6ft.
Properties	:Rasa - Madhura :Guna - Guru, Snigdha :Vipaka- Madhura :Virya - Sheeta
Part used	: Moola
Effect on dosha	:Vata Pitt Shamana
Karma	:Vedanasthapana, Shotha hara, Dahashamaka
Chemical composition:	Glycyrnizin, Liquiritin
Pharmacology	:Anti inflammatory, analgesic

4.2 Standardization and Quality Control parameters of the Trial Drugs:

The raw drugs were collected from the local market (Bhubaneswar and Cuttack) and analysed scientifically for establishment of Quality Control Parameters as per the standard guidelines set for the standardization and Quality control measures. These drugs were tested and analysed in the Department of Pharmaceutical Analysis and Quality Assurance, School of Pharmaceutical Sciences, Siksha 'O' Anusandhan University, Bhubaneswar.

The quality control parameters of one of the trial drugs namely- Jatyadi Ghrita have already been established and published, the test results of this drug have been compared with those which were published in the Ayurveda Pharmacopeia of India and Ayurveda Formulary of India and it was observed and ensured that the test results of the Jatyadi ghrita were conformed with the results published in these documents.

Since the the quality control parameters of the other two trial drugs namely- Yasthimadhu Ghrita (**Reference : Sample No. CIF/HS/01/2016**) and Panchasakara Churna (**Reference : Sample No. CIF/HS/02/2016**) are not available in Ayurveda Pharmacopeia of India and Ayurveda Formulary of India, these drugs were analysed scientifically for the establishment of quality control parameters as per the standard guidelines set for them.

The following Methods were adopted for the establishment of Quality Control Parameters for both the raw drugs and finished products (Yasthimadhu Ghrita and Panchasakara Churna):

4.2.1 Panchasakara Churna

Panchasakara Churna is prescribed in Ayurveda for diseases such as constipation, piles and other abdominal diseases [3]. Its main ingredients include Swarnapatri (*Cassia angustifolia*) leaf, Haritaki (*Terminalia chebula*) fruit, Shunti (*Zingiber officinale*) rhizome, Saunf (*Foeniculum vulgare*) fruit and Saindhava lavaṇa (rock salt) [3]. Currently there is no monograph for analysis of Panchasakara Churna in Indian Ayurvedic pharmacopoeia. Moreover, till date there is only a single report of its characterisation giving some basic information about its pharmacognostical characterization [4]. However, this report being insufficient as per the current requirements of Indian Ayurvedic pharmacopoeia, there is an urgent need to

characterise the formulation exhaustively based on present pharmacopoeial standards including organoleptic characters, chemical analysis, chromatographic pattern, microbiological evaluation etc. [5] Presently, due to lack of pharmacopoeial standards laid down and followed for quality control of Panchasakara Churna, the product may not have the desired quality and batch-to-batch consistency. Hence, the current work was undertaken with the objective of contributing to Ayurvedic pharmacopoeias by deriving consistent standards, proposing rapid authentication fingerprints for the formulation and preparing a concise monograph on the quality [6]. In this study, Panchasakara Churna is subjected to detailed pharmacognostic characterization, evaluation of physical characteristics, physicochemical testing, phytochemical investigation, determination of toxic contaminants like heavy metals, microbial limit test and TLC based fingerprinting for detection of its ingredients.

4.2.2 Methods

i. Preparation of Panchasakara Churna

The Panchasakara Churna was prepared as per the standard method described in Ayurvedic Formulary of India. As per the literature, all the ingredients were shade dried and powdered separately, passed through 80 # sieve and then mixed together in equal proportions to get uniformly blended churna [7].

ii. Pharmacognostical study

a. Determination of foreign matter

100 gms of the sample was spread out in a thin layer. The foreign matter was detected by inspection with the unaided eye or by the use of a lens (6x), separated, weighed and the percentage foreign matter was calculated [8].

b. Organoleptic parameters

The organoleptic characters like colour, odour, taste, appearance and texture of the ingredients and formulation samples were evaluated based on the reported method [9].

c. Fluorescence analysis

Fluorescence characteristics of powdered churna was observed in different standard reagent solutions towards ordinary visible light and Ultra Violet light (both long 365 nm and short 254 nm wave lengths) [10].

d. Microscopic study of Panchasakara Churna

5 mg of the sieved (80 #) powder samples (churna and ingredients) were taken and washed with plain water. Then the samples were treated separately with iodine, chloral hydrate, pholorglucinol or potassium iodide; a drop of glycerine was added and mounted. The powder sample characters were then observed by Carl Zeiss binocular microscope attached with camera according to standard method [11-12].

e. Physicochemical investigation

Different physicochemical investigations of churna and its raw materials were carried out using standard pharmacopoeial methods, including determination of alcohol soluble extractives, water soluble extractives, total ash, acid insoluble ash, loss on drying and pH determinations [5, 13].

f. Determination of powder flow properties

Physical characteristics like bulk density, tap density, angle of repose, Hausner's ratio and Carr's index were determined for the Churna formulations [14].

g. Qualitative Phytochemical Investigation

Comparative qualitative chemical tests were carried out for Panchasakara Churna and its ingredients on their different extracts of various polarities. These phytochemical screening included tests for alkaloids, tannins, steroid, glycoside, flavonoids, saponins, carbohydrates, terpenoids and proteins [15].

h. Determination of Toxic Contaminants

1) Heavy metal determination

Heavy metal analysis of Panchasakara Churna was performed using PERKIN ELMER AAS-200 instrument. As per protocol, sample digestion was carried out by multi-acid digestion system for Lead (Pb), Cadmium (Cd), Copper (Cu), Zinc (Zn), Nickel (Ni) and Chromium (Cr) [16]. After completion of digestion process, the filtered samples were analysed by Atomic Absorption Spectrometer (AAS). However being volatile, Mercury (Hg) and Arsenic (As) were digested using Nitric acid-Hydrochloric Acid-Potassium Permanganate system before analysis [17]. The Mercury Vapour Atomization (MVA) and Hybrid Vopour Generation (HVG)

attachments were utilised for AAS analysis of Hg and As respectively. The standards of Lead (Pb), Cadmium (Cd), Arsenic (As), Mercury (Hg), Cupper (Cu), Zinc (Zn), Nickel (Ni) and Chromium (Cr) were purchased from Merck, Germany and utilised for development of the respective calibration curves for these metals.

2) Microbial Limit Test

Microbial analysis was carried out as per standard procedure mentioned in Ayurvedic Pharmacopoeia of India. It included total bacterial count, total fungal Count, presence of pathogens like *Escherichia coli*, *Salmonella ebony*, *Pseudomonas aeruginosa* and *Staphylococcus aureus* [18].

i. Thin Layer Chromatographic (TLC) Study

Sample Preparation: Accurately weighed 1g of samples of churna and its ingredients were separately dissolved in 20 ml methanol and refluxed on water bath at 90-100⁰ C for 15 min. They were filter and evaporated up to 5 ml in porcelain dish and taken for TLC profiling.

Solvent System: The solvent system- Toluene: Ethyl Acetate: Formic acid (7.3:2.5:0.2 v/v), showing best separation through trial and error, was used for developing the TLC plates.

Development: Methanolic extracts of Churna and its ingredients were applied on 0.2 mm precoated Silica Gel 60 F₂₅₄ plates (Merck KGaA) and developed in the above mentioned solvent system.

Visualization: The developed TLC plates were examined under ultraviolet light at 254nm and 366nm [19]. The R_f values of the resolved spots were noted.

iii. Results

a. Pharmacognostical study

The in-house Panchasakara churna was found to be brownish yellow in colour with aromatic and pungent odour and tasted salty, aromatic and pungent. The tested foreign matter content of the churna ingredients were less than 0.5 % (w/w) as per the requirements of Ayurvedic Pharmacopoeia of India (API). In fluorescence study, the Churna and its ingredients exhibited characteristic

fluorescence colours as such as well as after the treatment with different reagent solutions towards ordinary light and ultraviolet light (both long 365 nm and short 254 nm wave lengths) as reported in Table 1.

Table 1: Fluorescence analysis of Panchasakara churna

Powdered drug	Visible/day light	Ultra violet light	
		254 nm	366 nm
Powder as such	Crimson to dark brown	Light yellow	Powder as such
Powder + conc. HCl	Yellowish grey	Green	Powder + conc. HCl
Powder + 10% K ₂ Cr ₂ O ₇	Dark brown	Fluorescent green	Powder + 10% K ₂ Cr ₂ O ₇
Powder + 1 M NaOH	Reddish orange	Yellowish green	Powder + 1 M NaOH
Powder + AgNO ₃	Grey	Yellowish brown	Powder + AgNO ₃
Powder + conc. HNO ₃	Yellowish brown	Fluorescent green	Powder + conc. HNO ₃
Powder + conc. H ₂ SO ₄	Dark brown	Greenish black	Powder + conc. H ₂ SO ₄
Powder + Br ₂ water	Dark brown	Dark brown	Powder + Br ₂ water
Powder + Methanol	Light brown	Yellow	Powder + Methanol
Powder + CH ₃ COOH	Light brown	Yellow	Powder + CH ₃ COOH
Powder + NH ₃	Dark brown	Fluorescent green	Powder + NH ₃
Powder + I ₂	Black	Fluorescent green	Powder + I ₂

In the powder microscopic analysis of Panchasakara Churna (Plate. 1), the diagnostic characters such as presence of starch grains, fragmented vessel elements, oil globule, fibre indicated the presence of Shunti (*Zingiber officinale*). Trichomes, epidermis surface, crystal fiber, water tubes indicated the presence of Swarnapatri (*Cassia angustifolia*). Elements from the fibro-vascular tissue, simple fibre, epicarp in surface, Vittae indicated the presence of Saunf (*Foeniculum vulgare*). Pitted Sclereids, sclereids with wide lumen, needle shape fibre, stone cell and starch grain were suggestive of Haritaki (*Terminalia chebula*).

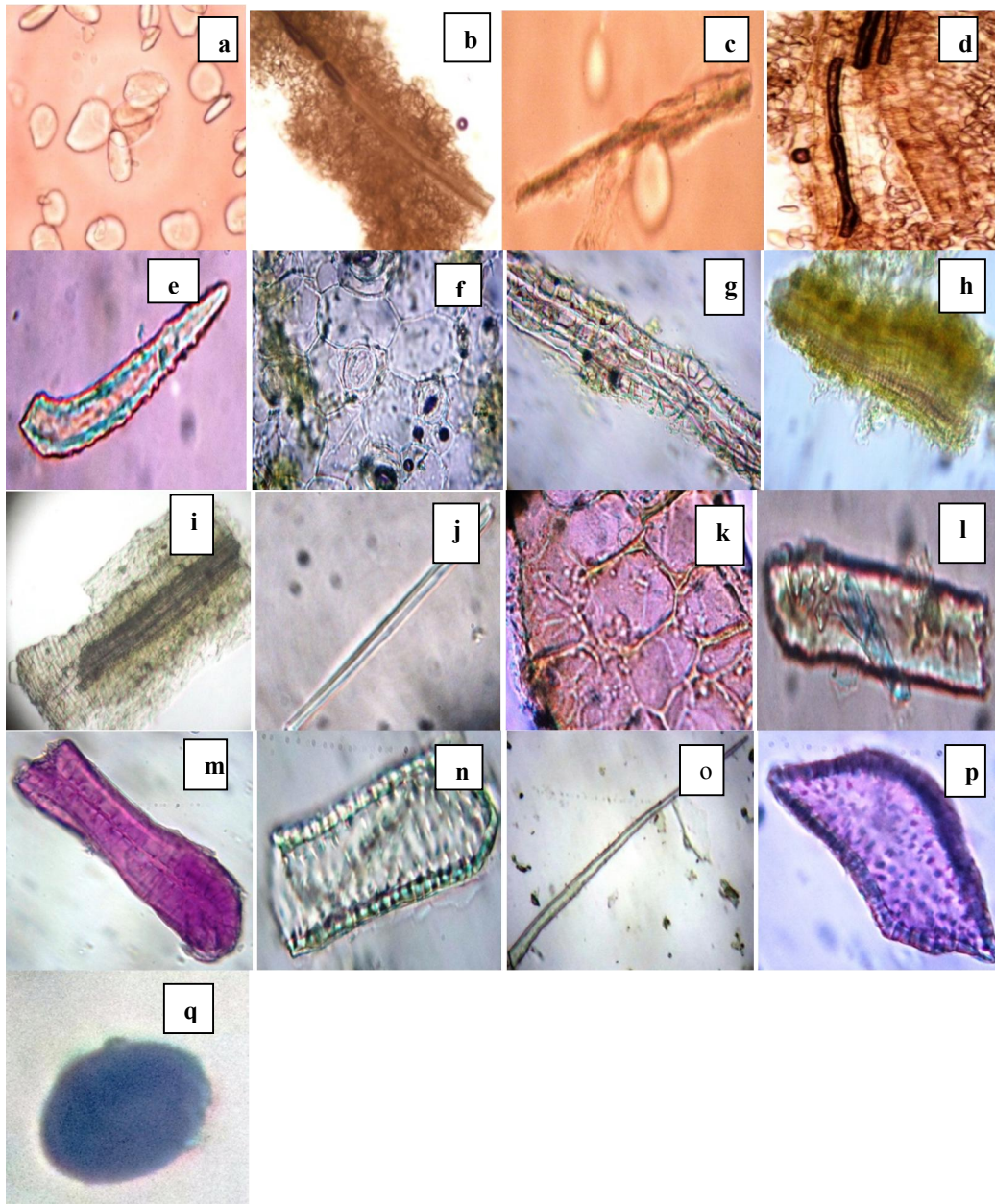


Plate. 1: Photographs of powder microscopic of Panchasakara churna. (a) Starch grains of Shunti, (b) Fragmented vessel elements of Shunti, (c) Oil globule of Shunti, (d) Fibre of Shunti, (e)Trichomes of Swarnapatri, (f) Epidermis, surface view of Swarnapatri, (g) Crystal fiber of Swarnapatri, (h) Water tubes of Swarnapatri, (i) Elements from the fibro- vascular tissue of Saunf, (j) Simple Fibre of Saunf, (k) Epicarp in surface view of Saunf, (l) Vittae of Saunf, (m) Pitted Sclereids of Haritaki, (n) Sclereids with wide lumen of Haritaki, (o) Needle shape Fibre of Haritaki, (p) Stone cell of Haritaki, (q) Starch grain of Haritaki.

b. Physicochemical, phytochemical and physical characteristics of Panchasakara churna

The standards of physicochemical parameters like ash values and extractive values of Panchasakara Churna were assessed and presented in Table 2. Moreover, the aqueous suspension of the prepared churna showed pH of 6.697 and 2.4% w/w loss on drying at 105° C. Phytochemical evaluation of Panchasakara Churna and its individual ingredients are presented in Table 3, while the physical characteristics of Panchasakara churna are given in Table 4.

Table 2: Results of ash values and extractive values in Panchasakara Churna and its raw materials.

Sample	Total ash (% w/w)		Acid insoluble ash (% w/w)		Alcohol soluble extractive (% w/w)		Water soluble extractive (% w/w)	
	Limit*	Result	Limit*	Result	Limit*	Result	Limit*	Result
Shunti	NMT 3.68	5.68	NMT 1.5	0.5	NMT 7	5	NLT 13	11
Swarnapatri	NMT 14	1.5	NMT 2	0.5	NLT 3	14	NLT 25	9
Saunf	NMT 12	6.20	NMT15	0.458	NLT 4	8	NLT 1	12
Haritaki	NMT 5	3.38	NMT 5	0.465	NLT 40	12	NLT 60	14
Saindhavalavana	NA	NA	NA	NA	NA	NA	NA	NA
Panchasakara Churna	NA	2.343	NA	0.441	NA	20.2481	NA	16.314

*Limits mentioned as per Ayurvedic Pharmacopoeia of India (API); NA -Not available; NMT – Not more than; NLT – Not less than.

Table 3: Phytochemical Investigation of each Raw materials present in Panchasakara Churna.

Material	Extracts	Phytoconstituents present
Shunti	Aqueous Extract	A, T, G, Sa, P
	Methanolic Extract	G, Sa, P
	Ethyl acetate Extract	G, Sa, P
	Chloroform Extract	C
	Pet. Ether Extract	----
Swarnapatri	Aqueous Extract	T, Sa, P
	Methanolic Extract	A, T, G, F, Sa, C
	Ethyl acetate Extract	Sa, C, P
	Chloroform Extract	A, St, G, F, C
	Pet. Ether Extract	St
Saunf	Aqueous Extract	G, Sa, C, P
	Methanolic Extract	A, Sa
	Ethyl acetate Extract	G, Sa, C
	Chloroform Extract	A, F, Sa, C
	Pet. Ether Extract	St
Haritaki	Aqueous Extract	A, T, G, Sa, P
	Methanolic Extract	A, G, Sa, P
	Ethyl acetate Extract	Te, P
	Chloroform Extract	St, F, Sa, C, P
	Pet. Ether Extract	St
Panchasakara Churna	Aqueous Extract	A, T, G, F, Sa, C, P
	Methanolic Extract	A, T, G, F, Sa, P
	Ethyl acetate Extract	St, G, F, C, P
	Chloroform Extract	St, G, F, Sa, C, P
	Pet. Ether Extract	St

A: Alkaloids, T: Tannins, St: Steroid, G: Glycoside, F: Flavonoids, Sa: Saponins, C: Carbohydrates, P: Proteins, Te: Terpenoids.

Table 4: Physical characteristics of Panchasakara churna.

Parameters	Value*
Tap density	0.462 ± 0.017
Bulk density	0.382 ± 0.013
Angle of repose	43.380 ± 0.020
Hausner's ratio	1.578 ± 0.003
Carr's index	34.66 ± 1.73

Values are represented as Mean± Standard deviation (n=3).

c. Determination of Toxic Contaminants

The microbial profile of the Panchasakara Churna was found to be satisfactory with total microbial plate count being 160 CFU/mL (below API limit of NMT 10⁵ CFU/mL), total yeast and mould were 46 CFU/mL (below API limit of NMT 10³ CFU/mL). The pathogenic bacteria, i.e. *Salmonella*, *Pseudomonas*, *Staphylococcus* and *E. coli* were also found to be absent (Plate. 2, Table 5). Moreover, the limits of all the API specified heavy metals in Panchasakara Churna were found within the acceptable limit (Table 6).

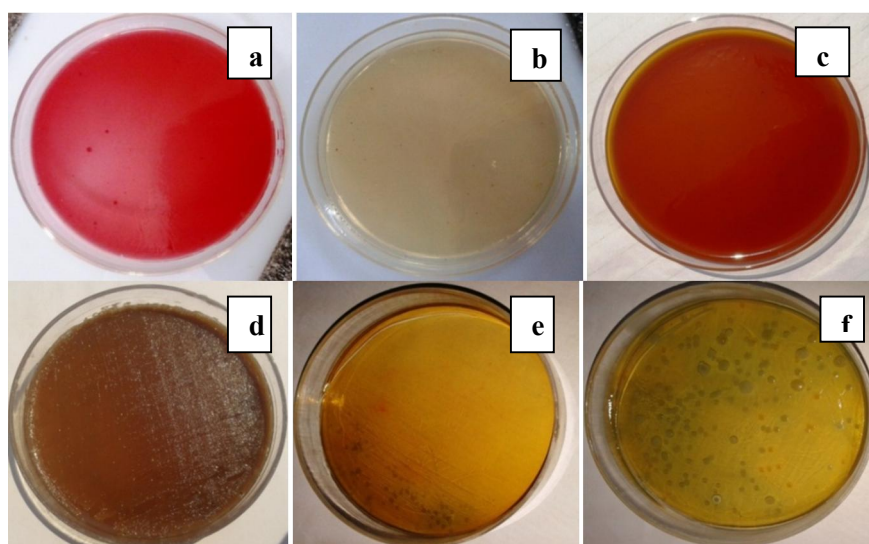


Plate. 2: Photographs of Microbiological limit test in Panchasakara churna. (a) *Escherichia coli*, (b) *Pseudomonas aeruginosa*, (c) *Salmonella ebony*, (d) *Staphylococcus aureus*, (e) Total Fungal Count, (f) Total bacterial count.

