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# CLINICAL STUDY TO EVALUATE THE EFFICACY OF TIKSHANA PRATISARNIYA PALASH KSHARA IN THE MANAGEMENT OF RAKTARSHA W.S.R. TO INTERNAL HAEMORRHOIDS

Vikash Kumar Sahu<sup>1</sup>\*, Ramesh Chand Arva<sup>2</sup>, Kulwant Singh Himaliyan<sup>3</sup> and Sudarshan Thakur<sup>4</sup>

<sup>1</sup>Assistant Professor, Shalya Tantra Department, Abhilashi Ayurvedic College & Research Institute, Chail Chowk, Distt. Mandi (H.P.)

<sup>2</sup>HOD, Shalya Tantra Deptt., Major S.D. Singh P.G. Ayurvedic Medical College & Hospital, Farrukhabad (U.P.)

<sup>3</sup>Associate Professor, Shalya Tantra Deptt, R.G.G.P.G. Ayurvedic College & Hospital, Paprola, Distt. Kangra (H.P.)

<sup>4</sup>Professor, Rasa Shastra & B.K. Deptt., Doon Institute of Medical Science, Sahaspur, Dehradun (U.K.)

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# \*Corresponding Author Dr. Vikash Kumar Sahu

Assistant Professor, Shalya Tantra Department, Abhilashi Ayurvedic College & Research Institute, Chail Chowk, Distt. Mandi (H.P.)

# **ABSTRACT**

The description of the disease Arsha in the Ayurvedic literature has similarity with the disease 'Haemorrhoids'. Arsha is a commonest clinical condition, an *Ayurvedic* practitioner comes across in day to day practice. Haemorrhoids dealt rationally under the concept of Arsha and in this study we are especially dealing with Raktarsha or internal haemorrhoids. Ksharakarma has been indicated for all the variety of Arsha. The repeated advocacy of ksharakarma by almost all the ancient Acharyas have given an inspiration to work on the disease of Arsha with the help of pratisarniya kshara. Ksharakarma intervention was done in the total of 20 patients of internal bleeding haemorrhoids under local anaesthesia. The pile mass and bleeding per anum resolved in 14 days and the patients were relieved from all symptoms within 21

days. The patients were followed up upto 1 month .No complications were reported after the procedure.

**KEYWORDS:** Raktarsha, Internal haemorrhoids, Tikshana pratisarniya palash kshara, Bleeding per anum, Ksharakarma.

#### INTRODUCTION

The description of the disease Arsha in the Ayurvedic literature has similarity with the disease 'Haemorrhoids'. Arsha is a commonest clinical condition, an Ayurvedic practitioner comes across in day to day practice. According to modern surgery, haemorrhoid is varicosity and dilatation of haemorrhoidal veins of anal-canal. Goligher (1975) estimates fifty percent of the people (over the age of fifty) on careful examination may be found to have haemorrhoids. It is mainly a disease of adulthood, with increasing frequency in advancing age. According to Ayurveda, Acharya Sushruta, the pioneer of surgery, has devoted separate chapter for anorectal disorder viz. Arsha. In Ayurveda, Arsha is the last disease of "annavahasrotus. The disease is characterized by one / more mansakura in the guda. These mansakuras ooze out rakta and kaphasrava with or without vedana and kandu. The treatment of Arsha is considerd very difficult and hence it is listed under "Ashtamahagada" in all Ayurveda Samhita. Haemorrhoids dealt rationally under the concept of Arsha and in this clinical study we are especially dealing with *Raktarsha* or bleeding haemorrhoids.

Acharya Charaka and Acharya Sushruta, both have described four types of measures for the treatment of Arsha. These are Bhesaja, Kshara, Agni and Sashtra. Acharya Charak has laid more emphases on Bhaishajya treatment (medical treatment). Whereas Acharya Sushruta stresses more about Kshara, Agni and Shastrakarma. While going through the chapter of treatment of the disease "Arsha", it becomes quite evident that Ksharakarma has been indicated for all the variety of Arsha. The repeated advocacy of ksharakarma by almost all the ancient Acharyas have given an inspiration to work on the disease Arsha with the help of pratisarniya kshara. Kshara has mainly Chedana, Bhedana, Lekhana, Sodhana, Stambhana, Shoshana, Ropana properties so palash kshara can be used for the treatment of this disease.

