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# Comparative Clinical Study of *Apamarga Kshara Lepa* and *Saptacchada Kshara Lepa* in Chronic Fissure-in-Ano

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## ABSTRACT

*Parikarthika* (Fissure-in-ano) is the most dreadful and commonest disease among ano-rectal region. In modern system of medicine, the treatment of choice for Chronic Fissure-in-ano is surgical correction. Surgical procedures often leads to complications such as faecal incontinence, prolonged healing and postoperative care for longer duration. To overcome such problems it is important to find a technique that is safe, economical, cost effective with minimal operative complications and recurrence. So keeping in this view, *Apamarga Kshara Lepa* and *Saptacchada Kshara Lepa* were selected to give new dimension in the management of Chronic Fissure-in-ano. Both these drugs attains the qualities of *Chedana*, *Lekhana* in the form of *Kshara*. Hence this study was undertaken to compare the efficacy of *Apamarga Kshara Lepa* with *Saptacchada Kshara Lepa* in the management of Chronic Fissure-in-ano. 40 patients suffering from Chronic Fissure-in-ano, were selected and randomly divided into two equal groups A and B. Group A - Patients were treated with *Apamarga Kshara Lepa* and Group B - Patients were treated with *Saptacchada Kshara Lepa*. The observations were made before and after the treatment. On the basis of assessment criteria and on overall results of treatment, *Apamarga Kshara Lepa* had significant effect over *Saptacchada Kshara Lepa* in Chronic Fissure-in-ano. Group A and B got 100% results in symptoms like bleeding and burning sensation. Also, there was statistically significant reduction in pain and sphincteric spasm observed in group A. Hence it can be concluded that *Apamarga Kshara Lepa* has significant effect over *Saptacchada Kshara Lepa* in the management of Chronic Fissure-in-ano.

**Key Words** *Chronic Fissure-in-ano, Parikarthika, Apamarga kshara Lepa, Saptacchada Kshara Lepa*

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## INTRODUCTION

An Anal Fissure is a longitudinal tear or ulcerated area in the distal anal canal, usually in the posterior or anterior midline and extending from the level of dentate line out to the anal verge<sup>1</sup>. An Acute anal fissure has the appearance of a clean longitudinal tear in the anoderm, with

surrounding inflammation. A Chronic Fissure is usually deeper and generally has exposed internal sphincter fibers in its base. It is frequently associated with a hypertrophic anal papillae at its upper aspect and a sentinel pile at its distal aspect. The disease Fissure-in-ano is one of the common and dreadful ano-rectal disease owing to



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pain. It is one of the outcome of a sedentary lifestyle due to abstinence from the principles of *Dinacharya*, *Sadvritta* and *Ritucharya*. The particular disease fits with the nomenclature of *Parikarthika* in *Ayurveda* by its classical signs and symptoms. According to modern medicine Lord's dilatation and Lateral sphincterotomy are the treatment of choice in Chronic Fissure-in-ano. which has limitations such as faecal incontinence and prolonged healing.

Glimpses of *Parikartika* is available in *Sushruta Samhita* as complication in *Virechana vyapad*<sup>2</sup>, *Basti vyapa*<sup>3</sup>, *Bastinetra vyapad*<sup>4</sup>. Being caused by constipation and trauma, Anal Fissure does not have systemic involvement. Hence this disease maybe included under *Dushta Vrana*. For the management of *Vrana* Acharya *Sushruta* advocates '*Shashti-upakrama*'<sup>5</sup>.

*Acharya Sushruta* in *Ksharapakavidhi Adhyaya* has mentioned '23' drugs for the preparation of *Kshara* and *Ksharasutra*<sup>6</sup>. '*Apamarga*' and '*Saptacchada*' are two among them. Both these drugs attains the qualities of *Chedana*, *Lekhana* in the form of *Kshara*. Also *Kshara* was inherited with properties of *Shoolaghna*, *Vranahara* and *Krimighna* property.

Surgical procedures in the management of Chronic Fissure-in-ano often leads to complications such as faecal incontinence and also addressed with limitations such as prolonged hospitalisation, need of regular dressing and postoperative care for longer duration. So to overcome such problems it is important to find a technique that is safe, economical, cost effective,

minimally invasive and giving satisfactory result with minimal operative complications and recurrence. So in this study an effort is made to compare the effect of *Apamarga Kshara Lepa* with *Saptacchada Kshara Lepa* in Chronic Fissure-in-ano

## AIMS AND OBJECTIVES

- To evaluate the efficacy of *Apamarga Kshara Lepa* and *Saptacchada Kshara Lepa* in the management of Chronic Fissure-in-ano.
- To evaluate the efficacy of *Apamarga Kshara Lepa* in comparison with *Saptacchada Kshara Lepa* in the management of Chronic Fissure-in-ano

## MATERIALS AND METHODS

### Source of data:

Minimum of 40 patients attending OPD and IPD, Alva's Ayurveda Medical college Hospital and Alvas health Centre, Moodbidri, medical camps and other referrals were selected.

