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A Clinical Study to Evaluate the Efficacy of *Bala Taila Pichu* Compared with *Jatyadi Taila Pichu* in the Management of *Parikartika* w.s.r. to Acute Fissure-in- Ano

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ABSTRACT:

Introduction: The squamous mucosa of the lower half of the anal canal is prone to superficial ulceration, which presents as an anal fissure. In Ayurveda, *Parikartika* is described as one of the commonest ailments of *guda pradasha*. *Parikartika* is described as the *vyapat*/complication of other diseases, like, *vamana-virechana vyapat* and *basti vyapat*. The location, signs and symptoms explained in Ayurveda resemble the description of Fissure-in-ano. Fissure-in-ano may occur due to various reasons like constipation, tuberculosis, Crohn's disease etc. The treatment procedures mentioned for *Parikartika* in Ayurveda are *Anuvasana/matra basti, pichu, parisheka, lepa* with *Sneha dravyas*.

Aims and objectives: Evaluation and comparison of the effects of *Bala taila pichu* and *Jatyadi taila pichu* in *Parikartika* w.s.r. to Acute Fissure-in-ano. **Materials and Methods:** A clinical trial conducted on 60 patients with established cases of Acute fissure-in-ano, divided them into two groups of 30 patients each. The patients were selected from department of Shalya tantra in Sri Shivayogeeswar Rural Ayurveda Medical College and Hospital, Inchal, Belagavi. Group 1 - *Bala taila pichu* for 7 days. Group 2- *Jatyadi taila pichu* for 7 days.

Results: After completion of this study, there was marked improvement in the signs and symptoms of the condition, with the treatment with both *Bala taila pichu* and *Jatyadi taila pichu*.

Key words: Acute fissure-in-ano, *Parikartika*, *Bala taila pichu*, *Jatyadi taila pichu*

INTRODUCTION

Parikartika is a condition wherein a person has severe pain and burning sensation with other associated symptoms at the anal region. Ayurveda *samhitas* describe it as a condition with *kartnavat shoola, daha*, and that which happens due to *anilasanga*. In *samhitas*, *Parikartika* is

described to be the *vyapat*/complication of other diseases, such as *vamana-virechana vyapat* and *basti vyapat*^{1,2}. The detailed explanation of treatment of *Parikartika* is given by *Acharya Charaka, Acharya Vagbhata, Acharya Sharangadhara, Acharya Kashayapa, Acharya Sushruta*



explains that in person having *mrudu koshta/ mandagni*, intake of *ati rooksha/ ati teekshna/ ati ushna/ ati lavana ahara*, causes vitiation of *anila* and *pitta* which in turn causes *Parikartika*. When the description of Fissure-in-ano^{3,4} is overviewed – the location, pathology, signs and symptoms are resembling with those of *Parikartika*. It presents with the symptoms like excruciating pain, burning sensation, itching, blood discharge etc. Fissure-in-ano may be caused by various reasons like constipation/diarrhoea, tuberculosis, abscesses, carcinoma, inflammatory bowel disorders, trauma during child birth, Crohn’s disease, ulcerative colitis etc. An anal fissure rests directly on the internal anal sphincter and are easily visible on inspection. The internal sphincter would have undergone a perpetual state of spasm due to irritation and hypertrophies. Fissure-in-ano is a medico-surgical condition. Medical treatment includes topical nitroglycerin, 5% xylocaine ointment or calcium channel blockers and surgical treatments like Lateral/Posterior sphincterotomy or Excision of Anal Ulcer or Lord’s anal dilatation. There are specific drawbacks with these modern approaches like gastric irritation, recurrence in conservative type of approach and complications in surgical approach like haematoma, faecal incontinence etc. This shows the area where Ayurvedic treatment modalities come to light which are easy to perform, effective, affordable and safe. The treatment procedures mentioned for *Parikartika* are *Anuvasana/matra basti, pichu, parisheka, lepa* with *Sneha dravyas*. In this present study, *pichu* is employed to be the treatment approach. *Pichu* is a modality of drug delivery which increases the contact time between the tissue and drug. *Pichu dharana* is a process in which a piece of gauze, or a cotton pad is soaked in the medicated drug and placed in the site of treatment. Hence in this study, an attempt is made to study the efficacy of *Bala taila pichu* which acts as *shoolaghna, daha shamaka, rakta stambhaka, vrana ropaka* and *shothaghna*, in *Parikartika* (acute fissure-in-ano) and the results will be compared with results obtained from *Jatyadi taila pichu* which is already proven to be effective from previous studies.

MATERIALS AND METHODS

Pichu application, an ayurveda approach, is a mode of drug delivery that enhances the contact time of drug with the tissue that improves the bio-availability of the drug. Based on this view, a clinical trial was conducted on 60 patients with established cases of Acute fissure-in-ano. They were divided into two groups with 30 patients in each of them.

