



A CLINICAL STUDY ON VEDANASTHAPAN MAHAKASHAYA OINTMENT AND VEDANASTHAPAN GHANVATI IN THE MANAGEMENT OF PARIKARTIKA W.S.R. TO ACUTE FISSURE-IN-ANO

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ABSTRACT

Parikartika (anorectal fissure) has become the most common and painful condition in anorectal disorders. Nowadays, people have faulty lifestyles and improper food habits, leading to the vitiation of *doshas*, particularly *Apana vayu*, which is a significant factor for deterioration in anal conditions leading to fissures in the ano with severe pain in the anal region.

In Modern science, various treatment modalities, including antibiotics, laxatics, sphincterectomy, fissurectomy, etc., are expensive and require long hospitalisation with other unwanted complications. Hence, pain management is the first step by Vedanasthapan drugs, which results in pain-relieving and rapid healing of the fissure. The lack of analgesics in ayurvedic medicines is a disadvantage, and there is a constant quest for an ideal *ayurvedic* analgesic medicine like *vedana-sthapan* drugs. The properties of *Vedanasthapanamahakashaya* ointment and *Vedanasthapan* ghanvati are the group of drugs which subside pain and restore all vitiated doshas in the body to an equilibrium state. So, the *Vedanasthapan Mahakashaya*, on the basis of the chemical constituents of each drug, can be estimated that the part of drugs which is used to subside the pain in the body and these classes of drugs have the qualities of analgesic, anti-inflammatory and wound healing properties.

Keywords: Vedanasthapan Mahakashaya Ointment and Vedanasthapan Ghanvati in the management of Parikartika

INTRODUCTION

Sushrut defined Parikartika in Ayurveda as a condition of Gud (anus) with cutting and burning pain, as well as this discomfort in the anus, penis, umbilical region, and neck of the urinary bladder with cessation of flatus.[1] In this regard, Acharya Sushrut explained the pathophysiology of the disease as follows: if a person is debilitated with *mrudukoshta* (moderate digestive power) or manage (weak appetite), more food with the attributes of *Ruksha* (dry), *Ushna* (hot), *Lavana* (salty), etc. is consumed. Vitiates *Pitta* and *Vata* and leads to manifestation of the disease² Acharya Charak and Vagbhat used two words, “*Vikartika*” and “*Parikartika*” to describe the disease. Charak recorded symptoms such as pricking discomfort in the groins and sacral area, scanty constipation, and frothy bleeding per anus.^[3] “fissure” generally denotes a crack, a split, or a cut. A fissure in ano is a tiny longitudinal ulcer in the lower anal canal's long axis. The anal fissure (fissure- in-ano) has been described as an acute superficial break in the continuity of the anal skin, usually in the anal margin. Fissure occurs most commonly in the mid-line posteriorly. *Vedanasthapan* is a class of herbal plants known as anodynes (a drug used to lessen pain), which eliminates pain and restores the body to its normal stage. According to charak, Vedanasthapan Mahakashaya has ten drugs which are affecting in relieving pain, and these are safe and may not produce any adverse effects^[9]. There are many analgesics like NSAIDs in modern medicine, but they have many negative effects and cause hypersensitivity reactions sometimes. So, in the present study, This *Vedanasthapan maha kashaya* group of drugs has been selected for the management of painful Acute Fissure in ano.

Material and Methods: The topic of the study, together with the case proforma, was submitted to the Institutional Ethical Committee (IEC/ACA/2021/5126-5274), the university. The significance of the aims and objectives, methodology,

and probable outcome of the study were clarified to the committee, and ethical clearance was obtained for the conduction of the study. The trial has been registered in CTRI with the reference no-CTRI/2022/09/046058.

SAMPLE SIZE – 30 Patients suffering from *Parikartika* (Acute Fissure-in-ano) fulfilling the inclusion criteria.

SOURCE – The patients shall be selected from OPD and IPD. Madan Mohan Malviya Govt. *Ayurveda* College and Hospital, Udaipur. Govt. *Ayurveda* Hospital, *Hathi Pole*, Udaipur. Through special camps arranged from time to time

SELECTION CRITERIA

Inclusion Criteria

- Male or Female, Age 16-60 years.
- Patients having Classical signs and symptoms of the *Parikartika* (Acute fissure-in- ano)
- Those ready to give written informed consent.