### Drug source:

Raw drugs were properly identified, selected and purchased from the local market. *Apamarga kshara lepa* and *Saptacchada kshara lepa* were prepared according to classical method in pharmacy Alva's Ayurveda Medical College, Moodubidire

### Method of collection of data:

**Study Design** – A Comparative clinical study.

**Sample Size** – Minimum 40 patients suffering from *Parikartika* fulfilling the Inclusion criteria



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were selected for comparative clinical study and assigned into two equal groups, A and B for the study, where group A is treated with *Apamarga kshara lepa* and group B is treated with *Saptacchada kshara lepa*

### Diagnostic criteria:

Signs & symptoms of *Parikartika* (Chronic Fissure-in-ano) such as:

- Gudagata Kartanvata Shoola* – cutting and tearing pain at anal region
- Daha* – burning sensation after defecation.
- Gudagata Raktasrava* -Blood streaks on the feces.
- Vibandha* – constipation.
- Vedana* -Tenderness at anal region

### Inclusion criteria :-

- Patients fulfilling the above mentioned diagnostic criteria.
- Patients between the age 15 to 60 , irrespective of sex , religion, occupation and economic status.

### Exclusion criteria :-

- Fissure secondary to Ulcerative colitis, Tuberculosis, Syphilis, Crohn's disease, inflammatory bowel diseases and other systemic disease pertaining to colo- rectum will be excluded from the study.
- Patients with Ca- rectum, Ca-a anus, fistula in-ano and haemorrhoids.
- Pregnant women.
- Patients with infectious diseases AIDS and HBsAg-Positive Patient

### Procedure:

The whole procedure is divided into 3 steps, *Purva*, *Pradhana*, and *Paschat Karma*. In *Purva*

*Karma*, Informed consent was taken from the patient and established investigation report with the patient. Part preparation was done followed by soap water enema given two hours prior to the procedure. In *Pradhana Karma*, patient was made to lie down in Lithotomy position. Painting, draping was done and local anaesthesia given with Inj. Lignocaine 2%. Two finger anal dilatation was done using lignocaine gel. Distal part of sentinel pile excised using curved tissue cutting scissors. Followed by this , in group A patients, *Apamarga Kshara Lepa* and in group B *Saptacchada Kshara Lepa* applied to the Fissure bed and edges using spatula and waited for *Shatamatrakala*. Afterwards, the *Kshara* removed and washed thoroughly with *Nimbu Swarasa*. *Yashti Madhu Thaila Pichu* applied after the procedure. Dressing was done under aseptic precautions .

### In *Paschat Karma*

- Sitz bath with lukewarm water given for 10-15 minutes twice a day.
- Tab. *Triphala Guggulu* 1 tablet (250mg) thrice a day after food.
- Tab. *Gandhaka Rasayana* 1 tablet (125mg) thrice a day after food

### Assessment Criteria:

Effect of treatment assessed on the basis of gradation of both subjective and objective parameters before and after treatment.

### Subjective Parameters:

- Severity of Pain
- Duration of pain
- Burning sensation



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### Objective Parameters:

- Size of ulcer
- Sphincteric spasm

**Study period:** Total study period including observation and follow up - 60 days

**Observation Period:** Observation done and parameters assessed before treatment on 1st day and after treatment on 3<sup>rd</sup>, 5<sup>th</sup>, 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup>, 28<sup>th</sup>.

**Follow up:** Follow up done on 45th and 60th day

**Statistical Method:** Non-parametric test Mann-Whitney U test was used to compare within the groups. Fishers F test was performed for comparing the effectiveness of treatment between Group- A and Group-B

## OBSERVATIONS AND RESULTS

In this study, 40 patients with Chronic Fissure-in-ano were selected and randomly distributed into 2 groups, Group A and Group B, containing 20 patients in each groups. Patients in group A were treated with *Apamarga Kshara Lepa* and patients in group B were treated with *Saptacchada Kshara Lepa*. The data was collected before treatment on 1<sup>st</sup> day and post operatively on 3<sup>rd</sup> day, 5<sup>th</sup> day, 7<sup>th</sup> day, 14<sup>th</sup> day, 21<sup>th</sup> day, 28<sup>th</sup> day. Symptoms like pain, bleeding, burning sensation, size of the ulcer and sphincteric spasm were used to evaluate the effectiveness of treatment in both groups. Univariate and multivariate analysis was done to find the significant association. Frequency tables were used for Univariate analysis for finding mean and standard deviation. Non-parametric test Mann-Whitney U test was

used to compare within the groups. Fishers F test was performed for comparing the effectiveness of treatment between Group- A and Group-B.

