A COMPARATIVE CLINICAL STUDY OF PRATISARNIYA APAMARG TEEKSHNA KSHAR APPLICATION AND SCLEROTHERAPY IN MANAGEMENT OF ABHYANTAR ARSHA W.S.R. HAEMORRHOIDS 1ST AND 2ND GRADE.

Wasnik Sumedh,1* Bhujbal Annasaheb,2 Dakhane Sandip.3

1. M.S. (Shalyatantra), Ph.D. (Scholar), M.B.A. (Scholar), PGDCR, Professor, HOD & PG Guide, Dept. of Shalyatantra, PMT’s Ayurved College, Shevgaon, Dist. Ahmednagar, MS, India.
2. M.S. (Shalyatantra), Associate Professor & PG Guide, Dept. of Shalyatantra, PMT’s Ayurved College, Shevgaon, Dist. Ahmednagar, MS, India.
3. B.A.M.S., PG Scholar, Dept. of Shalyatantra, PMT’s Ayurved College, Shevgaon, Dist. Ahmednagar, MS, India.

Received on: 29/08/18; Revised on: 04/09/18; Accepted on: 06/09/18

ABSTRACT

The disease which gives maximum trouble to mankind like enemy is Arsha. Sedentary life style, busy schedule of work, bad food habits and many hobbits related to life style gives arises to Arsha. The prime etiological factor is Mandagni is stated in Sushrut samhita. He provides four karma in the management of Arsha as Aushadhi chikitsa, Ksharkarma, Agnikarma and Shastra Karma. Among them Ksharkarma is most hidden method of practice. Modern medical science provides sclerotherapy, band ligation, IRC, DGHAL stapler etc. in the management of haemorrhoids. Present study is tried to highlight the ksharkarma method and also to compare with sclerotherapy particularly in haemorrhoids 1st and 2nd grade. 60 no patient are equally divided in two groups as group A and group B. A is treated with Apamarga Pratisarneeya Tikshana Kshara and B is treated with sclerotherapy Inj. Polidocanol. Average % Relief in Symptoms of Group A is 83.34% and in Symptoms of Group B is 71.07%. We can say that Ksharkarma is more effective management with less hospital stay, none of complication and economic also.

Key Wards: Arsha, Pratisarniya kshara, Haemorrhoids, Sclerotherapy.

1. INTRODUCTION:

In the present era of heavy workload, mental stress, lack of exercise and many more things related to life style. All these things hamper the digestive system of human body gives rise to many diseases which comes in a bunch of Anorectal diseases. Arsha is the one of the prime and commonest clinical condition which gives severe pain, troubles like enemy so why mentioned in Asthomahagada1 in classical text. Accordingly, mithya ahar vihar is one of the main etiological factors of Arsha, due to busy life style, heavy work load, less sleep, lack of exercise, and all the food habits of modern society. ARSHA becomes the very commonest clinical condition which gives maximum trouble to human being. The disease is characterized by formation of mansankur at gudpradesh, Raktastrava, daha and vedna during and after the defe...
they advised kshara treatment for Arsha. Ksharkarma is most hidden method of practice in the treatment of Arsha. Ksharkarma is very well illustrated in “ksharpak vidhi adhyay” in Sushrut samhita. Ksharkarma is said to be supreme modality among shashtra, anushashtra, yantra, upyantra and medicines. Kshara is caustic chemical, alkaline in nature obtained from the ashes of medicinal plants. It acts by Chedana, Bhedan, Lekhan karmas; as well its specialty is tridoshghnatwa and vishesh kriya awcharnat. Kshara can be administrated both internally as Paniya kshar and as well as externally local application as Pratisarniya kshar. In Present study out of 22 plants stated for kshara preparation Apamarga is selected for preparation of Teekshna kshara for local application in trial group and according to modern surgical practice for sclerotherapy Inj. Polidocanol 3% this drug is selected for control group. Patients are selected randomly from the OPD of Shalya tantra department properly taken their history, examinations, diagnosis, investigated and all findings were noted properly in given Performa. Clinical observations are recorded for the period of two month.

2. MATERIALS AND METHODES:

2.1. Aims and objective:

2.1.1. Aims:
To assess the comparative clinical study of pratisarniya apamarg teekshna kshar application and sclerotherapy in the management of haemorrhoids 1st and 2nd grade.

