A Comprehensive Approach to Treating Acute Fissure-in-ano (Parikartika) with the AYUHEAL Suppository

Mayur Pawaskar and Zishan Ahmad Ansari*

Department of Shalyatantra, D. Y. Patil School of Ayurveda, Nerul Navi Mumbai, India
E-mail/Orcid Id:

Abstract: Parikartika refers to a medical condition characterized by sharp pain in the anal region. Parikartika, in the context of Western medicine, can be understood as being similar to Fissure-in-ano. This condition is characterized by a combination of increased tension in the internal anal sphincter and reduced blood supply in the posterior midline area of the anal canal. This clinical study examines the effectiveness of the AYUHEAL suppository. This poly-herbal compound is designed to have both local and systemic effects in treating patients with Parikartika, explicitly focusing on acute Fissure-in-ano. A total of fifty patients were subjected to clinical examination and diagnosed with acute Fissure-in-ano based on symptoms including anal pain, per rectum bleeding, burning sensation during and after defecation and constipation. The AYUHEAL suppository was administered thrice daily for seven days. The therapeutic effects of the suppository were evaluated by assessing various parameters on days 1, 3, 5 and 7. The findings demonstrated a notable amelioration in the symptoms, encompassing anal pain, rectal bleeding, post-defecation burning sensation, and constipation throughout the treatment period. Subsequent evaluations on the 21st day showed no reappearance of Fissure-in-ano, indicating a consistently favorable result. This study shows that using AYUHEAL suppository as the cutting-edge treatment for seven days effectively reduced the symptoms of Parikartika, specifically acute Fissure-in-ano. The suppository's poly-herbal composition allows it to have an effect both at the local site and throughout the entire body, indicating its potential as a comprehensive approach to managing this condition. Additional research and extensive clinical trials are necessary to confirm these findings and investigate the long-term effectiveness of AYUHEAL suppositories in treating Parikartika.

Introduction

Anorectal disorders are progressively increasing in society precisely due to unsalutary lifestyles and food habits. Trauma, ischemia, and high anal pressure may cause anal Fissures. The posterior midline, where Fissures are most common, has less than half the anal canal's blood perfusion. Reduced blood flow may slow healing (Schouten et al., 1994). The Fissure site has lower blood flow than the posterior anal midline in control groups, according to studies (Schouten et al., 1996; Dhayagonde and Desai, 2022). Due to the increased tone of the internal anal sphincter and spasm of the surrounding musculature, anal Fissures cause elevated anal canal pressure (Keck et al., 1995). The initial trauma pain may have caused this spasm. An extensive analysis of the Cochrane database found that surgical intervention is now more efficacious than medical management in treating refractory Fissures. Crucially, the study found that none of the medical interventions investigated led to faecal incontinence (FI), a known complication linked to sphincterotomy (Nelson et al., 2012; Nyam et al., 1999).

Parikartika is extensively explained in Ayurvedic texts as a side effect of many different diseases and conditions, including Vatika Jwara, Vatika Pakwa...
Atisara, Sahaja Arsha, Kaphaja Arsha, Arsha Purvarupa, Udvarta, and its related occurrences. If purgatives or enemas are administered incorrectly, Parikartika might also occur. Classical descriptions of symptoms suggest that the disease Parikartika is similar to western medicine’s concept of Fissure-in- ano. The word Parikatika is derived from the root word Pari, which means all around and Kartanam, which means excruciating cutting type of pain (Pandey, 2018). According to Acharya Sushruta, Parikartika is a situation in which there is cutting pain in Guda, Nabhi and surrounding areas (Saini, 2021). Acharya Kashyap says that the one is having to cut and tear pain. Cutting and tearing pain, as said by Dalhana. Jejata has anticipated in a particular way that vatika pain in a specific area of Guda, is Parikartika (Shastri, 2007). It is a condition characterized by cutting pain around the anus. Acharya Sushruta, Charaka and Vagbhata have described Parikartika as a complication of various diseases or procedures. Only Acharya Kashyapa has highlighted Parikartika as an individual disease in Garbhini Vyapada, and it is an excruciating condition due to somatic nerve supply to the part.

As told by Acharya Sushruta, the Nidana of Parikartika can be divided into three types:

1. Nija nidana (Endogenous)
2. Agantuja nidana (Exogenous)
3. Nidanarthkari roga (Complications)

1. Nija nidana:

The Nidana that vitiates Apana vayu, Raka are the Nija nidana. Consumption of the causative factors for Apana Vikriti is Ruksha anna and Guru anna, holding the natural urges of micturition and defection, too much travelling by vehicle, and travelling repeatedly at various places by walking. Sushruta has given several more reasons for Parikartika (Shastri, 2002).

