A COMPERATIVE CLINICAL STUDY OF PRATIKSHARANIYA KSHAR IN MANAGEMENT OF ARSHA

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ABSTRACT

The present thesis work entitled “A comperative clinical study of pratiksharaniya kshar in management of arsha” comprises with conceptual Study, clinical Study, discussion, summary and conclusion. This study is conducted with aim and objective i.e. ‘To evaluate the clinical efficacy of local application of apamarg kshar in the management of Arsha.’ The kshar application is described in sushruta samhita in chikitsa sthan. It is indicated for the treatment of Arsha as local application. Hence it selected for the present study to access the effectiveness in management of 2nd degree Arhsa. In compresion of kshr sclerosing therappy has been taken. Injection sclerotherapy (IS) is a time-honored method and is widely practiced in the UK and other parts of the world to treat first and second degree haemorrhoids by creating this fibrous reaction. The use of IS started over a century ago and throughout its development different sclerosants have been used. Kshar work as on piles tisssue like a sclerosing agent. After application of kshr the tissue will become hard and tough so that it work on piles. In compresion of kshr we taken sclerosing agent polidocanal for this study. The advantage of this formulation is that the method of preparation is very simple and it can be used easily by the patient at his own convenience.

KEYWORDS: Apamarg kshar, arsha.

INTRODUCTION

The period of Sushruta was certainly Golden era in the field of Ayurvedic surgery. A bird view of the Ayurvedic Medical History in general and surgical History in particular reveals that various surgical procedures were performed in those days appears as miracles today. As the time progressed there was gradual decline in the surgical practice due to various
prevailing factors. To bring back the past glory of Ayurvedic surgery one has to concentrate on those area which poses challenges even to the Modern surgery. The field of proctology is one such area which still has lot of scope for research through Ayurvedic approach. Ayurveda certainly have immense potential to overcome the challenging unsolved problems of various Anorectal disorders.

Arshas are considered as one among the 8 Mahagadha’s by Acharya Sushrutha. It is considered so because of its position. Hence this condition has been attracting attention of surgeons for an ideal and suitable curative procedure. No single therapy is said to be self sufficient in the management of all types of Arsha, because each procedure has its own limitations. Probably, for this reason only Sushruta has mentioned fourfold therapeutic procedure in the management of Arsha, namely Bhashajakarma, Ksharakarma, Agnikarma and Sasthakarma. He has mentioned Bhashaja in special type of Arsha which is newly occurred, less symptoms and less complication.Although different kshara are being used successfully in the management of Abhyantara Arsha.

The word Arsha is generally translated as haemorrhoids, which is varicosity of Hemorrhoid vessels. It is a disease of adulthood, the frequency increase with advancing age. John Golighar (1975) estimates 45% of the people over the age of 50 years upon careful examination may be found to have haemorrhoids. The disease Arsha do not have any exception in regards to the race or sex.

In modern system injection therapy is very commonly use for hemorrhoid, it also named as sclerotherapy. In sclerosing therapy many sclerosing agent like carbolic acid, almond oil, Polidocanol, sodium tetradecey, ethanolamine oleate are used. In this study we will take ethanolamine oleate. This research work is in continuation of such efforts to find out solution on Arsha; the existing burning problem. The patients suffering from 2nd degree piles were selected for the present study. The patients were subjected for detail clinical examination and investigations as per the specially designed proforma. The present clinical study comprises of 30 patients. They were divided into two groups as Group-A and Group-B. The group-A patients were subjected to injection therapy and Group-B patients were treated by local kshar application at pile mass.

The present study includes Literary Review, Materials and Methods, Observations, Results, Discussion, Conclusion and Summary.
MATERIAL AND METHOD

PLAN OF STUDY

a) Conceptual study

The details of literature of Arsha, Apamarg kshar, was incorporated in great detail from samhitas and other Ayurvedic books. Detail of Haemorrhid and sclerosing therapy will incorporated from modern literature and by surfing the internet.

b) Clinical study

1. For clinical study patients attending the O.P.D. and I.P.D. of the Department of Shalaya Tantra samc & Hospital, Aligarh was selected by simple random sampling method.
2. The patient’s referred from other practitioners, hospitals, institutions was also consider for the present study.

Selection Criteria

Inclusion criteria
- The Abyantara Arshas of 2nd degree, which are soft, broad, deeply spread & bulged surface.
- Age between 20 to 60 years.
- Patients of either sex taken.