2.1.2 Objectives:
1. To assess the efficacy of pratisarniya apamarg teekshna kshar in the management of 1st and 2nd grade haemorrhoids. 2. To assess the efficacy of sclerotherapy, i.e. Inj. Polidocanol 3% given sub mucosal in 1st and 2nd grade haemorrhoids. 3. To compare the efficacy of ksharkarma with sclerotherapy in the management of 1st and 2nd grade haemorrhoids.

2.2 MATERIALS:
Sample source: The study included total 60 numbers of patients. Which were randomly selected from OPD of Shalya tantra department of Ayurveda College and Hospital, as per inclusive and exclusive criteria.

Drugs used: Group A: Apamarga teekshana Kshara Pratisaran. Group B: Inj. Polidocanol 3% diluted in equal amount of distilled water.

2.3 METHODOLOGY:

Study type: Simple randomized clinical trial.

Study Design: Randomly 60 patients were selected from OPD of Shalya tantra department, who were clinically diagnosed as per inclusive and exclusive criteria. They were divided in two groups.

Group A: 30 patients were treated by Apamarga teekshana Kshara Pratisaran. Which was prepared in Rasashashtra and Bhaiashajya-kalpana department of our Institute. Takra was used for dhavan after application of kshara.

Group B: 30 patients were treated by Inj. Polidocanol 3% diluted in equal amount of distilled water and given submucosally. Inj. Polidocanol 3% was made available from market.

Consent: A well informed written consent of all patients included in study was taken before starting treatment.

Duration: Two months.
Follow up: 0,1,2,3,8,15,30,45,60 Days.
Case data was collected accordingly.

2.4 Selection criteria:

2.4.1 Inclusive Criteria:
* Patients of age group 20-60 years of any gender.
* Patients who are diagnosed as Abhyantar Arsha 1st and 2nd grade Haemorrhoids.
* Patients who are ready to give written consent.

2.4.2 Exclusive Criteria:
* Patients with concurrent systemic disease like Diabetes mellitus;
* Hypertensions, Tuberculosis, HIV, HbsAg, CA-Rectum.
* Pregnancy
*Patients of Age group <20 and >60 years were excluded.

2.4.3 Investigations:
*Complete Blood Count
*Bleeding time and Clotting time
*HbsAg
*HIV
*Blood sugar- Random.

2.5 Procedure of application of Kshara & Sclerotherapy:
All procedure was carried out under local anesthesia. Employing xylocaine jelly in lithotomy position. Patient was kept 15 min. for rest. Well lubricated slit proctoscope Arshoyantra was then introduced in anal canal slowly and thorough inspection of anal canal done. Internal hemorrhoid protruding inside the proctoscope through slit was cleaned with gauze piece. Area other than desired pile mass is covered with cotton or gauze piece. Previously prepared drug Apanarga teekshna kshara applied with the help of Shalaka on entire haemorrhoidal cushion. To see the changes waits for 100 Matras (i.e. one and half minute) Then area was washed with Takra and the findings before and after application were seen and recorded. Same procedure was carried out in group B also and Inj, Polidocanol was given submucosally till appearance of straight sign. Anal packing was given. Slowly Arshoyantra was withdrawn. Patient was advised to take rest for some time.

2.6 Criteria for assessments:
Assessments were totally based on clinical observation and information given by the patients.

A) Pain:
Visual Analogue Scale (VAS)
The following scale (Table no 2) was used to help out assessing the severity of pain. Patients were asked to locate a finger at any of the numerical over the scale and the severity of pain was assessed according to that for which the numerical are labeled.
♦ Grade = 0 No pain 0 cm on scale
♦ Grade = 1 Mild pain; can be tolerated without medicine 1-3 cm on scale

B) Bleeding P/R
♦ Grade = 0 No Bleeding
♦ Grade = 1 Up to 10 drops during defecation
♦ Grade = 2 10 – 20 drops during defecation
♦ Grade = 3 More than 20 drops during defecation

C) Discharge:
♦ Grade = 0 No discharge
♦ Grade = 1 No requirement of pad
♦ Grade = 2 Change the pad 3 x 3 cm size ones a day
♦ Grade = 3 Change the pad 3 x 3 cm size more than 2 times a day.

