

## EFFECT OF APAMARG KSHAR AS A SCLEROSANT IN THE MANAGEMENT OF GRADE I & GRADE II HAEMORRHOIDS

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### ABSTRACT :

Conventionally, numerous non operative treatments have been proposed and are being extensively used for the management of hemorrhoids, as IRC, RBL, RFA, Ultroid and cryoablation, Acharya Sushruta explained Pratisaraneeya kshara as one of the treatment modalities for Arshas. So the present study was planned to study the effect of 'EFFECT OF APAMARG KSHAR AS A SCLEROSANT IN THE MANAGEMENT OF GRADE I & GRADE II HAEMORRHOIDS'. A pilot study was conducted on total 15 subjects, selected randomly, with ages ranging from 20 years to 60 years, irrespective of gender, religion etc. from OPD/IPD of Shalya tantra, National Institute of Ayurveda, Jaipur, Rajasthan. The subjects were treated with sclerotherapy in which apamarg kshar was used as a sclerosant. Duration of the trial was 4 weeks including follow-ups. Results were analyzed statistically and highly significant improvement was observed in Bleeding per anum (SD- 0.8452, SE- 0.2182,  $p <0.0001$ ) and significant result in Prolapse (SD-0.5164, SE-0.1333,  $p<0.05$ ). Sclerotherapy is a parasurgical procedure which requires minimum hospital stay. The wound created by sclerosant heals within two weeks. No adverse effects were reported by any of the patients during the course of treatment. In this way apamarg kshar in the form of sclerosant is considered efficient in the treatment of grade I & grade II haemorrhoids.

**Key words:** Sclerotherapy, Sclerosant, Apamarg Kshar.

**INTRODUCTION:** Hemorrhoids has become one of the commonest health problems of the modern society. It is the foremost common disease among Anorectal disorders and the area of concern even since the Vedic periods. This disease causes discomfort, bleeding and pain to the patient which creates problems in his daily routine. Because of its severity it is considered as one among Ashta Mahagada.<sup>1, 2</sup> Arsha is being described by all the classics of Ayurveda, which deals with diseases and its treatment. Conventionally, numerous non operative treatments have been proposed and are being extensively used for the

management of hemorrhoids. The treatment procedures commonly adopted are infrared coagulation (IRC), rubber band ligation (RBL) and chemical destruction of pile mass with a direct current probe (Ultroid) or by thermal destruction with bipolar diathermy (Bicap) and cryo ablation. The developing trend is to prefer an improved and consistently better technique for the ablation of haemorrhoids.

Acharya Sushruta has explained four modalities of treatment for Arshas i.e. Bheshaja, Kshara, Agni and Shastra karma.<sup>3</sup> Kshara karma is one of the

important methods which can be practiced safely.<sup>4,5</sup>

Present study was planned to evaluate the efficacy apamarg kshar in the form of sclerosant<sup>6</sup> in the treatment of grade I & grade II haemorrhoids. Along with the description of Kshara and its preparations, Acharyas have mentioned various drugs that are suitable for the formulation of Kshara.

#### AIMS:

1. To control the bleeding from hemorrhoids particularly grade I & II.
2. To check the prolapse of hemorrhoids particularly in grade II.
3. To evaluate the efficacy of apamarg kshar in menthol containing almond oil as sclerosant<sup>8</sup> in the management of the hemorrhoids particularly grade I & II.

#### OBJECTIVES:

1. To study the Aetiopathology, symptomatology, and Samprapti of the disease according to Ayurveda as well modern science
2. To review and analyze available literature of Kshar karma described in Ayurveda.
3. To evaluate the therapeutic effect of apamarg kshar in menthol containing almond oil as a sclerosant.

#### PROTOCOL DESIGNING:

1. Complete descriptions regarding the details of each research case were recorded in a pre-designed proforma.
2. During the course of selection a separate case proforma according to the protocol was used for documentation
3. Informed Consent: The study was explained clearly to the subjects and their signed, written informed consents were taken before starting the study.