Exclusion criteria
- External Haemorrhoids.
- Thrombosed Haemorrhoids.
- Pregnancy.
- Patients suffering from systemic diseases like Diabetes mellitus.
- Hepatitis, Tuberculosis, HIV infections, Chron’s disease carcinoma, radiation Actinomycosis and Chlamydia.

c) DRUG SOURCE

Apamarga Kshara was be prepared as per the guidelines given in Ayurvedic literatures. Sclerosent agent will purchased from market.

METHOD

The screened patients of haemorrhoids was be randomly selected and classified into two groups. Group A and Group B.
Group A

Pre. op.
Injection tt.5 ml.
Part preparation
Soap water enema before procedure.

Operative- Injection of sclerosing agent in internal haemorrhoids will be done under strict aseptic precautions and under suitable Anaesthesia.

Group B

Pre op.- same as group A

Operative
The Apamarga Pratisaraneeya Teekshna Kshara is applied with the help of rod & opening of the instrument is closed with hand & wait for 100 matra kala under strict aseptic precautions and under suitable Anaesthesia. Then it is cleaned with amla rasa & sterile water wash is given.

Paschat karma
Triphal Churna as laxative in both groups, jatayadi taila matra basti in group B.

Drug and doses
In Group A sclerosing agent 3-5ml injected in a one pedicle then after seven day in next pile mass injection therapy should give.

In Group B Apamarg Kshar will used as per requirement. In one time at one pile mass kshar application will do.

Observation period
- Daily follow up for 1 week for the every next day of procedure. Afterwards weekly interval till 4th week.
- All the patients are advised to not take spicy, oily substance food & laxatives are advised to relieve the constipation or easy defecation.
MATERIALS AND METHODS

Selection of Patients
The patient fulfilling the clinical criterias for diagnosis of haemorrhoids were randomly selected irrespective of their age, sex, religion, occupation etc. from OPD and IPD section of Department of Shalya tantra, SAMC & Hospital, Aligarh would be selected by simple random sampling method.

The patient’s referred from other practitioners, hospitals, institutions will also consider for the present study.

Inclusion Criteria
- The Abyantara Arshas of 2st degree, which are soft, broad, deeply spread & bulged surface.
- Age between 20 to 60 years.
- Patients of either sex taken.

Exclusion Criteria-The following patients were excluded from study
- Pregnancy
- External Haemorrhoids.
- Ca. Rectum
- Hepatitis
- 1st, 3rd and 4th degree piles
- Tuberculosis
- Leprosy
- Inflammed Piles
- Rectal prolapse
- Portal hypertension
- Haemorrhoids associated with fistula in ano.
- Thrombosed piles
- Piles with Fistula in ano
- Piles with Ulcerative Colitis
Diagnostic Criteria
a. All the patients were diagnosed & assessed on the basis of following Ayurvedic & modern Classical signs & symptoms of Arsha – Raktasrava (bleeding per rectum), Vedana (pain in ano), Bibandha (constipation), srava (discharge).
b. A special proforma was designed to record all details of the patients.
c. The routine Haematological, Urine, Stool, Biochemical & Radiological investigations were also carried out to exclude any other pathology.

PLAN OF WORK
The following plans were followed:
1. The patients were first registered in Ano-Rectal Clinic.
2. A complete history of the disease along with the presenting complaints was noted.
3. The patients had been examined for systemic and general examination.
4. Pathological evaluation of each patient was conducted.
5. Diagnosis was made on Ayurvedic as well as Modern view.
6. Treatment was given as per groups.
7. Result assessment was done as per criteria.
8. Statistical data presentation was recorded.

PROCESS OF DIAGNOSIS
Inspection
Following points were noted.
The condition of peri anal skin.
Anal verge - Fissure/ Sentinel tag.

Palpation: (Digital examination)
The digital examination includes tenderness, swelling, indurations, tone of sphincter i.e. normal, spasmodic or relaxed etc.

Proctoscopic Examination
Following findings of pile mass are to be noted:
1. Site – Internal/ External/ Interno external
2. Size -- < ½” / ½” / ½ “– 1” / 1” – 1½
3. Surface – Uneven / Tortuous / Smooth
4. Position – Primary– 3’o / 7’o / 11’o clock or Secondary.
After taking the complete history and local examination, the patient were clinically classified according to Doshik involvement e.g. Vataja Arsha, Pittaja Arsha etc. as well as degree and position of piles had been noted.