Table 5: Results of Microbial load of Panchasakara churna.

Microbial Analysis	Limit*	Observation
Total bacterial count	NMT 10 ⁵ CFU/mL	160 CFU/mL
Total yeast and mould	NMT 10 ³ CFU/mL	46 CFU/mL
<i>E. coli</i>	Absent	Absent
<i>S. spp.</i>	Absent	Absent
<i>S.aureus</i>	Absent	Absent
<i>P.aeruginosa</i>	Absent	Absent

*As per limits mentioned Ayurvedic Pharmacopoeia of India (API).

Table 6: Heavy metal analysis of Panchasakara churna.

Sr. No.	Heavy Metal	Standard Limit (ppm)	Observed Value (ppm)
1	Arsenic	3 ppm	0.02 ppm
2	Lead	10 ppm	4.33 ppm
3	Mercury	1 ppm	0.06 ppm
4	Cadmium	0.3 ppm	0.01 ppm
5	Nickel	NA	4.02 ppm
6	Zinc	NA	29.41 ppm
7	Copper	NA	23.19 ppm

*As per limits mentioned in Ayurvedic Pharmacopoeia of India (API). NA - Not available in Ayurvedic Pharmacopoeia of India.

d. TLC study

The TLC profiles of the methanolic extracts of the Churna with that of its ingredients using Toluene: Chloroform: Acetone: Ethyl acetate: Formic acid (7.3:2.5:0.2 v/v) solvent system showed good separation of its components with characteristic spots at R_f 0.76, 0.59, 0.10, 0.82, 0.05, 0.46 indicating presence of Shunti, Swarnapatri, Saunf, Haritaki respectively. The results of the TLC study at 254 nm and 366 nm are shown in Table 7-Table 8 and plate images shown in Plate. 3.

Table 7: TLC Screening of Raw materials vs. Panchasakara Churna at 254 nm.

R_f Values				
Track A (Shunti)	Track B (Swarnapatri)	Track C (Saunf)	Track D (Haritaki)	Track S (Panchasakara Churna)
0.42	0.06	0.02	0.05	0.05
0.76	0.12	0.10	-	0.10
-	0.59	0.17	-	0.12
-	-	0.29	-	0.17
-	-	0.31	-	0.29
-	-	0.34	-	0.31
-	-	0.82	-	0.34
-	-	-	-	0.42
-	-	-	-	0.59
-	-	-	-	0.76
-	-	-	-	0.82

Table 8: TLC Screening of Raw materials vs. Panchasakara Churna at 366 nm.

R_f Values				
Track A (Shunti)	Track B (Swarnapatri)	Track C (Saunf)	Track D (Haritaki)	Track S (Panchasakara Churna)
0.03	0.06	0.02	0.16	0.02
0.42	0.12	0.05	0.46	0.05
0.76	0.59	0.08	0.53	0.06
-	0.74	0.10	-	0.08
-	0.80	0.18	-	0.10
-	-	0.25	-	0.25
-	-	0.56	-	0.42
-	-	0.58	-	0.46
-	-	-	-	0.59
-	-	-	-	0.76
-	-	-	-	0.80

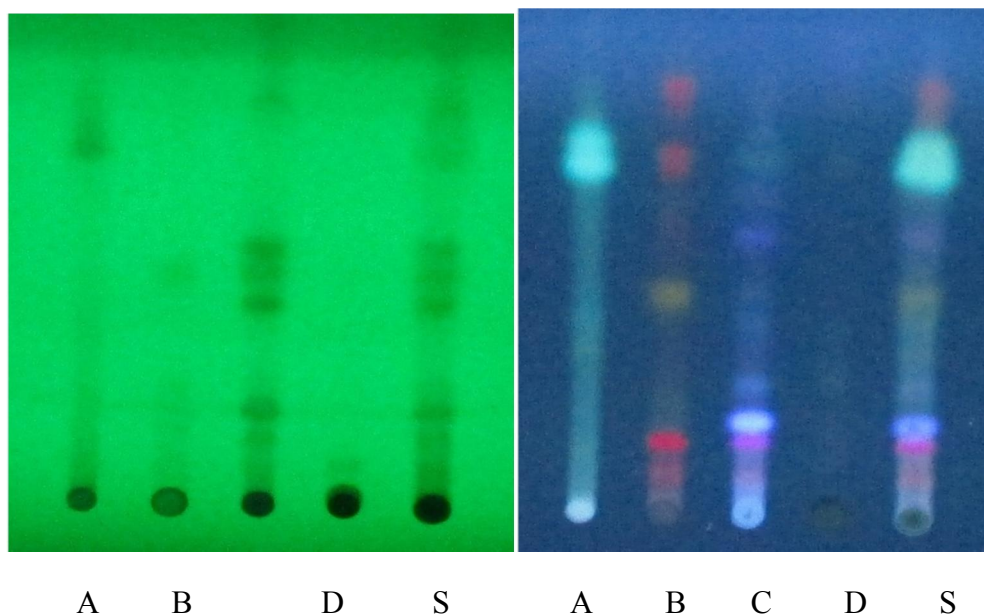


Plate. 3: Photographs of TLC plates of Panchasakara Churna and individual ingredients at 254 nm and 366 nm before derivatization. (A) Shunti, (B) Swarnapatri, (C) Saunf, (D) Haritaki, (S) Panchasakara churna.

In the present work, the classical Ayurvedic formulation Panchasakara Churna was characterized by pharmacognostic, physicochemical, pharmaceutical, microbiological, toxicological and chromatographic parameters as per the present standards of Ayurvedic Pharmacopoeia of India (API). Standardization guidelines provided by World Health Organization (WHO), European Agency for Evaluation of Medicinal Products (EMA) and United States Pharmacopoeias (USP) were also been considered [22-24]. This study may be utilised for rapid authentication fingerprints for the formulation, achieving batch-to-batch consistency and preparing a concise quality monograph for Panchasakara Churna.

4.3 The quality control parameters of Jatyadi Ghrita

The quality control parameters of one of the trial drugs namely- Jatyadi Ghrita have already been established and published, the test results of this drug have been compared with those which were published in the Ayurveda Pharmacopoeia of India and Ayurveda Formulary of India and it was observed and ensured that the test results of the Jatyadi ghrita were conformed with the results published in these documents.

4.4.1 Establishment of quality control parameters of Yasthimadhu Ghrita

Since the the quality control parameters of the other trial drug namely- Yasthimadhu Ghrita are not available in Ayurveda Pharmacopeia of India and Ayurveda Formulary of India, these drugs were analysed scientifically for the establishment of quality control parameters as per the standard guidelines set for them.

Table 1: Composition of Madhuyashti Ghrita

Sanskrit Name	Scientific Name	Part used	Quantity
Madhuyashtikalpa	<i>Glycerrhiza glabra</i> Linn.	Rhizome	50 part
Ghrita (Go Ghrita)	-	-	200 part
Water	-	-	800 part

Table 2: Organoleptic properties of raw materials and Madhuyashti Ghrita

Test	Cow's ghee	Madhuyashtikalpa	Madhuyashti Ghrita
Colour	Golden yellow	Brownish yellow	Dark yellow
Odour	Characteristic, pleasant	Sweetish	Characteristic, pleasant
Texture	Granular, oily	-	Oily
Touch	Oily	-	Oily
Taste	Characteristic	Sweet, bitter	Sweet, bitter

Table 3: Physicochemical parameters of Madhuyashti Ghrita

Test	Result
Acid value	4.712
Saponification value	214.79
Peroxide value	8.12
Refractive Index	1.4518
Rancidity test	Negative
pH value	5.2

Table 4: Heavy metal analysis of Madhuyashti Ghrita

Sr. No.	Heavy Metal	Observed Value (ppm)
1	Arsenic	0.55 ppm
2	Lead	3.60 ppm
3	Mercury	1.17 ppm
4	Cadmium	0.04 ppm
5	Nickel	1.30 ppm
6	Zinc	4.60 ppm
7	Copper	1.02 ppm
8	Chromium	1.65 ppm

*As per limits mentioned in Ayurvedic Pharmacopoeia of India (API).

NA -Not available in Ayurvedic Pharmacopoeia of India.

Table 5: TLC Screening of Madhuyashtikalpa vs. Madhuyashti Ghrita at 254 and 366 nm.

R_f Values			
254 nm		366 nm	
Track A (<i>Madhuyashtikalpa</i>)	Track B (<i>Madhuyashti Ghrita</i>)	Track A (<i>Madhuyashtikalpa</i>)	Track B (<i>Madhuyashti Ghrita</i>)
0.2	0.2	0.2	0.2
0.4	0.4	0.4	0.4
0.8	0.8	0.8	0.8
0.12	0.12	0.12	0.12
0.16	0.16	0.16	0.16
0.21	0.21	0.21	0.21
0.28	0.28	0.28	0.28
0.36	0.32	0.32	0.33
0.4	0.36	0.36	0.36
0.46	0.4	0.4	0.4
-	0.46	0.46	0.46
-	-	0.5	0.5

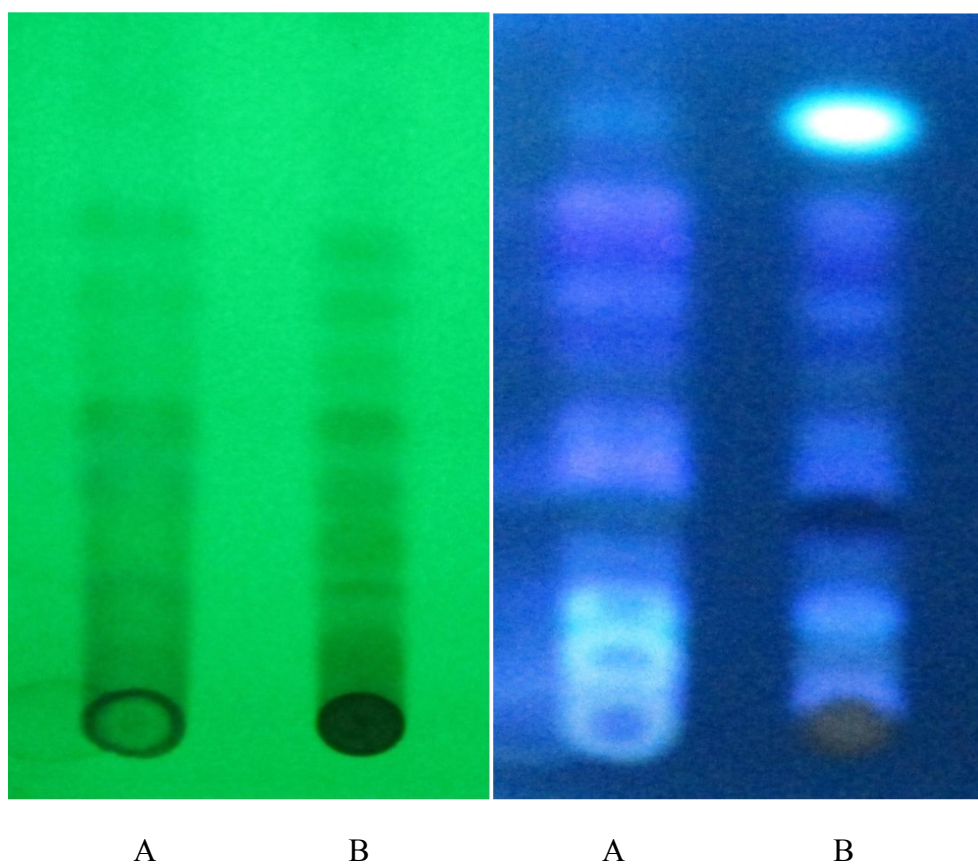


Plate 4: Photographs of TLC plates of Madhuyashti Ghrita and Madhuyashtikalpa at 254 nm and 366 nm before derivatization. (A) Madhuyashti Ghrita (B) Madhuyashtikalpa.

Table 6: Results of Microbial load of Madhuyashti Ghrita

Microbial Analysis	Observation
Total bacterial count	212 CFU/mL
Total yeast and mould	2 CFU/mL
<i>E. coli</i>	Absent
<i>S. spp.</i>	Absent
<i>S.aureus</i>	Absent
<i>P.areuginosa</i>	Absent

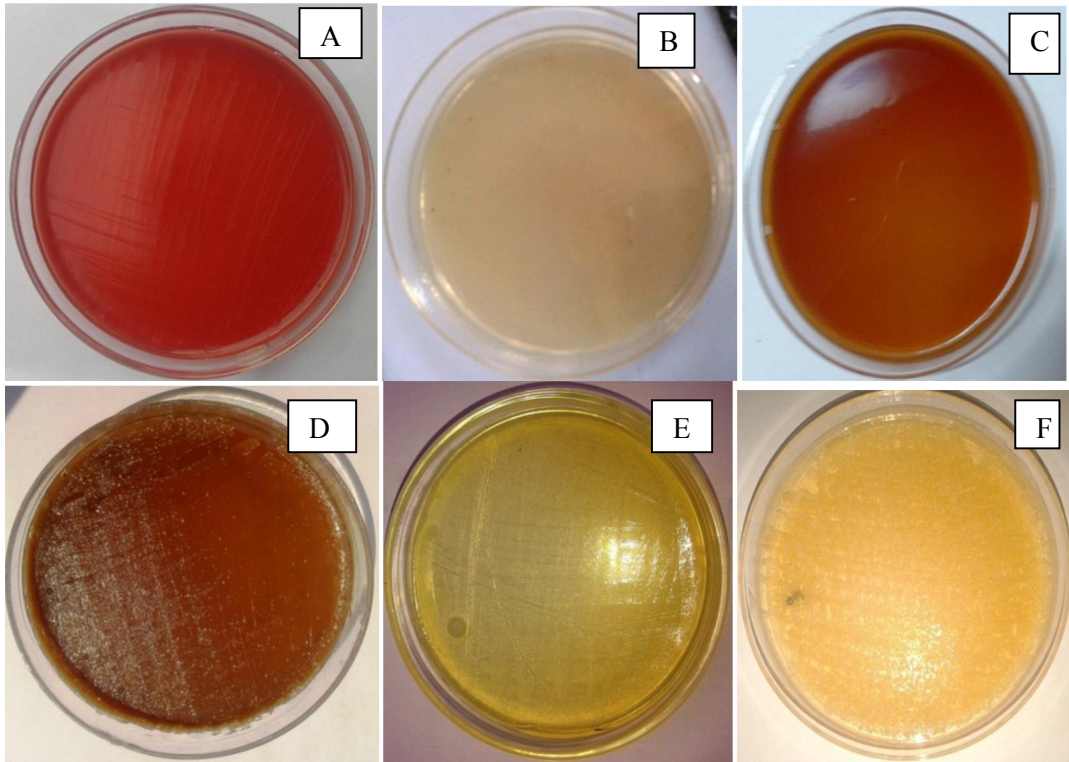


Plate 5: Photographs of Microbiological limit test in Madhuyashti Ghrita. (a) *Escherichia coli*, (b) *Pseudomonas aeruginosa*, (c) *Salmonella ebony*, (d) *Staphylococcus aureus*, (e) Total Fungal Count, (f) Total bacterial count.

4.5 Standard Operative Procedures

4.5.1 Churna

Definition: Churna is a fine powder of drug or drugs.

General Method of preparation:

Drugs mentioned in the Yoga are cleaned and dried properly (20 gm. Each). They are finely powdered and sieved. Where there are a number of drugs in yoga, the drugs are separately powdered and sieved. Each one of them (powder) is weighed separately, and well mixed together. As some of the drugs contain more fibrous matter than other, this method of powdering and weighing them separately them, according to the Yoga, and then mixing them together, is preferred.

In industry, however, all the drugs are cleaned, dried and powdered together by disintegrators. Mechanical sifters are also used. Salt, sugar, camphor etc., when mentioned are separately powdered and mixed with the rest at the end. Asafoetida (Hingu) and salt may also be roasted, powdered and then added. Drugs like Satavari, Guduci, etc., which are to be taken fresh, is made into a paste, dried, and then added.

Characteristics and preservation

The powder is fine of at least 80 mesh sieves. It should not adhere together or become moist. The finer the powder, the better is its therapeutic value. They retain potency for one year¹ and should be kept in air tight containers.

Note:

Potency of Churna is 1 year is according to Sarngadharasamhita, Prathamakhanda, Adhyaya 1; sloka 51-53, with commentary of Adhamalla.

4.5.2 Ghrita (Snehakalpa):

Definition:

Ghritas are preparations in which ghee is boiled with prescribed Kasayas (decoctions) and kalkas of drugs according to the formula. This process ensures absorption of the active therapeutic principles of the ingredients used.

General method of preparation:

1. There are generally three essential components for the preparation of sneha (Ghrita or Taila) viz:-
 - i. Drava (a liquid which may be one or more as Kasaya, Svarasa, Dugdha, Mastu, etc.)
 - ii. Kalka (a fine paste of the drug(s))
 - iii. Snehadravya (Ghrita, Murcchita Ghrita1).

2. Generally, unless otherwise mentioned in the text if kalka is one part by weight, sneha should be four parts and the drava-dravya should be sixteen parts.

Exceptions are:

- (i) Where no drava is prescribed, four parts of water is added to one part of sneha; the kalka is one fourth the weight of sneha.
- (ii) Where drava-dravya is Kvatha, kalka should be one -sixth of sneha.
- (iii) Where the dravadravya is svarasa, Ksira, Takra, Dadhi etc. The kalka should be one eighth of the sneha and then 4 times water is also added for good Paka.
- (iv) Where the number of dravadravys is four or less than four, each drava has to be taken four times the weight of sneha.
- (v) Where the dravadravys are 5 or more, each drava will be equal in weight to the sneha.
- (vi) If in a preparation, no kalka is prescribed, then the drugs of the Kasaya may be used as kalka.

3. The kalka and the drava are mixed together, sneha is then added, boiled on mild fire and stirred well continuously so that the kalka is not allowed to adhere to the vessel. Sometimes, the drava-dravyas are directed to be added one after another as the process of the boiling is continued till the dravadravaya added earlier has evaporated.
4. When all the drava dravyas have evaporated the moisture in the kalka will also begin to evaporate; at this stage, it has to be stirred more often and carefully to ensure that the kalka does not stick to the bottom of the vessel. The kalka is taken out of the ladle and tested from time to time to know the condition and stage of the Paka.
5. There are three stages of Paka
 - (i) Mrdu Paka,
 - (ii) Madhyama Paka and
 - (iii) Khara Paka.

In Mrdu Paka kalka is waxy and when rolled between the fingers, rolls like lac with slight sticking. In Madhyama Paka kalka is soft, non-sticky and rolls between fingers and when put in fire burns without any cracking noise. A further degree of heating leads to Khara paka which is slightly hard. Any further heating will lead to dagdha Paka and the sneha becomes unfit for use.

6. In the sneha group Sarkara if mentioned, is added in fine powder form to the final product when cool.
7. Where the Paka is to be done with Kvatha, Svarasa, Dugdha, Mamsarasa, etc. The Paka is to be done with these dravas separately in the above order. The period[^] of Paka with various dravyas should be as below:
 - i. Kvatha, Aranala, Takra etc. -5 days
 - ii. Svarasa -3 days
 - iii. Dugdha -2 days
 - iv. Mamsarasa -1 day

8. Patrapaka : Patrapaka is the process by which the sneha is flavoured or augmented by certain soluble or mixable substances. The powders of the drugs are placed in the vessel into which fairly warm sneha is filtered.

9. Mrdupaka Sneha is used for nasya; Madhyama paka Sneha is used for Pana, Vasti, etc.; Kharapaka Sneha is used only for Abhyanga.

10. In the beginning the boiling should be on mild fire and in the end also it should be only on mild (Mridagni) fire.

11. Whenever Lavanas and Ksaras are used in these preparations, they are added to the sneha and then strained.

Characteristics:

The Ghrita will generally solidify when cooled. It will have the colour, odour and taste of the drug(s) used.

Preservation:

Ghritas are preserved in glass, polythene or aluminium containers. Ghritapreparation for internal use keep their potency for about sixteen months.

Method of use:

Generally the Anupana for internal use, when not specified, is warm water or warm milk. The Ghrita has to be taken after warming. This is taken with the medium of other liquids also.

