

TO EVALUATE EFFICACY OF 'ARSHOHAR MALHAR' (LOCALLY) IN THE MANAGEMENT OF 'ABHYANTAR GUDARSH' W.S.R. TO GRADE 1 & GRADE 2 INTERNAL HAEMORRHOIDS

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ABSTRACT

Gudarsha has been known to mankind for a longer time and one of the commonest diseases to affect human being. Indulging in unsalutary lifestyle and food habits leads to indigestion, disturbed bowel habits and constipation due to *Agnimandya*. One prime condition arising from all these is *Gudarsha*. It is mentioned in '*Ashtamahagada*' category (group of diseases which are difficult to treat) by Sushruta and four fold treatment is advocated for *Arsha* viz. *Bheshaj* (Medicinal treatment), *Kshar karma* (Herbal caustic paste locally), *Agnikarma* (thermal heat burn) and *Shastra karma* (Surgery).

Further, local treatment i.e. *Ksharkarma* is more effective in *Dhatuvaigunya* (organic pathology due to local deformity) of anal structures. But for *Pratisaran* (local application) of *Kshar*, intervention of doctor is necessary and compulsory. Hence, concept of application of *Apamarg Kshar* by patient was presumed and for this purpose, *Apamarg Kshar Malhar* was prepared and named as *Arshohar Malhar*.

The present study was carried out to prove the therapeutic effect of application of *Apamarg Kshar* in *Malhar* (ointment) form in early internal haemorrhoids. The study revealed that *Arshohar malhar* is effective in reducing symptoms such as per rectal bleeding, discharge and colour of pile pedicle.

Key words: *Sushrut Samhita. Arsha. Ksharkarma. Apamarg Kshar. Haemorrhoids*

INTRODUCTION

In today's modernized world, shift duties, stressful life, eating of unhealthy foods makes people more prone to the disease like haemorrhoids. Dilation of the veins of the internal rectal plexis constitutes the condition of the internal haemorrhoids which are covered by the mucous membrane.^[1] Due to site of disease many of

the patients hesitate to go to doctor and they delay the examination and treatment which ultimately leads to worsen condition of the disease causing bleeding during defaecation and prolapse of piles.^[2,3]

According to Ayurvedic and Modern text, various modes of treatment are available for *Abhyantar Gudarsha* (internal piles). The treatment can be classified into surgical,

para-surgical and medicinal management. But somehow all are associated with disadvantages. Sushruta, the father of surgery has given the basic principles of treatment of *Arsha* as per *Avastha* i.e. stages.^[4,5,6]

The four fold treatment includes *Bheshaja*, *Kshar karma*, *Agnikarma* and *Shashtra karma*. *Arsha* in early stage with less signs and symptoms can be treated with medicinal treatment (*Bheshaja*) and which cannot be treated with medicines should be treated with *Ksharkarma* and *Agnikarma* and which are not cured with all above treatment should be treated with *Shastrakarma*. The management of *Abhyantar Gudarsha* (internal piles) is mentioned in all Ayurvedic classical texts but in Sushrut Samhita, Acharya Sushrut has described *Arsha* in detail.^[7,8] The *Dhatuvaigunya* (organic pathology due to local deformity) of anal structures requires local treatment. *Ksharkarma* is the treatment of choice and is more effective locally in early stage of disease.^[9,10]

However, for *pratisaran* (local application) of *Kshar*, intervention of doctor is necessary and compulsory. Hence, it was decided to make the process convenient for patient to apply the *Kshar* in internal haemorrhoids without doctors' intervention for application. Concept of application of *Kshar* by patient himself was presumed and for these purpose ointment of *Apamarg Kshar* has been preferred for this study. The product was named as '*Arshohar Malhar*'. Further, the study was carried out to prove the therapeutic effect of local application of *Arshohar Malhar (Apamarg Kshar Malhar)* in 1st and 2nd degree internal haemorrhoids.

AIM AND OBJECTIVES

1. To evaluate the therapeutic efficacy of *Arshohar Malhar* in *Abhyantar Gudarsh* w.s.r. to 1st and 2nd degree internal haemorrhoids.

2. To provide user friendly (convenient for patient to apply) Ayurvedic local medicine in form of *Malhar* - ointment in internal piles.

3. To see adverse effect of *Arshohar Malhar* if any.

MATERIALS & METHOD

Type of study- Open, uncontrolled (single arm) clinical study.