D) Protrusion:
♦ Grade = 0 No protrusion
♦ Grade = 1 Projecting slightly in lumen of Anal canal during defecation
♦ Grade = 2 Protruded at anal verge and returns spontaneously after motion
♦ Grade = 3 Protruded and replace digitally

E) Itching:
♦ Grade = 0 No Itching
♦ Grade = 1 Negligible itching within 10 – 12hrs gap.
♦ Grade = 2 Occasional itching with 4 – 6hrs gap.
♦ Grade = 3 Frequent itching with 2 – 3hrs gap

F) Constipation:
♦ Grade = 0 No need of any medication
♦ Grade = 1 Need medication on – off
♦ Grade = 2 Need medication daily.

INTERNATIONAL JOURNAL OF RESEARCH IN AYURVEDA AND MEDICAL SCIENCES

Research Article (www.ijrams.com) ISSN: 2582-2748 Vol. 1; Issue 1 (Inaugural Issue) Sept 2018

2.7 Criteria for result assessment:

1. **Marked Improvement**- More than 75% relief in signs & symptoms.

2. **Moderate Improvement**- Above 50 but below 75% relief in sign & symptoms.

3. **Mild Improvement**- Relief in signs & symptoms between 25 to 50%.

4. **Poor Improvement**- Less than 25% relief in signs & symptoms.

Result:- Marked / Moderate / Mild / Poor Improvement

3. OBSERVATIONS AND RESULTS

3.1 Effect of therapy according to % Relief in Symptoms

Table no 3 Relieved score and % Relief in Symptoms of Group A. Table no 4 Relieved score and % Relief in Symptoms of Group B. **Average % Relief** in Symptoms of Group A is 83.34% (Table 3) and in Symptoms of Group B is 71.07% (Table 4).

3.2 Overall Effect of Therapy in Patients

Table no 5 showing the Effect of Therapy according % Relief in Patients. 25 of group A and 16 of Group B have shown Marked Improvement while 5 of Group A and 13 of Group B have shown Moderate Improvement and only 1 patient from Group B has shown Mild Improvement none of both group have shown Poor Improvement. **Group A has shown better effect than Group B to reduce Patient’s score.** Hence in overall effect of therapy *Apamarg Teekshna Kshar Pratisaran* application is more effective than Sclerotherapy in Abhyantar Arsha (Haemorrhoides 1st and IInd grade).

3.3 Statistical Analysis in between the Group A and Group B

3.3.1. Subjective Parameters (By Mann Whitney’s U Test)

Mann Whitney’s U Test in between the Group A and Group B (Table no 6). Both groups were compared and analyzed statistically by Mann-Whitney’s U test.

Null Hypothesis (H₀)

*Apamarg Teekshna Kshar Pratisaran* is not effective than Sclerotherapy to reduce symptoms in the management of *Abhyantar Arsha* (Haemorrhoides 1st and IInd grade).

**Alternative Hypothesis (H₁)**

*Apamarg Teekshna Kshar Pratisaran* is effective than Sclerotherapy to reduce symptoms in the management of *Abhyantar Arsha* (Haemorrhoides 1st and IInd grade).

In the case of symptoms Bleeding P/R, Protrusion and Constipation the test has shown highly significant difference between mean differences of Group A and Group B. **H₁ is accepted and H₀ is rejected here, because mean difference scores of Group A are more than that of Group B.** It is hence concluded that *Apamarg Teekshna Kshar Pratisaran* is more effective than Sclerotherapy to reduce Bleeding P/R, Protrusion and Constipation symptoms in *Abhyantar Arsha* (Haemorrhoides 1st and IInd grade). In the case of symptom Pain, Discharge and Itching the test has shown insignificant difference between mean differences of Group A and Group B. It is hence concluded that *Apamarg Teekshna Kshar Pratisaran* is not effective than Sclerotherapy to reduce Pain, Discharge and Itching symptoms in *Abhyantar Arsha* (Haemorrhoides 1st and IInd grade).

4. DISCUSSION

4.1. Mode of Action

4.1.1. *Apamarg Teekshna Kshar Pratisaran*

Probable mode of action in haemorrhoids after application can be explained on the basis of: 1. Initial arrest of bleeding owing to chemical aseptic thrombosis of haemorrhoidal plexus. It is due to coagulation of protein in Haemorrhoidal plexus. Disintegration of Haem and globin. 2. Further necrosis of tissue due to obliteration of Haemorrhoidal radical, and necrosed tissue sought out as blackish and brown discharge. Further fibrosis and scar formation occurs at the site. 3. Aseptic inflammatory response owing to *Apamarga teekshna kshar* as a result of cell wall damage with fibroblast proliferation leads to progressive fibrosis in the sub mucosal plane resulting to arrest the bleeding and fixation of haemorrhoidal mass to gut wall.