Exclusion Criteria

- The subject who does not comes under inclusion.
- Malignancy non-cooperative patients
- Uncontrolled Hypertension and HIV, Immune deficiency syndrome.
- DM
- Heart disease like M.I., C.A.D, I.H.D.
- Immunosuppressive medications users

Subjective Parameters

- Pain, Bleeding, Burning Sensation in Ano, Constipation, Pruritis Ani, Tenderness in Anal Region, Sphincter Spasm, *Parikartika* Healing

INVESTIGATIONS: As required

- Hb gm%, ESR, TLC, DLC, BT,
- CT, HIV, HBsAg

STUDY DESIGN

Allocation- In an open-label clinical trial, the patients will be randomly divided into two groups using a computer-generated randomization sampling method.

GROUP – A Procedure: local application of ointment

| Quantity of ointment | According to need |
|----------------------|-------------------------|
| Time Frame | 6 Weeks |
| Trial Period | 4 Weeks |
| Follow up period | after treatment 2 Weeks |

GROUP – B Procedure: local application of ointment and oral *Vedanasthapan Ghanavati*

| Quantity of ointment | According to need |
|----------------------|-------------------------|
| Dose (Ghanvati) | 500 mg two times a day |
| Time Frame | 6 Weeks |
| Trial Period | 4 Weeks |
| Follow up period | after treatment 2 Weeks |

Observation and Results

- According to the socio-economic status of the patients, out of 15 patients, a maximum of nine patients (30.0%) were in the Lower class, five patients (16.7 %) were in the Middle class, and 1 (3.3%) patient were Upper Class Group A maximum seven patients (23.3%) were in the Lower class and six patients (23.3 %) were in the Middle class and 2 (6.7%) patients Upper Class in Group B.
- According to the gender of the patients, out of 15 patients, a maximum of 9 patients (30.0%) were Male, and 6 patients (20.0%) were female patients in Group A. Out of 15 patients, a maximum of 10 (33.3%) were male, and five (16.7%) were female. Group B.
- According to the mode of onset of the patients, Out of 15 patients, a maximum of 8 patients (26.7%) were in the Sudden, and 4 patients (13.3 %) were in the Traumatic and 3 (10.0%) patients were in the Gradual Group A. Out of 15 patients, a maximum of 7 patients (23.3%) were in the Sudden, two patients (6.7 %) were in the Traumatic, and 6 (20.0%) were in Gradual Group B.
- According to the marital status of the patients, out of 15 patients, maximum eight patients (26.7%) were in the Married, and 7 patients (23.3%) were in Unmarried patients Group A. 15 patients, maximum ten patients (233.3%) were in the Married and five patients (16.7%) were in

Unmarried patients Group B.

- According to the Religion of the patients, out of 15 patients in each group, a maximum of 13 patients (43.3%) were Hindu 2 (6.7%) were Muslim patients. Group A.14 patients (46.7%) were in the Hindu and 1 patient (3.3%) were in Muslim patients Group B
- According to the Nature of Work of the patients Out of 15 patients, 4 patients (13.3%) were in the Hard and 3 patients (10.0%) were in the Sitting and 2 patients (6.7%) were in the Standing and 6 patients (20.0%) were in the Travelling were in the Group A 15 patients, 5 patients (16.7%) were in the Hard and 3 patients (10.0%) were in the Sitting and 2 patients (6.7%) were in the Standing and 5 patients (16.7%) were in the Travelling were in the Group B
- According to the food habit of the patients Out of 15 patients Each Group, 4 patients (13.3%) were in the Mix and 3 patients (10.0 %) were in the Veg and 8 (26.7%) patients Non-Veg Group A, 15 patients, 5 patients (16.7%) were in the Mix and 2 patients (6.7 %) were in the Veg and 8 (26.7%) patients Non-Veg Group B,
- According to the bowel habit of the patients Out of 15 patients each group, 5 patients (16.7%) were in the Regular and 10 patients (33.3%) were in Irregular patients Group A, 6 patients (20.0%) were in the Regular and 9 patients (30.0%) were in Irregular patients Group B
- According to the appetite of the patients Out of

15 patients each group, 8 patients (26.7%) were in the Mandagni, and 7 patients (23.3%) were in Vishamagni patients Group A, out of 15 patients,

9 patients (30.0%) were in the Mandagni, and 6 patients (20.0%) were in Vishamagni patients Group B.