## DISCUSSION

It is well accepted that *Parikarthika* as per *Ayurvedic* terminology resembles much to Fissure-in-ano, as described in modern medicines. *Ayurvedic* texts reveals description of various diseases affecting ano-rectal region, namely *Arsha*, *Bhagandara*, *Guda bhramsha*, *Guda Kutta* etc. *Acharyas* have been explained the aetiopathogenesis, clinical features and treatments of these diseases. Apart from these diseases the term *Parikarthika* has been used at different contexts. It is surprising to note that *Parikarthika*, even being one of the most common ailments of ano-rectal region, has not been described as a separate disease entity by the *Acharyas*. However, a detailed exploration of literature suggests some words which clinically may resemble this condition. *Parikartika* is a word which has been referred in *Bruhat-trayi* as a complication of other diseases pertaining to ano-rectal and oesophageal regions and their therapies. Description of this condition is very much suggestive of the modern ailment Fissure-in-ano when it is limited to anal-region.

*Acharya Sushruta* has described *Parikartika* somewhat in descriptive manner not as a separate disease entity, but as a complication of other diseases or a condition produced while conducting therapies for other diseases. He has also described its treatment, but he has not given



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much description about its pathology, types, surgical and para surgical treatments.

In the present study, total 40 cases were divided into two groups. In first group the patients were treated with *Apamarga Kshara* and second group with *Saptacchada Kshara*.

### DISCUSSION ON OBSERVATION

The patients in this study were put into 5 age groups. The maximum number patients were in the age group of 15-24 years 37.5% while 17.5 % were from the age group of 25-34 years. This may be due to the reason that this age group people belong to students and working class, more prone to altered food habit and junk food intake. Life style disorders and digestive problems are also prominent in this age group. Which can lead to improper digestion and constipation, finally can result in Fissure-in-ano. The male patients constituted 60% and female patients constituted 40%. This may be because of the irregular food habits, office work and strenuous works. Students constituted the maximum number i.e., 47.5%. 22.5% of patients were housewife, 17.5% were office workers and 12.5% were labourers. This may be due to life styles and improper and irregular food intakes. 52.5% of patients were having mixed diet, while 47.5% were taking vegetarian diet. Majority of patients has no family history that is 97.5%, while 2.5% has family history. Maximum

number of patients belonged to the Hindu community 70%, followed by Christians 17.5% and Muslims 12.5%. This observation is in accordance with predominance of population in study area. In the present study, all 40 patients were having pain, presence of ulcer and sphincteric spasm as symptoms. 90% of patients were having burning sensation and 62.5 % were having bleeding as the presenting complaint.

### DISCUSSION ON RESULT

Distibtion of 40 patients according to present complaints were done (table no:1). Combined effect of treatment procedure along with medications prescribed in postoperative period was taken into consideration. Both groups got 100% results in the symptoms like bleeding, burning sensation and size of ulcer (table:3,4) . Where as in pain Group A got 95% and Group B got 55% result as shown in (table :2) . In sphincteric spasm Group A got 95% result, while Group B got 80% result as per (table:5) . Reduction of symptoms was there while using both *Kshara Lepas*. But *Apamarga Kshara Lepa* has significant effect than *Saptacchada Kshara Lepa* in Chronic Fissure-in-ano. Thus, the null hypothesis is rejected and alternate hypothesis H2 that is, *Apamarga Kshara Lepa* has significant effect over *Saptacchada Kshara Lepa* in Chronic Fissure-in-ano is accepted.