4.1.2. Sclerotherapy
Sclerotherapy in Haemorrhoids involves the injection of a sclerosing agent into the submucosal layer of the protruding hemorrhoidal node or in to the surrounding tissue of the arteries which supply it. It forms the aseptic thrombosis in hemorrhoidal cushion. The sclerosing agent provokes a discrete inflammatory reaction which results in a scarred structural change of submucosal connective tissue, which consequently achieves fixation of the haemorrhoid to the anorectal wall. In addition, the obliteration of the vascular bed in and near the hemorrhoidal node leads to shrinkage of the haemorrhoids. This results in rapid disappearance of symptoms after treatment.

5. CONCLUSION:

As we can say that from the prevalence rate that Haemorrhoids is very common in society and increasing problem in today’s era due to sedentary life style, improper food habits, irregular bowel habits and holding of natural urges for long time causes Agnimandya which is basic cause of Arsha. Disease occurs mainly in, middle age 30-50 age group. Ignorance, hesitation and shyness are factors which came across the treatment. Injection used for sclerotherapy has many side effects such as sensitivity, proctitis. While Apamarga Teekshna Kshara has no adverse effect like that if use properly by trained hands. Beside the effectiveness, Apamarga Teekshna Kshara, Pratisarniya Karma is also a very safe, easy procedure, less time consuming and no hospitalization required. Hence, we can say that Pratisarniya kshara is one among the most important preparation in Shalya Tantra. According to the preparation we can consider it to be caustic materials, obtained from the ashes after Distillation and are mostly alkaline in nature. The Kshara modality is the best one, taking into consideration its convenience, easy adoptability, cost-effectiveness and curative results.

6. REFERENCES:


Cite this article as:

Source of Support: Nil; Conflict of Interest: None detected.
7. TABLES

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Particulars</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Drug</td>
<td>Apamarg teeksha kshar</td>
<td>Inj. Inj. Polidocanol 3% diluted in equal distilled water.</td>
</tr>
<tr>
<td>2</td>
<td>Dose</td>
<td>2-3 gm. approx. on haemorrhoidal mass</td>
<td>2-3 ml solution / haemorrhoidal mass</td>
</tr>
<tr>
<td>3</td>
<td>Application method</td>
<td>Kshara is applied locally on mucosa of</td>
<td>Injecting sclerosent solution in haemorrhoidal mass</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Haemorrhoidal mass for 2 min.</td>
<td>submucosally.</td>
</tr>
</tbody>
</table>

Table No. 1: Method of Drug Administration

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Symptoms (Group B)</th>
<th>B.T.</th>
<th>A.T.</th>
<th>Relieved</th>
<th>% Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain</td>
<td>53</td>
<td>9</td>
<td>44</td>
<td>83.02</td>
</tr>
<tr>
<td>2</td>
<td>Bleeding P/R</td>
<td>68</td>
<td>20</td>
<td>48</td>
<td>70.59</td>
</tr>
<tr>
<td>3</td>
<td>Discharge</td>
<td>23</td>
<td>7</td>
<td>16</td>
<td>69.57</td>
</tr>
<tr>
<td>4</td>
<td>Protrusion</td>
<td>45</td>
<td>19</td>
<td>26</td>
<td>57.78</td>
</tr>
<tr>
<td>5</td>
<td>Itching</td>
<td>17</td>
<td>3</td>
<td>14</td>
<td>82.35</td>
</tr>
<tr>
<td>6</td>
<td>Constipation</td>
<td>38</td>
<td>14</td>
<td>24</td>
<td>63.16</td>
</tr>
<tr>
<td>7</td>
<td>Average Relief (B)</td>
<td></td>
<td></td>
<td></td>
<td>71.07%</td>
</tr>
</tbody>
</table>

