

Palaskhshar ointment in the management of Abhyantar Gudarsh – An Ayurvedic Management Protocol

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Abstract

Background: Hemorrhoids or piles are a common ailment among adults. More than half of men and women aged 50 years and older will develop hemorrhoid symptoms during their lifetime. This disease Gudarsha comes under the heading of Mahagada, as it is Dirghakalanubandhi, Dushchikitsya in nature, Tridoshaj and involves the Marma and it is well known for the chronicity and difficult to treat. **Aim & Objectives:-** To evaluate the effect of local application of *Palash Kshar* Ointment in Management of *Abhyantar Gudarsha*. **Methodology:-** The study is prospective randomized controlled clinical trial. Total 60 patients will be selected for this study, which will be further divided randomly into two groups. Each group consists of about 30 patients. In which group A, will be trial groups and group B will be control groups. Every patient will be observed at regular follow up. On 7th, 14th, 21th, 28th Day. **Results–** Results will be drawn from the observations of objective parameters. **Conclusion –** Conclusion of the study will be drawn on the basis of statistical data calculated from the collected data.

Keywords:- Internal Haemorrhoid, Abhyantar Gudarsh, Palaskhshar Ointment, Palash Kshar.

Introduction & Rationale

According to Acharya Sushruta, due to Hetu (like Viruddha – Aahar, Adhyashana, Stree- Prasanga, Utkatasana, Prustha – yaan, Veg – Vidharan etc.) Dosha Prakop occurs. The main Hetu is Mandagni, which is mentioned as ‘Visheshto Mandagne’. These prakupeet Doshas alone or all together with or without Rakta, enters in the pradhan Dhamani (main channel), go downward and reach at Guda. By vitating the Gudavalies, Produces the Mansa-Prarohas are known as Arsha¹. The management of abhyantar Gudarsha i.e.

Internal haemorrhoid is mainly divided in four types:- Bheshaj Chikitsa (Medicinal Treatment), Ksharchikitsa, Agnikarma (Cauterisation), Shastrakarma (Surgery).

In application of Kshar, intervention of doctor is necessary and compulsory. To make the process convenient for patient to apply the Kshar at internal haemorrhoid and to avoid doctor’s intervention for application of Kshar, Concept of application of Kshar by patient himself is presumed and for this purpose the **Ointment of Kshar** is preferred.

Therapeutic treatment of haemorrhoids ranges from dietary and lifestyle modification to radical surgery, depending on degree and severity of symptoms.^{2,3} The primary objective of most topical treatment aims to control the symptoms rather than to cure the disease. The number of topical preparations contains various ingredients such as local anaesthesia, corticosteroids, antibiotics and anti-inflammatory drugs.⁴ No radical topical is available. Hence radical non surgical treatment

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form of topical ointment is need of time.

Although effective but traditional Pratisarniya Ksharkarma is more complex and tedious process. So modification in it is necessary. Kshar ointment is modification of Kshar Pratisaran. Previous study with Yava Kshar ointment was done. Siktha tail is previously used as a base for Kshar ointment preparation is proven safe and effective as a base⁴. This showed encouraging results. But Yava Kshar is difficult to prepare and also expensive. Palash kshar is used as Pratisarniya Kshar at many places and is very effective.^{4,5}. Hence *Palash Kshar* is used in current study in place of *Yava Kshar*. *Palash Kshar* ointment which is an ointment of *Palash Kshar* with base *Siktha taila* is modified technique for *Ksharkarma* which will be used in current study.

Purpose of the study:-

1. Number of patients for per rectal bleeding secondary to internal haemorrhoids are more. Topical ointment as a radical treatment is not available hence its complete study is necessary and feasible.^{6,7}

2. Palash kshar is used from years as a Pratisarniya kshar for management of internal haemorrhoids. Hence it is ethical to use Palash kshar Ointment in the management of internal haemorrhoids.

3. In application of kshar, intervention of doctor is necessary and compulsory. To make the process convenient for patient to apply the Kshar at internal haemorrhoid and to avoid doctor’s intervention for application of kshara, concept of application of Kshar by patient himself is presumed and for this purpose the Ointment of Kshar is preferred.

4. Haemorrhoid is disease associated with per rectal bleeding which is one of major reason for anaemia and ultimately blood transfusion. Many patients refuse for surgery due to their personal reasons and wants conservative management. So interest is developed in radical management of internal haemorrhoids using local application of *Kshar* ointment

Aim –

To evaluate the effect of local application of Palash Kshar Ointment in Management of Abhyantar Arsha.

Objective -

To study effect of Palash Kshar Ointment in management of Abhyantar Arsha.

Research Question

Whether Palashkshar ointment is effective in Abhyantar Arsha Chikitsa to reduce per rectal bleeding and size of internal haemorrhoids?