1. **SAMPLE SIZE:** Total 30 subjects were selected randomly following computer generated random table for the study, with age group 20 to 60 years, irrespective of gender & religion etc.

#### 2. **SELECTION OF THE PATIENTS:**

Patients were selected for study attending OPD and IPD of P.G. Department of Shalya Tantra, National Institute of Ayurveda, Jaipur.

#### I. INCLUSION CRITERIA:

1. Patients of age group 20 - 60 years of any gender.
2. Patients having Hemorrhoids (Grade I & Grade II)
3. Patients who were ready to give written informed consent.

#### II. EXCLUSION CRITERIA:

1. Patients with concurrent systemic diseases like Uncontrolled Diabetes mellitus, H.T., Tuberculosis, HIV I&II, HBsAg etc.
2. Infective, Neoplastic conditions of rectum.
3. Pelvic pathology
4. Pregnancy
5. Patient of age <20 and >60 years were excluded.

#### INVESTIGATIONS:

Blood routine: Complete blood count, Bleeding time, Clotting time, Erythro sedimentation rate, HBsAg, HIV I&II, Blood sugar- Fasting, Post Prandial, Urine Complete examination, Other investigations like tuberculin test, Pus culture, biopsy, FNAC etc. (if needed).

#### GROUPING OF THE PATIENTS:

15 patients were selected of hemorrhoids Grade I & Grade II by computer generated random table.

## CLINICAL STUDY:

SR.NO.	PARTICULARS	
1.	<b>DRUG</b>	Apamarg kshar in menthol containing almond oil
2.	<b>DOSE</b>	2-3 ml/ haemorrhoidal mass
3.	<b>APPLICATION METHOD</b>	Injection in sub mucosal plane around the pedicle of haemorrhoidal mass at or above ano-rectal ring.
4.	<b>SCHEDULE</b>	Thrice (at 0, 21 <sup>st</sup> , 42 <sup>nd</sup> day)

**Subsequent sclerotherapy punctures were given on the sites other than the previously selected points.**

The entire above procedures were followed accordingly in all the patients.

### DRUG REVIEW

#### APAMARG

#### KSHARA

#### PREPARATION:

The dried whole plant (panchang) of Apamarga (Achyranthes aspera)<sup>7</sup> was used to prepare apamarg kshara preparation as per standered protocol.

#### SCLEROSING AGENT AND ITS APPLICATION IN HEMORRHOIDS:

A sclerosing agent that induces an aseptic inflammatory response leading to a fibrotic process.

Ex.- Albright solution, Polidocanol, Sodium tetradecyl sulphate etc.

Sclerosing agent ensues → aseptic inflammatory reaction & intravascular thrombosis → submucosal fibrosis & scarring leading to the fixation of redundant mucosa to the gut wall.

It checks bleeding and minimizes the extent of mucosal prolapse and potentially shrinkage of the haemorrhoidal mass.

#### METHOD OF

**ADMINISTRATION:**<sup>8</sup> After routine preparation, patients were put in lithotomy position .The proctoscope was gently introduced in the anal canal & rectum to