**Grouping**

A total number of 30 patients of Arsha were registered for the present study. They were randomly divided into two groups.

**Group-(A) Sclerosing Therapy**

The patients selected in this group were subjected to sclerosing therapy procedure.

**Group-(B) Kshar Application Therapy**

The patients selected in this group were subjected to kshar application procedure.

**PROCEDURE OF SCLEROSING THERAPY**

**Purvakarma**

It includes preparation in relation to the patient and the procedure-

- Written consent
- Inj. T.T (0.5ml) IM
- Part preparation.
- First the required instruments like slit Proctoscopes, Pile holding forceps, gabrel’s syringe, are kept ready with proper sterilization.
- The night prior to procedure, the patient is usually given light diet, afterwards nil orally.
- Soap water enema given at prior night and also 4 hours prior to procedure.
- N.B.M 6hr.

**Pradhah Karma**

**PROCEDURE OF SCLEROSING THERAPY**

**Materials**

Gabriel’s syringe bevel of needle, slit proctoscope, sclerosing agent ethylamine oleate.

**Method**

Patient was kept in lithotomy position on operation table. The part was cleaned with aseptic solutions and draping was done. Later on the positions of various pile masses were assessed by slit proctoscope.
The ethylamine oleate is injected into each pile pedicle in the sub mucosal space by Gabriel’s syringe at the level of the Ano-rectal ring, for large haemorrhoids 10ml may be injected in one sitting.

**KSHAR APPLICATION THERAPY**

**PRE OPERATIVE**- Same as in sclerosing therapy.

**PROCEDURE**
Patient was kept in lithotomy position on operation table. The part was cleaned with aseptic solutions and draping was done. Later on the positions of various pile masses were assessed by Arsho-yantra.

**Application of kshar**
The Arsha should be observed through it and pressed with rod and cleaned with cotton swab and then Kshara should applied. After applying the Kshara the opening of instrument should be closed with hand and wait for 100 matra. Then after cleaning, consideration for the reaplication, if necessary depending upon the strength of Kshara and the degree of cauterization (degree of burn by Kshara). When the haemorrhoidal mass attains the colour similar to ripe Jambu fruit (Syzygium cumini) and if it is shrunken and slightly bent, the reaplication should not be thought of.

**PASHCHAT KARMA:** After the completion of application of Kshara, sour fruit juice is used for neutralizing the cauterized site. The Ghrita mixed with Madhuka should be applied post operatively. The patient is advised for hot water sitz bath and sprinkled with cold water on face. In this way each haemorrhoid should be treated after one by one at a week interval. If there are multiple piles, at first right one should be tackled and then left one, then the posterior one and anterior one in last.

After that daily twice 10 ml of Jatayaditaila as matra basti given. This procedure was continued up to 7 days.

**Common Treatment (In Both Groups):** Triphal Churna 5gm. with warm water, one dose daily -at bed time.

**Follow Up Study**-4 Weeks.
CRITERIA FOR ASSESSMENT
The improvement provided by the therapy was assessed on the basis of classical signs & symptoms of Arsha. All the signs & symptoms were assigned score depending upon their severity, to assess the effect of the procedure objectively. The following pattern was adopted for the scoring:

Rakta Srava (Bleeding Per Rectum)
1. No Bleeding
2. Dropping
3. Syringing
4. Streaming

Vedana (Pain In Ano)
1. Pain less condition.
2. Dull pain, no requirement of medicine.
3. Pain, requires oral medication.
4. Unbearable pain requires, parenteral drug.

Kandu (Itching)
No kandu (itching)
Once or twice in a day
Often in a day and discomfort
Severe and constant itching whole day

Size of Pile Mass
1. Absent of pile mass
2. < 1/2”(less than half inch)
3. 1” (one inch)
4. > 1”(less than one inch)

Regestration data
1. Status of the patients.