The patients were selected from the out-patient and in-patient department of Shalya tantra in Sri Shivayogeeshwara Rural Ayurveda Medical College and Hospital, Inchal, Savadatti taluk, Belagavi. All the patients were explained about the clinical trial in the regional language or the language known to them, and written consents were obtained from the patient before initiation of the study. Approval from the ethical clearance committee was obtained (Ref. No. – SSRAMC/417/2020/EC).

Study design: Table 1

Inclusion Criteria:

1. Patients of both sexes.
2. Patients irrespective of religion, occupation, socio-economic status.
3. Patients who are clinically diagnosed as a case of *Parikartika*.
4. Patients preferably aged between 15-60 years.
5. Patients who are K/C/O hypertension, diabetes mellitus only which are under control.
6. Pregnant women.

Exclusion criteria:

1. Patients who are aged below 15, and more than 60 years.
2. Patients of *Parikartika* secondary to other diseases like Ca, ulcerative colitis, crohn’s disease, tuberculosis etc.
3. Patients with uncontrolled hypertension and Diabetes.
4. Patients who are diagnosed as HIV +ve, HBsAG +ve, severely anaemic. Materials required:

Sterile gloves, sterile swabs, sterile gauze pieces, sterile kidney trays, probe – to measure the length of the ulcer, *Bala taila, Jatyadi taila*.

Procedure:

Group-A:

Poorva karma

- Procedure was explained to the patient and consent was taken.
- Patient was made to lie in Lithotomy position on examination table.
- Per-rectal examination was done by using Lignocaine 2% gel for lubrication and anaesthetic purpose.
- Fissure was visualized by stretching the anal verge using fingers.

Pradhana karma

- Fissure was visualized by stretching the anal verge using fingers.
- A gauze piece (4x4cm) was dipped in *Bala taila* and then it was applied over the ulcer/fissure (*Bala taila pichu*). It was applied once in the morning after defecation and at night.
- Proper bandaging was done every time the pichu was placed over the ulcer.

Paschat karma

- Patient was asked to lie in supine position for 10minutes and the vitals were monitored carefully.
- Assessment of pain, burning sensation, itching, bleeding and size of the ulcer were made at regular intervals and also at the end of 7 days of application.
- All the patients were asked to take fiber rich diet, non-spicy foods, foods which are not oily/fried, plenty of oral liquids and advised Sitz bath with warm water.

Group-B:

Poorva karma

- Procedure was explained to the patient and consent was taken.
- Patient was made to lie in Lithotomy position on examination table.
- Per-rectal examination was done by using Lignocaine 2% gel for lubrication and anaesthetic purpose.
- Fissure was visualized by stretching the anal verge using fingers.

Pradhana karma

- Fissure was visualized by stretching the anal verge using fingers.
- A gauze piece (4x4cm) was dipped in *Jatyadi taila* and then it was applied over the ulcer/fissure (*Jatyadi taila pichu*). It was applied once in the morning after defecation and at night.
- Proper bandaging was done every time the pichu was placed over the ulcer.

Paschat karma

- Patient was asked to lie in supine position for 10minutes and the vitals were monitored carefully.
- Assessment of pain, burning sensation, itching, bleeding and size of the ulcer were made at regular intervals and also at the end of 7 days of application.
- All the patients were asked to take fiber rich diet, non-spicy foods, foods which are not oily/fried, plenty of oral liquids and advised Sitz bath with warm water.

Assessment criteria:

Changes in the subjective and objective parameters were observed before, during and after the treatment.

1. Visual analogue scale was used to assess pain.
2. Status of bleeding, burning sensation and itching were assessed by examination and interrogation.
3. Healing of the fissure is assessed by physical examination.

Assessment parameters: Subjective parameters table 2

Objective parameters: Table 3

Assessment of relief of symptoms after the treatment: Table 4

RESULTS OF OVERALL EFFECT OF THERAPY

Results on group-A Table 5, Table 6 Results on Group-B

DISCUSSION

Evaluation of clinical efficacy of *Bala taila pichu* and *Jatyadi taila pichu* in the management of Acute Fissure-in-ano w.s.r to *Parikartika* and comparative analytical study of unique drug delivery system with simple Pichu were the objectives of this study. The condition of *Parikartika* is not directly described as a separate disease in Ayurveda classics. The scattered information available in the texts explains that the condition occurs due to improper administration of *Virechana* and *Basti*, *Vataja atisara*, as a complication of pregnancy, *Apanavata avruta varchas* that leads to constipation, *rooksha* and *shushka aushadha*. If *rookshabasti* containing *lavana* and *teekshna dravyas* are administered in higher doses, it may produce *Parikartika*. This condition can be correlated with Fissure-in-ano since both the conditions have similar clinical manifestations and both occur in Guda. The characteristics of Fissure-in-ano are sharp cutting pain in the anal region, per rectal bleeding, ulcer. *Parikartika* is characterized by *Kartanavat peeda* and *chedanavat shoola* in Guda, *raktasrava*, *vrana* in