Note:

- i. The method or Mürccana of Ghrita is given in Paribhasakhanda.
- ii. Sarngadharasamhita, Madhyamakhanda , Adhyaya 9/12-16
- iii. Period as mentioned in VaidyakaParibhasapradipa which is reproduced below.

" ksiraedviratramsvarasaetriratramtakraranaladisupancartram
Snaehampacetvaidyavarahprayatnat....."

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Chapter 5 : Materials and Methods

The acute fissure is a superficial splitting of the anoderm characterized by severe pain, sometimes associated with bleeding per rectum during/after defaecation.

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.

Taking this view in to consideration, a clinical trial was kept on 200 patients of established cases of fissure-in-ano in two groups with 100 patients in each group. The patients in group-I were applied jatyadi ghrita while in group-II, Yasthimadhu ghrita both in Pichu form along with Panchasakara churna orally in both groups.

The patients were admitted for the clinical study from the Ano-Rectal Clinic of the Institute after getting due approval of the Institutional Ethical Committee of National Research Institute of Ayurvedic Drug Development, Bhubaneswar.

All the patients informed about the clinical trial and supplied a copy of Patient information sheet that was translated in to the regional language and written consent was obtained from the patients and their attendants also prior to the initiation of the study. All the standard guidelines were followed strictly which are laid down for the clinical study. The raw drugs used for the preparation of the trial drugs were identified and authenticated as per the standard quality control parameters and were prepared as per the Standard Operative Procedures.

The study was planned with the following aim and objectives:

1. Evaluation of clinical efficacy of *Pichu* application of *Jatyadi Grihta* and *Yasthimadhu Grihta* 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.

5.1 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,

5.2 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.

5.3 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 ghritha or Yastimadhu ghritha 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.

5.4 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.

5.5 Exclusion Criteria:

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

5.6 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).

5.7 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

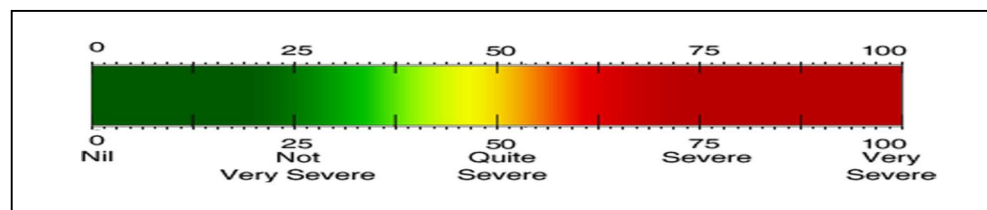
5.8 Assessment Criteria:

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.

5.8.1 Assessment Parameters:

(1) Clinical Parameters-

Visual Analogue Scale



Parameters Visual analogue Scale Score:

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

5.8.2 Criteria of Assessment :

Table 2 : Relief of Symptoms before and after treatment.

Sl. 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

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

Sl. 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

Sl. 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

5.8.3 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. Healing of Ulcer

- ◆ Not Healing
- ◆ Healing
- ◆ Completely Healed

3. Sphincter tone.

- ◆ Normal
- ◆ Spasmodic
- ◆ Tightly contracted

4. Anal sphincter tonicity is measured by self gradation method:

- ◆ 60 – 80 mm of Hg Grade 1 (Hypertonicity)
- ◆ 80 – 100 mm of Hg Grade 2 (Normal tonicity)
- ◆ 100 – 120 mm of Hg Grade 3 (Hypotonicity)

Chapter 6 : Observations and Results

Clinical study has been conducted on 200 clinically established patients of fissure-in-ano in the Ano-Rectal Clinic of National Research Institute of Ayurvedic Drug Development, Bhubaneswar. The observations were recorded under various parameters.

The total 200 patients have been divided in to two groups- Group-I and Group - II and 100 patients were kept in each group respectively. In Group - I, Jatyadi ghrita pichu was applied along with Panchasakara churna orally and in Group - II, Yasthimadhu ghrita pichu was applied along with Panchasakara churna orally and results were correlated and compared.

Careful observations were recorded under the following headings:

1. Condition of Patients on Admission: Age, Sex, Marrital Status, Religion, Habitat, Food Habits, Bowel Habits, Prakruti.
2. Characteristics of Fissure-in-ano (Parikartika) on Admission: Duration of illness, Onset of fissure, Severity of pain, Previous H/O treatment, Type of fissure, History of any Associated diseases.
3. Clinical features of Fissure-in-ano (Parikartika) on Admission: Itching Ani (Pruritis), Type of Edges, Position (O-Clock) of Fissure-in-ano, Sphincter tone Tenderness.
4. Result of the treatment : a) Subjective parameters : Pain on VAS, Bleeding, Constipation, b) Objective parameters : Sphincteric spasm, Size of Ulcer, Healing of Ulcer.

6.1 Observations

6.1.1 General (Demographical) Observations

Table 1: Distribution of patients according to age (Fig : 1):

Total number of 200 patients was divided in to four groups as shown in the table. The youngest patient has been of 21 years while the eldest patient has been of 60 years.

Age Groups (in Years)	No of Patients		Total No. Of Patients	Percentage%
	Group - I	Group - II		
21-30	21	15	36	18
31-40	41	51	92	46
41-50	24	26	50	25
51-60	14	8	22	11
Total	100	100	200	100

Above table shows the incidence of fissure was maximum (46%) under the age group of 31-40 yrs. while minimum of 11 percent in the age up of 51-60 years.

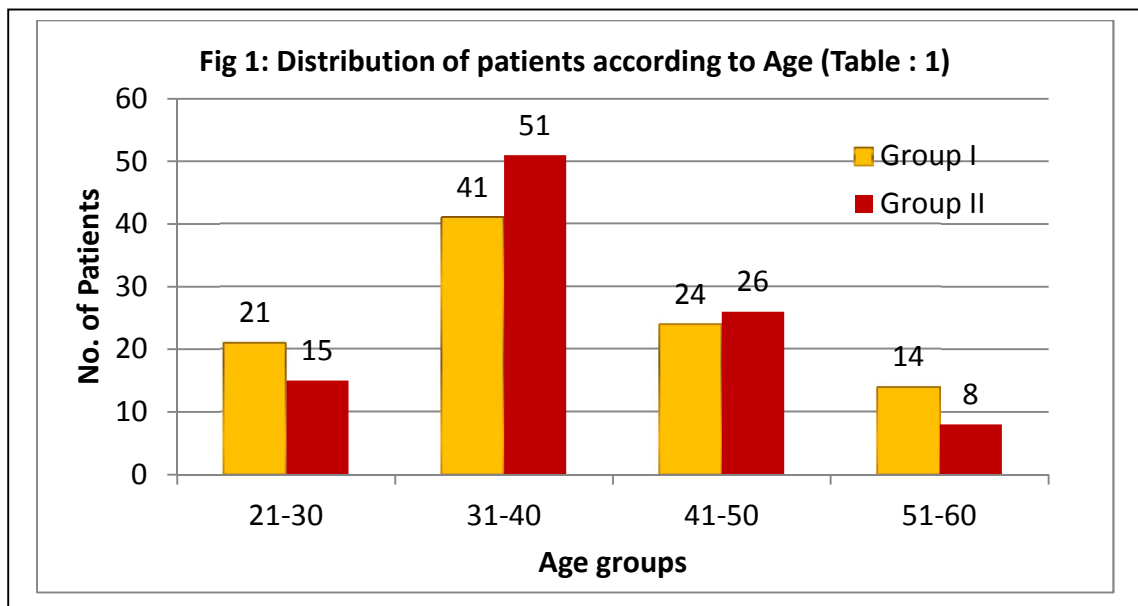


Table 2: Distribution of patients according to Gender (Fig : 2):

Gender	No of Patients		Total No. of Patients	Percentage%
	Group - I	Group – II		
Male	59	61	120	60
Female	41	39	80	40
Total	100	100	200	100

The maximum number of 120 patients (60 %) was males while the incidence was recorded minimum 80 cases (40 %) were females. This data suggest that the disease is predominantly common in males.

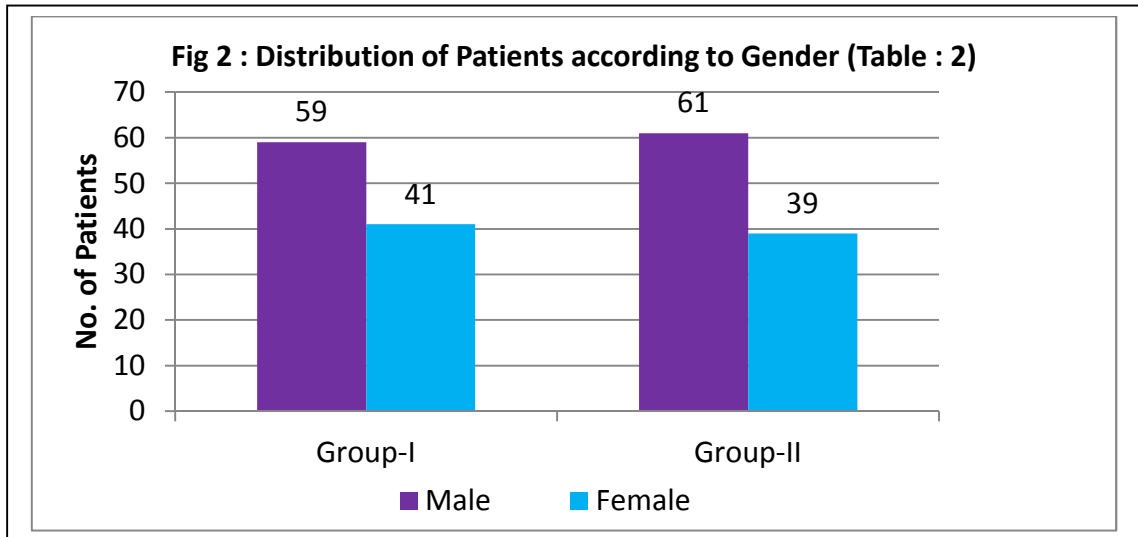


Table 3: Distribution of patients according to marital Status (Fig : 3):

Marital Status	No of Patients		Total No. of Patients	Percentage%
	Group - I	Group - II		
Married	84	88	172	86
Unmarried	16	12	28	14
Total	100	100	200	100

Married patients were reported maximum (86 %) while unmarried category was just 12%.

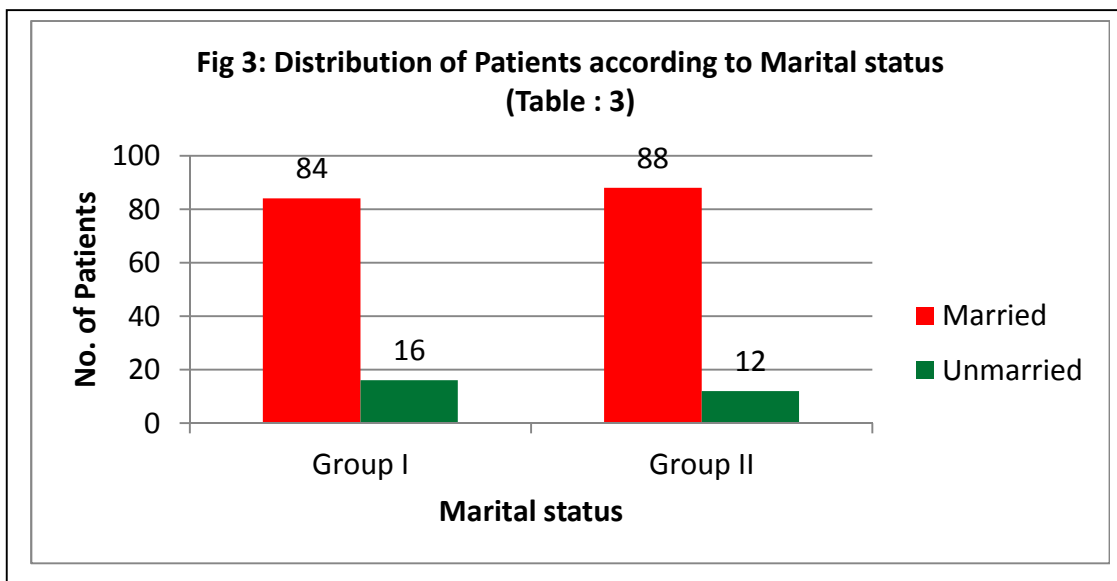


Table 4: Distribution of patients according to Religion (Fig : 4):

Religion	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Hindu	99	100	199	99.5
Muslim	01	0	01	0.5
Total	100	100	200	100

The maximum number of patients about 99.5 percent was from Hindu community.

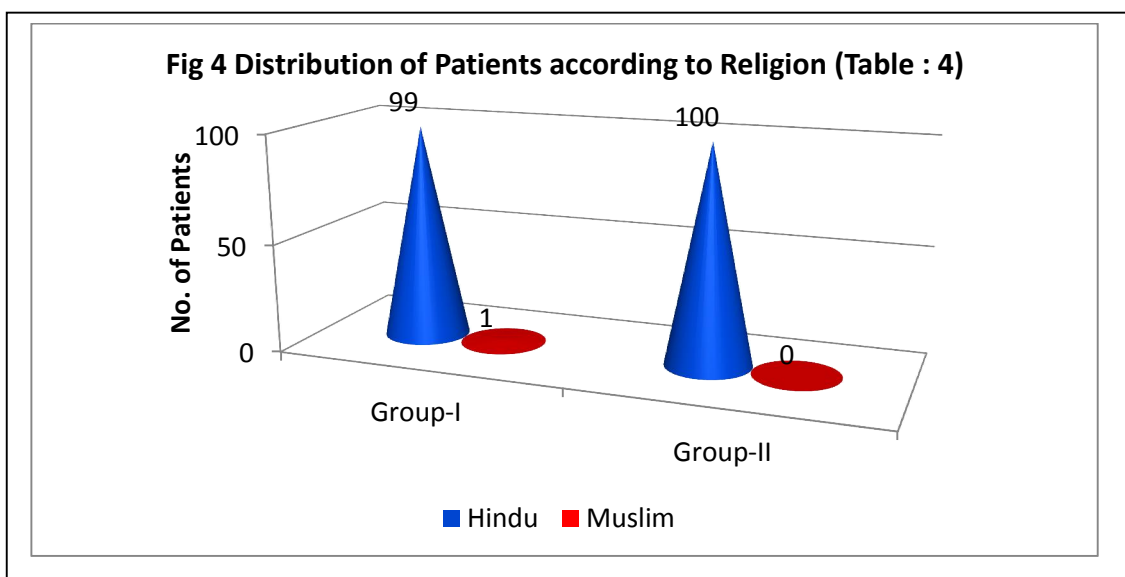


Table 5: Distribution of patients according to Habitat of Patients (Fig : 5):

Habitat	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Rural	28	4	32	16
Urban	72	96	168	84
Total	100	100	200	100

In the study it was observed that majority of the patients (84%) belonged to the Rural areas and rest of the patients (16%) belonged to Urban areas.

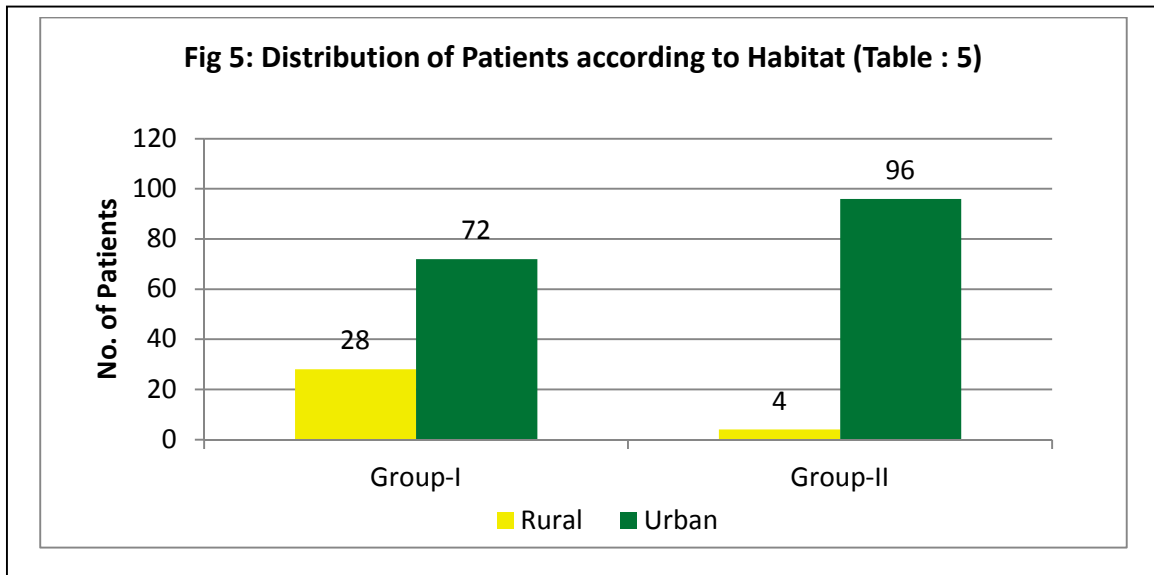


Table 6: Distribution of patients based on the food habits (Fig : 6):

Food Habits	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Non-Vegetarian	86	95	181	90.5
Vegetarian	14	05	19	9.5
Total	100	100	200	100

It was observed in the study that majority of the patients (90.5%) were non-vegetarians and 9.5 percent of the patients were vegetarians.

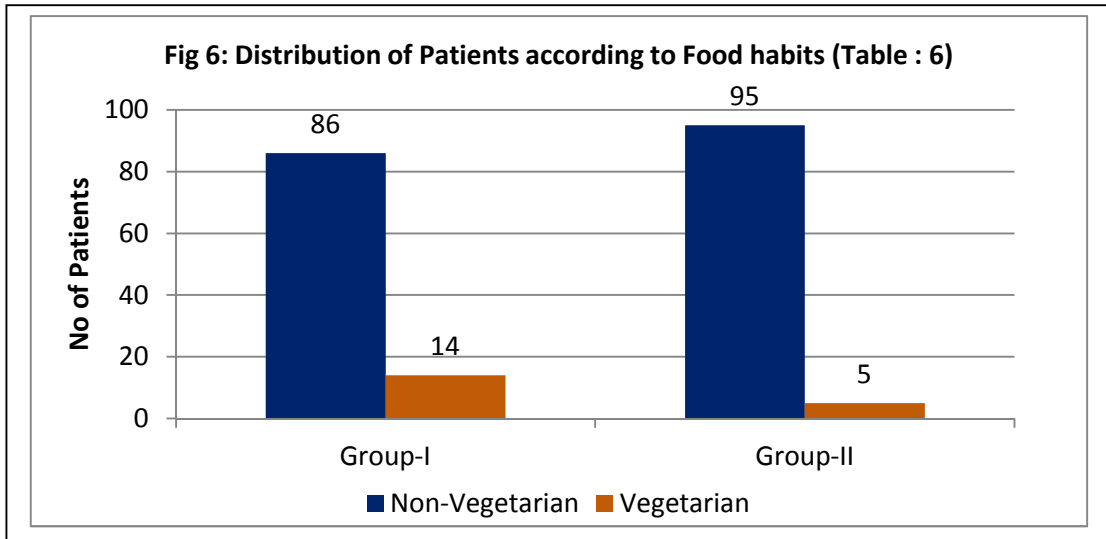


Table 7: Distribution of cases based on the bowel habits:

Religion	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Regular	02	01	02	1.5
Constipated	98	99	198	98.5
Total	100	100	200	100

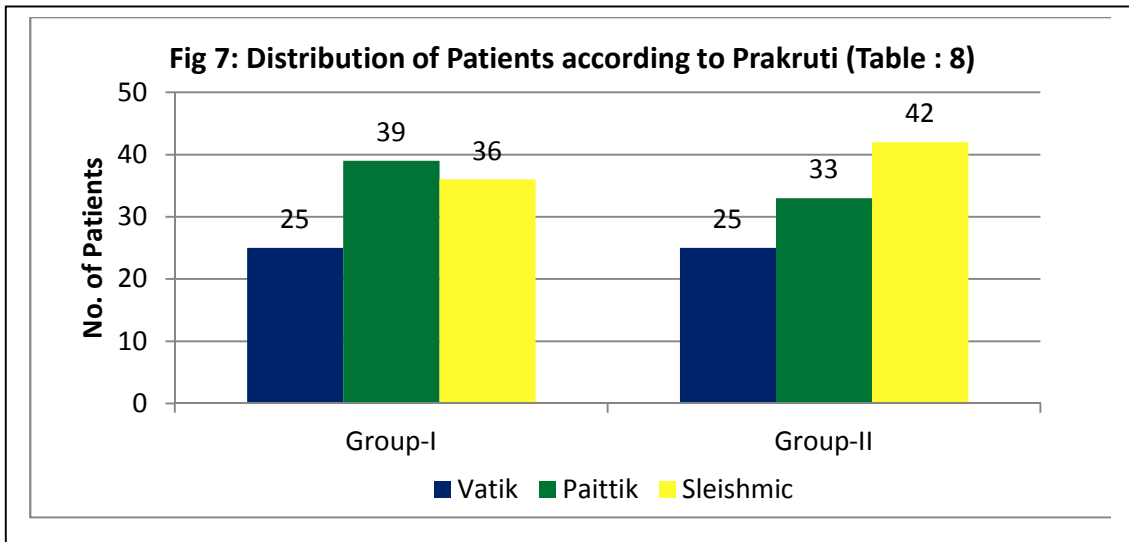
It was observed that majority of the patients (98.5%) suffered from constipation and few of the patients (1.5%) had regular bowel habits.

