A CLINICAL STUDY ON THE MANAGEMENT OF ARSHAS WITH NISHADI LEPA

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Abstract:
Arsha is as old as mankind being an abnormal to routine life. Arsha does not cause any threat to life but troubles a lot, so it is included in one of the Astha Maharogas by Sushruta. This disease is largely confined to the Guda but also in Nasa, Netra, Karna, Twacha, etc., regions. Etiological factors are vitiation of doshas in Guda valis, injury due to thorn, stone, nail, riding on horse, vehicles, sitting on irregular surfaces, regular contact of cold water etc.

Haemorrhoids are the varicosity of hemorrhoidal veins. Depending on the site these are 3 types viz, Internal, External & Intero-external Haemorrhoids. Depending upon bleeding these is of 2 types which are, bleeding & non-bleeding piles. The presently available treatment measures are oushadha, shastra, kshara & agni karmas. Local external application is described by Sushruta. Hence a controlled clinical study is planned to evaluate the efficacy of “Nishadi lepa” in the management of arshas. In this study sample size of 30 patients were selected by simple random sampling, 15 in trial and 15 in control groups. In trial group “Nishadi lepa” was used where as in the control group sclerotherapy was carried out. The therapeutic effects are analyzed by using the subjective parameters viz. Pain and discomfort during sitting and objective parameters viz. Size, healing index. The duration of treatment was 10 days and clinical assessments were done in 5 days interval.

Keywords: Ayurveda; Arshas; Haemorrhoids; Nishadi lepa; Sclerotherapy

INTRODUCTION:
Susruta is an ancient surgeon and he is known as “father of surgery”. His treatise sushruta samhita is complete and comprehensive is regarding the Indian surgery. Ayurvedic texts described
with various types of medical and surgical ailments including Arshas and their management.

Arshas described in Ayurveda as one of the mahagada. The ancient regarded this disease as a surgical domain since final resort of the treatment is surgery. In Vedas the Arshas was referred as durnam. The disease which tortures the person like an enemy is called as Arshas.

The Arshas in modern concept can be compared with piles or hemorrhoids. Hemorrhoids is a Greek word derived from two words ““Haem” = Blood, “Rhoos” = flow, means that blood flows and another name is Pile. “Pile” is a Latin word derived from “Pila” denotes the ‘ball’. So it seems to be ‘ball like structure’.

Piles clinical entity it occupies an important place in the ano-rectal region. Anatomically, physiologically & pathologically Ano-rectal region is an important junction area, which offers many challenges to the physician & surgeon also.

As per sushruta, the doshas due to their aggravating causes, dislodges from their normal seat (alone or combined with other including the rakta) and reaches the mala dwara in pradhana dhamani and causes the vitiation of guda valis resulting in the production of mamsankura especially in mandagni persons. Irritation to guda by koshta, upala loshta, vastra, and sheetodaka sparsha leads to further aggravation of dosha.1

Ayurveda propounded a comprehensive chikitsa for Arshas which includes medicinal, surgical as well as para-surgical treatments as prevailing today. Susruta advocates the management of Arshas under four headings. As follows:

1) Oushadha karma
2) Shastra karma
3) Kshara karma
4) Agni karma

Inclusion of number of techniques shows the lack of universal acceptance of particular treatment to avoid surgical complication and achieve good results.

So some of the local and external applications have brought out as simple, effective, economical and in the eyes of patients they have the great psychological disadvantage of being applied directly to the site of origin of their symptoms.

In this present era, more number of patients are interested to avoid the surgical procedures due to complications.

As mentioned earlier that the ancient acharyas i.e. sushruta, charaka, chakradutta, vangasena were explained curative measures for management of Arshas. Among them one local application is undertaken for the present study, known as “Nishadi Lepam” which is mentioned in the Arshodhikar chapter of Vangasena samhita.

The local application was applied to relieve the inflammation and indurations of the pile
masses. The ingredients of this preparation acts directly on the arshas. Apart from this, it also relieves pain, reduction of pile masses, arresting of local bleeding and relief from other symptoms.

Objective:
1. evaluate the efficacy of Nishadi Lepam in the management of Arshas

METHODOLOGY:
1. Selection of cases:
   All the cases come with complaint of pain and discomfort treated as outpatient. The persons suffering from the systemic diseases were rejected.

2. Materials and Methods:
   Source of Data: The present clinical study was carried out on both male and female patients, attending at out-patient department of Shalya Tantra with complaints of pain & bleeding during and after defecation and inflammation, mucous discharge, discomfort etc.

   Methods of collection of data:
   All the patients were selected by simple randomized sampling procedure.