Place of study – Shalyatantra Department, Dr.D.Y.Patil Ayurvedic Hospital, Navi Mumbai.

Outdoor & Indoor patients from the Shalyatantra Department of Dr. D. Y. Patil Ayurvedic Hospital enrolled and participated in the study.

Sample size – 30

Drug profile – *Arshohar (Apamarg Kshar) Malhar*

Dose: Local (per rectal digital application) of *Arshohar malhar* once daily for 6 days.

Duration of study: 1 month.

Follow up: Patients were called for application of *Arshohar malhar* daily for 6 days on OPD basis and change in anal mucosa was observed then after, follow up was taken on 7th, 14th, 21st and 30th day and when needed.

Ethical Clearance– Ethical clearance was taken from IEC Dr. D. Y. Patil Ayurvedic Hospital. (IEC Reference no.DYP PG/ MS/ 112030019/ 2013)

METHODOLOGY:

Preparation of Arshohar (Apamarg Kshar) malhar:

Apamargakshar malhar was prepared by the method as mentioned in Sharangdhar Samhita, using base material for preparation of *malhar* as Bee-wax (*Madhu chcheshta*). 5kg of dried *Apamarg (Achyranthes Aspera Linn)* plant *panchang* is burnt to get 500

Gm of *Achyranthes Aspera* ash (*bhasm*). This ash is kept mixed with 2 liter of water (4 times) and kept in mud pot for overnight. Next morning clear supernatant water is decanted in clean vessel and filtered 21 times with different samples of water. Thereafter, this solution was boiled & evaporated till it appeared like cow's urine colour /slight reddish. Further, this is boiled till all water content evaporated and only dried marvels of *pratisaraneeya Apamarga Kshar* was obtained. This was mixed uniformly with Bee-wax(*Madhu chcheshta*) to get *Arshohar (Apamarga kshar) malhar*. [11,12,13,14]

Methodology of Arshohar malhar application: The diagnosed and selected patient was given lithotomy position after the first defecation in the morning hours. Perianal region was cleaned with savlon solution and Lox2% jelly was applied locally. The Arshayantra (Proctoscope) was introduced into the rectum. Slowly after locating the position of the pile mass, Arshohar (Apamarga kshar) malhar was applied with the help of shalaka (probe) over the pile mass. Slowly Proctoscope was withdrawn. Patient was advised to rest for

some time. This procedure was practiced daily for 6 days on OPD basis.

INCLUSION CRITERIA:

- Both males and females with age group of 20-60 yrs.
- The patient of firsh and second degree Internal piles were included in this study.
- All Cases were fresh/new who didn't received any local treatment.

EXCLUSIVE CRITERIA:

- Post-operated (Post haemorrhoidectomy) patients.
- Patients having Diabetes, IHD, Malignancies, AIDS,Koch's, any portal obstruction.
- Haemorrhoids with fissure or fistula in ano
- Pregnant women.
- 3rd degree proplapsed Haemorrhoids and thrombsed Haemorrhoids.
- Ca (Malignancy) Rectum.

ASSESSMENT PARAMETER:

- 1.Per rectal bleeding
 - 2.Discharge
 - 3.Size of pedicle(on proctoscopy)
 - 4.Colour of pile pedicle
- 1.Per rectal bleeding (as per patients complaints)

P/R bleeding	Grade
Baseline	+++
50% relief	++
25% relief	+
Complete relief	0

Table 1: Gradation criterion of per rectal bleeding (as per patients complaints)

2.Per rectal discharge

Discharge	Grade
Purulent	+++
With blood	++
Watery	+
With odour	0

Table 2: Gradation criterion of discharge

3. Size of pedicle (on proctoscopy)

Size of pedicle	Grade
Size resembling the size of ground nut or larger than ground nut	+++
Size resembling the size same as pea nut	++
Size resembling the size smaller than pea nut	+
No pile pedicle visualised	0

Table 3: Gradation criterion of size of pedicle (on proctoscopy)

4. Colour of pile pedicle

Colour of pile pedicle	Grade
Bluish or Blackish colour	+++
Reddish colour	++
Pinkish colour	+
Colour resembling that of mucosa	0

Table 4: Gradation criterion of colour of pile pedicle

OBSERVATION AND RESULT

DEMOGRAPHIC ANALYSIS

The observations made in this present study on 30 patients. Out of 30 cases selected 20 (66.67 %) were male and 10 (33.33 %) were female.