**Table 1** Distribution of 40 patients according to presenting symptoms

Symptoms	Group A		Group B		Total	
	No:	%	No:	%	No:	%
Pain	20	100	20	100	40	100



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Bleeding	12	60	13	65	25	62.5
Burning sensation	18	90	18	90	36	90
Presence of ulcer	20	100	20	100	40	100
Sphincteric spasam	20	100	20	100	40	100

Table 2 Effect on Pain between Groups

Days	Group A		Group B		Z	P
	Mean	SD	Mean	SD		
1 <sup>st</sup> Day	2.95	0.224	2.95	0.224	0	1
3 <sup>rd</sup> day	2.85	0.366	2.85	0.366	0	1
5 <sup>th</sup> day	2.70	0.571	2.70	0.571	0	1
7 <sup>th</sup> day	1.90	0.308	1.90	0.308	0	1
14 <sup>th</sup> day	1.70	0.470	1.70	0.470	0	1
21 <sup>st</sup> day	1.20	0.523	1.25	0.550	-1	0.317
28 <sup>th</sup> day	0.85	0.489	0.95	0.510	-1	0.317
ANOVA	F=284.42	P<0.001	134.62	P<0.001	P<0.000	
Percentage decrease from 1 <sup>st</sup> day to 28 <sup>th</sup> day	95%		55%			

Table 3 Effect on bleeding between groups

Days	Group A		Group B		Z	P
	Mean	SD	Mean	SD		
1 <sup>st</sup> Day	0.70	0.657	0.70	0.657	0	1
3 <sup>rd</sup> day	0.45	0.510	0.45	0.510	0	1
5 <sup>th</sup> day	0.10	0.308	0.10	0.308	0	1
7 <sup>th</sup> day	0.00	0.000	0.00	0.000	0	1
14 <sup>th</sup> day	0.00	0.000	0.00	0.000	0	1
21 <sup>st</sup> day	0.00	0.000	0.00	0.000	0	1
28 <sup>th</sup> day	0.00	0.000	0.10	0.447	-1	0.317
ANOVA	13.18	P<0.001	12.28	P<0.001		
Percentage decrease from 1 <sup>st</sup> day to 28 <sup>th</sup> day	100%		95%		P<0.05	

Table 4 Effect on size of ulcer between groups

Days	Group A		Group B		Z	P
	Mean	SD	Mean	SD		
1 <sup>st</sup> Day	1.90	0.788	1.90	0.788	0	1
3 <sup>rd</sup> day	1.80	0.696	1.80	0.696	0	1
5 <sup>th</sup> day	1.40	0.598	1.40	0.598	0	1
7 <sup>th</sup> day	0.70	0.657	0.70	0.657	0	1
14 <sup>th</sup> day	0.55	0.605	0.55	0.605	0	1
21 <sup>st</sup> day	0.30	0.571	0.30	0.571	0	1
28 <sup>th</sup> day	0.05	0.224	0.05	0.224	0	1
ANOVA	F=61.70	P<0.001	F=61.70	P<0.001	P value<0.05	
Percentage decrease from 1 <sup>st</sup> day to 28 <sup>th</sup> day	95%		95%			

Table 5 Effect on sphincteric spasm between groups

Days	Group A		Group B		Z	P
	Mean	SD	Mean	SD		
1 <sup>st</sup> Day	1.35	0.489	1.35	0.489	0	1
3 <sup>rd</sup> day	1.20	0.523	1.20	0.523	0	1
5 <sup>th</sup> day	0.80	0.616	0.85	0.671	-1	0.317



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7 <sup>th</sup> day	0.25	0.444	0.40	0.598	-1	0.317
14 <sup>th</sup> day	0.10	0.308	0.20	0.410	-1	0.317
21 <sup>st</sup> day	0.05	0.224	0.20	0.410	-1	0.317
28 <sup>th</sup> day	0.05	0.224	0.20	0.410	-1	0.317
ANOVA	F=42.34	P<0.001	F=23.68	P<0.001	P<0.05	
Percentage decrease from 1 <sup>st</sup> day to 28 <sup>th</sup> day	95%		80%			

CONCLUSION

Fissure-in-ano is the most common and most painful disease among ano-rectal disorders. It is a crack or longitudinal ulcer in the long axis of anoderm with excruciating pain during and few hours after defecation. On the basis of causes and excruciating pain as dominant symptoms, the disease Fissure-in-ano can be correlated to the disease *Parikartika* described in *Ayurvedic* classics. Chronic Fissure-in-ano has the chief complaints of severe pain, bleeding, burning sensation, sphincteric spasm along with sentinel pile. So these symptoms are taken as assessment criteria for this study. During treatment period as well as follow up period, no adverse effect of any drugs or procedure was noticed. In the follow up study, it was observed that the results achieved were effective and stable. Based on the clinical study it can be concluded as *Apamarga Kshara* has significant effect over *Saptacchada Kshara* in Chronic Fissure-in-ano. However further studies with large samples and various study groups, may be beneficial to establish the results obtained in the present study.



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