   Sample size 15 in each group

   Grouping:
   All the 30 selected patients were grouped into two categories of equal size i.e., 15 Patients each on the basis of treatment module advocated.

   Group I was the trial group where the drug combination (i.e., Nisha + Koshataki + Saindhava Lavana + Gomutra) was used as a local application (Lepa) The Nishadi lepa was prepared as per the description available in Sharangadhara samhita. This was applied externally on the Arsha ankura. Being an external application, the quantity of the drug depends upon the size of Arsha ankura.

   Group II was the control group, where the Injection therapy i.e., Sclerosing agent was injected into the sub mucosa of the pile mass.

   Thorough history of every patient was taken regarding the complaints, duration, personal habits etc.

   After interrogation, local and general examination was carried out. Local examination has given utmost importance and recorded on a special case sheet

   Inclusive Criteria:
   1) Patients of all age groups, irrespective of sex.
   2) Patients unwilling for surgery.
   3) Patients with 1st and 2nd degree pile mass.

   Exclusive Criteria:
   1) Patients having IDDM/ NIDDM
   2) Patients with other co-morbid condition, other systemic pathology and other local lesion.
   3) 3rd degree piles and Procedentia.
TREATMENT MODULE:- GROUP-I
NISHADI LEPA APPLICATION

GROUP-II

SCLEROSANT INJECTION THERAPY:
Duration of Treatment:
The duration of treatment for both the group was 10 days in.

Progress:
Progress report was made on every 5th day up to 10 days and was noted in the progress chart.

Instructions:
The patients were advised to maintain the hygiene, nidana parivarjan like riding, sitting on hard surface for long time, excessive coitus, food which leads to constipation, and contact of cold water at anal region were to be avoided.

Pathyapathya:
Deepana, Pachana, Shakas, Yava, Yusha, Mamsa rasã, khada, ksheera, takra & vatanulomana, agni bala vruddhikara ahara oushadhas were advised to all the patients. Regarding diet the fish, meat, spicy foods etc., were restricted. Green leafy vegetables, fruits and butter milk were particularly advised in association with regular and timely intake good sleep, avoiding overstrains etc.

PARAMETERS FOR ASSESSMENT:

Pain: - was assessed by Visual analog scale G0 – Absence of pain/no pain. (0 on scale)
G1 – Mild – Pain that can easily be ignored. (1 to 3 on scale)
G2 – Moderate – pain that cannot be ignored, interferes with function, and needs treatment from time to time. (4 to 6 on scale)
G3 – Severe – That is present most of the time demanding constant attention.(7 to 10 on scale)

Discomfort during defecation: - was assessed by history of discomfort during defecation
G0 - No discomfort G1 - Mild discomfort
G2 - discomfort but tolerable G3 - Too discomfort to defecate

Discomfort during Sitting G0 - No discomfort G1 - Mild discomfort
G2 - discomfort but it is tolerable and it is possible to work G3 - Too discomfort to sit

Size of Arshankura (Haemorrhoid) G0 - Almost none
G1 - Size of the tip of little finger (approx. 2 cm3) G2 - Size of the tip of index finger (approx. 3 cm3) G3 - ≥Size of the tip of thumb (approx. 4 cm3)

Bleeding per rectum (nature, character & amount) G0 - No bleeding
G1 - Found on toilet paper G2 - Dripping
G3 - Sluice
Clinical assessment of result: - Will be as per the following criteria.

Cure – 100% free from cardinal sign and symptom, these are pain, discomfort during defecation, sitting, size of hemorrhoid and bleeding per rectum.

Max. Improvement – 75% to 99% improvement of the above mentioned cardinal sign and symptom.

Moderate Improvement – 50% to 74% improvement of the above mentioned cardinal sign and symptom.

Mild Improvement – 25% to 49% improvement of the above mentioned cardinal sign and symptom.

No. Improvement – Less than 25% improvement of the above mentioned cardinal sign and symptom.

Study design: According to the procedure stated above thirty patients of 1st & 2nd degree hemorrhoid without any chronic systemic pathology were selected for the study. Out of 30 patients, 15 patients were in the trial group, rest 15 patients were in the control group.


Group – II – 15 – control.

Result and discussion:

The aim of the present clinical study was to assess the effect of Nishadi lepa in piles. The assessments of the results were based mainly on the improvement of the said different parameters.

The clinical analysis shows that the cases with short duration of haemorrhoids were improved in 3 to 4 sittings. The patients with less duration of the illness showed quicker response than the chronic.

Sedentary habit, non-vegetarian diet played an important role in the treatment of haemorrhoids.

