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Case Study

A CASE REPORT ON THE CLINICAL EFFICACY OF KANKAYANA VATI AND PILOVOS OINTMENT, A NOVEL TOPICAL AGENT, IN THE MANAGEMENT OF SECOND-DEGREE **HEMORRHOIDS**

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ABSTRACT

Haemorrhoids, caused by the inflammation and symptomatic enlargement of anal cushions, are a common pathological condition. The conventional medical treatment of haemorrhoids shares similarities with *Arsoroga* in Ayurveda, both in terms of etiology and clinical features. Kankayana Vati is a widely used internal medicine for haemorrhoids, although the dosage has not been explicitly specified. Additionally, a novel ointment, Pilovos, has been developed for local application to provide symptomatic relief. This case study explores the combined efficacy of Kankayana Vati (2 grams per day) and Pilovos ointment in the management of second-degree haemorrhoids in a 32-year-old male patient.

INTRODUCTION

Hemorrhoids are dilated veins in the anal canal in the sub epithelial region formed by radicals of superior, middle and inferior rectal veins. Bleeding, burning sensation, prolapsed mass and sometimes pain are the main complaints for which the patient of hemorrhoids usually seeks medical advice.

The diagnosis of hemorrhoidal disease is based on the history of clinical signs and symptoms like bleeding and prolapses, while proctoscopy findings confirm the diagnosis. So, there is a need for comprehensive management of hemorrhoidal disease using Ayurveda principles.

According to Ayurveda, Arshas is an Adhimamsa vikara formed in *Gudavalis*. The vitiation of *Doshas* along with vitiated Twak, Mamsa and Medas causes manifestation of *Arshas*. While describing the treatment principles of Arshoroga, Acharya Vagbhata has mentioned the use of various local applications. Acharva Sushruta has mentioned four types of management in Arshoroga.

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They are Bhaishajya, Kshara, Agni, and Shastrakarma; and Bhaishajya chikitsa is recommended as the first line of treatment in 1st and 2nd degrees of Arshoroga which suggest internal and external medication.

Medical treatments such as topical ointments and suppositories deserve comment. Many of these products will combine a barrier protect-ant with some other active ingredient. Local application is very significant for hemorrhoids in reducing symptoms like swelling, burning pain, and itching along with suitable internal medication. The active ingredients of topical applications can include vasoconstriction agents, local anesthetics. anti-inflammatory agents astringents.[1]

The ingredients of Kankayana Vati are Yavani (Hyoscyamus niger), Jiraka (Cuminum cyminum), Dhanyka (Coriandrum sativum), Maricha (Piper nigrum), Girikarnika (Convolvulus pluricaulis), Ajamoda (Apium leptophyllum), Upakunchika (Nigella sativa), Hingu (Ferula foetida), two Kshara and 5 Lavana, Trivruth (Operculina turpethum), Danti (Baliospermum montanum), Shathi (Hedychium spicatum), Pushkara (Inula racemosa), Vidanga (Embelia ribes), Dadima (Punica granatum), Shiva (Terminalia chebula), Chithraka (Plumbago zeylanica), Amlavethasa (Solena amplexicaulis), Shunti (Zingiber officinale), levigated with Beeja poora rasa (Citrus limon). After it attains fine particle size reduction, it is granulated and punched with a tablet of 500mg. Other than Hemorrhoids, it is indicated in many conditions like sprue, colic pain, intestinal worms.

Externally an Pilovos ointment (P&P product of VOSPLTD) has been developed at Vaidyartanam Ayurveda Research Institute with a combination of drugs like Lajjalu (Mimosa pudica), Surana-(Amorphophallus companulatus), Kantakari -(Solanum xanthocarpum), Haridra - (Curcuma longa), Sariba-(Hemidesmus indicus), Guggulu- (Commiphora mukul), Pippali - (Piper longum), and Kera thaila - coconut oil in a ointment form has been developed in a user-friendly form.

Here is a case study conducted to identify the combined effectiveness of 2gm *Kankayana Vati* mentioned in Sarangdhara Samhitha [2] internally 500mg tablets two times in a day just 15 minutes before food and Pilovos ointment externally after cleaning the area.

Case Report

This case report consists of a study of case on 2nd degree haemorrhoids in which pilovos ointment was applied locally along with internal medications for 30 days. A 32 yr old male patient came to the Shalvatanthra OPD of Vaidvaratnam Avurveda Foundation, Thrissur, with the presenting complaints of mass bulging at anal region, intermittent bleeding per rectum since 2 months. Patient had a history of constipation since last 3 months. Patient was examined and on interrogation history has taken. The patient was an auto driver by occupation since 8 years, who use to have prolonged sitting for nearly 6 - 8 hrs, daily intake of spicy food especially non-veg food. He also has smoking (1packet/day) and alcoholism (2 pegs daily) since 10 yrs. No history of any major illness was found. On general examination, moderate built and afebrile, P/R - 70/mint, BP - 130/80 mmHg, No pallor or icterus present. Per rectal examination implies non tender, soft, mild spasm and proctoscopic examination showed 2nd degree pile mass at 3 and 110 clock positions all the other Laboratory investigations like CBC, BT, CT, RBS, LFT, RFT - normal, HIV, HCV, HBsAg, VDRL were non reactive

Medical Intervention

Duration- 30 days

Follow up – Patient observed on initial, 10^{th} , 20^{th} and $31^{st}\,\text{day}$

Orally: 2 tablets of *Kankayana Vati* 500mg suggested to have with butter milk 15 minutes before food for two times in a day.

Locally: Pilovos ointment - Morning after evacuation of bowel after cleaning the area and apply it for 3 times in a day.