Hypothesis

Hypothesis of this PhD thesis will be -

Palash Kshar ointment applied locally at internal haemorrhoids once a day for 14 days is effective in reducing per rectal bleeding and degree of internal haemorrhoids.

H₀ = *Palash Kshar* ointment applied locally at internal haemorrhoids once a day for 15 days is not effective in reducing per rectal bleeding and degree of internal haemorrhoids.

H₁ = *Palash Kshar* ointment applied locally at internal haemorrhoids once a day for 15 days is effective in reducing per rectal bleeding and degree of internal haemorrhoids.

STUDY DESIGN

Review of Ayurvedic Literature

Literary Review Review of Modern Literature

Review of Previous Work Done

Identification of *Palash* (Botanist)

Preparation of Drug Preparation Of *Palash Kshar*

Preparation of *Palash Kshar* ointment

Physio Chemical Analysis of *Palash Kshar*

Clinical Study

Observation

Assesment STATISTICAL ANALYSIS

DISCUSSION

CONCLUSION

Figure 1 Flow diagram of the study procedure

Clinical Study

Open labeled prospective randomized controlled clinical trial

Signed and dated informed consent by subject will be participated

Screening of subject according to inclusion and exclusion Criteria and

Baseline Assessment

Randomization allocation of groups

Group A	Group B
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Trial Group	Control Group
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Application of Palash	<i>Palash Kshar</i>
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<i>Kshar ointment and Pathya</i> and <i>Pathya</i>	<i>Pratisaran</i>
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Initial assessment on 0th day

Assessment at follow up on 7th, 14th, 21th and 28th day

Observation

Statistical Analysis

Conclusion

Figure 2 Flow diagram of Clinical Study

Methodology

1] Type of Study Design :-

Randomized open labelled controlled clinical study

2] Location Of Study:-

Clinical Study:- Patients will be randomly selected from the OPD of the Dept. of Shalya Tantra of M.G.A.C.H & R.C. Salod (Hirapur), Wardha. A written informed consent will be obtained by counseling the patients of *Arsha* (Internal Haemorrhoids) for participation in the study. The selection of method of patient will be Lottery method of Simple Random Sampling.

Drugs:- Drug Name:- Palash (*Butea Monosperma*)

Part used - The leaves, Flowers, Seeds, gum and stem. The parts will be collected in their respective Dravya-Grahan Kaal. The trial drugs will be collected from the local area and certified by Foundation for Revitalisation of Local Health Traditions, Bangalore (FRLHT) and the Standardisation of Palashakshara will be done in Pharmacy of the Institute of M.G.A.C.H & R.C. Salod (Hirapur), Wardha. .

3] Duration of Study:- In the schedule of Ph.D course. (3 year)

4] Plan of study:-

A) *Kshar* ointment

1) Preparation of ointment base *Siktha* Taila⁷

2) Preparation of Ointment.

a. Preparation of *Palash Kshar* Ointment base *Siktha* taila i.e. *Palash Kshar* 1 part and *Siktha* taila 5 part.

Methodology

The study is prospective randomized controlled clinical trial. Total 60 patients will be selected for this study, which will be further divided randomly into two groups. Each group consists of about 30 patients. In which group A, will be trial groups and group B will be control groups.

Selection criteria for patients:

· The patients having clinical symptoms

of internal hemorrhoids will be included in study irrespective of sex, religion, diet habit.

- Patients having age between 21 years to 70 years.

- The patients of IInd and IIIrd degree internal haemorrhoids will be included in this study.

Rejection Criteria for patients:

- The patients of piles having previous history of haemorrhoidectomy.

- Pregnant woman will not include in this study.

- Patients taking other treatment from any pathy for the same problem during clinical trial.

- Patients who are suspected of serious systemic disease i.e. DM, TB, malignancy, Syphilis or having portal obstruction

- Patients Suspected of carcinoma of rectum, proctalgiafugax, chron's disease, fistula in ano & where it is contraindicated

- Patients with severe anaemia i.e haemoglobin less than 5%

Withdrawal Criteria for patients:

- The patients not following protocol of study.

- Patients requiring emergency treatment or surgical treatment or other treatment

- Patients not ready to continue treatment.

Treatment allowed for patients:

Patients requiring treatment for hypertension or other life saving activity

Haematenics, Blood transfusion.

Any short term treatment not more than 5 days for sudden onset disease like fever, which will not disturb protocol of study.

Methodology

Group A : Study Group

Local Application of *Palash Kshar* Ointment with

Pathya

Group B : Control Group

Palash Kshar Pratisaran with Pathya

Pathya for both Groups^{6,7}

- Hot sitz bath twice a day

- Advice the patient to keep the local site hygienically clean.

- Laxative – Avipattikar Churna 2-6 gm at bedtime with lukewarm water (Dose will be adjusted as per requirement of patient. when constipation will not be relieved dose may be increase).

- Dietary control will be advised.