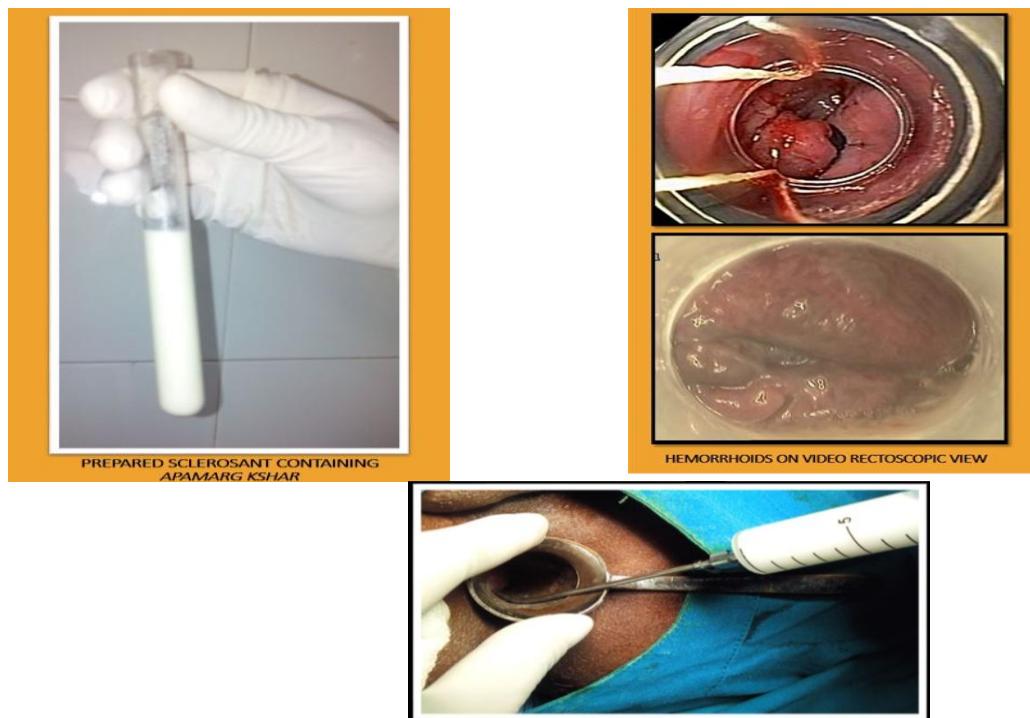
visualize the interior of distal bowel. Thereafter, the proctoscope was gradually withdrawn to see the hemorrhoid masses at or just above the level of Anorectal Ring.

Using the syringe with the bevel of Gabriel's needle directed towards lumen, loaded with modified sclerosant, solution was injected into sub-mucosal plane at the base of each pile mass at or just above the anorectal ring. Approximately 3 ml of the solution was given at each site. The solution spreads in the submucosa upwards to the pedicle and down words to the internal hemorrhoids and secondary hemorrhoids if present, it is prevented by intermuscular septum from reaching the external hemorrhoids. Following similar method modified sclerosant was injected circumferentially at 4-5 points in sub-mucosal plane at or above the anorectal ring.

The recognition of precise injection was made by striation-sign<sup>9</sup> i.e. mucosal and sub mucosal vessels were seen radiating from the yellowish background of wheel.

Varicose vein particularly the solitary varix the modified sclerosant is directly administered to emptied collapsed vein following the standard method of sclerotherapy for varicose veins.





**ASSESSMENT CRITERIA:** Effect of therapy were evaluated before, during & after the course of treatment by using parameters as stated below with standard grading.

- Bleeding per anus
- Prolapse of haemorrhoidal mass

**ASSESSMENT:** The patients undergone the treatment were assessed for sclerosing property on the basis of symptom rating score depicted below for improvement in specific symptomatology of Hemorrhoids.

### 1) BLEEDING PER ANUS :

- 0- No bleeding
- 1- Soiling of faeces with blood or staining of hand/tissue paper on cleaning after defecation
- 2- Drop by drop - 5 to 10 drops
- 3- Drop by drop - >10 drops/during entire act of defecation
- 4- Splashes in the pan

### 2) DEGREE OF PILES :

- 0- First degree hemorrhoids : Do not prolapse.
- 1- Second degree hemorrhoids : Prolapsed but Reduced Spontaneously.
- 2- Third degree hemorrhoids :

Prolapsed but has to be Reduced Manually.

3- Fourth degree hemorrhoids: Permanently prolapsed and cannot be Reduced

### CRITERIA FOR ASSESSMENT OF RESULT:

**Complete relief:** 100% relief in presenting signs symptoms of the disease.

**Marked relief:** above 75% relief of signs symptoms.

**Moderate relief:** 51% to 75% relief of signs symptoms.

**Mild relief:** 25% to 50% relief of signs symptoms.

**No relief:** below 25% relief of sign symptoms.

**STATISTICAL ANALYSIS:** Overall effect of intervention are compared with before treatment assessment done on day 1<sup>st</sup> compared with the assessment done on 9<sup>th</sup> week.