#### AIMS AND OBJECTIVES

- 1. To explore the literature about the Arsha (haemorrhoids) in modern as well as in Ayurveda.
- 2. To explore literature regarding the *Kshara* in Ayurveda.
- 3. To evaluate the clinical efficacy of Tikshna Pratisarniya Palash Kshara in the management of Raktarsha.

- 4. To provide an alternative therapeutic principle to the sufferers of *Raktarsha* through cost effective and less complicated procedure.
- 5. To standardise the *Ksharkarma* procedure.

# Selection of the drug

Tikshana pratisarniya Palash kshara having Chedana, Bhedana, Lekhana, Sodhana, Stambhana, Shoshana, Ropana properties can effectively cure the disease.

#### MATERIAL AND METHODS

A total number of 20 patients were selected for this study, from deptt. Of *shalya tantra* O.P.D. and I.P.D. of R.G.G.P.G. Ayurvedic Hospital Paprola after taking consent. Case selection was random regardless of caste, occupation, religion, and socio economic status etc.

## Criteria for selection of patient

#### **Inclusion criteria**

- ❖ Patients willing to undergo trial.
- ❖ Patients of either sex between the age 20 to 60 years
- Patients having the complaints of internal haemorrhoids viz, bleeding per anum, prolapse of pile mass, pain, constipation, discharge and heaviness in anorectal region.
- ❖ The patients were randomly selected irrespective of age, sex, religion, education, socioeconomic status etc.

# Following criteria for exclusion

- ❖ Patients not willing to undergo trial or not ready to give informed consent.
- ❖ Patients with uncontrolled systemic disorders like- diabetes mellitus, tuberculosis, uncontrolled hypertension, ischaemic heart disease.
- ❖ HIV and hepatitis B/C positive patients.
- ❖ Patients with any type of endocrinal disorders.
- **Patient with evidence of malignancy.**
- \* Rectal polyp in association with crohn's disease, ulcerative colitis.
- ❖ Patients contraindicated for *Kshara Karma* therapy like- *Bala*, *Vridha*, *Pramehi*, *Garbhini*.
- Haemorrhagic disorders.
- Severe anaemia.
- Lactating mother.

Method of study: The present study was a clinical study. Most of the study was done in indoor patients of department. This study was carried out in 20 patients.

**Trial group-1:-** Total 20 patients were included in this group and were given:-Local application of Tikshana pratisarniya palash kshara for 2-3 minutes in all patients, the Kshara Karma was given with localanaesthesia (Checked procedure Samyakadagdhalakshanas, like pakvajambuphalvatvarna) (blackish) followed by Kshara was washed out thoroughly from the pile mass with kanji. After that Yastimadhu churna + *Ghrita* has locally applied two times a day for 3 to 4 days to overcome the burning sensation.

#### Procedure of kshara karma





**Selection of Haemorrhoidal Mass** 







Pakvajambuphalavata Lakshana after application of kshara

**Duration of trial:-** The duration of trial was 14 days. The patients were assessed at an interval of 1 week.

**Follow up:-** There are total 4 follow-ups after completion of trial with the interval of 7 days.

**Patient consent:** The purpose of the study, the procedure to be carried out and the potential risks and benefits were explained to the in detail in non-technical terms and in their language. Thereafter their written consent was taken before starting the procedure.

#### **Discontinuation criteria**

- 1. Patient who was discontinued the treatment themselves due to any reason.
- 2. Patients who did not returned for the final follow ups.
- 3. Worsening of symptoms if occur.

**Ethical clearance:** Ethical clearance for conduction of the clinical trial involving human subjects was taken from the IEC before the commencement of trial (No.Ayu/IEC/2017/1142 Dated-01/09/2018).

#### Criteria of assessment

The patients treated in trial group were assessed by presence or absence of sign and symptoms before and after treatment. Symptomatic relief obtained by the treatment after every 7 days of scoring till the completion of treatment. Results were noted on the basis of marked improvement/moderate improvement/mild/no improvement.

**Subjective criteria:-** Presence or absence of the symptoms of Arsha(internal haemorrhoids) formed subjective criteria, For making the assessment rational and scientific, the symptoms were given grades according to their severity.