Treatment of subject⁸ :

Period

Group A : Trial Group - Once a daily for 14 days.

Group B : Control Group – Once a week for 4 weeks

Dosage for both groups – as required depending upon surface.

Dosage schedule – After defecation in morning once a day.

Route of administration - Topical (Locally on internal haemorrhoids)

Procedure for local application of *Palash Kshar* ointment⁸:

Patient will be taken for local application after Hot sitz bath patient will be given lithotomy position i.e the patients is positioned supine comfortably with the knees flexed and abducted and buttocks projection well over the edge of table. The legs should be flexed at the hips and knees. Then local application at haemorrhoids will be applied. After that, a sterile pad kept at the anal verge to avoid soilage of clothes.

Procedure for local application of *Palash Pratisarniya Kshar*⁶:

Patient will be taken for local application after Hot sitz bath patient will be given lithotomy position. The *Kshar karma* will be performed with the help of slit-type proctoscope under local anesthesia. *Kshar* will be applied on internal hemorrhoids one after the other. After application on each hemorrhoid, the applied *Kshar* will be cleansed with lemon juice after changes in colour approx one to three minute. Yashtimadhu ghruta is applied over haemorrhoids. After that, a sterile pad kept at the anal verge to avoid soilage of clothes.

Assessment –

Gradation of Internal Haemorrhoids(As per Goligher⁹) -

I- Haemorrhoids projecting slightly in lumen of anal canal, when veins are congested at defecation.

II - Haemorrhoids prolapse out of the anus on straining, but return spontaneously to the anal canal when motion has been passed and the defecation has ceased.

III - Haemorrhoids prolapse but don't reduce spontaneously and remain prolapsed afterwards and have to be replaced digitally.

IV - Completely irreducible haemorrhoids, usually are long standing and acquire a component of skin.

P/R Bleeding grade⁶:

I Grade – 0 to 5 drops

II Grade – 6 to 15 drops

III Grade – 16 and above drops

Discharge⁸ –

Severe - Changing sanitary pads or cotton pads minimum 2 times a day

Moder ate - Changing of pads once a day only

Mild - No requirement of pads

Nil - Area is completely dry

Complication Assesment

To assess anal pain⁸ -

Severe - To relieve from pain, analgesic injections are required/Pain or discomfort dose not reduce after oral analgesics.

Moderate - To relieve from pain, oral analgesics are required.

Mild - Feeling discomfort within tolerable limit, no requirement of analgesic either orally or in other route.

Nil - No discomfort in any manner in the site, no analgesics.

Tenderness standard assessment⁸

Severe - Patient feeling pain by touching perianal area. Not possible to perform P/R examination.

Moderate - Little finger P/R can be done, patient feeling very much tolerable pain

Mild - Index finger P/R done with very much tolerable pain

Nil - Index finger insertion to anal canal without any pain or discomfort

Every patient will be observed at **regular follow up. On 7th, 14th, 21th, 28th**. For visual recording the **regular photographs** of selected patients from each group will be taken for observing the local changes at internal haemorrhoid.

Routine investigations of all patients and some specific investigations will be carried out as and when required

A. Lab Investigations -

Laboratory Investigations will be carried out before including the patient's under the study to rule out any other pathological conditions

a. Routine Hematological Investigation –

a. Complete Blood Count

b. Random Blood Sugar

b. If Required :

a. Urine Examination - Routine & Microscopic

- b. Stool Examination - Routine & Microscopic
- c. Biochemical Examination –
- d. Histopathological Investigation

Criteria for assessing the Result⁶ :

Completely Cured : Complete relief in all parameters

Improved : Improvement in 1 or 2 parameters

Uncured : When there was no improvement in any parameter.

Complication : When there was any complication due to hypersensitivity reaction to ointment (i.e. Itching, Severe pain, infection)

Observation

Maintained records & analyzed data collected after the study will be the source of observation & results

drawn consequently will be discussed in the dissertation.

Statistical Analysis

Statistical Analysis will be done on observed results irrespective of sex, religion, socio-economic status, occupation, etc.

The confidence limit will be fixed at 95% and the level of significance will be at 5%. Paired and unpaired ‘t’ test will be applied for objective parameter and chi square test will be applied for subjective parameter. If required Mann Whitney U test may be applied for subjective parameter.

Discussion

After obtaining the analyzed data Discussion will be done according to Ayurvedic and Modern text will be done.

Figure no. 1 Gantt Chart (Quarterly based)

Item	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Enrollment of Volunteer	█	█	█	█				
Data collection	█	█	█	█	█	█		
Writing thesis up to methods		█	█	█	█			
Data analysis					█	█	█	
Writing thesis up to results and Conclusions							█	█
Submission								█

Conclusion

On the basis of available literature, observations & discussion conclusion will be precisely drawn and whole dissertation work will be summarized in the final dissertation.

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