PERCENTAGE OF DIFFERENCE AFTER TREATMENT

| S. No | Variable | % Diff. in group A | % Diff.in group B |
|-------|-------------------------|--------------------|-------------------|
| 1 | Pain | 79.3 | 91.17 |
| 2 | Bleeding | 72.72 | 87.50 |
| 3 | Burning sensation | 55.01 | 94.12 |
| 4 | Constipation | 79.3 | 92.30 |
| 5 | Pruritis Ani | 100 | 77.78 |
| 6 | Tenderness | 53.33 | 89.46 |
| 7 | Sphincter Spasm | 100 | 100 |
| 8 | Healing of Fissure | 73.33 | 95.02 |
| | Avg. % of Relief | 76.5 | 90.91 |

The improvements in the symptoms of *Parikartika* (Acute fissure in ano) are more relief in Group B 90.91%, than in Group A 76.5%

DISCUSSION

mode of action of *Vedanasthapan maha kashaya ointment and ghanvati*

Without a doubt, Ayurveda discloses that medications function through *veerya*, which is entertained and interpreted in various ways depending on the chemical, biological, and therapeutic equivalences, including *Rasapanchaka*. Drugs act through *Rasapanchaka*, which includes *rasa*, *guna*, *veerya*, *vipaka*, and *Prabhava*, and these principles are known as *gunas* in general. Certain medications, according to *Acharya Charak*, exert their action through their *Rasa*, while others through *Guna*, *Veerya*, *Vipaka*, and *Prabhava*. If the *rasa*, *vipaka*, *veerya*, and *prabhava* have equal strength, the *rasa* is superceded by *vipaka* by nature, both are superceded by *veerya*, and *prabhava* supercedes all other principles. Analgesics of various forms are available in current science. However, many of them can have adverse side effects in some patients and have numerous contraindications to their use. The origin of pain, according to *Ayurveda*, is vitiated *vata dosha*. However, reducing pitta dosha is also essential in this case. *Vedanasthapanaka*, as the name implies, has ten *dravyas* with qualities comparable to *vedana sthapan*.

Discussion on Assessment parameters

➤ Discussion on Pain

When the effect of *Vedanasthapan mahakashaya ointment* and *Vedanasthapan ghanavati* on pain was statistically compared to both groups using the Wilcoxon signed rank test, the results were significant. On clinical assessment, *Vedanasthapan mahakashaya ointment* and *Vedanasthapan ghanavati* showed analgesic activity. On comparing the mean Pain in both the groups, by Mann Whitney U test, statistically, no significant difference was found. The percentage of relief in Pain relief group A was 79.3%, and group B after treatment was 91.7%. Therefore, it is clear from the above analysis that *Vedanasthapan mahakashaya ointment* and *Vedanasthapan ghanavati* were more efficient than *Vedanasthapan mahakashaya ointment* in reducing pain because of the anti-inflammatory action of the chemical constituents of each medicine. It can be estimated that the part of the medicine that is asked to be used to relieve pain in the body must function based on the chemical contained.

➤ Discussion on Bleeding

When the effect of *Vedanasthapan mahakashaya ointment* and *Vedanasthapan ghanavati* on Bleeding was analysed statistically, a comparison of both groups by Wilcoxon signed rank test was significant. On comparing the mean bleeding in both groups, the Whitney U test found a statistically non-significant

difference. The percentage of relief in Group A patients was 72.75%, and Group B after treatment was 87.50%. Therefore, it is clear from the above discussion that *Vedanasthapan maha kashaya* ointment and *Vedanasthapan ghanavati* are more efficient in stopping bleeding caused due to these group of drugs are *kashya ras pardhan* and properties of *Kashaya rasa* is anti hemolytic and anti-inflammatory action *Acharya Susruta* said about *sandhana*, *skandhna*, *pachana* and *dahana*. In this, *Kashaya rasa dravya* causes the *sandhanata* of the *vrana*.

➤ Discussion on Burning sensation.

When the effect of *Vedanasthapan mahakashaya* ointment and *Vedanasthapan ghanavati* on Bleeding was analysed statistically, a comparison of both groups by Wilcoxon signed rank test was significant. The Whitney U test found A statistically non-significant difference when comparing the mean burning sensation in both groups. The percentage of relief in bleeding in Group A patients was 55.01%, and in Group B, after treatment, it was 94.12%. Therefore, it is clear from the above discussion that *Vedanasthapan maha kashaya* ointment and *Vedanasthapan ghanavati* are more efficient in stopping the burning sensation caused by *Vedanasthapan maha kashaya*. Almost all drugs, *snigdha guna* and *sheet virya* of drug help in reducing the *Pitta*, and *pitta dosha* is the leading cause of the burning sensation.

➤ Discussion on Pruritis Ani

When the effect of *Vedanasthapan mahakashaya* ointment and *Vedanasthapan ghanavati* on Itching was analysed statistically using the Wilcoxon signed rank test, the results were found significant in the patients of both groups. On comparing the mean pruritis ani in both groups, the Mann-Whitney U test found a statistically non-significant difference. The percentage of relief in Itching of group A patients was 77.78%, and in group B, it was 100%. From this, we can conclude that *Vedanasthapan mahakashaya* ointment and *Vedanasthapan ghanavati* are more efficient than *Vedanasthapan mahakashaya* ointment alone in reducing itching because of their antipruritic properties.