guda. In the present work, clinical efficacy of *Bala taila pichu* and *Jatyadi taila pichu* is studied which has the role of *shodhana, vrana ropana, shothahara, vrana prasdana, shoola hara, raktha stambhana, tridosahara*. *Taila* being one of the major ingredients has *vrana ropana* property. *Pichu* is the treatment modality that increases the contact time of the tissue with the medication. Here, a clinical study is conducted on 60 clinically established patients of Fissure-in-ano in SSRAMCH, Inchal. The patients were randomly divided into two groups- Group A and Group B with 30 patients in each group. Group A was treated with *Bala taila pichu* and Group B was treated with *Jatyadi taila pichu*. The results were correlated, compared and analyzed.

Discussion on overall effect of the therapy

It was noticed that in Group A, 73.33% of patients were completely cured of the condition within 7 days of treatment with *Bala taila pichu*. In Group B, 76.66% of patients were completely cured of the condition within 7 days of treatment with *Jatyadi taila pichu*. It is very clear from this discussion that both *Bala taila pichu* and *Jatyadi taila pichu* have definite roles in the management of Acute Fissure-in-ano. It shows that both the drugs are equally effective.

Probable mode of action of *Bala taila pichu* and *Jatyadi taila pichu*

The action of *Pichu* is based on the cellular absorption of the drug, which acts as *vrana ropaka, snehana, lekhana* etc. The ingredients embodied in the compound formulations like *Jatyadi taila* and *Bala taila* are attributed with properties like anti-inflammatory, wound healing, anti- microbial actions.

Jatyadi taila – it is explained in the context of *vrana shothadhikara* in the chapter of *Snehakalpadhyaya* i.e., 9th chapter of *Sharangadhara Samhita*. It is also explained in *Vranashothadhikara*- 47th chapter of *Bhaishajya Ratnavali*. The drugs like *Jati, Nimba, Patola, Haridra, Darharidra, Manjishta, Sariva, taila, sikata* etc., are having *vrana shodhana* and *vrana ropana* properties. *Tuttha* i.e., copper sulphate reduces the cellular hypertrophy of the wound.

Bala taila – it is explained in the context of *Garbhini chikitsa* i.e., Chapter 2 of *Ashtanga hrudaya Shareera sthana*. The drugs like *Bala, Ashwagandha, Sariva, Manjishta, Dashamoola, tila taila* etc., have properties like *vrana shodhana, vrana ropana, shoolahna* properties.

The healing of Fissure-in-ano is very different from the healing of any other ulcers. It is because, in fissures, there is constant contamination of the ulcerated area by faeces and the frequent friction of the wound with mucosa causes continuous spasm of the sphincteric muscle.

- In such conditions, the drugs that produce soothing effect, which have *Vata-pitta hara, shoola hara, vrana shodhana, vrana ropana* properties will act best on the wound.
- The drugs that are having *tikta rasa* acts as *pitta shamaka*, reducing burning sensation, which is the peculiar symptom of *Pittaja Parikartika*.
- According to modern pharmacology, we can call the action of these drugs as anti-inflammatory, anti-microbial actions that help in wound healing.

CONCLUSION

In the present study, 60 patients of established cases of *Parikartika* (Acute fissure-in-ano) were randomly selected and assigned into two groups with 30 patients each. Patients in Group A were treated with *Bala taila pichu* and Group B were treated with *Jatyadi taila pichu*, for 7 days. Observations during and after the treatment were recorded. This study also includes literary aspects of *Parikartika*, Fissure-in-ano, *Bala taila pichu*, and *Jatyadi taila pichu*. On application of significant tests over the observations obtained, it was found that both the formulations were significant in the treatment of *Parikartika*. When the tests were applied on the individual symptoms, the outcome showed that both the *dravyas* were effective in relieving pain, burning sensation, pruritis, bleeding, tenderness. Overall calculation of the results showed that both *Bala taila pichu* and *Jatyadi taila pichu* were having equal efficacy over *Parikartika*. There has been no untoward effect found during or after the treatment. Technique of administration is simple. The therapy was well tolerated. Based on this clinical study, it can be concluded that the efficacy of *Bala taila pichu* is equal to *Jatyadi taila pichu* in the management of *Parikartika* w.s.r. to Acute Fissure-in-ano.

