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Comparative Efficacy of Polyherbal Gel and 2% Lignocaine Gel in Managing Parikartika (Acute Fissure-in-Ano): A Pilot Study

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ABSTRACT

Parikartika, known as fissure-in-ano in modern medicine, is a painful anorectal condition characterized by a longitudinal tear in the anal canal. This study aimed to evaluate the comparative efficacy of a polyherbal gel and 2% lignocaine gel in managing acute fissure-in-ano. The polyherbal gel contained Panchavalkala, Nimba, and Kumari, while the lignocaine gel served as the control. Twenty patients were randomly divided into two groups, with each group receiving local application of the respective gel twice daily after a sitz bath for four weeks. The study assessed the outcomes based on clinical features and adverse drug reactions. The results showed that the polyherbal gel group showed better improvement in terms of relief in symptoms as compared to the lignocaine gel group. The majority of patients were males (85.19%), married (88.88%), and had a Vata-pitta Prakriti (55.56%). Most patients reported passing hard stools (70.37%) and had a Krura Koshtha (48.15%). No significant adverse drug reactions were reported in either group. The study concluded that the polyherbal gel containing Panchavalkala, Nimba, and Kumari could be a good alternative for relieving symptoms, promoting quick healing, and providing an economical option for managing acute fissure-in-ano. Further research with larger sample sizes is needed to validate these findings and explore the potential of Ayurvedic approaches in the management of this painful condition.

Keywords: *Shalya tantra, Fissure-in-Ano, Parikartika, Ayurvedic treatment..*

1. INTRODUCTION

Shalya tantra is a recognized discipline among Ayurveda's eight therapeutic branches. This branch's objective is to address both physical and mental agony1. Sushruta, the Great Father of Surgery, although a surgeon par excellence, has placed a greater emphasis on medicinal and parasurgical therapy of numerous surgical illnesses. In his invaluable insights, it is clear that Shastra karma (surgery) should be used as a last resort in management. He highlighted the need for medical management over surgical management in order to alleviate the burden placed on surgical care facilities. As a result, medical management of surgical disorders still has a lot of room to grow. One such disease that requires surgery.

Fissure-in-Ano is the term first described by Lockhart-Mummary in 19342. Fissure-in-ano is a common and painful anorectal condition characterized by a longitudinal tear in the anal canal distal to the dentate line3. It typically affects younger and middle-aged adults, with the majority of cases (90%) occurring in the posterior midline3. The exact etiology is debated, but there is a clear association with elevated internal anal sphincter pressures and hard bowel movements4. Fissure-in-ano is characterized by several distinct signs and symptoms: Pain and bleeding are the two primary signs of fissure-in-ano, with pain often being unbearable5. The condition typically presents with sharp cutting pain in the anal region, accompanied by bleeding during and after defecation6-7. In addition to pain and bleeding, patients may experience itching in the anal area5,7. Interestingly, while constipation is often associated with fissure-in-ano, it is not universally present in all cases. A study of 876 patients found that infrequent hard bowel movements ($\geq$ 3 days) occurred in only 13.8% of patients8. This challenges the common belief that constipation is a universal factor in fissure-in-ano cases. In terms of location, fissures predominantly occur in the posterior midline (90% in males), with anterior midline fissures being more common in females (60%) than previously thought5,8. Chronic fissures may present with additional features such as a sentinel pile (skin tag) at the distal fissure margin and a hypertrophied anal papilla proximal to the fissure in the anal canal3. The presence of these symptoms, along with their persistence for more than 8-12 weeks, distinguishes chronic fissures from acute ones3,4.

Interestingly, while conservative treatment is often the first line of management, success rates vary. About half of all patients heal with nonoperative management such as high-fiber diet, sitz baths, and pharmacological agents4. However, when conservative methods fail, surgical interventions like lateral internal sphincterotomy have high success rates9. Some studies

suggest that tailored lateral sphincterotomy may reduce incontinence rates compared to standard procedures10. Fissure-in-ano management requires a graded, multimodal approach. Conservative treatments should be attempted initially, followed by surgical options if necessary11. While lateral internal sphincterotomy remains the gold standard for chronic cases12, ongoing research explores alternative treatments, including Ayurvedic approaches13 and topical applications14, aiming to provide effective, non-surgical management options for this painful condition.