<table>
<thead>
<tr>
<th>Groups</th>
<th>ST</th>
<th>KA</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total registered</td>
<td>15</td>
<td>15</td>
<td>30</td>
<td>100%</td>
</tr>
<tr>
<td>Discontinue</td>
<td>00</td>
<td>00</td>
<td>00</td>
<td>0</td>
</tr>
<tr>
<td>Completed</td>
<td>15</td>
<td>15</td>
<td>30</td>
<td>100%</td>
</tr>
</tbody>
</table>
ST= sclerosing therapy KA=kshar aplication
Total 30 patients were registered in present study. Equal i.e. 15 patients were completed the treatment course in both groups.

Statitical analysis
Effect of therapy
Effect of sclerosing therapy

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>N</th>
<th>B.T. Mean score</th>
<th>A.T. Mean score</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>‘t’</th>
<th>‘p’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raktasrava</td>
<td>13</td>
<td>1.62</td>
<td>1.38</td>
<td>85.71</td>
<td>0.65</td>
<td>0.18</td>
<td>7.68</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Size of pile mass</td>
<td>15</td>
<td>1.53</td>
<td>0.27</td>
<td>17.39</td>
<td>0.46</td>
<td>0.12</td>
<td>2.26</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Vedana</td>
<td>12</td>
<td>1.25</td>
<td>1.16</td>
<td>93.33</td>
<td>0.39</td>
<td>0.11</td>
<td>10.38</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gud kandu</td>
<td>6</td>
<td>0.60</td>
<td>0.60</td>
<td>100</td>
<td>0.82</td>
<td>0.26</td>
<td>2.29</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Above table shows that, patients got highly significant relief in raktasrava (85.71%), vedana (93.33%) and malabaddhata (100%), followed by significant results were obtained in size of pile mass (13.04%) after completion of 4th week.

2. Effect of kshar application

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>N</th>
<th>B.T. Mean score</th>
<th>A.T. Mean score</th>
<th>%</th>
<th>SD</th>
<th>SE</th>
<th>‘t’</th>
<th>‘p’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raktasrava</td>
<td>14</td>
<td>1.64</td>
<td>1.64</td>
<td>100</td>
<td>0.84</td>
<td>0.22</td>
<td>7.30</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Size of pile mass</td>
<td>15</td>
<td>1.6</td>
<td>0.67</td>
<td>41.67</td>
<td>0.48</td>
<td>0.12</td>
<td>5.29</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vedana</td>
<td>7</td>
<td>1</td>
<td>1</td>
<td>100</td>
<td>1.13</td>
<td>0.29</td>
<td>3.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gud kandu</td>
<td>11</td>
<td>.93</td>
<td>.93</td>
<td>100</td>
<td>0.96</td>
<td>0.28</td>
<td>3.22</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Above table shows that, patients got statistically highly significant relief in raktasrava (100%) and size of pile mass (41.67%) after completion of 4th week.

3. Overall percentile effect of therapy in both groups.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Overall Effect of therapy</th>
<th>Group- A</th>
<th>Group- B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of patients</td>
<td>%</td>
<td>No. of patients</td>
</tr>
<tr>
<td>Cured</td>
<td>9</td>
<td>60</td>
<td>13</td>
</tr>
<tr>
<td>Marked improvement</td>
<td>5</td>
<td>33.33</td>
<td>2</td>
</tr>
<tr>
<td>Moderate improvement</td>
<td>1</td>
<td>6.67</td>
<td>0</td>
</tr>
<tr>
<td>No change</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

In above table the percentage wise relief in both groups shows that in group- A, 60% patients were cured which were lower than group B (86.67%).
In Group- B marked improvement was seen in 13.33% of patients while in group A 33.33% of patients. In group- A 6.67% of patient got moderate improvement.

RESULT
In sclerosing therapy Group-A On completion of treatment, patients were got relief in raktasrava by 85.71%, in vedana 93.33% and 100% in gudkandu, followed by reduction in size of pile masses by 17.39%. No recurrence and side effects were observed on completion of follow up. So, the overall result was significant on completion of treatment.

In kshar application Group-B, On completion of treatment, patients were got relief in raktasrava by 100%, in vedana 100% and 100% in gudkandu, followed by reduction in size of pile masses by 41.67%. No recurrence and side effects were observed on completion of follow up.

CONCLUSION
after completion of studdy both group show good result, on the basis of objective parametre kshr group show 100% result but on objective parameter that is size of mass, which show 41.67% result. Over all statically both group show good result.

REFERENCE
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2. Goligher j, duthie h, nixon h. (eds) surgery of the anus, rectum and colon, 5th edn.