Table 8: Distribution of patients according to Prakruti (Fig : 7):

Prakruti	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Vatik	25	25	50	25
Paittik	39	33	72	36
Shleishmic	36	42	78	39
Total	100	100	200	100

The Prakruti of patients was determined as per standard proforma designed in the Institute (CCRAS).

Out of 200 cases, maximum number of (39%) patients was belonged to Shleishmic prakruti, 36% to Paittik and 25% belonged to Vatik prakruti.



6.1.2 Characteristics of Fissure-in-ano (Parikartika) on Admission:

Table 9: Distribution of cases in the study based on the chronicity of the disease (Fig : 8):

Duration of Illness (in days)	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Upto 365	47	48	95	47.5
366-730	21	24	45	22.5
731-1095	32	28	60	30
Total	100	100	200	100

The total patients were categorized in to three groups according to duration of the disease as shown in the above table.

Out of 200 patients, 47.5 percent reported chronicity of one year or less, 30 percent were reported with the duration of illness of 1-2 years and 22.5 percent of cases had more than 3 years of duration. The data reveals that maximum number of patients has the chronicity of one year or less.

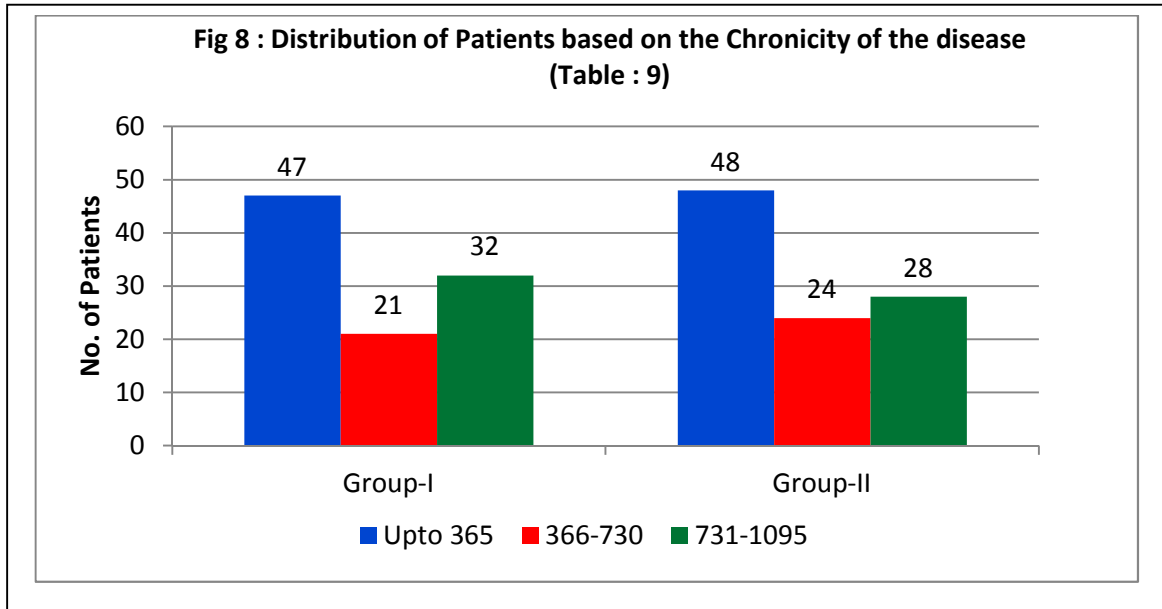


Table 10: Distribution of cases in the study based on the onset of the disease (Fig : 9):

Onset of fissure	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Acute	62	73	135	65.5
Gradual	38	27	65	32.5
Total	100	100	200	100

The above table shows that the maximum number of cases (65.5%) had acute onset while 32.5 percent had gradual onset of the disease.

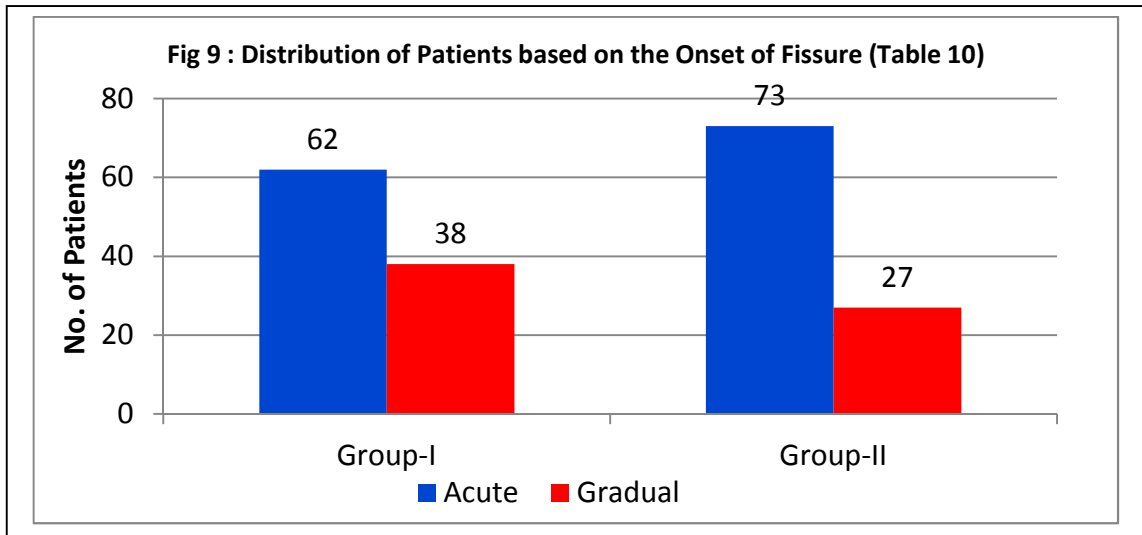


Table 11: Distribution of cases in the study based on the severity of Pain (Fig : 10):

Severity of Pain	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Mild	28	34	62	31
Moderate	50	48	98	49
Severe	22	18	40	20
Total	100	100	200	100

As per the data, maximum number patients (49%) suffered from moderate pain, 31 percent of patients has mild pain while 20 percent of patients had severe pain.

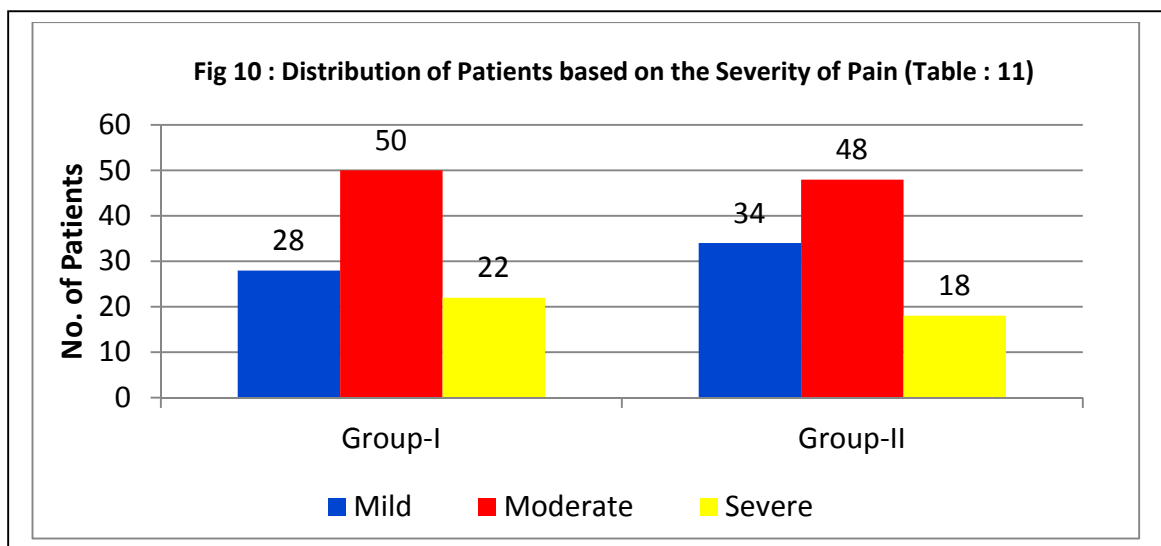


Table 12: Distribution of cases in the study based on previous history of treatment (Fig : 11):

Previous H/O Treatment	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Fresh	69	55	124	62
Medical	28	30	58	29
Surgical	3	15	18	9
Total	100	100	200	100

Cases were analysed in view of previously treated (medical and or surgical) and fresh cases in fissure-in-ano.

Out of 200 cases 62 percent were reported as fresh cases while 29 had medical intervention and 9 percent had previous history of operation i.e hemorrhoidectomy.

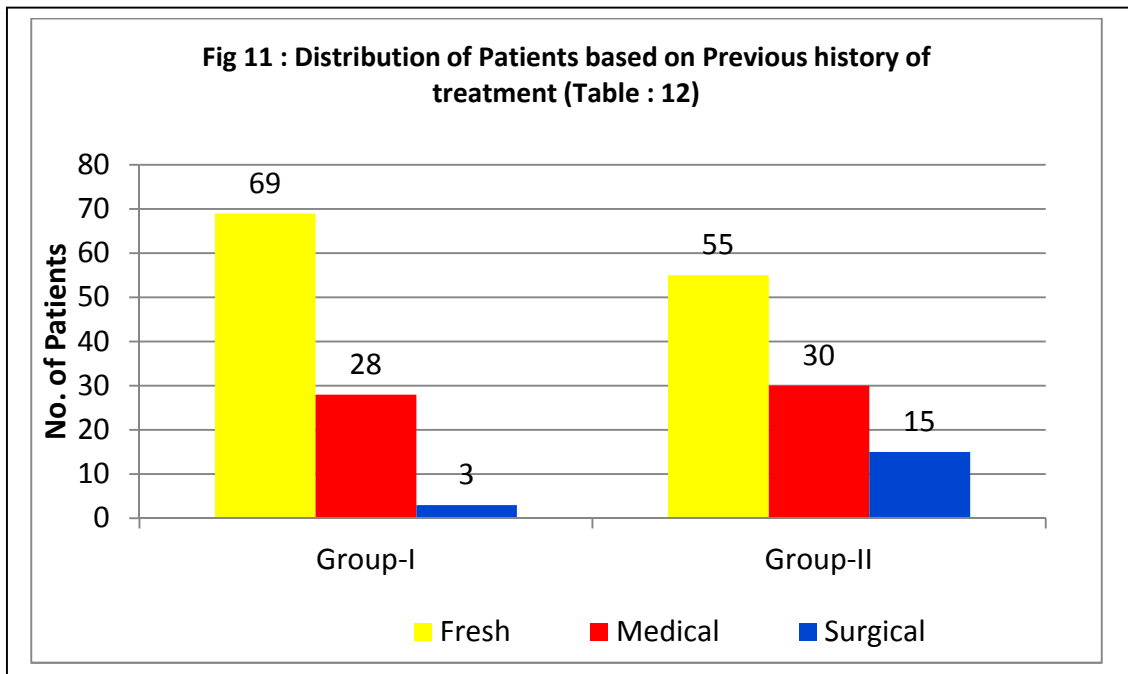


Table 13: Distribution of cases in the study based on type of fissure (Fig : 12):

Type of Fissure	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Acute	41	32	73	36.5
Acute on Chronic	32	44	76	38
Chronic	27	24	51	25.5
Total	100	100	200	100

The study revealed that maximum number (38%) of cases reported with acute type of fissures.

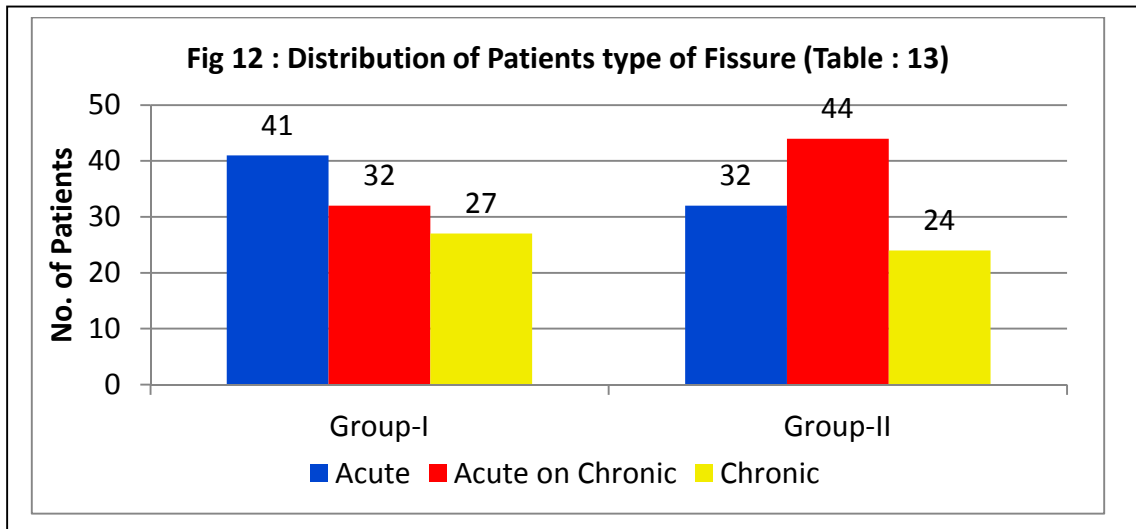
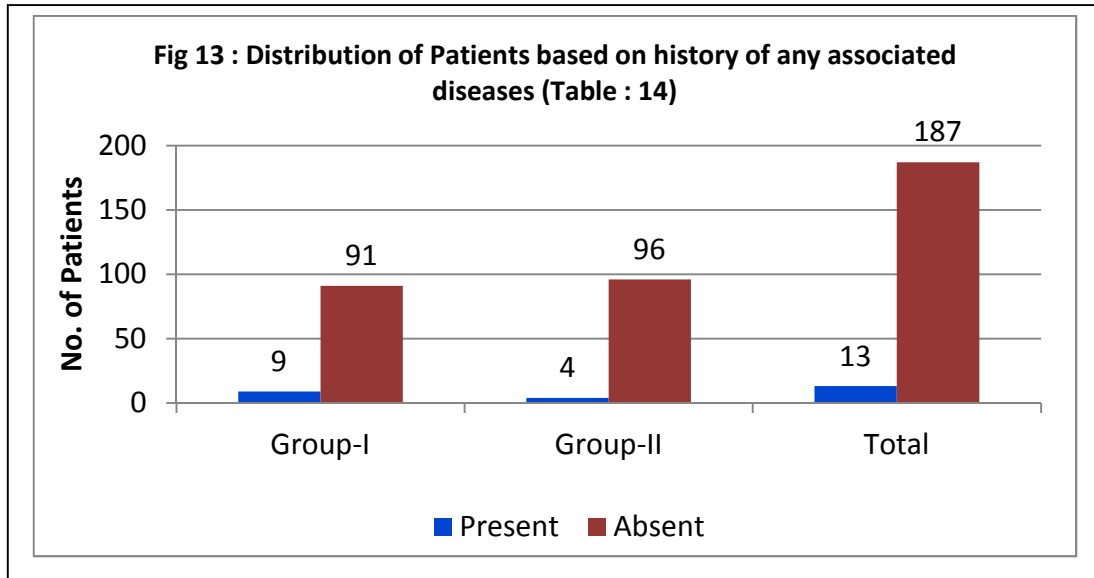


Table 14: Distribution of cases in the study based on history of any associated diseases (Fig : 13):

History of any Associated Diseases	No of Patients		Total No. of Patients	Percentage %
	Group-I	Group-II		
Present	9	4	13	6.5
Absent	91	96	187	93.5
Total	100	100	200	100

The above table shows that 93.5 percent of cases had no history of any associated diseases while 6.5 percent had some other diseases which directly had no relation with fissure-in-ano.

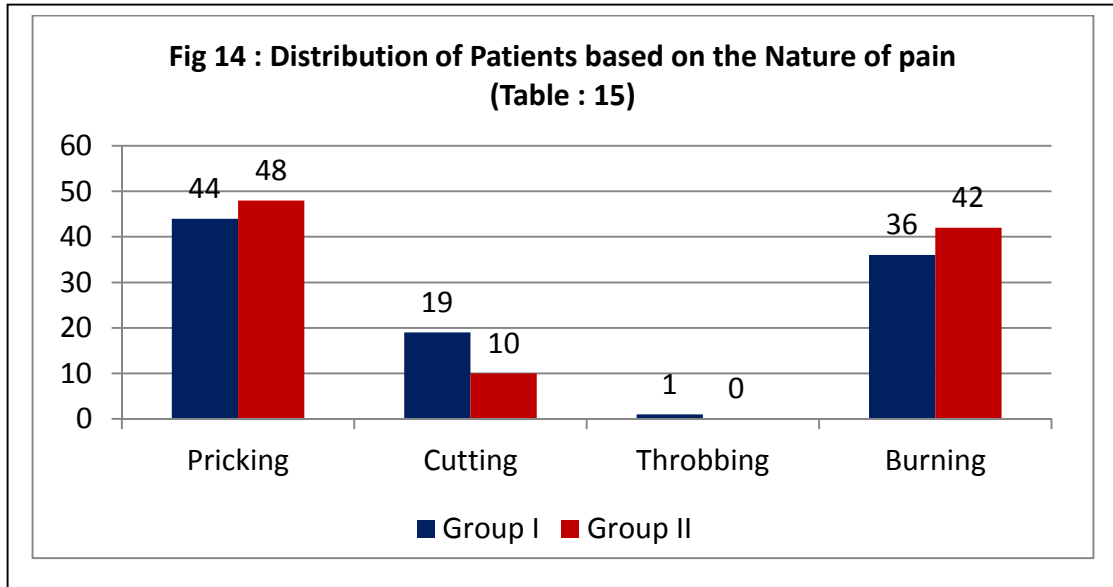


6.1.3 Clinical features of Fissure-in-ano (Parikartika) on Admission:

Table 15: Distribution of cases in the study based on nature of pain (Fig : 14):

Nature of Pain	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Pricking	44	48	92	46
Cutting	19	10	29	14.5
Throbbing	1	0	01	0.5
Burning	36	42	78	39
Lehing	0	0	00	0
Total	100	100	200	100

An attempt was made to record the nature of pain that patients suffered from and the above table shows that maximum number (46%) of cases had pricking type of pain followed by burning type of pain with the incidence of 39 percent.



**Table 16: Distribution of cases in the study based on the type of bleeding
(Fig : 15):**

Type of Bleeding	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Persistent	0	0	00	0
During / Defecation	59	45	104	52
Mixed with Stool	41	55	96	48
Malena	0	0	00	0
Total	100	100	200	100

The above table shows that maximum number (52%) of patients had bleeding per rectum during / after the defaecation and 48 percent of cases had mixed with stool.