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Study design: Table 1

Study type	Interventional
Study type (timing)	Prospective
End point	Efficacy
Number of groups	Two
Sample size	Group-A: 30; Group-B: 30
Duration of the treatment	7 days of study period. Follow up at an interval of 1 week for 6 weeks.

Table 2 Assessment parameters:

Subjective parameters

1. <i>Gudagata kartanavat peeda</i> (cutting /burning/ pricking type of pain)	0 = no pain 1 = mild pain 2 = moderate pain 3 = severe pain
2. <i>Gudagata raktasrava</i> (bleeding per anum)	0 = no bleeding 1 = mild bleeding 2 = moderate bleeding 3 = severe bleeding
3. Constipation	0 = absent 1 = present
4. <i>Guda daha</i> (burning sensation)	0 = absent 1 = mild 2 = moderate 3 = severe
5. <i>Guda kandu</i> (itching)	0 = no itching 1 = mild 2 = moderate 3 = severe

Table 3 :-Objective parameters:

1. Tenderness	0 = no tenderness 1 = mild tenderness (pain on touch) 2 = moderate tenderness (patient hesitates to allow the physician to examine) 3 = severe pain (patient does not allow even to touch and feels difficulty in sitting)
2. Size of the ulcer (fissure bed)	1 = Small (1mm to 4mm) 2 = Medium (5mm to 8mm) 3 = Big (9mm to 12mm)
3. Sphincteric tone	0 = Normal 1 = Spasmodic 2 = Hypertonic

Table 4 Assessment of relief of symptoms after the treatment:

Marked relief	Above 75%. Complete relief of symptoms, absence of complications and recurrence. (51-75%)
Moderate relief	51-75% reduction of symptoms, absence of complications and with or without recurrence.
Mild relief	Up to 50% relief from symptoms, no marked change in the size of the ulceration of fissure. (26-50%)
No relief	No relief in the symptoms, no changes in the size of the ulceration of fissure. (0-25%)
Treatment withdrawal/ Dropout	1. Discontinuation of the treatment during the study. 2. Aggravation of the symptoms. Development of any complications or any side effects of the trial drug.

RESULTS OF OVERALL EFFECT OF THERAPY

Table 5 Results on group-A

EFFECT OF TREATMENT ON GROUP-A		
Class	Grading	No. of patients
0-25%	No improvement	0
26-50%	Mild improvement	1(3.33%)
51-75%	Moderate improvement	7(23.33%)
76-100%	Marked improvement	22(73.33%)

Graph-:

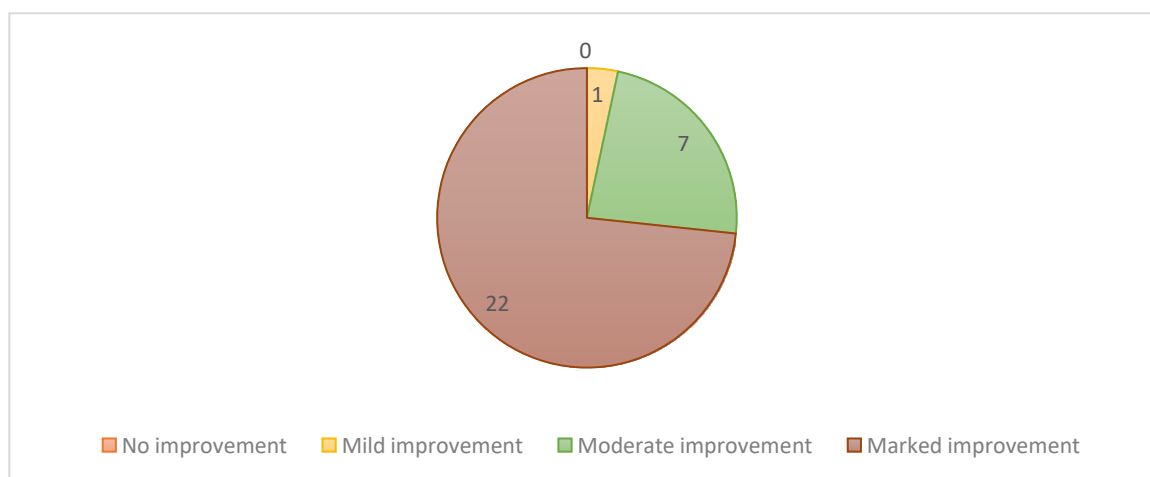


Table 6 Results on Group-B

EFFECT OF TREATMENT ON GROUP-B		
Class	Grading	No. of patients
0-25%	No improvement	0
26-50%	Mild improvement	0
51-75%	Moderate improvement	7(23.33%)
76-100%	Marked improvement	23(76.66%)

Graph-:

