DOI: https://doi.org/10.52756/ijerr.2023.v35spl.015 ***Int. J. Exp. Res. Rev.*, Vol. 35: 160-168 (2023)**

Original Article | *Peer Reviewed* | *Open Access*

International Journal of Experimental Research and Review (IJERR)

ISSN: 2455-4855 (Online)
www.iaph.in
ISSN 2455-4855

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

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Article History:

Received: 29th Oct., 2023
Accepted: 17th Nov., 2023
Published: 30th Nov., 2023

Keywords:

AYUHEAL Suppository, Fissure in ano, *Guda Varti*, *Parikartika*, rectum bleeding

How to cite this Article:

Mayur Pawaskar and Zishan Ahmad Ansari (2023). A Comprehensive Approach to Treating Acute Fissure-in-ano (Parikartika) with the AYUHEAL Suppository. *International Journal of Experimental Research and Review*, *35*(Spl.), 160-168.

DOI : https://doi.org/10.52756/ijerr.2023.v35spl.015

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

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Atisara, Sahaja Arsha, Kaphaja Arsha, Arsha Purvarupa, Udavarta, 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. Jejjata 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. *Nidanarthakari roga* (Complications)

1. *Nija nidana*:

The *Nidana* that vitiates *Apana vayu*, *Rakta* 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 defecation, 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 *Udavarta*, 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 garbhini 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 puborectalis 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).

DOI: https://doi.org/10.52756/ijerr.2023.v35spl.014

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 L_{1-2}) and Parasympathetic (Pelvicsphlanchnic S_{2-3-4}) nerves. Both of them carry pain sensations.

2. Below the pectinate line, it is supplied by somatic (inferior rectal S_{2-3-4}) 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 heal. The sentinel tag formed by the chronicity of the ulcer also prevents the Fissure from healing. Throbbing pain and burning sensation with or without bleeding during defecation (streaks of blood with stool) are an indication of Fissure.

There are many drugs in Ayurvedic Samhitas which are known to reduce pain by their *vednasthapak* and *shoolhara* properties, to heal wounds by their *varanaropana* and *vranashodhana* properties, to stop bleeding by their *raktastambhaka* and *shonistapana* properties, to reduce constipation by their *deepana*, *pachana* and *anulomana* properties. Keeping all these considerations in mind, we have planned this study using six drugs for management of pain, bleeding per rectum, constipation, ulcer and anal spasm.

Multiple modes of administration for drugs are given in ayurvedic Samhitas out of which *varti kalpana* is selected in this study, and *guda varti* is made named as "AYUHEAL SUPPOSITORY", which is composed of *jati*, *madhuyashti*, *mocharasa*, *nagkesara*, *bilva* and *haritaki.*

Varti kalpana is derivative of *Vati kalpana*. The method of *Varti* preparation is the same as that of *Vati*. However, Varti differs in its shape, use, and indication. These are solid and wick-shaped (elongated with tapering ends) medicated preparations, shaped for ready introduction into one of the body's orifices other than the oral cavity (Angadi Ravindra, 2011). Based on their site of application and action, they are of different types, like *Yoni varti*, *Guda varti*, *Netravarti*, *Dhumra varti* and *Vrana varti* (Ravindra, 2011). These can be co-related to suppositories, defined as the medicated solid dosage form generally intended for use in the rectum, vagina and, to a lesser extent, the urethra (Leon and Herbert, 2009).

This study is aimed to evaluate the effect of "AYUHEAL SUPPOSITORY" in *Parikartika* w.s.r. to Acute Fissure in ano.

According to Western medicine, the available treatments are:

1. Anaesthetic creams
2. Antibiotics
3. Agents which decrease anal sphincter pressure
4. Surgery like left lateral sphincterotomy, Fissurectomy, etc. (Das, 2018).

According to Ayurveda the treatment principles are:

1. *Deepana-pachana* (Shukla and Tripathi 2017)
2. Internal medications
3. *Pichu* and *matra basti*

It has been observed that antibiotics and analgesics lead to various adverse effects on the body, and many patients suffer from varied degrees of incontinence, recurrence and wound infections after surgical treatment for Fissure-in-ano. Many studies have been conducted in various Ayurvedic institutes for the conservative management of *Parikartika* (Fissure in Ano). However, they have an anecdotal approach.

Keeping all these factors in mind, we planned to formulate a compound that would act locally as well as systemically to comprehensively manage the patients of *Parikartika* w.s.r. to acute fissure.

DOI: https://doi.org/10.52756/ijerr.2023.v35spl.014

Materials and Methods

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

Sr. No.	Name	Quantity (in parts)	Part used
1	Jati	2	Rhizome
2	Yashtimadhu	2	Roots
3	Mocharasa	1	Gum
4	Nagkesara	1	Flowers
5	Bilva	1	Unripe or half-ripe fruits
6	Haritaki	3	fruits

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-kapha 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).

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Table 2. Gradation of parameters

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

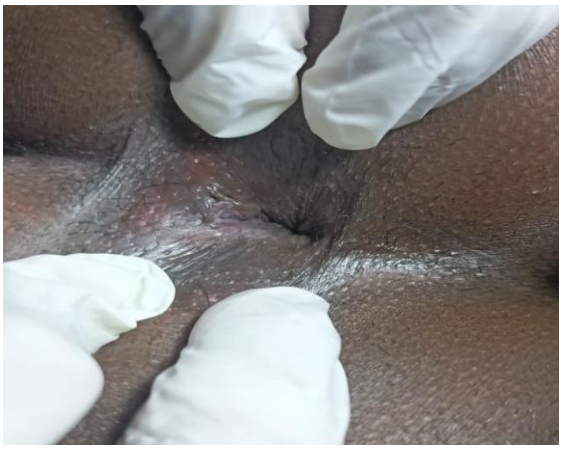
Initially on the first day, size of ulcer was 3 and median was 3.00. The ulcer's size was reduced. On the seventh day of treatment, the minimum grade of ulcer size was reduced to 0 and the median value was 0. There was no ulcer when the patient returned for a follow-up visit on day 21. (Figure 3e and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

When the patients had altered *aahar* and *vihar*, it led to *agni-dushti*, 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.

(a)



(b)

Figure 1(a & b). Condition of ulcer at follow-up visit on day 21

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Table 3. Overall assessment

Result	Assessment criteria
Complete relief	100% disappearance of symptoms and absence of complications and recurrence.
Moderate relief	75% disappearance of symptoms and absence of complications and recurrence.
Mild relief	About 50% relief in presenting symptoms and some recurrence of Fissure.
No relief	No relief in presenting symptoms and no change in the ulceration of Fissure-in-ano.

Table 4. Overall statistical analysis of the parameters.

Parameters	Statistical Analysis	AYUHEAL SUPPOSITORY					
		1st Day	3rd Day	5th Day	7th Day	21st Day	AT
Pain	Median	3	2	1	0	0	0
	Range	2-3	1-3	0-3	0-3	0-3	0-3
	Total Score	137	89	43	9	5	5
	Sample Size	50					
	P Value	p value<0.001, Highly Significant					
Per Rectal Bleeding	Median	2	1	0	0	0	0
	Range	1-3	0-3	0-3	0-3	0-3	0-3
	Total Score	97	48	15	3	2	2
	Sample Size	50					
	P Value	p value<0.001, Highly Significant					
Constipation	Median	3	2	1	0	0	0
	Range	1-3	0-3	0-3	0-3	0-3	0-3
	Total Score	127	90	50	11	11	11
	Sample Size	50					
	P Value	p value<0.001, Highly Significant					
Anal Spasm	Median	3	2	1	0	0	0
	Range	1-3	1-3	0-3	0-3	0-3	0-3
	Total Score	116	88	44	9	4	4
	Sample Size	50					
	P Value	p value<0.001, Highly Significant					
Size of Fissure	Median	3	2	1	0	0	0
	Range	3	1-3	0-3	0-3	0-3	0-3
	Total Score	150	96	51	7	7	7
	Sample Size	50					
	P Value	p value<0.001, Highly Significant					

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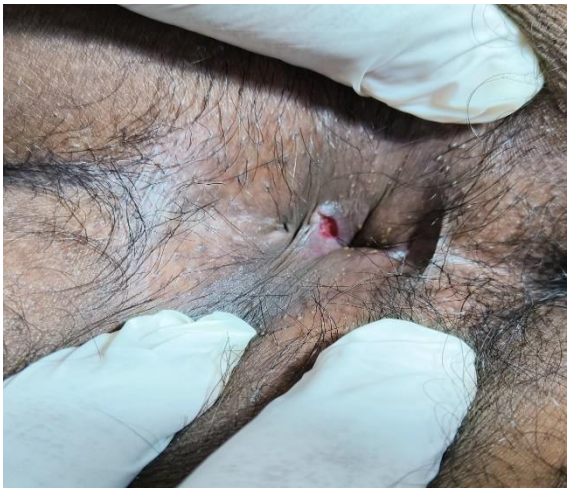