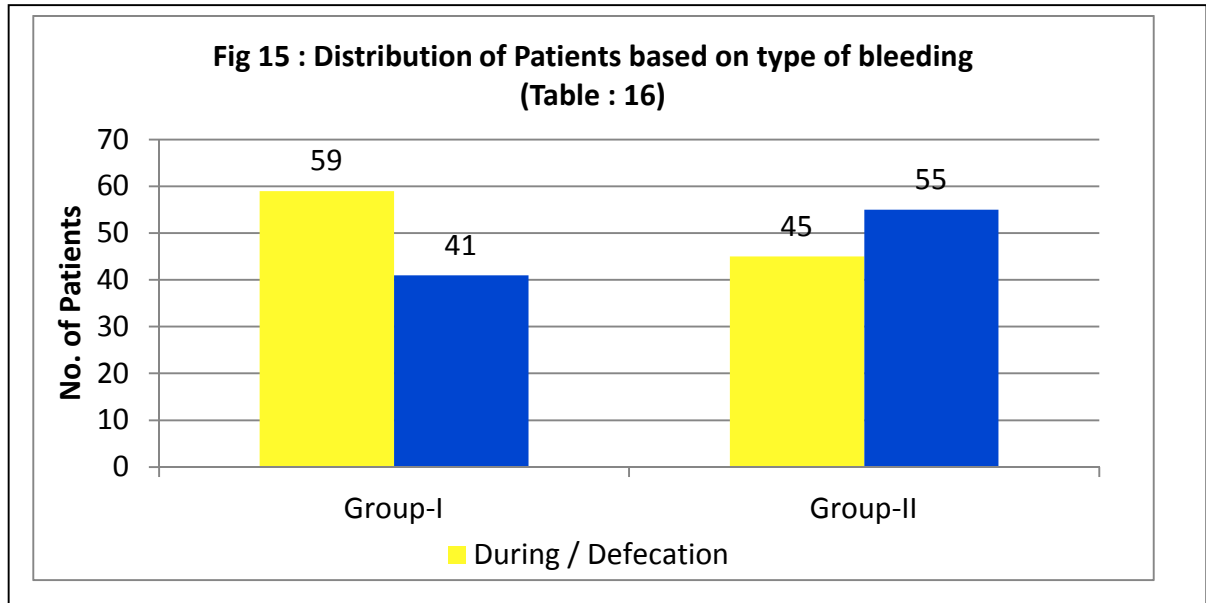


Table 17: Distribution of cases in the study based on Pruritis (Itching ani) (Fig : 16):

Itching Ani (Pruritis)	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Present	25	80	105	52.5
Absent	75	20	95	47.5
Total	100	100	200	100

The analysis shows that 52.5 percent of patients had itching ani.

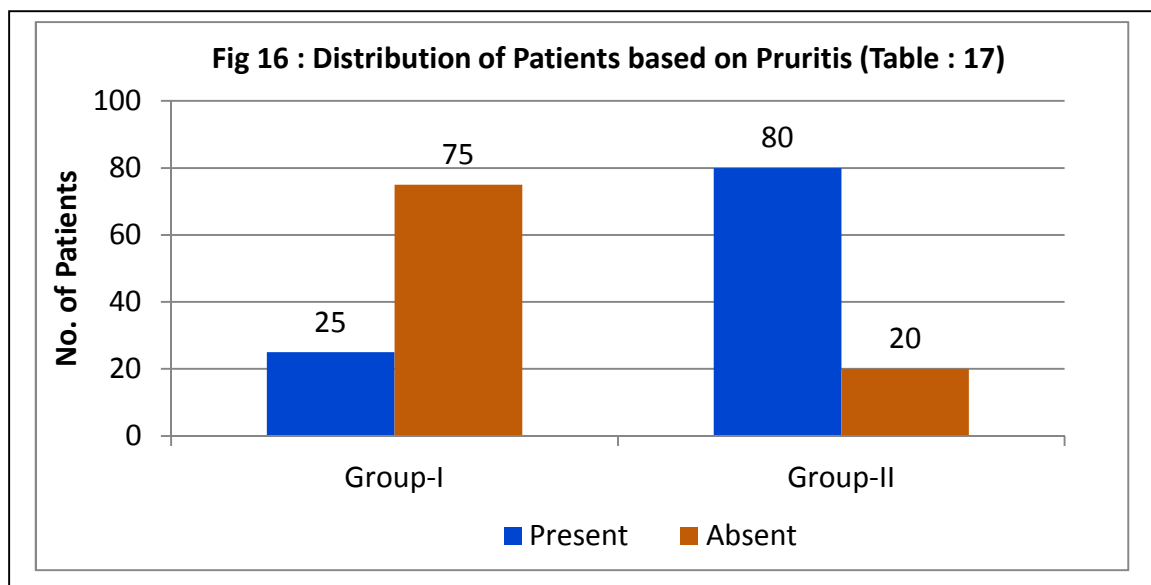


Table 18: Distribution of cases in the study based on Position (O-Clock) of Fissure-in-ano (Fig : 17):

Position (O-Clock) of Fissure-in-ano	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
2	1	0	01	0.5
3	1	3	04	2
4	3	5	08	4
5	13	7	20	10
6	55	57	112	56
7	21	19	40	20
10	1	2	03	1.5
11	0	2	02	1
12	5	5	10	5
Total	100	100	200	100

Clock wise position of the presence of fissure-in-ano was also studied to find out the commonest O' clock position of the disease.

Analysis shows that commonest position of the fissure was at 6 O' clock with maximum incidence of 56 percent.

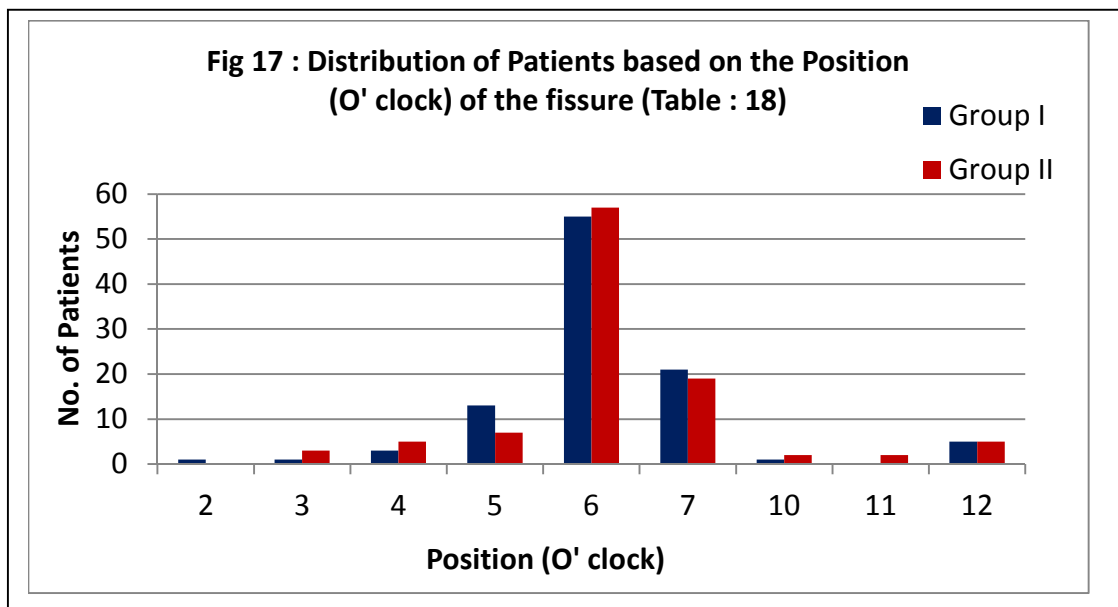


Table 19: Distribution of cases in the study based on Sphincter tone (Fig : 18):

Sphincter tone	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Normal	8	7	15	7.5
Hypertonic	92	93	185	92.5
Total	100	100	200	100

Efforts were made to record the intensity of the spasm of the sphincter as per the criteria laid down for this purpose. Analysis shows that maximum number of (92.5%) patients had the hypertonic sphincter.

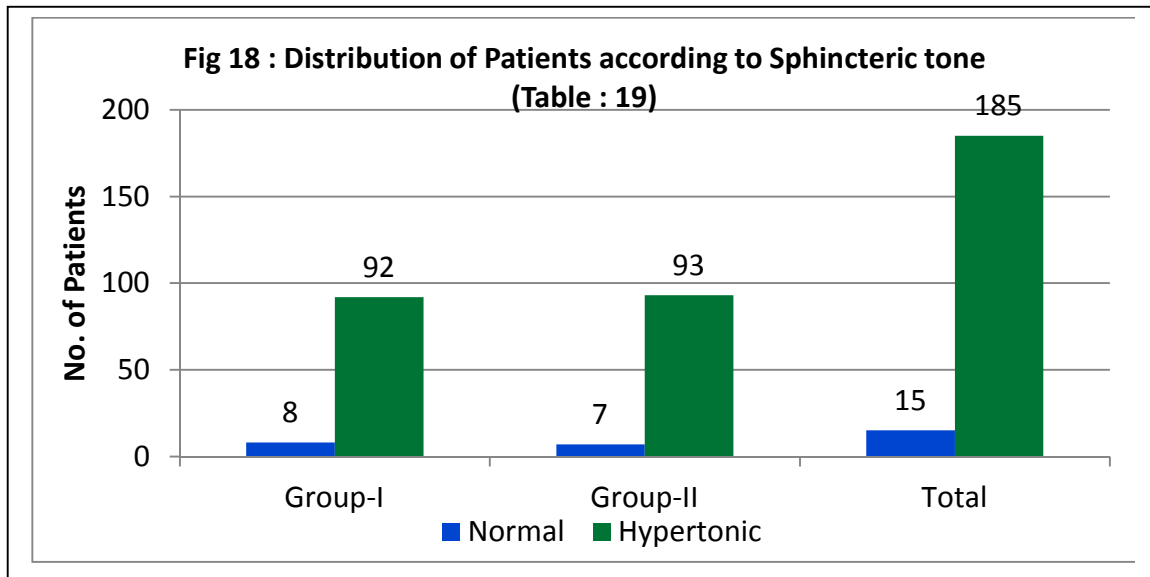
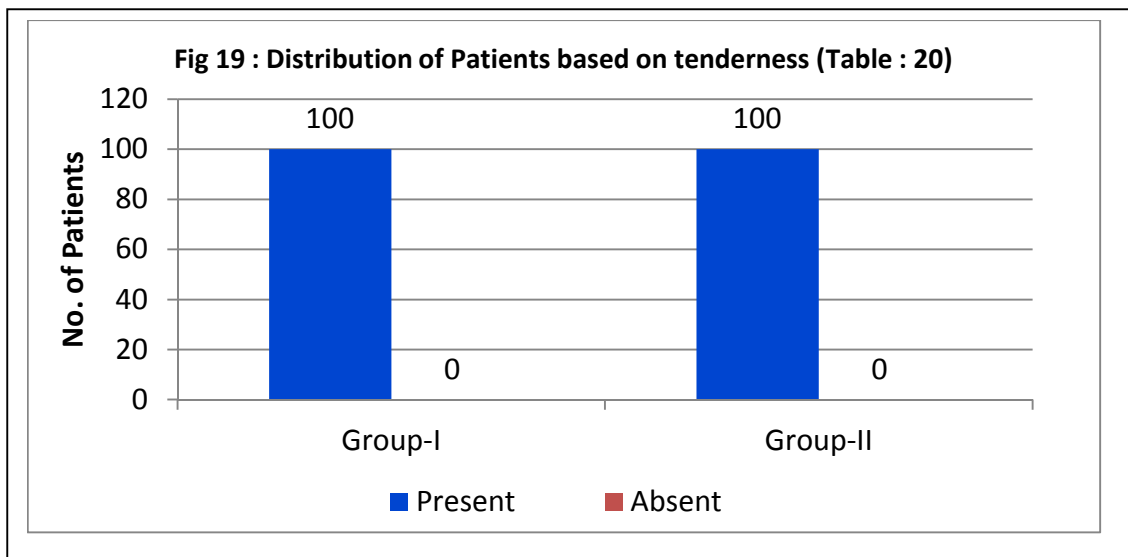


Table 20: Distribution of cases in the study based on tenderness (Fig : 19):

Tenderness	No of Patients		Total No. of Patients	Percentage%
	Group-I	Group-II		
Present	100	100	200	100
Absent	0	0	0	0
Total	100	100	200	100

The above table shows that all the patients had the tenderness because of presence of active ulcer at the site.



6.2 Results

In this study, a total number of 200 patients of Fissure-in-ano were treated in two groups each comprising of 100 patients. The patients of one group were applied Pichu of Jatyadi ghrita along with oral administration of Panchasakara churna (Group-I) and patients of other group were applied Pichu of Yasthimadhu ghrita along with oral administration of Panchasakara churna (Group-II). The results obtained were analysed systematically and scientifically under as per the assessment criteria laid down for this purpose.

6.2.1 Assessment of the Treatment with jatyadi ghrita (Group-I) and Yasthimadhu ghrita (Group-II):

As indicated above the trial drugs were applied in the form of pichu i.e the sterile gauze was dipped in the respective trial drugs and placed on the fissure bed daily once for 21 days or till the fissure / ulcer is completely healed or till the complaints are completely alleviated whichever is earlier. Its effect on both subjective and objective parameters were summarized and analysed as hereunder:

6.2.2 Subjective Parameters

Table 21 : Effect on Pain (Guda shoola) on VAS (Fig ; 20):

Signs & Symptoms	Group	Mean \pm SE (BT)	Follow-up	Mean \pm SE	't' value	P value	Effectiveness
A. Subjective Parameters							
1. Pain on VAS	Group - I	2.556 \pm 0.13	AT1	0.86 \pm 0.14	19.16864	<0.0001	Highly significant
			AT2	1.40 \pm 0.14	9.658595	<0.0001	Highly significant
			AT3	1.97 \pm 0.15	13.30896	<0.0001	Highly significant
	Group - II	2.6 \pm 0.12	AT1	1.01 \pm 0.10	9.212632	<0.0001	Highly significant
			AT2	1.53 \pm 0.12	12.23121	<0.0001	Highly significant
			AT3	2.14 \pm 0.133	16.04818	<0.0001	Highly significant

In Group – I: The initial (BT) mean score of the symptom Pain was 2.556 which was reduced to 0.86 on 7th day (AT1), 1.40 on 14th day (AT2) and 1.97 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

In Group – II: The initial (BT) mean score of the symptom Pain was 2.6 which was reduced to 1.01 on 7th day (AT1), 1.53 on 14th day (AT2) and 2.14 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

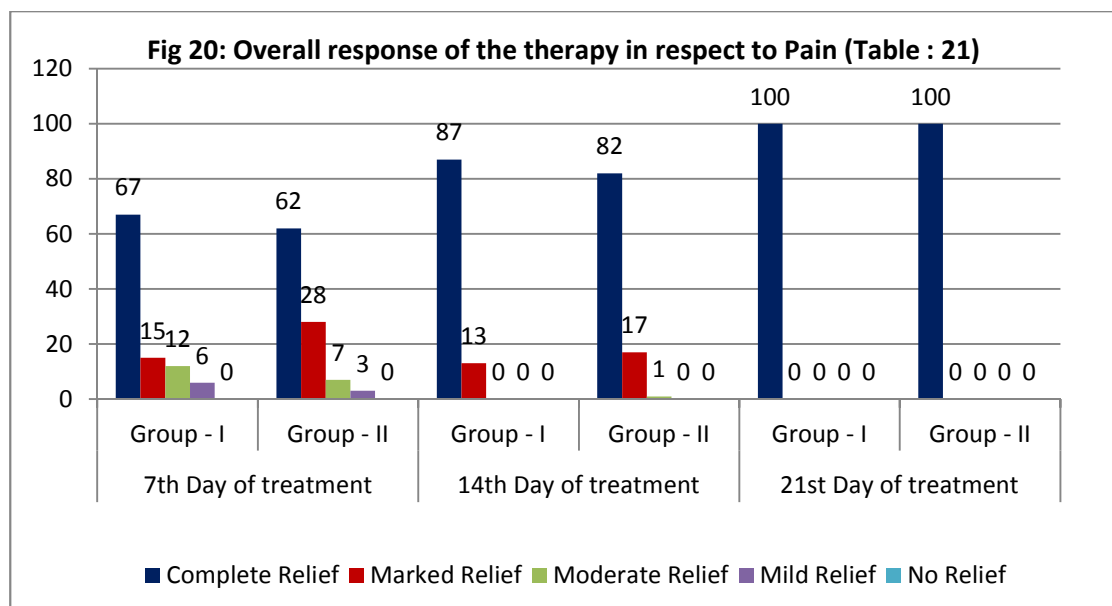


Table 22: Effect on Bleeding (Fig : 21):

Signs & Symptoms	Group	Mean \pm SE (BT)	Follow-up	Mean \pm SE	't' value	P value	Effectiveness
B. Subjective Parameters							
2. Bleeding	Group - I	1.63 \pm 0.05	AT1	1.63 \pm 0.06	10.9389	<0.0001	Highly significant
			AT2	1.02 \pm 0.08	12.69006	<0.0001	Highly significant
			AT3	0.16 \pm 0.06	25.49594	<0.0001	Highly significant
	Group - II	1.68 \pm 0.04	AT1	1.64 \pm 0.06	10.19161	<0.0001	Highly significant
			AT2	1.04 \pm 0.07	14.37204	<0.0001	Highly significant
			AT3	1.49 \pm 0.05	26.63134	<0.0001	Highly significant

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.63 which was remained unchanged at 1.63 on 7th day (AT1), 1.02 on 14th day (AT2) and 1.16 on 21st day (AT3) of the treatment. The effectiveness of the treatment was Statistically Highly Significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.68 which was reduced to 1.64 on 7th day (AT1), 1.04 on 14th day (AT2) and 1.49 on 21st day (AT3) of the treatment. The effectiveness of the treatment was Statistically Highly Significant with ‘p’ value <0.0001.