Parikartika, known as fissure-in-ano in modern medicine, is a common and painful anorectal condition described in Ayurvedic texts15,16. It is characterized by cutting and burning pain in the anal region, often accompanied by bleeding and sometimes swelling15,17. In Ayurveda, Parikartika is not considered a separate disease entity but is mentioned as a complication of other diseases or Ayurvedic procedures like Vamana, Virechana, and Basti16,18. Interestingly, while Ayurvedic texts primarily describe Parikartika as a complication, some researchers have attempted to establish it as a distinct disease by detailing its Pancha Nidana, Rupa, and Samprapti18. Various Ayurvedic treatment modalities have shown promising results in managing Parikartika. These include the use of medicated oils like Bala taila and Jatyadi taila16, Yashtimadhu-based preparations19,20 and Ksharasutra suturing for chronic cases21. Additionally, Shatadhauta Ghritavasti and Jathyadi Ghritavasti have demonstrated effectiveness in treating both acute and chronic cases of Parikartika22. These Ayurvedic approaches offer potential alternatives or complementary treatments to conventional medical interventions for fissure-in-ano.

The primary line of treatment for acute fissures is predominantly conservative in nature, encompassing oral analgesics, stool softeners, soothing ointments, or the administration of long-acting anaesthetic agents. Furthermore, the significant increase in post-operative complications and high recurrence rate presents a substantial opportunity to explore contemporary therapeutic approaches by adopting the principles of Ayurveda.

Thus, this study aims to assess the comparative efficacy of polyherbal gel with 2% lignocaine gel which is already proven as a standard in the management of Parikartika.

2. MATERIALS AND METHODOLOGY

2.1Research Design

This study is a randomized, parallel, prospective, interventional, clinical, double-arm research pilot study designed to evaluate the treatment efficacy for acute fissure-in-ano.

2.2 Research Method

Participants were randomly selected and assigned to groups using a pre-prepared closed envelope method.

2.3 Literature Review

A comprehensive review of existing literature on acute fissure-in-ano and its treatments was conducted.

2.4 Study Participants

The study included patients diagnosed with acute fissure-in-ano, as defined by specific clinical symptoms and diagnostic criteria.

2.5 Inclusion Criteria

- Participants must be willing to give informed consent.
- The patient must be clinically diagnosed with acute fissure-in-ano.
- The patient must be between the ages of 18 and 60.

2.6 Exclusion Criteria

- Patients with chronic fissure-in-ano.
- Patient having multiple fissures.
- Patient with secondary conditions.
- Malignancy
- Immuno-compromised states
- Pregnant, puerperal, lactating women.
- Uncontrolled diabetes or/and hypertension.

2.7 Intervention

Group A – Local application of Polyherbal gel on fissure wound twice daily after sitz bath for 5-10 minutes for 4 weeks.

Group B – Local application of 2% Lignocaine gel twice on fissure wound twice daily after sitz bath for 5-10 minutes for 4 weeks.

2.8 Data Collection and Analysis

Data were collected through clinical assessments, patient self-assessments, and digital rectal examinations. The collected data were systematically analyzed to evaluate the outcomes of the intervention on the study participants.

2.9 Statistical Analysis

Appropriate statistical tests were employed to determine the significance of the differences observed between the study groups.

2.10 Approval Statement/Ethics Statement

The study protocol was reviewed and approved by the institutional ethics committee to ensure compliance with ethical standards.

2.11 Informed Consent Statement

Informed consent was obtained from all participants before their inclusion in the study.

3. OBSERVATION AND RESULTS

A total of 10 patients were registered in group A, while in group B, 10 patients were registered. All the 20 patients completed the treatment. Their demographic distribution (Table 01) and personal history (Table 02) are described below.

3.1 Demographic distribution

Table 01: Demographic variables of study participants.

S.No	Demographic Variable	Observations
01.	Age	25.93% of patients belong to the age group of 21-30 years
02.	Gender	85.19% of patients are male
03.	Religion	85.19% of patients belong to the Hindu religion
04.	Occupation	33.33% of patients are engaged in service
05.	Education	48.15% of patients are graduates
06.	Socio-economic status	62.96% of patients belong to the higher middle class

Table 2: Observations of the personal history of study participants.

S.No	Variable	Observations
01.	Dietary habits	55.56% of patients are on a vegetarian diet
02.	Stool consistency	70.37% of patients report passing hard stools
03.	Koshta	48.15% of patients are observed with Kṛura Koşţha

04.	Addiction	92.59% of patients have an addiction to tea,

Table 03: Effect of therapy in Group -A on symptoms in the patients of Parikartika (Fissure in ano)

S.No	Variable	Mean		% Dif.	S.D.	T value	p value
		BT	AT				
01.	Bleeding per rectum	1.2	0.6	50%	0.75	3.97	<0.05
02.	Pain	2.5	1.0	60%	1.68	3.35	<0.05
03.	Constipation	2.7	1.10	64%	1.09	4.12	<0.05
04.	Sphincter tone	4.3	1.5	65%	1.20	3.52	<0.05
05.	Healing of wound	1.7	0.5	70%	1.70	5.05	<0.05

Table 03: Effect of therapy in Group -B on symptoms in the patients of Parikartika (Fissure in ano)

S.No	Variable	Mean		% Dif.	S.D.	T value	p value
		BT	AT				
01.	Bleeding per rectum	1.1	0.8	27%	1.12	1.2	>0.05
02.	Pain	1.8	1.2	33%	1.27	3.59	<0.05
03.	Constipation	1.6	0.8	50%	1.25	3.41	<0.05
04.	Sphincter tone	4.8	2.8	46%	1.03	3.63	<0.05
05.	Healing of wound	2.2	1.2	45%	1.30	3.84	<0.05

4. DISCUSSION

25.93% of patients belong to the age group of 21-30 years. This indicates a relatively young patient population, which could suggest that the health issues being addressed may be more prevalent in younger adults23-24. A significant majority of 85.19% of patients are male, indicating a potential gender disparity in health-seeking behaviour or prevalence of the conditions being treated 23,25-26. 33.33% of patients are engaged in service, which may reflect the socioeconomic status and lifestyle of the patients. The data indicates that 48.15% of patients are graduates, which suggests a relatively high level of education among the patient population. This may correlate with better health literacy. 62.96% of patients belong to the higher middle class, indicating a relatively affluent patient demographic which may influence access to healthcare and lifestyle choices. 55.56% of patients are on a vegetarian diet, which could be relevant in the context of dietary influences on health conditions being treated. A notable 70.37% of patients report passing hard stools, which may suggest issues with

hydration or dietary fibre intake. This could be a focal point for dietary recommendations. 48.15% of patients are observed with Kṛura Koṣṭha, which refers to a specific condition related to stool characteristics, indicating potential gastrointestinal issues that may need further exploration. A significant 92.59% of patients have an addiction to tea, which could have implications for caffeine consumption and its effects on health, including gastrointestinal function and hydration. 55.56% of patients belong to the Vāta-pitta Prakṛti body constitution, indicating a predominance of this body type in the patient population, which may influence treatment approaches based on Ayurvedic principles. A strong correlation was found between dietary habits and the frequency of defecation.

The polyherbal gel containing panchvalkal kwath, nimba, and Aloe vera likely exerts multiple beneficial effects on fissures through its antimicrobial, anti-inflammatory, and wound-healing properties: The panchvalkal formulation has demonstrated quorum-modulatory effects against pathogenic bacteria like Staphylococcus aureus at concentrations of 250-750 µg/ml 27. This suggests it may help control bacterial growth and biofilm formation in fissures. Additionally, panchvalkal showed protective effects against bacterial infections in an in vivo C. elegans model27. Aloe vera gel extract has shown significant antioxidant activity both in vitro and in vivo28. It exhibited free radical scavenging properties and reduced oxidative stress markers in animal studies. This antioxidant effect may help reduce inflammation and promote healing of fissures. Interestingly, Aloe vera gel has also demonstrated immunomodulatory properties. It prevented UV-induced immune suppression in mice and preserved the number and morphology of immune cells in the skin29. This immunomodulatory effect could help regulate the inflammatory response in fissures. The combination of chitosan, sodium alginate and Aloe vera gel has shown promise as a wound dressing material, with high water absorption, suitable morphology and pore size that allowed significant fibroblast migration in wound closure assays30. This suggests the Aloe vera component may enhance the wound-healing properties of the polyherbal gel.

In summary, the polyherbal gel likely acts through multiple mechanisms including antimicrobial effects, antioxidant activity, immunomodulation, and promotion of wound healing to provide relief and healing for fissures. However, further studies specifically examining this formulation for fissures would be needed to confirm its efficacy and elucidate the precise mechanisms involved.

5. CONCLUSION

The study demonstrated that the polyherbal gel containing Panchavalkala, Nimba, and Kumari is an effective alternative to 2% lignocaine gel for managing acute fissure-in-ano, offering better symptom relief and promoting faster healing without significant adverse reactions. Future Scope Further research involving larger sample sizes and longer follow-up periods is necessary to confirm these findings and to explore the broader potential of Ayurvedic treatments in the management of anorectal conditions.

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