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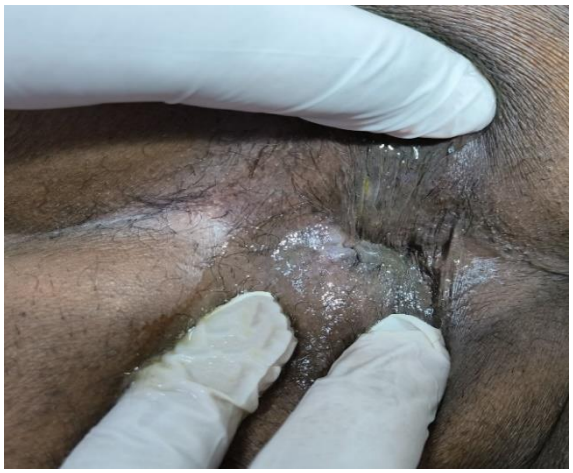
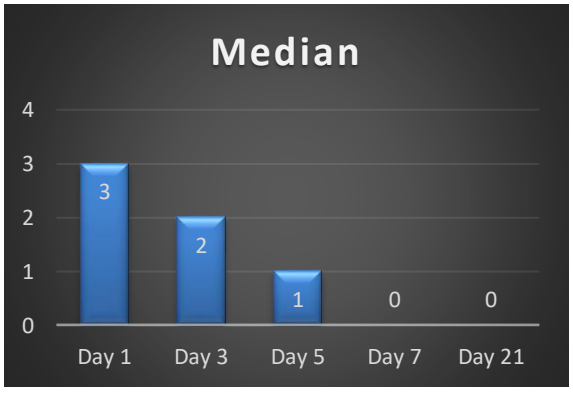


(b)

Figure 2 (a & b). Various stages of acute Fissure



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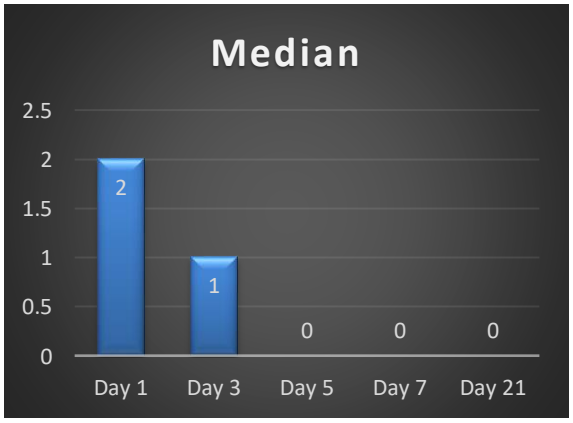

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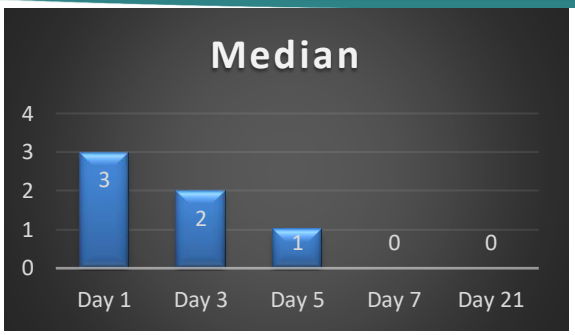

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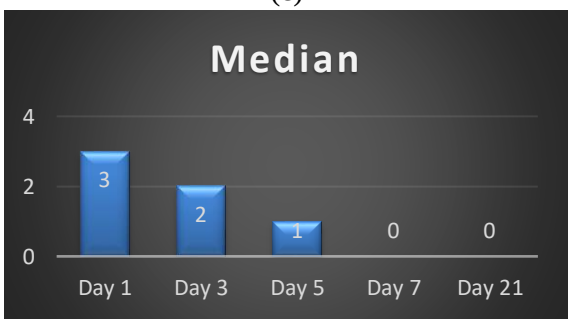
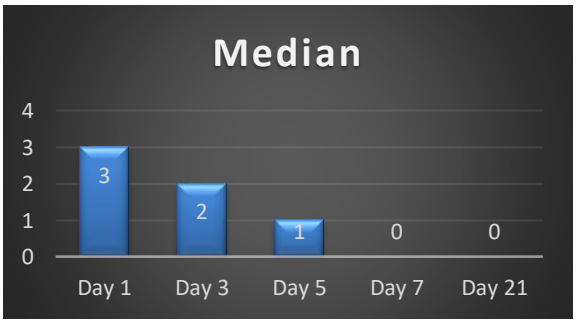


(d)



(e)

Figure 3 (a, b, c, d & e). Range of pain and median value at different stages

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

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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, anthelminthic and intoxicating (Pandey, 2005).

Mode of action of *Yashtimadhu*:

It is analgesic (*vednasthapana*) 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 *raktastambhana* (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 vednasthapana, shonitsthapana, 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.

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How to cite this Article:

Mayur Pawaskar and Zishan Ahmad Ansari (2023) A Comprehensive Approach to Treating Acute Fissure-in-ano (Parikartika) with the AYUHEAL Suppository. *International Journal of Experimental Research and Review*, *35*(Spl.), 160-168.

DOI : https://doi.org/10.52756/ ijerr.2023.v35spl.015