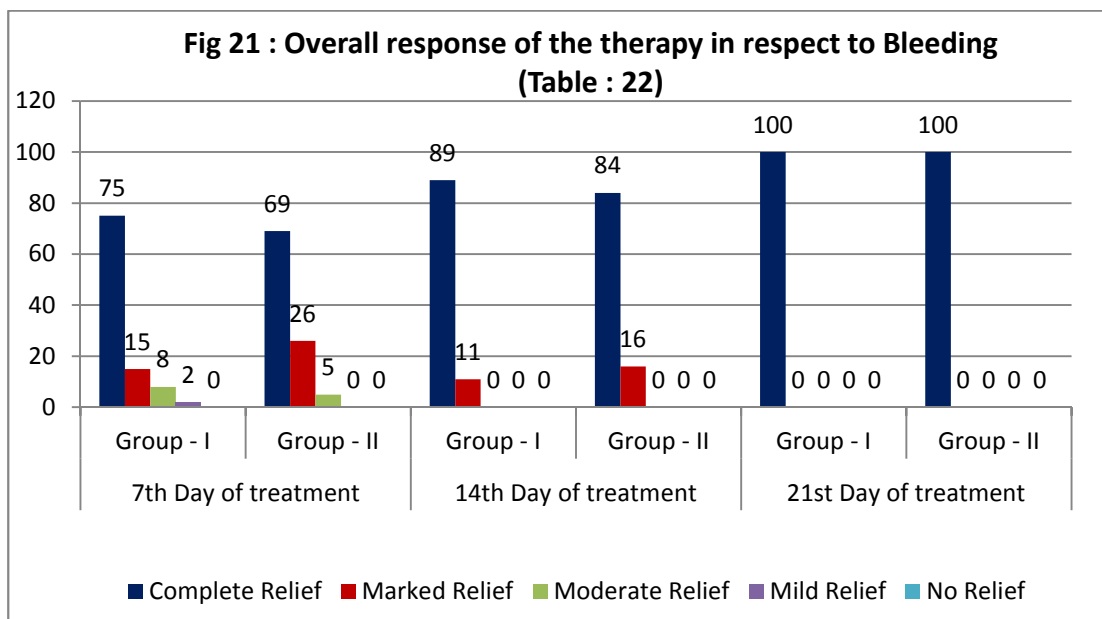


Table 23: Effect on Constipation:

Signs & Symptoms	Group	Mean \pm SE (BT)	Follo w-up	Mean \pm SE	't' value	P value	Effectiveness
C. Subjective Parameters							
3. Constipation	Group - I	1.62 \pm 0.04	AT1	0.82 \pm 0.08	10.64365	<0.0001	Highly significant
			AT2	0.97 \pm 0.08	13.80036	<0.0001	Highly significant
			AT3	1.45 \pm 0.06	26.01735	<0.0001	Highly significant
	Group - II	1.6 \pm 0.04	AT1	0.68 \pm 0.07	8.902519	<0.0001	Highly significant
			AT2	1.01 \pm 0.07	13.5518	<0.0001	Highly significant
			AT3	1.45 \pm 0.06	23.7989	<0.0001	Highly significant

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.62 which was reduced to 0.82 on 7th day (AT1), 0.97 on 14th day (AT2) and 1.45 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.6 which was reduced to 0.68 on 7th day (AT1), 1.01 on 14th day (AT2) and 1.45 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

6.2.3 Objective Parameters

Table 24 : Effect on Sphincteric spasm (Fig : 22):

Signs & Symptoms	Group	Mean \pm SE (BT)	Follow-up	Mean \pm SE	't' value	P value	Effectiveness
D. Objective Parameters							
4. Sphincteric spasm	Group - I	1.61 \pm 0.05	AT1	0.68 \pm 0.08	8.902519	<0.0001	Highly significant
			AT2	1.01 \pm 0.07	14.07332	<0.0001	Highly significant
			AT3	1.39 \pm 0.06	20.89993	<0.0001	Highly significant

Observations and Results

	Group - II	1.66± 0.04	AT1	0.75 ± 0.07	9.574271	<0.0001	Highly significant
			AT2	1.08 ± 0.06	16.31912	<0.0001	Highly significant
			AT3	1.45 ± 0.06	23.7989	<0.0001	Highly significant

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.61 which was reduced to 0.68 on 7th day (AT1), 1.01 on 14th day (AT2) and 1.39 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.66 which was reduced to 0.75 on 7th day (AT1), 1.08 on 14th day (AT2) and 1.45 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

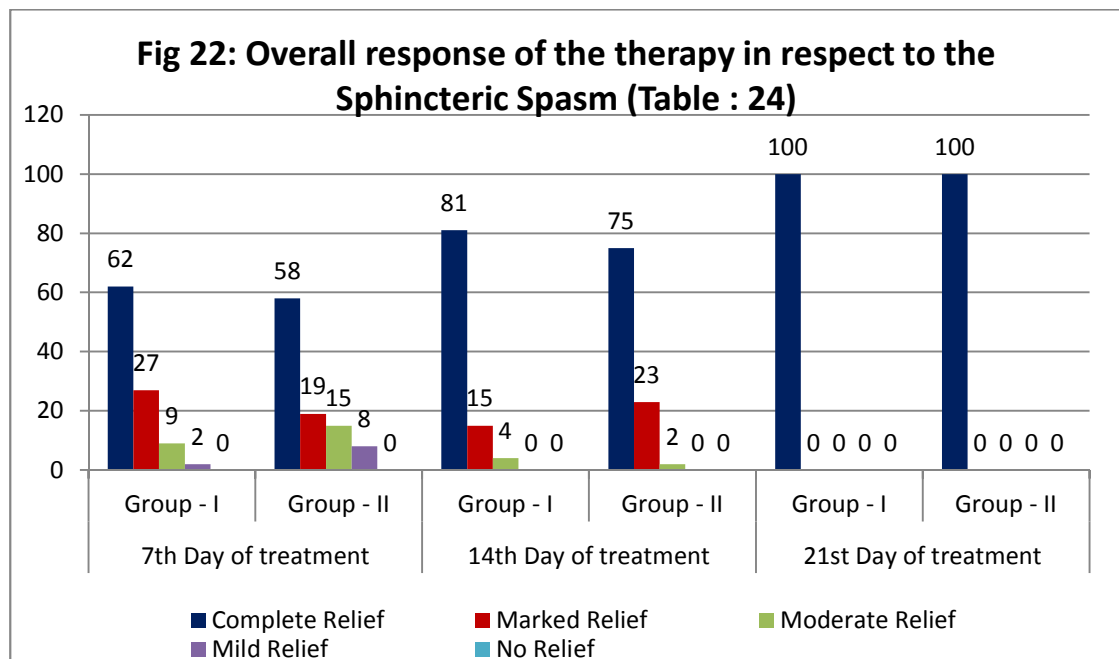


Table 25 : Effect on Size of Ulcer (Fig : 23):

Signs & Symptoms	Group	Mean \pm SE (BT)	Follow-up	Mean \pm SE	't' value	P value	Effectiveness
E. Objective Parameters							
5. Size of Ulcer	Group - I	1.63 \pm 0.04	AT1	0.66 \pm 0.06	9.636413	<0.0001	Highly significant
			AT2	1.11 \pm 0.07	15.05878	<0.0001	Highly significant
			AT3	1.48 \pm 0.05	27.36403	<0.0001	Highly significant
	Group - II	1.6 \pm 0.04	AT1	0.64 \pm 0.06	9.940172	<0.0001	Highly significant
			AT2	1.11 \pm 0.06	15.97615	<0.0001	Highly significant
			AT3	1.41 \pm 0.05	25.53319	<0.0001	Highly significant

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.63 which was reduced to 0.66 on 7th day (AT1), 1.11 on 14th day (AT2) and 1.48 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.6 which was reduced to 0.64 on 7th day (AT1), 1.11 on 14th day (AT2) and 1.41 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

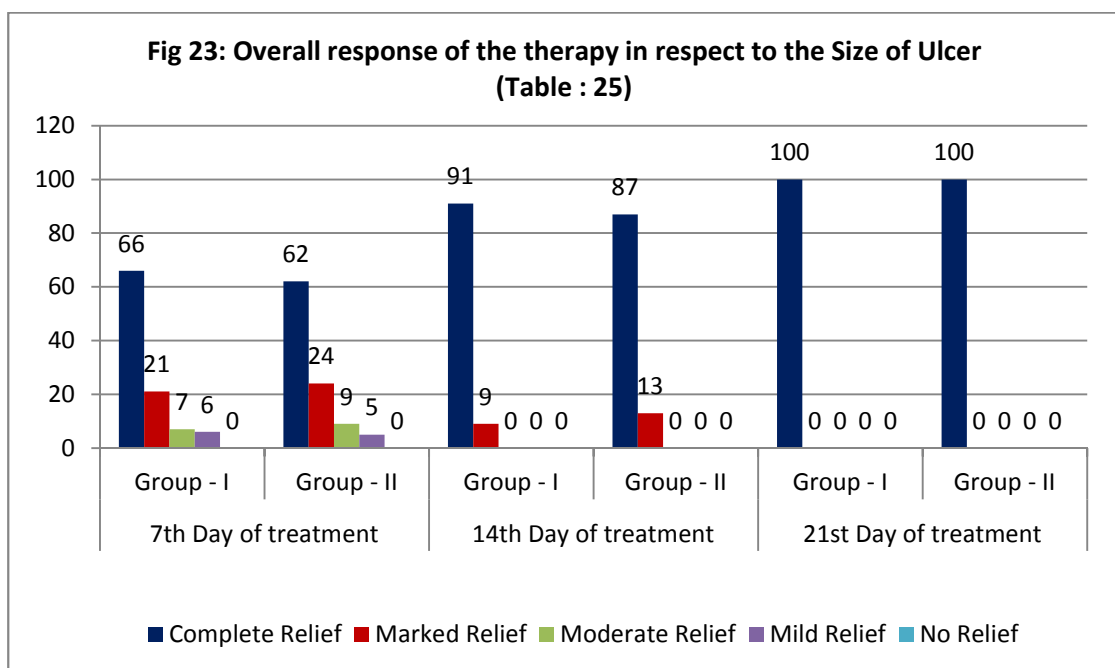


Table 26: Effect on Healing of Ulcer (Fig : 24):

Signs & Symptoms	Group	Mean \pm SE (BT)	Follow-up	Mean \pm SE	't' value	P value	Effectiveness
F. Objective Parameters							
6. Healing of Ulcer	Group - I	1.62 \pm 0.04	AT1	0.73 \pm 0.05	12.51011	<0.0001	Highly significant
			AT2	1.22 \pm 0.06	17.67627	<0.0001	Highly significant
			AT3	1.49 \pm 0.05	27.53466	<0.0001	Highly significant
	Group - II	1.68 \pm 0.04	AT1	0.79 \pm 0.05	13.36501	<0.0001	Highly significant
			AT2	1.25 \pm 0.06	18.19017	<0.0001	Highly significant
			AT3	1.52 \pm 0.05	29.12737	<0.0001	Highly significant

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.62 which was reduced to 0.73 on 7th day (AT1), 1.22 on 14th day (AT2) and 1.49 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.68 which was reduced to 0.79 on 7th day (AT1), 1.25 on 14th day (AT2) and 1.52 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

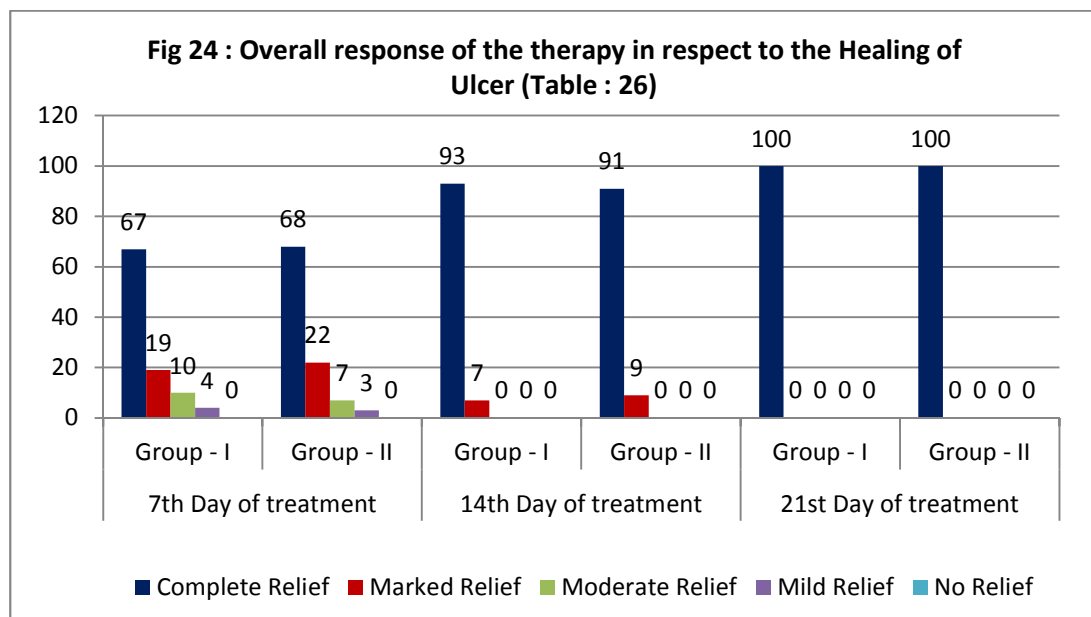


Table 27 : Overall response of the therapy in respect to the Pain in between two groups:

Study period	Group	No. of Pts.	Overall response of the therapy in respect to the Pain										
			Complete Relief		Marked Relief		Moderate Relief		Mild Relief		No Relief		
			No.	%	No.	%	No.	%	No.	%	No.	%	
Before treatment	Group - I	100	0	0	0	0	0	0	0	0	0	100	100
	Group - II	100	0	0	0	0	0	0	0	0	0	0	0
7th Day of treatment	Group - I	100	67	67	15	15	12	12	6	6	0	0	0
	Group - II	100	62	62	28	28	7	7	3	3	0	0	0
14th Day of treatment	Group - I	100	87	87	13	13	0	0	0	0	0	0	0
	Group - II	100	82	82	17	17	1	1	0	0	0	0	0
21st Day of treatment	Group - I	100	100	100	0	0	0	0	0	0	0	0	0
	Group - II	100	100	100	0	0	0	0	0	0	0	0	0
Overall Response	Group - I	100	100	100	0	0	0	0	0	0	0	0	0
	Group - II	100	100	100	0	0	0	0	0	0	0	0	0

In Group – I, as regards to the improvement in Pain, the study revealed that about 67 percent of the patients got Complete relief, 15 percent got marked relief, 12% got moderate relief while 6 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 87 percent got complete relief and 13 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 62 percent of the patients got complete relief, 28 percent got marked relief, 7% got moderate relief while 3 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 82 percent got complete relief and 17 percent got marked relief while 1 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.

Table 28 : Overall response of the therapy in respect to the Bleeding in between two groups:

Study period	Group	No. of Pts.	Overall response of the therapy in respect to the Bleeding									
			Complete Relief		Marked Relief		Moderate Relief		Mild Relief		No Relief	
			No.	%	No.	%	No.	%	No.	%	No.	%
Before treatment	Group - I	100	0	0	0	0	0	0	0	0	100	100
	Group - II	100	0	0	0	0	0	0	0	0	0	0
7th Day of treatment	Group - I	100	75	75	15	15	8	8	2	2	0	0
	Group - II	100	69	69	26	26	5	5	0	0	0	0
14th Day of treatment	Group - I	100	89	89	11	11	0	0	0	0	0	0
	Group - II	100	84	84	16	16	0	0	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, as regards to the improvement in Bleeding per rectum, the study revealed that about 75 percent of the patients got Complete relief, 15 percent got marked relief, 8% got moderate relief while 2 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 89 percent got complete relief and 11 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 69 percent of the patients got Complete relief, 26 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 84 percent got complete relief and 16 percent got marked 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.

Table 29 : Overall response of the therapy in respect to Sphincteric Spasm in between two groups:

Study period	Group	No. of Pts.	Overall response of the therapy in respect to the Sphincteric Spasm									
			Complete Relief		Marked Relief		Moderate Relief		Mild Relief		No Relief	
			No.	%	No.	%	No.	%	No.	%	No.	%
Before treatment	Group - I	100	0	0	0	0	0	0	0	0	100	100
	Group - II	100	0	0	0	0	0	0	0	0	0	0
7th Day of treatment	Group - I	100	62	62	27	27	9	9	2	2	0	0
	Group - II	100	58	58	19	19	15	15	8	8	0	0
14th Day of treatment	Group - I	100	81	81	15	15	4	4	0	0	0	0
	Group - II	100	75	75	23	23	2	2	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, as regards to the improvement in Sphincteric Spasm, the study revealed that about 62 percent of the patients got Complete relief, 27 percent got marked relief, 9% got moderate relief while 2 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 81 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 58 percent of the patients got Complete relief, 19 percent got marked relief, 15% got moderate relief while 8 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 75 percent got complete relief and 23 percent got marked relief while 2 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.

Table 30 : Overall response of the therapy in respect to Size of Ulcer in between two groups:

Study period	Group	No. of Pts.	Overall response of the therapy in respect to the Size of Ulcer									
			Complete Relief		Marked Relief		Moderate Relief		Mild Relief		No Relief	
			No.	%	No.	%	No.	%	No.	%	No.	%
Before treatment	Group - I	100	0	0	0	0	0	0	0	0	100	100
	Group - II	100	0	0	0	0	0	0	0	0	0	0
7th Day of treatment	Group - I	100	66	66	21	21	7	7	6	6	0	0
	Group - II	100	62	62	24	24	9	9	5	5	0	0
14th Day of treatment	Group - I	100	91	91	9	9	0	0	0	0	0	0
	Group - II	100	87	87	13	13	0	0	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, as regards to the improvement in Size of Ulcer, the study revealed that about 66 percent of the patients got Complete relief, 21 percent got marked relief, 7% got moderate relief while 6 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 91 percent got complete relief and 9 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 62 percent of the patients got Complete relief, 24 percent got marked relief, 9% got moderate relief while 5 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 87 percent got complete relief and 13 percent got marked 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.

Table 31 : Overall response of the therapy in respect to Healing of Ulcer in between two groups:

Study period	Group	No. of Pts.	Overall response of the therapy in respect to the Healing of Ulcer									
			Complete Relief		Marked Relief		Moderate Relief		Mild Relief		No Relief	
			No.	%	No.	%	No.	%	No.	%	No.	%
Before treatment	Group - I	100	0	0	0	0	0	0	0	0	100	100
	Group - II	100	0	0	0	0	0	0	0	0	0	0
7th Day of treatment	Group - I	100	67	67	19	19	10	10	4	4	0	0
	Group - II	100	68	68	22	22	7	7	3	3	0	0
14th Day of treatment	Group - I	100	93	93	7	7	0	0	0	0	0	0
	Group - II	100	91	91	9	9	0	0	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, as regards to the improvement in Healing of Ulcer, the study revealed that about 67 percent of the patients got Complete relief, 19 percent got marked relief, 10% got moderate relief while 4 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 93 percent got complete relief and 7 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, 22 percent got marked relief, 7% got moderate relief while 3 percent got mild relief during first week of the treatment i.e by 7th day. By the end of 14th day 91 percent got complete relief and 9 percent got marked 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.

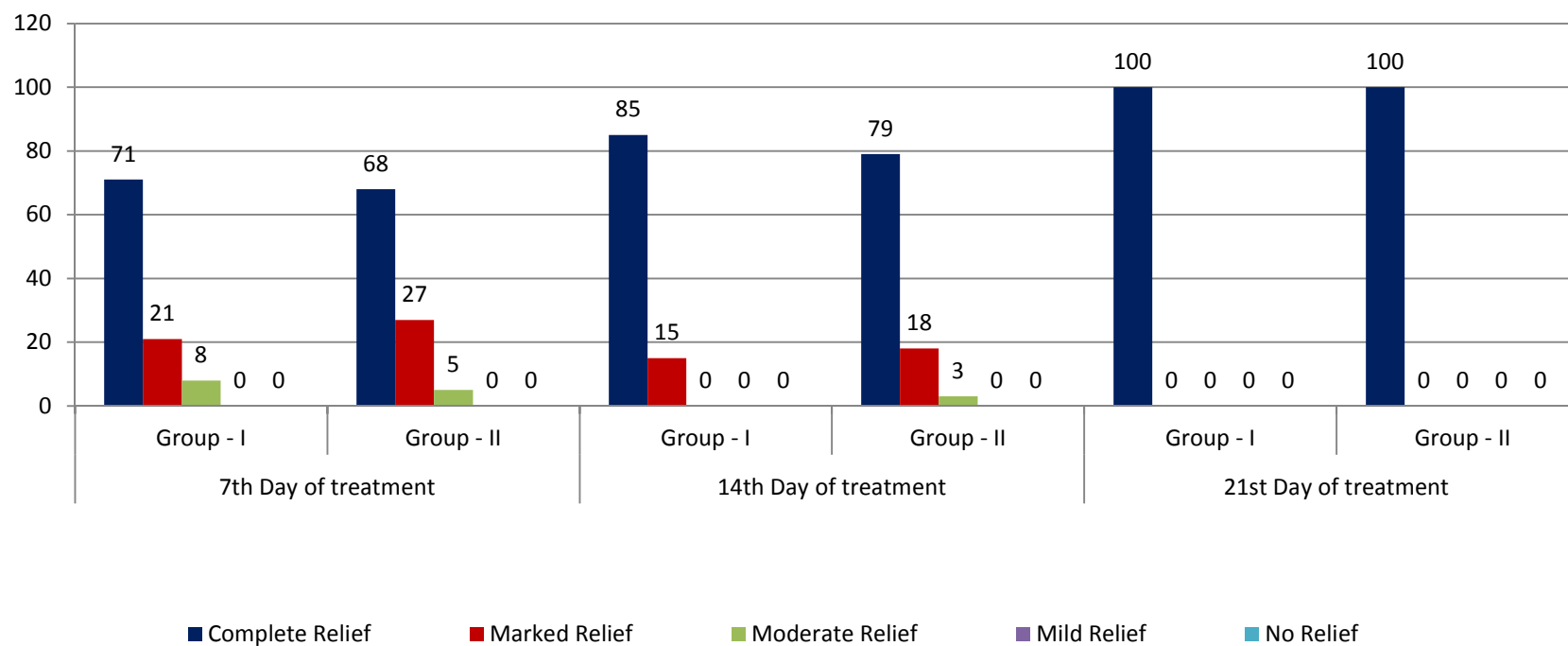
Table 32 : Overall Clinical Assessment of the therapy (Fig : 25)

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

Fig 25 : Overall Clinical Assessment of the therapy (Table : 32)



Chapter 7 : Discussion

The objective of the study was to Evaluation of clinical efficacy of Pichu application of Jatyadi Grihta and Yasthimadhu Grihta 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.