Table No. 2: Visual Analog Scale

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Symptoms (Group B)</th>
<th>B.T.</th>
<th>A.T.</th>
<th>Relieved</th>
<th>% Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain</td>
<td>53</td>
<td>9</td>
<td>44</td>
<td>83.02</td>
</tr>
<tr>
<td>2</td>
<td>Bleeding P/R</td>
<td>68</td>
<td>20</td>
<td>48</td>
<td>70.59</td>
</tr>
<tr>
<td>3</td>
<td>Discharge</td>
<td>23</td>
<td>7</td>
<td>16</td>
<td>69.57</td>
</tr>
<tr>
<td>4</td>
<td>Protrusion</td>
<td>45</td>
<td>19</td>
<td>26</td>
<td>57.78</td>
</tr>
<tr>
<td>5</td>
<td>Itching</td>
<td>17</td>
<td>3</td>
<td>14</td>
<td>82.35</td>
</tr>
<tr>
<td>6</td>
<td>Constipation</td>
<td>38</td>
<td>14</td>
<td>24</td>
<td>63.16</td>
</tr>
<tr>
<td>7</td>
<td>Average Relief (B)</td>
<td></td>
<td></td>
<td></td>
<td>71.07%</td>
</tr>
</tbody>
</table>

Table No. 3: Relieved score and % Relief in Symptoms of Group A

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Symptoms (Group B)</th>
<th>B.T.</th>
<th>A.T.</th>
<th>Relieved</th>
<th>% Relief</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain</td>
<td>53</td>
<td>9</td>
<td>44</td>
<td>83.02</td>
</tr>
<tr>
<td>2</td>
<td>Bleeding P/R</td>
<td>68</td>
<td>20</td>
<td>48</td>
<td>70.59</td>
</tr>
<tr>
<td>3</td>
<td>Discharge</td>
<td>23</td>
<td>7</td>
<td>16</td>
<td>69.57</td>
</tr>
<tr>
<td>4</td>
<td>Protrusion</td>
<td>45</td>
<td>19</td>
<td>26</td>
<td>57.78</td>
</tr>
<tr>
<td>5</td>
<td>Itching</td>
<td>17</td>
<td>3</td>
<td>14</td>
<td>82.35</td>
</tr>
<tr>
<td>6</td>
<td>Constipation</td>
<td>38</td>
<td>14</td>
<td>24</td>
<td>63.16</td>
</tr>
<tr>
<td>7</td>
<td>Average Relief (B)</td>
<td></td>
<td></td>
<td></td>
<td>71.07%</td>
</tr>
</tbody>
</table>

Table No. 4: Relieved score and % Relief in Symptoms of Group B
Table No. 5: Effect of Therapy according % Relief in Patients

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Improvement Grade</th>
<th>Criteria</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Group A</td>
</tr>
<tr>
<td>1</td>
<td>Marked</td>
<td>&gt; 75%</td>
<td>25</td>
</tr>
<tr>
<td>2</td>
<td>Moderate</td>
<td>50% - 75%</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>Mild</td>
<td>25% - 50%</td>
<td>0</td>
</tr>
<tr>
<td>4</td>
<td>Poor</td>
<td>&lt; 25%</td>
<td>0</td>
</tr>
</tbody>
</table>

Table No. 6: Mann Whitney’s U Test in between the Group A and Group B

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Symptom</th>
<th>U</th>
<th>P</th>
<th>Significance</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain</td>
<td>366</td>
<td>0.209</td>
<td>Not Significant</td>
<td>A = B</td>
</tr>
<tr>
<td>2</td>
<td>Bleeding P/R</td>
<td>264</td>
<td>0.0051</td>
<td>Significant</td>
<td>A &gt; B</td>
</tr>
<tr>
<td>3</td>
<td>Discharge</td>
<td>413</td>
<td>0.583</td>
<td>Not Significant</td>
<td>A = B</td>
</tr>
<tr>
<td>4</td>
<td>Protrusion</td>
<td>302</td>
<td>0.026</td>
<td>Significant</td>
<td>A &gt; B</td>
</tr>
<tr>
<td>5</td>
<td>Itching</td>
<td>405</td>
<td>0.502</td>
<td>Not Significant</td>
<td>A = B</td>
</tr>
<tr>
<td>6</td>
<td>Constipation</td>
<td>308.5</td>
<td>0.032</td>
<td>Significant</td>
<td>A &gt; B</td>
</tr>
</tbody>
</table>

(“=” means statistically equal & not exact equal)