2. Agantuja nidana:

The trauma at Guda leads to Parikatika. During Panchakarma procedures like Virechana and Basti iatrogenic complications may develop in the form of Parikartika. This is also known as Vaidya Nimittaja.

Virachana vyapada: Sushruta has mentioned one important complication, ‘Parikartika’, if ingesting Tikshna, Ushna and Ruksha drugs for Virechana (Shukla, 2007).

Basti vyapada: If Ruksha Basti containing Tikshna and Lavana drugs is administered in heavy doses, it may produce Parikartika (Shukla, 2007).

Basti netra vyapada: The inappropriate administration of Basti netra and defects in Basti netra may cause this disease.

3. Nidanarthkari roga:

Nidanarthkari roga are such disorders that are produced due to any pre-existing diseases. The chief disease is Udvarta, which produces Parikartika. Acharya Charak has described this condition as a lakshan of Atisara.

Acharya Kashyapa has described the involvement of all three Doshas, e.g. Vata, Pitta and Kapha in the Adhyaya garbhnī chikitsa while giving the detailed chikitsa of the disease Parikartika. The anal canal is 3.8 cm long. It extends from the anorectal junction to the anus. It is directed downwards and backwards. The anal canal is surrounded by inner involuntary and outer voluntary sphincters, which keep the lumen closed in the form of an anteroposterior slit (Chaurasia, 2020). Anal canal is developed from a fusion of the post-allantoic gut with the proctodeum (Shenoy and Shenoy, 2020). In the normal living subject, the anal canal is wholly collapsed owing to the tonic contraction of anal sphincters and the anal orifice is represented by an anteroposterior slit in the anal skin (Pawaskar, 2019; Sreerag and Dhule, 2021).

A complex of anal sphincters, internal and external, surrounds the anal walls. They together form the sphincter mechanism of the anal canal.

The internal sphincter:

The thickened circular muscle coat of this part of the gut forms it. It surrounds the upper three-fourths, i.e., 30 mm of the anal canal extending from the upper end of the canal to the white line of Hilton (Chaurasia, 2020).

The external sphincter:

It is formed by striated muscle fibres intermingled with longitudinal muscle fibres of the rectum, which are attached to the skin of the perianal region. It has superficial, deep and subcutaneous portions (Shenoy and Shenoy, 2020).

The funnel-shaped configuration of the paired levator ani muscles forms a significant part of the pelvic floor, and their fibres decussate medially with the contralateral side to fuse with the perineal body around the prostate or vagina.

The longitudinal layer:

It is the continuation of the longitudinal muscle coat of the rectum. At the anorectal junction, the puborectal fibres of the levator ani fuse with the longitudinal unstriped muscle coat of the rectum to form a conjoined longitudinal muscle coat for the anal canal between the internal and external sphincters (Das, 2018).

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Arterial Supply of the Rectum and Anal Canal are as under (Snell, 2018):
1) The superior rectal or Haemorrhoidal artery.
2) The middle rectal or haemorrhoidal arteries.
3) The inferior rectal or haemorrhoidal arteries.
4) The middle sacral artery.

The veins of the rectum and anal canal comprise-
1) The superior haemorrhoidal vein drains into the inferior mesenteric vein and portal system.
2) Middle and inferior haemorrhoidal veins enter the systemic venous circulation in the internal iliac veins.

Nerve supply of the anal canal (Chaurasia, 2020):
1. Above the pectinate line, the anal canal is surrounded by autonomic nerves, both sympathetic (inferior hypogastric plexus L1,2) and Parasympathetic (Pelvisphlanchnic S2-4) nerves. Both of them carry pain sensations.
2. Below the pectinate line, it is supplied by somatic (inferior rectal S2-4) nerves.
3. Sphincters-The internal sphincter is contracted by sympathetic nerves and relaxed by parasympathetic nerves. The fourth sacral nerve's inferior rectal and perineal branches supply the external sphincter.

History of Anal disorders is as old as the history of mankind. It includes various pathological conditions. The similarity of all these disorders is in producing remarkable anal discomfort. Prevalence rate of anal Fissure is 18% as compared to 11% of haemorrhoids (Chaudhary et al., 2109). Anal Fissure can be easily diagnosed by complaints like bright red Bleeding, painful defecation, and signs of anal spasm with Skin tags and palpable Fissure (Rinait et al., 2020). Longitudinal tear in the lower end of anal canal results in Fissure in ano (Shenoy and Shenoy 2020). It is the most painful condition affecting the anal region. Commonly seen in young patients (Shenoy and Shenoy, 2020).

Improper dietary habits like spicy and junk foods, bakery products and constipation are major risk factors causing Fissure in ano. Most of anal Fissures are caused by stretching of the anal mucosa beyond its capability, either due to hard stool or diarrhoea. Due to constant faecal contamination in diarrhoea and strenuous evacuation in constipation, it refuses to evacuate in constipation, it refuses to faecal contamination in diarrhoea and strenuous evacuation in constipation, it refuses to evacuate in constipation, it refuses to evac.
Patients of Parikartika (acute Fissure in ano) having signs and symptoms, i.e., pain, per rectal bleeding, size of ulcer at either anterior or posterior part of anus, anal spasm and constipation, were selected from OPD of Shalyatantra, irrespective of gender, religion, occupation etc. The Institutional Ethical Committee (IEC) approved the study before starting the clinical trials. The study was also registered in the Clinical Trail Register of India, with CTRI/2022/05/042610 registration numbers.

Inclusion criteria

- Subjects with a clinical diagnosis of Acute Fissure in the Anus (onset up to 21 days) who do not have a sentinel tag or anal papillae.
- Patients aged 21-60 years, irrespective of gender, were included in this study.

Exclusion criteria

- Chronic Fissure in ano (onset more than 21 days) with sentinel tag & anal papillae.
- Psychiatric illness and pregnant women.
- Patients suffering from Ca rectum, Ulcerative colitis, Crohn’s disease, Syphilis, Tuberculosis, HIV and Hepatitis.

Diagnostic criteria

The diagnosis was made based on external findings.

Diet

Diet plays a vital role in the development of fissures in ano. All patients were advised not to eat spicy (like hot chili peppers, peppers, etc.) and oily foods. Eating the right amount of fibre and adequate water helps prevent stool from being too hard and causing constipation.

Materials

50 patients were registered and treated with AYUHEAL suppository.

Table 1. AYUHEAL suppository

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Name</th>
<th>Quantity (in parts)</th>
<th>Part used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jati</td>
<td>2</td>
<td>Rhizome</td>
</tr>
<tr>
<td>2</td>
<td>Yashimadhu</td>
<td>2</td>
<td>Roots</td>
</tr>
<tr>
<td>3</td>
<td>Mocharasa</td>
<td>1</td>
<td>Gum</td>
</tr>
<tr>
<td>4</td>
<td>Nagkesara</td>
<td>1</td>
<td>Flowers</td>
</tr>
<tr>
<td>5</td>
<td>Bilva</td>
<td>1</td>
<td>Unripe or half-ripe fruits</td>
</tr>
<tr>
<td>6</td>
<td>Haritaki</td>
<td>3</td>
<td>fruits</td>
</tr>
</tbody>
</table>

Methodology

Per rectal administration of AYUHEAL suppository was advised three times a day for 7 days in Parikartika (acute Fissure in ano).

Assessment parameters

The gradation adopted for assessing symptoms is mentioned in Table 2 and the overall assessment is in Table 3.

Follow up

Patients were assessed on 1st, 3rd, 5th and 7th day. And further, patients were asked for follow-up on 14th day after the completion of the treatment.

Observations

In this clinical study, the maximum patients are 30-40 years of age, male, Hindu, vata-prakruti, and have a mixed diet. During the inspection, most patients showed Fissure at the 6 o’clock position without a sentinel tag in any patient.

In this present study, a maximum of 74% of patients had severe pain in the anal region, 46% of patients had moderate per rectal bleeding, 58% of patients were severely constipated, and 100% of patients had ulcers in the anal region. On per rectal digital examination, 56% of patients were found to have severe anal spasm.

Results and Discussion

The assessment of the results was made based on pain reduction, per rectal bleeding, constipation, anal spasm and size of the ulcer, which are mentioned in Table 4.

On the first day, the pain was maximum in the grade of 3 and the median value was 3.00. There was a significant reduction in the symptoms of pain. On day 7th of treatment, the range of pain was wholly reduced to 0 and the median value was 0. There was no pain when the patient came for follow-up on 21st day (Figure 3a).

On Day 1, the grade of per rectal bleeding was 1 and the median value was 2.00. The symptom of per rectal bleeding was significantly reduced. The minimal grade of per rectal bleeding was totally decreased to zero on day seven of treatment, and the median value was also zero. No per rectal bleeding occurred when the patient was examined on day 21 (Figure 3b).

Before starting the treatment, on the first day, the minimum grade of constipation was 1, the maximum range 3 and the median was 3.00. The constipation symptom showed marked relief. The minimal grade of constipation was totally reduced to 0 and the median value was 0 on the seventh day of treatment. No constipation patient returned on day 21 for follow-up (Figure 3c).

On first day, minimum grade of anal spasm was 1, the maximum grade 3 and median was 3.00. Anal spasm was significantly reduced. On the seventh day of treatment, the grade of anal spasm minimum grade and median values were both 0. There was no anal spasm when the patient came for follow-up on the 21st day (Figure 3d).
Initially on the first day, size of ulcer was 3 and median was 3.00. The ulcer's size was reduced. On the seventh day of treatment, the minimum grade of ulcer size was reduced to 0 and the median value was 0. There was no ulcer when the patient returned for a follow-up visit on day 21. (Figure 3e and Figure 1a & 1b).

When the patients had altered aahar and vihar, it led to agni-dushthi, which resulted in constipation. And constipation was primarily responsible for Parikartika.

Acharya Sushrutha has mentioned Parikartika as a combination of two words Pari (around the anus) and Kartika (cutting pain), which means cutting pain around the anus, which is a cardinal symptom of Parikartika. Constipation is a causative factor of Parikartika. During defecation, direct pressure of stool at the posterior wall of anal canal and less muscular support results in ulceration at 6 o’clock position. Spasmodic anal sphincter is due to the increased intrarectal pressure.

Rectal administration is a potential drug delivery system particularly for the drugs that are either too irritating for the gut or more effective when the drug cannot be metabolized by the liver from oral route. Suppositories offer patients an option that is minimally invasive and easy to use in relieving rectal complaints.

<table>
<thead>
<tr>
<th>Gradation</th>
<th>Pain</th>
<th>Per rectal bleeding</th>
<th>Constipation</th>
<th>Anal spasm</th>
<th>Size of ulcer</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Free from pain</td>
<td>No bleeding</td>
<td>Minimal effort to defecate</td>
<td>No spasm/ per rectal digital examination can be done without pain</td>
<td>No ulcer</td>
</tr>
<tr>
<td>1</td>
<td>Pain at the time of defecation and subside within 30 min</td>
<td>Mild (&lt; 5 drops)</td>
<td>Mild effort or straining is required to defecate</td>
<td>Per rectal digital examination can be done with mild pain</td>
<td>Wound size reduced to 50%</td>
</tr>
<tr>
<td>2</td>
<td>Pain at the time of defecation and subside &gt; 30 min to 1 hr</td>
<td>Moderate (5-10 drops)</td>
<td>Moderate effort or straining is required to defecate</td>
<td>Per rectal digital examination can be done with moderate pain</td>
<td>Wound size reduced to 75%</td>
</tr>
<tr>
<td>3</td>
<td>Continuous unbearable pain and subside &gt; 1 hr</td>
<td>Severe (&gt; 10 drops)</td>
<td>Unable to defecate despite maximum effort or straining</td>
<td>Not allowing per rectal digital examination</td>
<td>Baseline (actual size on day 1)</td>
</tr>
</tbody>
</table>

Table 2. Gradation of parameters

(a)

(b)

Figure 1(a & b). Condition of ulcer at follow-up visit on day 21
### Table 3. Overall assessment

<table>
<thead>
<tr>
<th>Result</th>
<th>Assessment criteria</th>
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<tr>
<td>Complete relief</td>
<td>100% disappearance of symptoms and absence of complications and recurrence.</td>
</tr>
<tr>
<td>Moderate relief</td>
<td>75% disappearance of symptoms and absence of complications and recurrence.</td>
</tr>
<tr>
<td>Mild relief</td>
<td>About 50% relief in presenting symptoms and some recurrence of Fissure.</td>
</tr>
<tr>
<td>No relief</td>
<td>No relief in presenting symptoms and no change in the ulceration of Fissure-in-ano.</td>
</tr>
</tbody>
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### Table 4. Overall statistical analysis of the parameters.

<table>
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<tr>
<th>Parameters</th>
<th>Statistical Analysis</th>
<th>AYUHEAL SUPPOSITORY</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; Day</th>
<th>3&lt;sup&gt;rd&lt;/sup&gt; Day</th>
<th>5&lt;sup&gt;th&lt;/sup&gt; Day</th>
<th>7&lt;sup&gt;th&lt;/sup&gt; Day</th>
<th>21&lt;sup&gt;st&lt;/sup&gt; Day</th>
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<td>0</td>
<td>0</td>
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<td>Per Rectal Bleeding</td>
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For Fissure, there needs to be a treatment that acts locally and systemically. However, this would involve two modes of drug delivery viz; rectal and oral. So, we came up with this single mode of drug delivery in the form of a suppository, which would act locally as well as systemically. The absorption site is near the administration site, i.e., the anoderm. Therefore, rapid absorption with a rapid increase in plasma drug level can be achieved. Formulations can be readily prepared to provide desired release characteristics (Nishihata et al., 1984). A drug mixed with various adjuvants and administered through the rectal route provides satisfactory pharmacokinetics with acceptable local tolerance. In (the osmosis process) drugs transfer from the suppository formulation across the membrane through the rectum into haemorrhoid veins (Krishna and Haneefunnis, 2018). The inferior and the middle haemorrhoid veins bypass through the liver and do not undergo first-pass metabolism. The paracellular transport mechanism implies that drugs diffuse through a space between epithelial cells. So, suppositories would act
locally for wound healing and systemically for haemostasis, laxative etc.

Therefore, the drugs delivered through suppositories to the lower and middle haemorrhoid veins are absorbed rapidly and effectively.

Mode of action of Jati:

It is vranaropana (wound healing), vednasthapana (analgesic) and anulomana. Tridoshahara property alleviates vitiation of all 3 doshas. It contains salicylic acid, which has antibacterial, anti-inflammatory and antifungal properties. The roots are purgative, anthelmintic and intoxicating (Pandey, 2005).

Mode of action of Yashtimadhu:

It is analgesic (vednaspathana) and anti-inflammatory (shothhara). In managing wounds and ulcers, Yashtimadhu has been recommended in the indigenous system of medicine. The drug is a good wound healer and is useful in post-operative care (Pandey, 2004).

Mode of action of Mocharasa:

It has antihemolytic (rakhtastambhana) activity by phenolic compounds like flavonoids, neutralising the free radicals causing haemolysis. Other bioactive components like flavanoids, phenols, and tannin protect the erythrocyte membrane from destruction and lysis (Pandey, 2004).

Mode of action of Nagkesara:

The drug Nagkesara helps treat several diseases, and it is specifically valued as stambhana, pacana, and rakta stambhana (antihemolytic). One of the most significant health benefits of Nagkesar is its ability to arrest bleeding. It is mainly used in Ayurveda for treating bleeding disorders caused due to Pitta imbalance (Pandey, 2004).

Mode of action of Bilva:

A plant's unripe fruit or half-ripe fruit is medicinally potent; the pulp of unripe or half-ripe fruit is aromatic, cooling and laxative. The pulp of unripe or half-ripe fruit is astringent, digestive and stomachic (Pandey, 2005).

Mode of action of Haritaki:

Anulomana karma helps normalize bowel movements. Alleviates vitiation of all 3 doshas, i.e., Tridoshahara due to sweet, bitter and astringent tastes; it balances Pitta, due to its pungent, bitter and astringent tastes, it balances Kapha, and due to its sweet and sour taste, it balances Vata dosha (Pandey, 2005).

Conclusion

The AYUHEAL suppository showed remarkable effectiveness in treating several aspects of Parikartika, including acute Fissure-in-ano. It was made with vednaspathana, shonisthapana, deepan-pachana, vranaropana, and vranashodhana dravyas. There was a constant positive correlation between the assessment's objective (anal spasm and ulcer size) and subjective (anal pain, per rectum haemorrhage, burning feeling during and after defecation, and constipation) metrics and the therapy outcomes.

Patients reported significant symptom reduction and no adverse medication responses or side effects over the seven-day therapy period. The continued efficacy of the AYUHEAL suppository is further supported by the fact that no fissure-in-ano was observed during the 21st day of reevaluation.

In the case of acute Fissure-in-ano, these results highlight the possibility of the poly-herbal AYUHEAL suppository as a feasible, economical, and non-invasive method of treating Parikartika. However, more research with more extensive samples and longer follow-up times is needed to prove its long-term effectiveness and generalizability. The suppository's poly-herbal composition makes it an all-encompassing therapeutic approach that deserves more research in Parikartika treatment since it has local and systemic effects.

Conflict of Interest

The authors stated that this publication does not conflict with any interests in any way.

References


