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A Clinico-Comparative Study To Evaluate The Efficacy Of *Lajjalu Taila Pichu* And *Jatyadi Taila Pichu* In The Management Of *Parikartika* W.S.R. To Fissure-In-Ano

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ABSTRACT: An anal 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 may heal with conservative management but once the fissure is recurrent or chronic, surgical intervention is required. Contrary to modern therapeutic modalities, Ayurveda offers safe, effective and cost effective therapeutic modalities in the management of Fissure-in-ano (*Parikartika*). With the aims and objectives of Evaluation of clinical efficacy of *Pichu* application of *Lajjalu taila and Jatyadi Taila* in the management of Fissure-in-ano (Both acute and chronic), the present research work has been planned. It is a clinico-comparative study where 60 patients of fissure-in-ano were taken in two groups with 30 patients in each group viz: Group I - Application of *Lajjalu Taila Pichu*. Group II - Application of *Jatyadi Taila Pichu*. Both preceded by sitz bath with luke warm water and internal administration of *Anuloma Churna* (Only for Constipated patients) 3-5 grams at bed time with Luke warm water. The *Pichu* was applied on daily basis for 7days (One week) (at OPD / IPD level) and thereafter, asked to visit the Ano-rectal clinic at an interval of 7 days for one month of follow-up. **Results:** After the completion of this study, when overall results on symptoms were calculated, *Jatyadi Taila pichu* was found better than *Lajjalu Taila pichu*. *Jatyadi Taila pichu* showed 90% relief in reducing the symptoms shown in the observation.

KEY WORDS: *Parikartika, Lajjalu taila pichu, Jatyadi taila pichu, Anuloma churna*

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INTRODUCTION:

Fissure-in-ano is a troubling and painful condition that affects a great majority of the population over the world. It is equally one of the most common reasons of bleeding per rectum. Acharya Sushruta has described “*Parikartika*” as a *Kartanavat shoola*, *Anilasanga* and *Daha* in the Guda¹. He explains it as a complication of *Virechana karma*, *Basti karma* and also as a sequel of *Atisara*, *Jwara*, *Garbhini vyapad*^{12,13}. Wound healing is one of the treatment modalities in the treatment of chronic fissures. *Lajjalu* (*Mimosa pudica* Linn.) is known to possess *Vrunaghna*, *Sandhaniya* and *Raktasthambhana* properties, & indicated mainly in *Raktapitta*, *Daaha*, *Vruna*, *Shotha*⁷, etc. which are essential in the management of anal fissure. Considering these different aspects in mind,

the study was planned to see the effect of *Lajjalu taila* in the management of fissure-in-ano. Moreover, drug in the taila medium gives good lubricating action relieving muscular spasm. Many previous works are already done by using *jatyadi taila* and proved to be effective. Here, an attempt is made to study comparative efficacy of both *taila* in *parikartika*.

Objectives of the study:

- Detailed literary review of *Parikartika*.
- Detailed literary review of Fissure-in-ano.
- Evaluation of the effect of *Lajjalu taila pichu* in *Parikartika*.
- Evaluation of the effect of *Jatyadi taila pichu* in *Parikartika*

- Compare and ascertain the effect of *pichu* of *Lajjala taila* & *Jatyadi taila* in *Parikartika*

MATERIALS AND METHODS:

Study Design

It is a single blind study with minimum of 60 patients fulfilling the diagnostic and inclusion criteria of either sex will be

selected for the study and divided in two groups. Namely Group-A & Group-B

- Group-A: Minimum number of patients 30.

Procedure : Per rectal application of *lajjala taila pichhu* once daily.

- Group-B : Minimum number of patients 30.

Procedure : Per rectal application of *jatyadi taila pichhu* once daily.

Study Plan

Study Type	:	Interventional
Purpose	:	Treatment
Masking	:	Open label
Timing	:	Prospective
End Point	:	Efficacy
No. of Groups	:	Two
Sample size	:	60 (Group – I : 30 ; Group – II : 30)
Duration of the treatment	:	Seven Days. (Duration of the Study Period) Follow up at an interval of one week for a period of one month
Centre	:	S.S.R. Ayurvedic Medical College Hospital, Inchal. Tq: Saundatti, Dist: Belgaum, Karnataka.

Advice:

Anuloma choorna one karsha will be given daily at night during the procedure period with warm water as stool softener. As passing of hard stool will hinder the process of healing and to avoid further complications.

Roughage diet, intake of plenty of fluids and avoiding spicy, oily food and vehicle riding.

Inclusion Criteria:

1. Clinically diagnosed cases of *Parikartika* (both acute and chronic) will be taken for the study.
2. Patients irrespective of sex, religion, occupation & economic status.
3. Patients of both the sexes in between the age group of 18 to 60 years.
4. Patients of *Parikartika* with systemic diseases like Diabetes and Hypertension which are under control, are also included in the study.
5. Female patients with pregnancy were also included.

Exclusion Criteria:

1. Patients with uncontrolled Diabetes and Hypertension.
2. Patients having *Parikartika* (Fissure-in-ano) secondary to Ulcerative colitis, Syphilis, Crohn's disease, Tuberculosis and Ca of rectum and anal canal.
3. Patients with infectious diseases like HIV and HbsAg.
4. Patients suffering from any other ano rectal diseases like Hemorrhoids, Perineal abscess, Fistula-in-ano.
5. Patients below the age of 18yrs and above the age of 60 yrs.

Assessment Criteria: The patients will be assessed on the basis of subjective and objective parameters before and after treatment.

Subjective parameters:

- *Gudagata kartanavat peeda* (cutting and burning type of pain).
- *Gudagata raktasrava* (per rectal bleeding).
- Constipation
- *Gudadaaha*.

Criteria of Assessment:**Table 4 : Relief of Symptoms before and after treatment.**

Relief, Withdrawal	Description
Complete Relief	Above 75 % Complete disappearance of known symptoms and absence of complications and Recurrence
Marked Relief	Above 50% to 75% disappearance of known symptoms and absence of complications and Recurrence
Moderate Relief	Above 50 % relief in presenting symptoms and some recurrence of fissure
Mild Relief	25 % and above relief in presenting symptoms with negligible change in the ulceration of fissure
No Relief	No relief in presenting symptoms and no change in the ulceration of fissure
Withdrawal / Dropout	<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 5 : Healing status of Ulcer

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

Table 6 : Gradation: Subjective Parameters

Symptoms	Before Treatment	After Treatment
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
Bleeding	Severe – 3 Moderate – 2 Mild-1 No –0	Severe – 3 Moderate – 2 Mild – 1 No – 0
Constipation	Severe – 3 Moderate – 2 Mild-1 No –0	Severe – 3 Moderate – 2 Mild – 1 No – 0
Gudadaaha	Severe – 3 Moderate – 2 Mild-1 No –0	Severe – 3 Moderate – 2 Mild – 1 No – 0

Objective parameters:

- Tenderness.
- Size of the ulcer(Fissure bed).
- Sphincteric spasm.

- **Gradation: Objective Parameters, Table 7**

Symptoms	Before Treatment	After Treatment
Sphincter tone assessment	Tightly contracted -2 Spasmodic -1 Normal-0.	Tightly contracted -2 Spasmodic -1 Normal-0.
Size of Ulcer	Big – 3 Medium - 2 Small - 1 No ulcer – 0	Big – 3 Medium - 2 Small - 1 No ulcer- 0
Tenderness	Completely Tenderness - 2 Tenderness - 1 No Tenderness -0	Completely Tenderness – 2 Tenderness - 1 No Tenderness -0

A-Gradation of Subjective parameters:

1-Bleeding:

- **No Bleeding**
- **Mild** : Streak wise bleeding along with defecation only over the stool
- **Moderate**: Drop wise bleeding during and after defecation 10-20 drops, stopped.
- **Severe** : Profuse bleeding drop wise or stream wise amounting more than 20 drops in each defecation.

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 stools once in a week with difficulty

3 Gudagata kartanavat peeda :

- **No Pain**
- **Mild**: Pain is relieved after defecation immediately on its own
- **Discomforting**: Pain persists for few hours after defecation and relieved without medicine
- **Distressing**: Pain persists for few hours after defecation and relieved with medicine
- **Horrible**: Executing pain during and after defecation and relieved only with medicine, hampering normal routine
- **Excruciating**: Patient struggles due to pain all the daylong and patient had drastic medicine for the same

4- Guda daaha :

- No Daaha
- Mild
- Moderate
- Severe- constant burning sensation

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. Tenderness

- No Tenderness
- Tenderness: Pain on touch
- Completely Tenderness: Patient does not allow even to touch and feels difficulty in sitting

3. Sphincter tone.

- Normal
- Spasmodic
- Tightly contracted

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

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

OVERALL RESULT ASSESSMENT:

Overall effect of the therapy was assessed in terms of Cured, Marked Improvement, Moderate Improvement, Mild Improvement and Unchanged by adopting the following criteria.

Cured	100% relief in chief complaints and no recurrence during follow up study was considered as cured.
Marked Improvement	> 75% improvement in chief complaints was recorded as marked improvement.
Moderate Improvement	51 to 75% improvement in chief complaints was considered as moderate improvement.
Mild Improvement	26 to 50 % improvement in chief complaints was considered as mild improvement.
Unchanged	Up to 25% reduction in chief complaints was noted as unchanged.

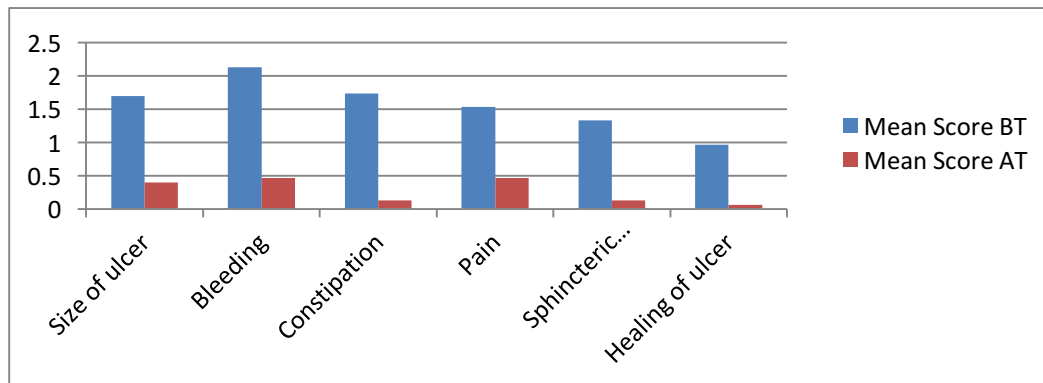
OBSERVATIONS

Assessment of the Treatment with *Lajjalu taila* (Group-I) and *Jatyadi taila* (Group-II):

Group-I (Effect of therapy by *Lajjalu Taila*):

Symptoms	Mean Score BT	Mean Score AT	% Relief
Size of ulcer	1.7	0.4	76.47
Bleeding	2.13	0.46	78.40
Constipation	1.73	0.13	92.48
Pain	1.53	0.46	74.82
Sphincteric spasm	1.33	0.13	90.22
Healing of Ulcer	0.96	0.06	93.75

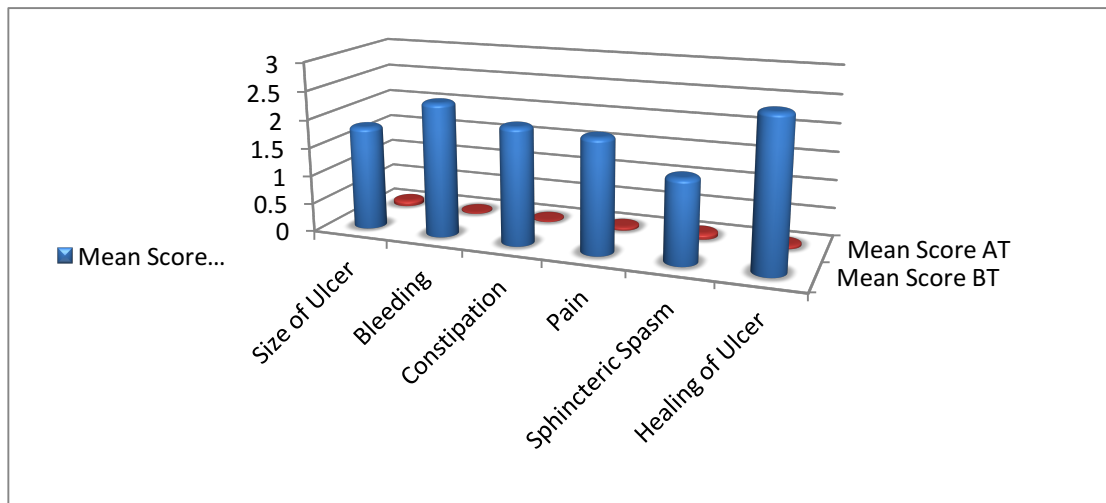
Incidence of effect of therapy by *Lajjala Taila pichu*.



Group-II (Effect of Therapy by *Jatyadi Taila Pichu*):-

Symptoms	Mean score BT	Mean score AT	% Relief
Size of ulcer	1.83	0.10	96.17%
Bleeding	2.36	0.03	98.22%
Constipation	2.06	0.03	98.54%
Pain	2.00	0.06	97%
Sphincteric Spasm	1.46	0.10	93.15%
Healing of Ulcer	2.63	0.06	97.71%

Incidence of effect of therapy by Jatyadi Taila Pichu:



Overall effect of Therapy:

Result	Group – I		Group – II	
	No Of Patients	%	No Of Patients	%
Cured	20	66.67	28	93.33
Improved	10	33.33	2	6.67
Total	30	100	30	100

It was noticed that in Group I, maximum 66.67% patients had complete healing which was occurred within 7 days and improved cases were 33.33%.

In Group II, 93.33% patients showed complete healing within 7 days followed by 6.67% patients with improved healing.

Comparative result between Group-I & Group-II

Sl. No	Symptom	Mean +SE (Diff.)	P value	Remarks
1	Size of ulcer	0.43 ± 0.12	<0.05	Significant
2	Bleeding	0.66 ± 0.19	<0.05	Significant
3	Constipation	0.43 ± 0.22	>0.05	Significant
4	Pain	0.86 ± 0.17	<0.05	Significant
5	Sphinctric Spasm	0.16 ± 0.18	>0.05	Significant
6	Healing of Ulcer	0.60 ± 0.18	<0.05	Significant

DISCUSSION

Careful observations were recorded under the following headings:

1. Condition of Patients on Admission: Age, Sex, Marital 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.

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 (43%) 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 over straining,

increased travelling, stress and strain, improper attention to bowel habits, local unhygienic, improper dietary habits, sedentary lifestyle, 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 suggests 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 both the 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 (83.3%) habituated to a non-vegetarian diet suffered from the disease compared to the patients following a vegetarian (16%) 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 (95%) suffered from constipation and few of the patients (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 (81.6%) 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 cases have a chronicity of one year, 48.3 percent of the patients of fissure in ano reported a chronicity of less than one year.

Condition of the disease: Majority of the patients (58%) of fissure-in-ano had attended the OPD as fresh cases while 33.3 percent of cases had undergone medical treatment for the same purpose, hence it revealed that repeated incidences were seen even after taking modern therapy for the fissures.

Position of the disease: Fissures were commonly found (51.6%) at 6 O' clock

position with indurated edges. About 58 percent of fissure patients had itching ani.

Discussion on overall effect of the therapy:- It was noticed that in Group I, maximum 65% were cured by complete healing occurred within 7 days and improved cases were 35%. While in Group II, 90% patients showed complete healing within 7 days followed by 10% patients with improved healing. The Difference might be due to effect of *Jatyadi taila pichu* which was performed in Group II.

It is very clear from the above discussion that the present study (both I and II group) has a definite role in the management of Fissure-in-ano statistically. When comparative differences were analyzed, group II was found more significant for reducing some symptoms like Pain, Healing of ulcer and Sphincteric spasm. But clinically group II was found more effective as compared to group I in reducing the symptoms of Fissure-in-ano. This difference might be due to the effect of *Jatyadi taila pichu*, which was performed in group II. The efficacy and safety profile of the study drug and *Jatyadi Taila pichu* were excellent in curing the symptoms of Fissure-in-ano.

CONCLUSION:

After the completion of this study, on applying the test over the observation, it was found that both the groups were significant. On applying the test over the individual symptoms present i.e, pain and spasm can be relieved much earlier by the application of *Jatyadi Taila* rather than *Lajjalu Taila*.

When overall results on symptoms were calculated, *Jatyadi Taila pichu* was found better than *Lajjalu Taila pichu*. *Jatyadi Taila pichu* showed 90% relief in reducing the symptoms shown in the observation.

Hence by looking at the overall results of both groups it was found that group II-*Jatyadi Taila Pichu* showed better results in reducing symptoms and also in

healing the fissure faster. Based on this study it can be concluded that, *Jatyadi Taila pichu* gives better results in the management of *Parikartika*.

SCOPE OF FURTHER STUDY

The present study is carried out in small number of subjects. Here we suggest further study to be conducted in larger number of patients so as to get still more correct values.

In Group II, *Jatyadi Taila Pichu* got better results than the group I, where *Lajjalu Taila pichu* was applied. So there is scope for further study for still better results by using many drugs, local applications along with internal medicine and local application of *Lajjalu Taila Pichu* in managing *Parikartika*.

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