From an Ayurvedic perspective, itching may be due to *Kaphadushti* and *Raktadushti*. As *Parikartika* is predominated by *Pitta Dosha*, the involvement of *Raktadushti* is also to be considered due to the *Ashraya ashrayi bhava*. These groups of drugs are *tikta*, *Madhura Kashaya rasa*, which helps in achieving *Rakta prasadana* and thereby reducing the *kandu*.

➤ Discussion on Tenderness

When the effect of *Vedanasthapan mahakashaya* ointment and *Vedanasthapan ghanavati* and *Vedanasthapan mahakashaya* ointment on tenderness was analysed statistically by using the Wilcoxon signed rank test, the results were found significant in the patients of both the groups. The Mann-Whitney U test found a statistically non-significant difference in comparing both groups' mean tenderness. The percentage of relief in tenderness Group A patients was 53.33%, and in Group B after treatment, it was 89.46%. From the above discussion, it can be concluded that *Vedanasthapan mahakashaya* ointment is more efficient than *Vedanasthapan mahakashaya* ointment and *Vedanasthapan ghanavati* in reducing tenderness because of topical application of ointment has soothing and healing action on skin lesions. This group of drugs induces vascular endothelial growth factor expression in wounds. It also reduces cellular hypertrophy of the wound. It has anti-inflammatory and wound-healing properties.

➤ Discussion on Healing

When the effect of *Vedanasthapan mahakashaya* ointment and *Vedanasthapan ghanavati* on healing was analysed statistically using the Wilcoxon signed rank test, the results were found significant in the patients of both groups. Comparing the mean healing in both groups, the Whitney U test found a statistically non-significant difference. The percentage of relief in healing Group A treatment in patients was 73.33%, and after treatment, it was 95.02%. From the above discussion, it can be concluded that *Vedanasthapan maha kashaya* ointment and *Vedanasthapan ghanavati* are more efficient than *Vedanasthapan maha kashaya* ointment in healing anal fissures because of their wound-healing property.

Vedanasthapan maha kashaya almost drugs are kashaya Madhura and tikka, rasa, laugh and snigdha guna and sheet virya. Madhura rasa has dhatu-wardhana (tissue growth), preenana (nutrition) and poshana (nourishment) effects. This helps in the regeneration of cells, contraction of wounds and epithelialisation.

Tikta and Kashaya rasa exhibit Raktashodhana (blood purifying) property. Raktashodhana and varnya properties help to improve local blood circulation. Remember the phenomenon of relative ischemia at the posterior midline, which plays a significant role in the pathogenesis of anal fissures. Kashaya rasa also has visada guna, which helps in lekhana karma (scraping slough) from wounds. Snigdha Guna counteracts the aggravated Vata Dosha, whereas Madhura. Tikta and Kashaya rasa do the shamana of Pitta and Rakta. Sheeta virya of the drug helps in reducing the Pitta and inflammatory changes.

Considering all the observations, results, statistical analysis and interpretation of the present study, the Null hypothesis is rejected, and the Alternative hypothesis is accepted. Vedanasthapan maha kashaya ointment and Vedanasthapan ghanavati in the management of Parikartika (Anal fissures) are found to be effective.

CONCLUSION

An anal fissure is a split in the anoderm and is related to the trauma caused by either passage of hard stool or repeated diarrhoea. An acute anal fissure is characterised by painful defecation, sphincter spasm, and the passage of bright streaks of blood along with the stool or seen in the tissue paper. It commonly occurs in the posterior midline of the anus (ratio of occurrence of fissure at the posterior midline vs the anterior midline is 90:10 in males; 60:40 in females). Final Conclusions were drawn based on the Observations and Results of the study, which are described as follows.

❖ Incidence of Fissure in ano was more common in

middle age group.

- ❖ Males were more prone to this disease than females.
- ❖ Most cases belonged to a middle socioeconomic group, were literate, were married, and had an average build.
- ❖ Fissures in ano were also very common in people who indulged in alcohol, took mixed diets and had irregular bowel habits.
- ❖ The majority of the cases in this study belonged to rural habitats.

In this present research work, the evaluation of the efficacy of vedanasthapan mahakashaya ointment in the management of Parikartika (anal fissures) was done by comparing its results with that of ointment and ghanvati. In this study, group A (n=15) was subjected to the application of vedanasthapan mahakashaya ointment and group B was used to the application of ointment and oral ghanvati over Parikartika (fissure in ano).

By this intervention, the targets achieved in Group B (n=15) were that pain, itching, bleeding, and tenderness were significantly reduced, and healing was considerably more as compared to Group A (n=15) patients, where the ointment was applied.

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