Fissure-in ano is ailment that does not have any direct correlation in the Ayurvedic text. As per the literature available, the condition 'Parikartika' occurring due to improper administration of Virechana and Basti can be compared with fissure-in ano, since both the conditions occur in Guda and have similar clinical manifestations.

It literally means to cut circumferentially or to cut all around. The description of this condition as an independent disease is not found in any of the Ayurvedic texts. But the term Parikartika has been mentioned at various contexts such as complication of Virechana karma, Basti karma and also as Basti netra vyapad. Acharya Sushruta holds Rooksha and Shushka aushadha are the main cause. If ruksha vasti containing teekshana and lavana dravyas are administered in heavy dose, it may produce Parikartika. Charaka and Vagbhata opine that Parikartika is a symptom in Vataja Atisara due to trauma by hard stools.

This condition resembles the disease Fissure in Ano described in modern Medical science. Thus fissure-in-ano can be compared with Parikartika as follows;

- Parikartika is characterized by Kartanavat and Chedanavat Shoola in Guda, Basti and Nabhi. Similarly fissure in ano is also characterized by sharp cutting pain in anal region.
- In Parikartika Guda-Kshata is result of Virechana Atiyoga, just as Kantaka-Shanana in Vamana Atiyoga where Kshanana implies injured tissue. In the same way fissure in ano is evident by the longitudinal tear in the anal canal. Since the location, nature of pathology and the predominant clinical feature are same, it can be said that the condition Parikartika is the clinical condition known in current surgical practice as fissure in ano.

Review of modern literature suggests that constipation is the greatest contributing factor in the development of fissure-in-ano. In kashyapa Samhita, this disease has been described as a complication of pregnancy in women.

The comparison of these two conditions as per Ayurveda and Modern medical system is summarized hereunder:

- a) The factors responsible for the causation of the condition – Parikartika vis-à-vis Fissure-in-ano are:
 - i) As per Ayurveda Classics: Ati Teekshana, Ushna and lavana ahara, Malabaddhata, Atisara and Grahani, defective basti netra, Garbha in Garbhini.
 - ii) As per modern literature : Trauma by hard stool, Loss of elasticity, Tear of Anal mucosa by a foreign body, Improper instrumentation, Anal infection, Poor blood supply to the anal canal Pressure exerted during pregnancy.
- b) The aetiopathogenesis:
 - i) As per Ayurveda Classics: Due to nidana sevana vata and pitta prakopa. Prakupita doshas will travel down wards along with adhogami dhamanis and reaches guda Avayava. Due to excessive pressure and dusti in rakta and mamsa a Kshata is produced. This condition is called as Parikartika.
 - ii) As per modern literature : Hard stools and excessive straining causes pressure over anal canal. This results in tear of mucous membrane resulting into ulcer formation which is termed as Fissure in Ano.
- c) The Clinical features of the disease:
 - i) As per Ayurveda Classics: Vibandha, Raktashrava, Vrana prateeti, Gudagata shoola etc.
 - ii) As per modern literature : Constipation, per rectal bleeding, Ulcer, pain etc.

In this study Jatyadi Ghita and Yasthimadhu ghruta were selected to evaluate its role in the management of Parikartika because it has Shodhana, Vrana Ropana, Shothahara, Varna Prasadana and Shulahara properties along with Tridosahara, Rakta

Stambhaka and Rakta Shodhaka actions. Go-Ghrita being one of the potent ingredients of these trial drugs, possess Vrana Ropana properties.

Clinical study has been conducted on 200 clinically established patients of fissure-in-ano in the Ano-Rectal Clinic of National Research Institute of Ayurvedic Drug Development, Bhubaneswar. The observations were recorded under various parameters.

The total 200 patients have been divided in to two groups- Group-I and Group - II and 100 patients were kept in each group respectively. In Group - I, Jatyadi ghrita pichu was applied along with Panchasakara churna orally and in Group - II, Yasthimadhu ghrita pichu was applied along with Panchasakara churna orally and results were correlated and compared.

Careful observations were recorded under the following headings:

1. Condition of Patients on Admission: Age, Sex, Marrital Status, Religion, Habitat, Food Habits, Bowel Habits, Prakruti.
2. Characteristics of Fissure-in-ano (Parikartika) on Admission: Duration of illness, Onset of fissure, Severity of pain, Previous H/O treatment, Type of fissure, History of any Associated diseases.
3. Clinical features of Fissure-in-ano (Parikartika) on Admission: Itching Ani (Pruritis), Type of Edges, Position (O-Clock) of Fissure-in-ano, Sphincter tone Tenderness.
4. Result of the treatment : a) Subjective parameters : Pain on VAS, Bleeding, Constipation, b) Objective parameters : Sphincteric spasm, Size of Ulcer, Healing of Ulcer.

7.1 Significant Clinical Observations:

Age: The youngest patient has been of 21 years while the eldest patient has been of 60 years. In the study it was observed that the incidence of fissure was highest (46%) in the age group of 31-40 yrs. More than the half of the patients belonged to the middle age. This age is the most active phase of the life of any human and hence overstraining, increased travelling, stress and strain, improper attention to bowel habits, local unhygienic, improper dietary habits, sedentary life style, long hours of

sitting in the same posture etc. all increase the incidence of the disease in the patients belonged to this age group.

Sex: The current study revealed that the incidence of fissure was little higher in males (60%) compared to females (40%). Male to female ratio was 1.5:1. This data suggest that the disease is predominantly common in males. The anatomical difference in the structure of the pelvic cavity between male and female patients due to the presence of uterus and enough space for child bearing may also be responsible for the difference in the incidence of fissure in the both sexes. The description given in Sushruta Samhita regarding the circumference of the ano-rectal canal suggests that it is wider in females than in males. This may also be responsible for less incidence of fissure in females. Long hours of sedentary jobs, local unhygienic, distribution of hairs, increased sweating and unhealthy food habits, stress and strain may have increased the incidence in males. Lack of proper knowledge regarding the disease and lack of privacy in the set up may be the main triggers for the disease in females.

Diet: While discussing the nature of diet, it was observed in the study that a greater percentage of patients (90.5%) habituated to a non-vegetarian diet suffered from the disease compared to the patients following a vegetarian (9.5%) diet. Lack of roughage, low fiber content and spicy in the food of the non-vegetarians leads to constipation repeatedly, which is one of the main causes known to aggravate the condition.

Bowel habits: It was observed that majority of the patients (98.5%) suffered from constipation and few of the patients (1.5%) had regular bowel habits. This results in long hours of straining and ineffective evacuation of bowels. Stasis of the faecal contents in the anal columns and repeated straining injures the mucous membrane of the anal columns and thus causes ulcer in the anal canal.

Type of fissures: The study revealed that maximum number (38%) of cases reported with acute type of fissures. Most of the patients reported for early intervention because of the intensity of the pain.

Spasm of the sphincter: Efforts were made to record the intensity of the spasm of the sphincter as per the criteria laid down for this purpose. Analysis shows that maximum number of (92.5%) patients had the hypertonic sphincter, this is because of the hypersensitivity in the ulcer area.

Occupation: It was observed in the study that the rate of the disease was highest in patients who are leading a sedentary life cycle. Business men and those doing office jobs need to sit constantly in the same posture over the perianal area, lack of exercise, eventually lead to constipation and culminates the causation of fissure-in-ano.

Chronicity of the disease: The current study revealed that a large portion of the cases have a chronicity of one year, 47.5 percent of the patients of fissure in ano reported a chronicity of less than one year.

Condition of the disease: Majority of the patients (62%) of fissure in ano had attended the OPD as fresh cases while 29 percent of cases had undergone medical treatment for the same purpose hence it revealed that repeated incidences even after taking modern therapy for the fissures.

Position of the disease: Fissures were commonly found (56%) at 6 O' clock position with indurated edges. About 52 percent of fissure patients had itching ani.

7.2 Effect of jatyadi ghrita (Group-I) and Yasthimadhu ghrita (Group-II):

As indicated above the trial drugs were applied in the form of pichu i.e the sterile gauze was dipped in the respective trial drugs and placed on the fissure bed daily once for 21 days or till the fissure / ulcer is completely healed or till the complaints are completely alleviated whichever is earlier. Its effect on both subjective and objective parameters were summarized and analysed as hereunder:

7.2.1 Effect on Pain:

In Group – I: The initial (BT) mean score of the symptom Pain was 2.556 which was reduced to 0.86 on 7th day (AT1), 1.40 on 14th day (AT2) and 1.97 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with 'p' value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 2.6 which was reduced to 1.01 on 7th day (AT1), 1.53 on 14th day (AT2) and 2.14 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with 'p' value <0.0001.

Clearly the effects of Jatyadi Ghrita in relieving the pain of the patients of fissure in ano were far better in comparison to Yasthimadhu Ghrita. The anti-inflammatory and analgesic property of Jati in Jatyadi Ghrita helps to relieve the pain and inflammation.

7.2.2 Effect on Bleeding:

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.63 which was remained unchanged at 1.63 on 7th day (AT1), 1.02 on 14th day (AT2) and 1.16 on 21st day (AT3) of the treatment. The effectiveness of the treatment was Statistically Highly Significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.68 which was reduced to 1.64 on 7th day (AT1), 1.04 on 14th day (AT2) and 1.49 on 21st day (AT3) of the treatment. The effectiveness of the treatment was Statistically Highly Significant with ‘p’ value <0.0001.

It mainly occurs because of Rakta Stambhana, Rakta Shodhana and Ropana property of Jatyadi and Yasthimadhu Ghrita.

7.2.3 Effect of on Sphincteric spasm:

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.61 which was reduced to 0.68 on 7th day (AT1), 1.01 on 14th day (AT2) and 1.39 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.66 which was reduced to 0.75 on 7th day (AT1), 1.08 on 14th day (AT2) and 1.45 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

It is evident from the above results that the effect of Jatyadi Ghrita in providing the relief in the sphincter tone of the patients of fissure in ano was for better in comparison to Yasthimadhu Ghrita. It mainly occurs due to muscle relaxation by Snehana action and Vedana Shamaka property of Jatyadi and Yasthimadhu Ghrita.

7.2.4 Effect of on Size of Ulcer:

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.63 which was reduced to 0.66 on 7th day (AT1), 1.11 on 14th day (AT2) and 1.48 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.6 which was reduced to 0.64 on 7th day (AT1), 1.11 on 14th day (AT2) and 1.41 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

7.2.5 Effect of on Healing of Ulcer:

In Group – I: The initial (BT) mean score of the symptom Bleeding was 1.62 which was reduced to 0.73 on 7th day (AT1), 1.22 on 14th day (AT2) and 1.49 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001. .

In Group – II: The initial (BT) mean score of the symptom Pain was 1.68 which was reduced to 0.79 on 7th day (AT1), 1.25 on 14th day (AT2) and 1.52 on 21st day (AT3) of the treatment. The effectiveness of the treatment was statistically Highly significant with ‘p’ value <0.0001.

7.2.6 Overall Clinical Assessment of the therapy

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 15percent 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.

It is obvious from the above results that the overall effects of Jatyadi Ghrita in providing the overall relief to the patients of fissure in ano were also for better in comparison to Yasthimadhu Ghrita.

Comparison of the effect obtained in both the groups showed the local application of Pichu of Jatyadi Ghrita provided significantly better relief in Guda Shoola, Bleeding per rectum, healing the ulcer and to increase the sphincter tone in comparison to the application of Paichu dipper in Yasthimadhu Ghrita.

7.3 Probable Mode of Action of Trial Drugs:

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. This formulation- Jatyadi ghrita is explained in the context of vranashothadhikara in the chapter of snehakalpadhyaya, 9th chapter of sharangadhara samhita. This also explained in vrunashothadhikara, 47th chapter of Bhaishajjya Ratnavali. The combination is ideal for vrunas that are situated in marmas, delicate tissues, and that are painful and seated in the deep tissues. It is proven drug in the treatment of parikartika. Hence the probable mode of action is

- The Jati, Nimba, Patola, Haridra, Daruharidra, Kauki, Manjistha, Sariva, Karanja ingredients are having vrunashodhana property.
- Ghrita and sikta are vrunaropana.
- Tutha ie copper sulphate reduces the cellular hypertrophy of the wound.

The drugs are having tikta rasa and thus act as pitta shamaka which intern help in reducing daha which is the peculiar symptom of pitta vrudhi. The natural essential oils in the formula are proven to penetrate into cell membranes to provide immediate relief from anal fissures.

The healing of fissure is different from the healing of any other ulcer because in the former there is constant contamination of the wound by faeces and its frequent friction with the mucosa while there is continuous spasm of the sphincteric muscle. They are the important factors which keep a fissure away for normal healing. In such situation a drug which produces a soothing effect, Vata-Pittahara, Vedna Sthapana, Vrana Shodhana, Vrana Ropana and influences reduction of inflammation with be more suitable the drug which may act as the best healer of ulcer on other parts of the body. These Ghrita preparations probably has these properties. But as far as main symptoms are concerned pain (Burning and Cutting) may be relieved due to the action of Vedan Sthapana, Dahaprashamana and Vata Pittahara, it's well know fact that the Vata and Pitta Dosha are predominant in pain as well as in fissure. According to modern pharmacological action consult, the drug has a patient anti inflammatory and steroidal activity. Other drugs also have been reported to have a similar type of property but the clinical study reveals that its activity is less as compared to the of Jatyadi Ghrita. It is the amount of inflammation and spasm which is responsible for producing the agonizing pain in cases of fissure-in-ano. These preparations probably is able to counteract these two factors more efficiently that the other drugs. The relief of severe pain within 24 hours is something remarkable about the drug although the ulcer takes as many as three to four weeks for complete healing.

Probable mode of action of Panchasakara churna: It appears that the churna improve Agni, will reduce bacterial lode in the stool, will check the gati of vata by virtue of anulomana effect, It reduces the purisha gadhata, Kosta shodhana will reduce congestion in haemorrhoidal vessels thus minimizing pressure on anal mucosa. Conservative measures include avoidance of constipation by means of mrudu rechakas to enable the passage of soft stools. Repeated anal trauma by passage of hard faeces can be avoided by laxatives such as Panchasakara choorna especially suitable for they tend to produce soft easily passable motions. Teekshna rechakas must be avoided since frequent passage of loose stools causes agony intern worsens the condition.

Ushna Jala awagah sweda (Hot water sitz bath): Probable mode of action: In Abhyanga, Parisheka, lepa and Avagaha sweda the Veerya of the dravya enters the body through the roma kupas present in the twacha. The jala used for Avagaha sweda is Luke warm. Heating the tissues increases metabolic activity, increases blood flow inturn improves the venous return and stimulates neural receptors. Heat appears to produce definite sedative effects and muscle relaxation. Because of these factors Avagaha sweda relieves Vedana and also acts as wound cleaning process.

Chapter 8 : Conclusion and Summary

8.1 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 61 percent got marked relief during the first week while in group two with Yasthimadhu ghrita the complete and marked relief were 68 and 57 percent respectively during first week i.e. by 7th day of the treatment.

8.2 Summary

The outcomes of the clinical research work are summarized in this section. Present clinical study entitled “Comparative Study of efficacy of Jatyadi Ghrita Pichu and Yasthimadhu Ghrita Pichu in the management of Parikartika (Fissure-in-ano)” was completed with expected Outcome measures through a clinical research study purely based on scientific parameters..

- Primary Outcome Measure: Change in the Clinical Parameters.
- Secondary Outcome Measures : Change in the bowel habit, Clinical safety.
- The entire work has been produced under 3 parts. Part I includes Introduction, objectives of the study, and literary review (Ayurvedic, Modern, Drug).
- During the study, the available literature in the ancient and modern medical books with regard to Parikartika and Fissure-in-ano was compiled and critically analyzed in Ayurvedic and modern review.
- The definition of pariakrtika, very vividly describes the nature and location of the disease.
- The detailed description of anatomical and physiological aspects of Guda, has been presented as described in both classics as well as in modern literature.
- Development of Quality standard parameters for the trial formulations as per the standard guidelines, Standard Operative Procedures for manufacturing of trial formulations were discussed under the Drug review.
- The essential drugs required for the study along with their properties are described under the section of drug review.
- Part II deals with methodology and along with study design was mentioned under the heading of methodology.

- The patients suffering from Parikartika who fulfill the criteria of selection of the present study were randomly selected.
- The patients were subjected for detail clinical examination and investigations as per the specially designed proforma.
- In this study, a total number of 200 patients were registered and were distributed in to two groups each containing of 100 patients each.
- Part III dealt with Observations, Results, Discussion, conclusion and summary.
- In the clinical study the incidence of fissure in ano was observed to be higher in males.
- Patients of the age group 31-40 years were affected by fissure in ano in greatest proportion.
- Most of the patients reported were from the urban background.
- The patients habituated to a non-vegetarian diet were more affected by this disease.
- The study revealed that constipation was the common cause for the disease.
- The patients of sedentary life styles were affected more by this disease.
- Maximum number of patients reported a chronicity of less than one year.
- Majority of the cases were fresh cases.
- Majority of fissures were located at 6 O' clock position.
- 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.
- 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.
- The effectiveness of the treatment in both trial groups reveals statistically Highly significant with the 'p' value of <0.0001 in both groups.
- So, from the above mentioned data and results it can be summarized that Jatyadi Ghrita can be good for relieving cardinal symptoms, general symptoms and quick healing of ulcer in the patients of Parikartika (fissure-in-ano) and even economical also to the patients than Yasthimadhu ghrita.

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Chapter 10 : Appendix

10.1 Study Schedule

Study Schedule	Screening	Baseline	At the end of 7th, 14th and 21st day	At the end of 28th day.
Informed consent				
Demographics and medical history				
Investigations				
Clinical Examination				
Assessment of Ayurvedic parameters				
Concomitant medication				
Rescue medication				
Assessment of ADRs / AEs				
Assessment of Drug compliance				
Issue of drugs and Drug Compliance Report Form every week				

10.2 Determination of Prakruti

Central Council for Research in Ayurvedic Sciences (Enter a ✓ in the appropriate box)

1. Physiological Status (PHS)

1.01 Status of Appetite: (AD)

- a. Good appetite
- b. Stable appetite with usually moderate desire to eat
- c. Variable appetite

1.02 Dietary/Eating habits (DH)

- a. Enjoys eating, ready to eat mostly & hates to miss food
- b. Regular food habits, but can spend hours without food
- c. Desirous to take food, eats less at a time, needs mid-meals snacks

1.03 Bowel Habits (BH)

- a. Regular, once-a-day, stool well formed, if constipated it is mild
(Respond to medium strength laxative)
- b. Regular & frequent, stool semisolid or loose, rarely constipated.
(Respond to mild laxatives sometimes even milk, fig., raisins etc.)
- c. Variation seen, mostly constipated (strong purgatives are needed)

1.04 Sleeping Pattern (SH)

- a. Sleeps easily but light
- b. Sleeps easily and sound (heavily)
- c. Trouble to get sleep, light sleeper / Variable sleep pattern

1.05 Morning feelings, after leaving the bed(MF)

- a. Don't feel fresh
- b. Feel fresh. Feel well even with less sleep.
- c. Feel fresh but not good when have less hours of sleep.

1.06 Dreams (DM)

- a. Cool and peaceful dreams, not bothers to remember
- b. Passionate dreams, sees heat, light & remembers well
- c. Plenty of dreams, mostly related to motion, usually forgets

1.07 Physical working capacity/physical strength

- a. Starts with speed & gets exhausted easily
- b. Loves hard work, has moderate capacity
- c. Good stamina but slow and not interested for physical work.