The information collected on the basis of observation was analyzed using appropriate statistical test (Paired' test was used for parametric data) to evaluate the

significances at different levels i.e. at 0.05, 0.01 and 0.001 levels.

The obtained results were interpreted as follows-

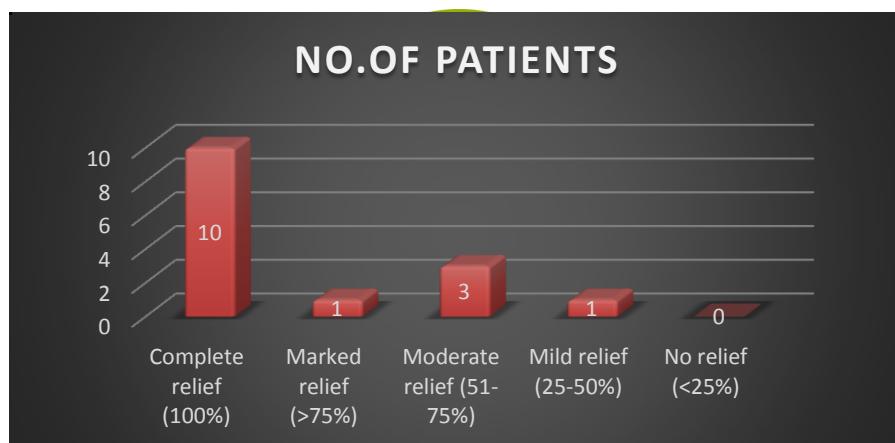
- Insignificant or Not significant (NS or NQS) -  $p>0.05$
- Significant (S) -  $p<0.05$

- More or very Significant -  $p<0.01$
- Highly or Extremely Significant -  $p<0.001$

**RESULT:** Out of 15 patients complete relief was seen in the 10 patients, marked relief in 01 patients, moderate relief in 03 patients, mild relief in 01 patients and no patient was seen with no relief.

### OVERALL EFFECT OF THERAPY:

EFFECT OF THERAPY	NO.OF PATIENTS	%
Complete relief (100%)	10	66.67
Marked relief (>75%)	01	6.67
Moderate relief (51-75%)	03	20
Mild relief (25-50%)	01	6.67
No relief (<25%)	00	00



### DISCUSSION:

**PROBABLE MODE OF ACTION OF SCLEROSANT<sup>10</sup>:** Sclerotherapy results not only in occlusion of vascular structures similar to embolization, but also may limit recurrence, proliferation, or collateralization by permanently disrupting the endothelium of targeted vascular structures. In addition to above sclerotherapy also results in extraction of proteins from lipids, denaturation of proteins, cell dehydration by osmosis, and physical obstruction by polymerization. The result of these processes is controlled

disruption of the targeted tissues biologic function.

1. Initial arrest of the bleeding owing to Chemical thrombosis of the hemorrhoidal plexus. It also ensues Aseptic inflammatory response owing to phenol and kshar.

2. The inflammatory response as a result of cell damage with fibroblast proliferation leads to sclerosis (progressive fibrosis) in the sub mucosal plane resulting to arrest of bleeding and fixation of hemorrhoidal mass to anal/rectal wall.

## CONCLUSION:

1. Bleeding was the principle & earliest symptoms of hemorrhoids grade I<sup>st</sup> & II<sup>nd</sup> hemorrhoids for which patient seeks medical advice.
2. Sclerotherapy was done as an O.P.D. procedure done without administration of any type of anesthesia.
3. No complication like prostatic abscess, inter sphincter abscess, retention of urine, urinary fistula, gangrene of the anal canal, stricture anal canal, disturbance from oil embolism, etc. were observed in any trial subject.
4. Sclerotherapy is a cost effective Para surgical procedure which requires minimum hospital stay. The wound created by sclerosant heals within two weeks. No any severe adverse effects were reported by any of the patients during the course of treatment. In this way apamarg kshar in the form of sclerosant is considered efficient in the treatment of grade I & grade II haemorrhoids.

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