Assessment Criteria

Both pre and post assessment of the patient was done on the basis of clinical symptoms and necessary investigations, clinical improvements were noted along with rectal and proctoscopic examination.

Subjective parameters: Nature of pile mass as mentioned by patient, constipation, mucous discharge, itching, bleeding.

Objective parameter: Size of pile mass based on proctoscopic examination

Objective Parameters - Degree of internal hemorrhoid		
a	1st degree	Pile mass does not come out of anus.
b	2 nd degree	Pile mass comes out only during defecation and is reduced spontaneously after defecation.
Subjective parameters		
1	Constipation	present/absent
2	Pruritus ani	present/absent
3	Mucous discharge	present/absent
Ala a	Per rectal bleeding	a. Absent (0) - No bleeding during defaecation.b. Mild (+) - 5-10 drops per bowel habit.
RVP	Can a Real	c. Moderate (++) - 10-20 drops per bowel habit. d. Severe (+++) – More than 20 drops per bowel habit.

ASSESSMENT AND OBSERVATIONS

The patient's symptoms were assessed before and during the treatment period, considering subjective parameters such as constipation, pruritus ani, mucous discharge, and rectal bleeding, as well as objective parameters including the size of the pile mass observed during proctoscopic examination. Throughout the treatment, the patient reported symptomatic relief, and physical examinations showed improvements, including reduced edema, pain, pruritus ani, and the absence of a pile mass during proctoscopy.



Fig.1a. Before treatment



Fig.1b After 30 days treatment Images of medicament used



Fig. 2a. Image of Kankayana Vati



Fig. 2b. Image of Pilovos Ointment DISCUSSION

The disease *Arshoroga* perhaps is at the top of the list of all the ailments of the anorectal region, and the current lifestyle and working culture make the people more prone to such disease. Hemorrhoids usually managed with internal medicines along with suitable topical applications like suppository, Ointment etc and surgical interventions. The majority of patients presented with complaints like bleeding per rectum, mucus discharge per rectum, painful defecation, prolapse of pile mass and constipation. The main causes of haemorrhoids are improper digestive system, straining, constipation, Viruddha ahara-vihara, excessive travelling etc. Agnimandya Malasthambana are the root causes of Arshas.

The Kankayana vati is formulated with 26 ingredients and almost all of these drugs are having the property of *Deepan, Pachana, Vatanulomana, Krimighna,* and *Ushna guna* hence will have *Shulaprashamana* or the pain relieving activity and are said to be the best appetizers. The dosage fixation of same is also having major role in efficacy as it is not mentioned in *Sarangdhara*. Based upon a clinical study report of *Kankayana Vati* with *Baishajaratnavali* reference we have developed *Kankayana Vati* with a dose of 500mg (two tablets twice daily) which will helps to maintain the dose of 2 gram of medicament in a day.^[3] All the physico chemical parameters analyzed for the tablet dosage form for making sure of its bio availability.

Topical therapy is the other first-line therapeutic alternative to treating the acute symptoms of hemorrhoid disease. [4] A large number of options are available, although the evidence supporting their efficacy are weak. Topical therapies reduce symptoms by exerting a local anesthetic effect, which eliminates the burning and itching associated with hemorrhoid prolapse. Hence to evaluate the supporting role of external application Pilovos ointment has been developed.

The herbs used for the preparation of Pilovos ointm<mark>e</mark>nt are *Lajjalu, Surana, Kantakari, Haridra,* Sariba, Guggulu, Pippali along with the base Kera thailam as an ointment which shows significant effect as topical application in reducing symptoms like pain, bleeding, itching and discharge. Lajjalu due to Tiktha kashaya rasa, Laghu rooksha guna (Soshana of Kleda), Kaphapitha haratwa (discharge and itching), Sheeta raktastambana property (discharge bleeding) subdues deranged Kapha and Pitta beneficial in hemorrhagic diseases, diarrhea, and gynecological disorders.[5] Flavanoids in the drug orientin, isoorientin has anti bacterial and anti inflammatory property. Leaves of the plant have anti-inflammatory activity against both exudative and proliferative phases of inflammation (shrinkage of pile mass).

Surana is Kaphavatahara, Kashaya katu rasa and has anti-haemorrhoidal action (tubers), anti-inflammatory and homeostatic actions. Kantakari and Guggulu has Tiktha rasa and Ruksha guna and thus reduce inflammation, mucous discharge and has an analgesic effect. [6] Haridra is Vrana ropana and has antimicrobial property. It prevents secondary microbial infections and fastens healing of inflamed skin and mucous membrane. [7]

Sariba is having Sheeta veerya and it arrest bleeding. Eases the skin over the anal region due to its emollient property (easy evacuation of bowel).[8] Pippali is having Madhura vipaka and Anushna veerya. It has got Vatanulomana guna. Piperine, which is the

prime constituent of fruit, is reported to be having significant anti inflammatory activity^[9]. Coconut oil which is the base of ointment is *Pitta hara, Sheeta virya, Snigdha guna* (easy evacuation of bowel), reduces burning sensation and helps in wound healing.^[10]

Special care was given for identifying the ingredients and its preparation. Analytically LOD, pH, spread-ability, homogeneity and melting range done for the Pilovos ointment. Patient was comfortable with the usage of Pilovos ointment and no staining and irritation noted.

CONCLUSION

The integrated approach of using *Kankayana Vati* and Pilovos ointment demonstrates promising results in the management of second-degree hemorrhoids. The combined medication effectively alleviated symptoms and showed significant improvements in the patient's condition. This case study highlights the importance of comprehensive treatment strategies for hemorrhoids, addressing both internal and external aspects of the condition.

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