The statistical analysis shows that in case of pain the mean ± S.E. before treatment was 1.93 ± 0.18 and was reduced to 1.33 ± 0.15 after 5 days, 0.6 ± 0.13 after 10 days. The test of significance shows that Nishadi lepa is Significant to reduce pain with the P-value 0.002 in AT1, & in AT2 P-value 1.87E-05 which shows highly significant.

In case of Discomfort during Defecation the mean ± S.E. before treatment was 2.13 ± 0.13 and was reduced to 1.4 ± 0.13 after 5 days, 0.53 ± 0.13 after 10 days. The test of significance shows that Nishadi lepa is highly Significant to reduce Discomfort during Defecation with the P-value <0.01 in AT1 & AT2 respectively.

In case of Discomfort during sitting the mean ± S.E. before treatment was 2.06 ± 0.18 and was reduced to 1.46 ± 0.16 after 5 days & 0.53 ± 0.16 after 10 days. The test of significance shows that Nishadi lepa is highly Significant to reduce Discomfort during sitting with the P-value <0.01 in AT1 & AT2 respectively.

In case of Size of Arshankura the mean ± S.E. before treatment was 2.06 ± 0.06 and was
The test of significance shows that Nishadi lepa is highly significant to reduce Size of Arshankura with the P-value <0.01 in AT1 & AT2 respectively. In case of Bleeding per Rectum, the mean ± S.E. before treatment was 2.06 ± 0.15 and was reduced to 1.2 ± 0.10 after 5 days, 0.4 ± 0.13 after 10 days. The test of significance shows that Nishadi lepa is highly significant to reduce Bleeding per Rectum with the P-value <0.001 in AT1 & AT2 respectively.

**Bleeding per rectum (BPR).**

Mild BPR was relieved within 5 days and in severe cases BPR relieved by the end of 10 days. Due to madhura guna and sheeta veerya of the drugs present in “Nishadi lepam.”

**Pain:**

Mild pain was relieved within 5 days and in severe cases pain relieved by the end of 10 days. Because of ushna veerya, teekshna guna, and shoola prashamana of the drugs might be the cause to reduce the pain. “Nishadi lepam” is important to reduce the pain since it has an analgesic effect.

**Size:**

Mild arshankura was reduced by the end of 5 days, where as moderate size was reduced by the end of 10 days due to the lekhana karma of “Nishadi lepam”.

The cases suffering with piles associated with symptoms of constipation were found in maximum number of patients. The selected drug also have got properties of deepana, pachana as well as laxative effect to improve appetite to relieve constipation. The constipation factor during defecation due to more strain at the anal canal and rectum which creates pressure over then hemorrhoidal veins, this causes dilation of rectal veins which causes piles.

The above mentioned drugs shown the efficacy in shedding off pile masses as well as shrinkage of prolapsed pile masses and arrest of mucous discharge along with reduction of pain was observed.

In case of 3rd degree piles there is no reduction of masses, instead to some extent the pain was reduced.

Hence it can be concluded that the administration of the “Nishadi lepam” as external application was most effective to relieve the symptoms, without any complications. The recurrences of protruding masses were not seen during follow up.

It shows this medicine is not for complete eradication of the disease. It is only a partial treatment, which help the patient to get relief from symptoms and more over the present study helps to avoid the surgical intervention and its complications and helps to those patients who were unwilling for surgery. In this way the present study shows significant effects in relieving symptoms and brings the patients to the stage of palliative treatment to avoid the surgery.
Conclusion:

The review of literature and clinical study provides certain useful conclusions as follows.

1) Sushruta considered the disease piles as one of the maharogas being it difficult to treat.

2) Management of haemorrhoids has become a problem to all the surgeons and proctologists even today due to many unavoidable drawbacks and complications such as incontinence and recurrence, etc.,

3) Males are more prone than females.

4) Patients of 31-40 yrs of age group may more prone than other age groups.

5) Sedentary and moderate working habits may result in occurrence of Arshas.

6) “Nishadi Lepam” shown complete regression of 1st degree piles. However majority of cases shows partial regression of pile masses and total disappearance of signs & symptoms.

7) All most all age groups were responded to “Nishadi Lepam”. In majority of cases, symptoms are relieved in span of 10 days.

8) “Nishadi Lepam” is curative, safe and effective in relieving symptoms in early stage of disease and also useful in patients who are unwilling for surgery.

9) “Nishadi Lepam” helps in relieving agony and discomfort to the patients without hospitalization. Hence it may be a poor man’s choice as it is easily available, more economical and effective.

10) So the use of “Nishadi Lepam” is an ambulatory type of treatment which gives quick action and also can be used as a better alternative to surgery.

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