Table no. 1

Parameters	%age relief			
Marked improvement	75% to 100%			
Moderate improvement	50% to 75%			
Mild improvement	25 to 50%			
No improvement	<25%			

# Statistical analysis of data

The data obtained in clinical study before and after treatment was expressed in term of mean, standard deviation (+\_SD) and standard error(+\_SE). Appropriate test like t-test was applied to observe the significance between before and after treatment. The obtained results were interpreted as follows-

*	Insignificant or not significant (NS)	-	p > 0.05
*	Significant	-	p < 0.05
*	More and very significant	-	p < 0.01
*	Highly and extremely significant	-	p < 0.001

#### **RESULTS**

In the present study 20 patients were studied, these patients were treated in single groups. All patients complete the trial. In this group 20 patients were registered for local applications of *Tikshana pratisarniya palash kshara* followed by *Kshara* was washed out thoroughly from the pile mass with kanji. After that *Yastimadhu churna* + *Ghrita* has locally applied two times a day for 3 to 4 days to overcome the burning sensation.

Table no. 2: Cardinal symptoms of assessment criteria found in 20 patients.

Symptoms	No. of Patient	%age
Proctorrhagia	20	100
Haemorrhoidal prolapse	18	90
Pain	5	25
Constipation	15	75
Discharge	0	0
Heaviness & discomfort in ano-rectal region	15	75

Table no. 3: Pre and post treatment assessment.

Downerstows	Mean		J	%age	SD	CE.	T	
Parameters	BT	AT	d	Relief	±	SE ±	T	p
Proctorrhagia								
(Bleeding per	2.65	0.05	2.6	98.11	0.598	0.134	19.436	< 0.001
anum)								
Prolapse								
(Arsha	0.9	00	0.9	100	0.308	0.0688	13.077	< 0.001
Bhransha)								
Pain (Vedana)	0.25	00	0.25	100	0.444	0.0993	2.517	0.021
Constipation	0.85	0.25	0.6	70.58	0.598	0.134	4.485	< 0.001
(Vibandh)	0.03	0.23	0.0	70.50	0.570	0.134	4.403	<0.001
Discharge	00	00	00	00	0.000	0.000	-	0.000
Heaviness&								
discomfort in	0.9	00	0.9	100	0.641	0.143	6.282	< 0.001
anorectal	0.9	00	0.9	100	0.041	0.143	0.202	<0.001
region								

❖ Statistically highly significant relief (p<0.001) was found in proctorrhagia (%age relief=98.11%), prolapse (%age relief=100%), constipation (%age relief=70.58%), heaviness & discomfort in anorectal region (%age relief=100%)

❖ Statistically significant relief (p<0.05) was found in pain (%age relief=100%).

Table no. 4: Percentage of relief of therapy in 20 patients.

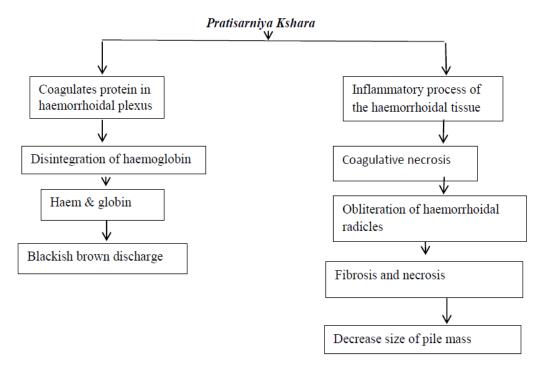
Percentage relief	Effects	Number of patients	Percentage
75-100	Markedly improved	18	90
51-74	Moderate improvement	02	10
25-50	Mild improvement	00	00

#### **DISCUSSION**

Probable action of *Tikshana pratisarniya palash kshara* is based on curative and preventive aspect of disease. *Kshara* having *Lekhana*, *Sodhana*, *Stambhana*, *Ropana* properties. It causes phyto-chemical cauterization and necrosis of tissue of pile mass and works as *raktastambhan*, *vedanasthapan* and relieves other associated symptoms also.

#### Probable mode of action

Application of Pratisarniya Kshara in Internal Haemorrhoid



#### **CONCLUSION**

- ➤ Ksharakarma (Local application of kshara) is effective in early stage of Arsha and has greatest advantage and wider acceptability.
- ➤ The trial drug (*Tikshna Palash Kshara*) of the present study was found simple, safe and effective in treating *Raktarsha*.

- Kshara has mainly chedana, bhedana, lekhana properties it shrinks the pile mass, and destroyed the associated symptoms of the disease of Arsha.
- > Symptoms of *Raktarsha* like bleeding per anum, prolapse, heaviness in anorectal region, pain, discharge, constipation etc. have subsided by ksharakarma and statically it has shown highly significant results.
- No recurrences of cases were reported during the follow up in treated patients.

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