1.08 Performance of activities

- a. Quickly with a lot of initiative
- b. Moderately with medium initiative
- c. Slow, steady and balance activities

- 1.09 Talking**
- a. Very fast missing words
 - b. Sharp, provocative and clear-cut
 - c. Slow, clear and stable
- 1.10 Walking**
- a. Very quick with swift movement
 - b. Normal and rhythm
 - c. Slow and steady
- 1.11 Associated movements of body while working**
- a. Excessive and frequent, difficult to tolerate
 - b. Less thirst, easy to tolerate
 - c. Moderate perspiration, consistent to climate, with pleasant smell.
- 1.12 Nature of Thirst (TN)**
- a. Excessive and frequent, difficult to tolerate
 - b. Less thirst, easy to tolerate
 - c. Moderate and variable thirst
- 1.13 Status of Perspiration (SP)**
- a. Scanty even in hot climate but odourless
 - b. Profuse with strong odour
 - c. Moderate perspiration, consistent to climate, with pleasant smell.
- 1.14 Sexual qualities (SQ)**
- a. Variable, strong desire, overindulgence, & gets exhausted
 - b. Moderate with dominating behavior
 - c. Usually low and steady desire, with good stamina
- 1.15 Quantity of seminal discharge**
- a. Scanty and comparatively thin in consistency
 - b. Moderate and normal
 - c. Plenty and thick
- 1.16 Fertility or productivity**
- a. Comparatively lesser
 - b. Less
 - c. Capable of producing good no. of off springs
- 1.17 Longevity or average age**
- a. Short life span
 - b. Moderate life span
 - c. Long life span
- 1.18 Resistance to diseases (RD)**
- a. Usually poor. Frequently fall ill.
 - b. Medium
 - c. Good. Able to tolerate seasonal variation, food etc. well

- 1.19 Climatic Preferences (CP)**
- a. Prefers warm, avoids cold climate
- b. Likes cold, but intolerant to warm/hot
- c. Likes normal climate & prefers warm in comparison to cold
- 2. Mental/Psychological Status:**
- 2.01 Mental Reactions (MR)/Personality Traits:**
- a. Very sensitive, reacts quickly
- b. Gets Irritated easily & sustains it.
- c. Cool, calm, avoids confrontations
- 2.02 Memory Status (MS)**
- a. Remembers easily & tends to forget easily
- b. Takes time to grasp, but retains for long
- c. Remembers easily and tends to retain
- 2.03 Leadership quality(LQ)**
- a. Don't like to lead and happy as a follower.
- b. Requires commanding status.
- c. Avoid leading.
- 2.04 Decision making capacity(DMC)**
- a. Takes immediate decision without thinking much.
- b. Takes decision after properly analyzing the facts.
- c. Avoid taking decision. Usually keeps them pending.
- 2.05 Concentration Power (CP)**
- a. Very easy to concentrate on a work, but not for long duration
- b. Difficult to concentrate on a work
- c. Retains concentration for a long period
- 2.06 Attitude towards problems or difficulties**
- Lot of worrying, instability in reaction
- Angry, over awed, easily provoked and highly irritable
- Peaceful, slow, steady and balance
- 2.07 Nature**
- a. Easily irritable, irritating to others, exaggerating, anxious materialistic liking
- b. Polite but hot-tempered, proudy, brave, bold, less but good friendship
- c. Polite, decent, not greedy, appreciating, have good and long lasting friendship
- 2.08 Liking about taste (TL)**
- a. Sweet, salt & sour
- b. Sweet, bitter & astringent
- c. Pungent, astringent & bitter

3. Physical Features: (PF)**3.01 Body frame (BF)**

- a. Thin body frame, unusually long/short
- b. Medium frame
- c. Broad, Large frame

3.02 Body weight (BW)

- a. Moderate/Average weight
- b. Underweight or Tendency of fluctuation
- c. Over weight or with a tendency to gain weight

3.03 Distribution of body fat (DBF)

- a. Unequal/on specific areas
- b. Evenly distribution
- c. Scanty deposition of body fat.

3.04 Nature/Texture of skin

- a. Delicate, Irritable skin, gets wrinkles easily
- b. Dry, rough, cracked, or having a tendency of cracking
- c. Smooth, firm, soft, clear with good lusture, not prone to disorders

3.05 Complexion/skin color (SC)

- a. Highly fair / pinkish
- b. Fair, reddish, burns easily
- c. Comparatively dull or darkish, tans easily

3.06 Body Hair (BH)

- a. Dry, rough, coarse, lustureless & curly
- b. Soft, scanty, straight, fine textured
- c. Thick, shiny, moderate

3.07 Forehead (FH)

- a. Large
- b. Medium
- c. Small

3.08 Eyes (EF)

- a. Rolling, restless, small, dull & lusterless
- b. Sharp, medium sized with sclera of reddish tinge
- c. Large calm stable eyes with milky white sclera

3.09 Teeth (TE)

- a. Teeth are of average size, yellowish, prone to cavities
- b. Dry, cracked, irregular dull white
- c. Large, even, gleaming white

3.10 Tongue (TO)

- a. Thin tongue, with blackish spots, often coated with thin adherent coating
- b. Medium, Reddish, occasionally coated with yellow or red coating
- c. Thick usually clear, rarely coated, coating is usually thick white

- 3.11 Lips (LP)**
- a. Soft, moist & reddish
 - b. Dry, thin & blackish
 - c. Thick & glossy
- 3.12 Blood Vessels (BV)**
- a. Prominent
 - b. Less prominent
 - c. Not visible
- 3.13 Scalp Hair (SH)**
- a. Dark in Shade, coarse, rough, easily prone to dandruff and split ends.
 - b. Thin, delicate, straight, light coloured, turn grey at an early age
 - c. Strong, thick, dark, slightly wavy with good lusture, oiliness is usually one of the chief complaints
- 3.14 Joints (JT)**
- a. Crackling joints, hyper mobile in nature
 - b. Comparatively normal but have soft and loose ligaments
 - c. Well lubricated, strongly built joints which are well organized, well covered
- 3.15 Voice (VR)**
- a. Rough, unclear voice, which turns hoarse or cracks on strain
 - b. Concise, sharp voice, intense in nature & high pitched
 - c. Deep, pleasant, resonant voice which is melodious, resonating, but lower in pitch and intensity
- 3.16 Nail (NL)**
- a. Hard, brittle, rough & differ in size from one another, bluish/grayish in contour
 - b. Soft, Strong, well formed, Lustrous, pink in colour
 - c. Strong, large, thick symmetrical & somewhat pale in colour
- 3.17 Body temperature**
- a. Feels slightly cold on touch
 - b. Feels slightly warm on touch
 - c. Normal
- 3.18 Shape of Palms and feet**
- a. Short and broad
 - b. Medium and slim
 - c. Long and broad
- 3.19 Face**
- a. Small and broad with uneven features
 - b. Medium & oval with sharply defined features
 - c. Round, babbly and attractive with balance features

4 Social or economical status

4.01 Economy

- a. Getting less outcome with hard work
 b. Getting good outcome with moderate efforts
 c. Enjoys lavishly and royal life

SCORE SHEET FOR DETERMINATION OF PRAKRUTI

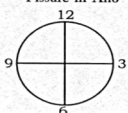
Sl. no. of the subject. _____

S.No.	Observation Code	Options			Identified Area (V/P/K)
		a	b	c	
1.	1.01	P	K	V	
2.	1.02	P	K	V	
3.	1.03	K	P	V	
4.	1.04	P	K	V	
5.	1.05	V	P	K	
6.	1.06	K	P	V	
7.	1.07	V	P	K	
8.	1.08	V	P	K	
9.	1.09	V	P	K	
10.	1.10	V	P	K	
11.	1.11	V	P	K	
12.	1.12	P	K	V	
13.	1.13	V	P	K	
14.	1.14	V	P	K	
15.	1.15	V	P	K	
16.	1.16	V	P	K	
17.	1.17	V	P	K	
18.	1.18	V	P	K	
19.	1.19	V	P	K	
20.	2.01	V	P	K	
21.	2.02	V	K	P	
22.	2.03	K	P	V	
23.	2.04	V	P	K	
24.	2.05	P	V	K	
25.	2.06	V	P	K	
26.	2.07	V	P	K	
27.	2.08	V	P	K	
28.	3.01	V	P	K	
29.	3.02	P	V	K	
30.	3.03	K	P	V	
31.	3.04	P	V	K	
32.	3.05	K	P	V	
33.	3.06	V	P	K	
34.	3.07	K	P	V	
35.	3.08	V	P	K	
36.	3.09	P	V	K	
37.	3.10	V	P	K	
38.	3.11	P	V	K	

39.	3.12	V	P	K			
40.	3.13	V	P	K			
41.	3.14	V	P	K			
42.	3.15	V	P	K			
43.	3.16	V	P	K			
44.	3.17	V	P	K			
45.	3.18	V	P	K			
46.	3.19	V	P	K			
47.	4.01	V	P	K			
INDIVIDUAL SCORE OF VPK					V	P	K
PERCENTAGE OF VPK					V=	P=	K=
TYPE OF PRAKRUTI							

Abbreviations-V-Vata, P-Pitta, K-Kapha

10.3 Case Record Format & Assessment Record

PARIKARTIKA (FISSURE-IN-ANO) PROFORMA					
O.P.D. No. : A.R.C. No. :		AYURVEDA CENTRAL RESEARCH INSTITUTE आयुर्वेद केन्द्रीय अनुसंधान संस्थान ROAD NO. 66, PUNJABI BAGH (W.) NEW DELHI रोड नं. 66, पंजाबी बाग(प.) नई दिल्ली		Sl. No. : DATE :	
Pricking <input type="checkbox"/> Cutting <input type="checkbox"/> Throbbing <input type="checkbox"/> Burning <input type="checkbox"/> Leching <input type="checkbox"/>	Pain Y <input type="checkbox"/> N <input type="checkbox"/> Duration Onset Severity Upto 1 Yr. <input type="checkbox"/> Acute <input type="checkbox"/> Mild <input type="checkbox"/> 1-2 Yr. <input type="checkbox"/> Gradual <input type="checkbox"/> Moderate <input type="checkbox"/> Above 3 Yr. <input type="checkbox"/> Severe <input type="checkbox"/>	Bleeding Type of bleeding <input type="checkbox"/> Persistent <input type="checkbox"/> During/after defaecation <input type="checkbox"/> Mixed with stool <input type="checkbox"/> Malena <input type="checkbox"/>	Pruritis Present <input type="checkbox"/> Absent <input type="checkbox"/>	Bowel habits Normal <input type="checkbox"/> Constipated <input type="checkbox"/> Diarrhoea <input type="checkbox"/> With mucus <input type="checkbox"/>	
Previous H/o surgery Y <input type="checkbox"/> N <input type="checkbox"/> Hemorrhoidectomy <input type="checkbox"/> Fissurectomy <input type="checkbox"/> Fistulectomy <input type="checkbox"/> Any operation at Perineal region <input type="checkbox"/>	Name of the Patient _____ Age _____ Sex _____ Contact No. _____ Occupation _____ Income/cap./month-Rs. _____ Education _____ Address _____ Addiction _____ Total family members _____ Marital Status _____ Trial Started on _____ Total No. of days taken for cure _____ Result _____ <div style="text-align: right;">Signature of the Investigator</div>			Type of Fissure-in-Ano Acute <input type="checkbox"/> Acute on chronic <input type="checkbox"/> Chronic <input type="checkbox"/> Edges: Indurated <input type="checkbox"/> Undermined <input type="checkbox"/>	
Family History Present <input type="checkbox"/> Absent <input type="checkbox"/>	Associated diseases Y <input type="checkbox"/> N <input type="checkbox"/> Tuberculosis <input type="checkbox"/> Ulcerative colitis <input type="checkbox"/> Crohn's disease <input type="checkbox"/> Syphilis <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Others <input type="checkbox"/>	Position of Fissure-in-Ano 			Digital Examination Sphincter tone Normal <input type="checkbox"/> Hypertonic <input type="checkbox"/> Hypotonic <input type="checkbox"/>
		Tenderness Present <input type="checkbox"/> Absent <input type="checkbox"/>		Prostate Normal <input type="checkbox"/> Enlarged <input type="checkbox"/>	

COURTESY : ARC, IMS, BHU

CLINICAL ASSESSMENT AND FOLLOW-UP RECORD

Follow-ups (In weeks)	Pain	Bleeding	Inflammation	Discharge	Remarks
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

+ Mild
 ++ Moderatae
 +++ Severe

PROGRESS RECORD

Parameter	Before-Treatment	After Treatment	
		After 30 days	After 45 days
Hemoglobin%			
Pulse rate (Per minute)			
Blood Pressure (mm Hg.)			
Body Weight			

10.3 Patient Information Sheet

Clinical evaluation of Jatyadi gritha Pichu and Yasthimadhu gritha Pichu in the management of Fissure- in-ano (Parikartika)

Patient Information Sheet

1. Study title: Clinical Evaluation of Jatyadi gritha Pichu and Yasthimadhu gritha Pichu in the management of Fissure- in-ano (Parikartika)

2. Invitation

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve, please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

To evaluate clinical efficacy of Jatyadi gritha Pichu and Yasthimadhu gritha Pichu in the management of Fissure- in-ano (Parikartika)

4. Why have I been chosen?

Being a patient of Fissure- in-ano (Parikartika) you are considered as an ideal candidate for the study.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form later. If you agree to take part you are still free to withdraw at any time and without giving any reason. This will not affect the standard of care you receive.

6. What will happen to me if I take part?

If you agree to take part in this study you will be prescribed Ayurvedic formulations which will be given for 03 weeks if you give your consent to continue in the study. You have to come at every week for follow-up clinical examination and for collecting

the medicine for the next week. You have to undergo general physical examination and laboratory investigations from time to time for the assessment of the effect of the medicine you would be taking at that time. Thereafter, in the subsequent visits it may take nearly 15 – 20 minutes to make the assessment.

7. What do I have to do?

You have to adhere to the instructions given to you by your Investigator regarding taking the medicines as advised and reporting for follow up on the prescribed day.

8. What are the alternatives for diagnosis or treatment?

The modern system of treatment of Fissure- in-ano (Parikartika) involves the application of anesthetics (local), injections of botulin, fissurectomy, lateral sphincterotomy etc. which associated with side effects and expensive. The present study is being undertaken to scientifically study and validate the effect of this Ayurvedic formulation.

9. What if new information becomes available?

If during the course of the clinical trial some new information becomes available about the Ayurvedic treatment being studied, you will be informed about that by your investigator after which you are free to decide whether you want to continue in the study or not. If you decide to withdraw, this will not adversely affect your routine care in the hospital. If you decide to continue in the study, you will be asked to sign a fresh consent form. On the other hand upon receiving new information your investigator might consider it to be in your best interests to withdraw you from the study. Your investigator will explain the reasons for dropping you from the study and arrange for your routine care to continue.

10. What will happen to the results of the research study?

The results of the clinical trial will be published in leading medical journals so that other doctors and researchers can benefit from the results. You can ask your investigator for a copy of the publication. If published, your identity and personal details will be kept strictly confidential. No named information about you will be published in any of the trial reports.

11. Contact for further information

If desirous of any relevant information at any stage of the clinical trial, you may feel free to ask your investigator for that information. You would be given a copy of the information sheet and a signed consent form.

Translation of Patient information sheet into regional languages to be done by Investigator.

10.4 Consent Form

Clinical evaluation of Jatyadi gritha Pichu and Yasthimadhu gritha Pichu in the management of Fissure- in-ano (Parikartika)

Consent Form - To be signed on the day of Screening

1. Centre Code: -----
2. Participant enrollment ID for this trial: -----
3. Name of the Investigator -----
4. I confirm that I have read / the study has been explained to me adequately and I have understood the information sheet for the above study and had the opportunity to ask questions.
5. I hope to complete the study, but I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, and without my medical care or legal rights being affected.
6. I understand that my doctor will provide information about my progress,.
7. I understand that the information will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that sections of any of my medical notes may be looked at by the Sponsors or responsible individuals from the members of the IEC, Regulatory authorities. If necessary. I give permission for these individuals to have access to my records.
8. I understand what is involved in this trial and agree to take part in the clinical trial for a period of 14 weeks (including the follow up period of 2 weeks).


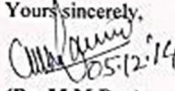
Name of the Patient	Signature	Date
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Name of the Witness	Signature	Date
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Name of the Investigator	Signature	Date
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Translation of Consent form into regional languages to be done

10.5 Institutional Ethics Committee's Certificate

	<p>राष्ट्रीय आयुर्वेद औषधि विकास अनुसंधान संस्थान सी. सी. आर.ए.एस्, आयुष मंत्रालय, भारत सरकार, नई दिल्ली भरतपुर, भुवनेश्वर - ७५१००३</p> <p>NATIONAL RESEARCH INSTITUTE OF AYURVEDIC DRUG DEVELOPMENT C.C.R.A.S, Ministry of AYUSH, Govt. Of India, New Delhi BHARATPUR, BHUBANESWAR- 751003, Email : nriadd-bhubaneswar@gov.in</p>	<p>Office Tel/Fax : 0674-2387702 Hospital : 0674-2387225 Director : 0674-2387703</p>
<p>संदर्भ क्रमांक/Ref.No.....</p>		<p>दिनांक/Date.....</p>
<p>INSTITUTIONAL ETHICS COMMITTEE</p>		
<p>Chairperson: Justice Sh.B.K.Behera Retd. Judge, 93, Kharavela Nagar, Bhubaneswar</p> <p>Members:</p> <ul style="list-style-type: none"> • Dr.P.R.Mishra Director, Asian Institute of Public Health, Bhubaneswar. • Prof. P.K.Nathsharma Ex-Principal, KATS Ayurvedic College, Ganjam. • Prof. K.B.Mahapatra Ex-Principal, Gopabandhu Ayurveda Mahavidyalaya, Puri • Dr. D.P.Sahu Medical Road, Athagarh,Cuttack. • Dr. N.P.Hota Research Officer Directorate of AYUSH, Govt. of Odisha • Prof. Sudarshan Behera Principal, Gopabandhu Ayurveda Mahavidyalaya, Puri, • Prof. Rita Roy Ex-Professor, Deptt. of Sociology, Utkal University, Bhubaneswar • Smt. Jayashree Mohapatra, 256,Sahid Nagar, Bhubaneswar <p>Member Secretary: Dr. M.M.Rao Director (Instt.) NRIADD, Bhubaneswar.</p>	<p>Ref. No: F.No. 6-137/2012-NRIADD/BBSR/Tech/1122 Dated 05.12.2014</p> <p>To Dr. M.M.Rao , Director (Instt.) Principal Investigator.</p> <p>Sub: Comparative study of Efficacy of Jatyadi Ghrit Pichu and Yasthimadhu Ghrita Pichu in the management of Parikartika (Fissure-in-Ano) - reg</p> <p>Sir,</p> <p>This is with reference to your letter regarding your above mentioned project for obtaining the approval from the IEC. The project has been reviewed in the IEC meeting held on 29.11.2014 and is "Ethically approved for all prospective cases w.e.f 29.11.2014".</p> <p>The study is valid for a period of 2 years, the entire study period according to this protocol under the responsibility of Dr. M.M.Rao, Director (Instt.) as Principal Investigator.</p> <p>You can commence your work on your Research Project on the condition that you inform the I.E.C. of the following.</p> <ul style="list-style-type: none"> • No significant changes to the research protocol should be made and implemented without prior consent of the IEC and any changes/deviations from the protocol which increase the risk for the subjects should be submitted to the IEC and approved prior to implementation. • IEC should be informed about all SAFs /Drug Reactions and /or Death while conducting this trial. • (a) Discontinuation (b) Abandonment (c) Completion of this Trial, stating the reasons, if the situation of (a) or (b) is encountered. • On completion of the above Research Project, the Principal Investigator is responsible for submitting a brief summary of the result obtained to the Chairperson of the IEC. • The study progress report should be made available for the IEC review on every 6 months. • It is hereby confirmed that neither you nor any of the study team members have participated in the voting decision making procedures of the Committee. <p>Yours sincerely,  (Dr. M.M.Rao) Member Secretary Ethics Committee</p>	