Out of 30 patients 6 (20%) were under age group of 21 to 30 years, 10 (33.33%) were under age group of 31 to 40 years, 11 (36.67%) were under age group of 41 to 50 years and 3 (10%) were under age group of 51 to 60 years.

Out of 30 selected cases 11 (36.67%) were comes under sedentary work style, 14 (46.66%) were comes under active work and 5 (16.67%) comes under labour work.

STATISTICAL ANALYSIS

1) Per rectal bleeding (as per patients complaints)

The Statistical analysis shows that in case of P/R Bleeding the mean before treatment was 3 and was reduced to 0.733 after 60 days.

H₀: No significant difference due to the effect of *Arshohar malhar* on p/r bleeding

H₁: Significant difference due to the effect of *Arshohar malhar* on p/r bleeding.

Decision criterion: Reject H₀ if p value is less than 0.05

After applying the Wilcoxon signed rank test, we get p - value < 0.0001 and hence we reject H₀. Therefore we can say that the treatment i.e. *Arshohar malhar* is significantly effective in reducing p/r Bleeding.

No. of Patients	0 Day	7 th DAY	14 th DAY	21 st DAY	28 th DAY
1	3	2	2	1	0
2	3	2	1	1	0
3	3	3	3	2	2
4	3	3	2	1	1
5	3	2	2	2	1
6	3	2	2	1	0
7	3	3	2	2	1
8	3	2	2	1	0

9	3	2	1	1	0
10	3	2	2	1	0
11	3	2	1	1	0
12	3	2	1	0	0
13	3	3	3	3	2
14	3	2	1	1	0
15	3	2	1	1	1
16	3	2	2	2	1
17	3	3	3	2	2
18	3	2	2	2	1
19	3	2	2	1	1
20	3	2	2	1	1
21	3	2	2	1	0
22	3	2	2	2	1
23	3	2	2	2	1
24	3	3	3	3	2
25	3	2	2	1	1
26	3	2	1	1	0
27	3	2	2	2	1
28	3	3	2	2	2
29	3	2	1	1	0
30	3	2	1	1	0

Table 5: Assessment of per rectal bleeding (as per patients complaints) in 30 patients

2)Discharge

The Statistical analysis shows that in case of p/r discharge the mean before treatment was 6.933 and was reduced to 0.5 after 60 days.

H₀: No significant difference due to the effect of *Arshohar malhar* in p/r discharge

H₁: Significant difference due to the effect of *Arshohar malhar* in p/r discharge.

Decision criterion: Reject H₀ if p value is less than 0.05

After applying the Wilcoxon signed rank test, we get p - value < 0.0001 and hence we reject H₀. Therefore we can say that the treatment i.e. *Arshohar malhar* is significantly effective in reducing p/r discharge.

No. of Patients	0 Day	7 th DAY	14 th DAY	21 st DAY	28 th DAY
1	1	1	1	1	0
2	0	0	0	0	0
3	2	1	1	1	1
4	0	0	0	0	0
5	1	1	1	1	1
6	0	0	0	0	0
7	2	2	1	1	1
8	0	0	0	0	0
9	0	0	0	0	0

10	1	1	1	1	0
11	0	0	0	0	0
12	0	0	0	0	0
13	4	3	2	2	2
14	0	0	0	0	0
15	0	0	0	0	0
16	2	1	1	1	1
17	3	2	2	2	2
18	1	1	1	1	1
19	0	0	0	0	0
20	0	0	0	0	0
21	1	1	1	1	1
22	0	0	0	0	0
23	2	2	1	1	1
24	3	3	2	2	2
25	0	0	0	0	0
26	0	0	0	0	0
27	2	1	1	1	0
28	2	1	1	1	1
29	0	0	0	0	0
30	1	1	1	1	1

Table 6: Assessment of per rectal discharge (as per patients complaints) in 30 patients

3. Size of pedicle (on proctoscopy)

The Statistical analysis shows that in case of size of pile pedical the mean before treatment was 1.4666 and was reduced to 1.0666 after 60 days.

H₀: No significant difference due to the effect of *Arshohar malhar* in size of pile pedical.

H₁: Significant difference due to the effect of *Arshohar malhar* in size of pile pedical.

Decision criterion: Reject H₀ if p value is less than 0.05

After applying the Wilcoxon signed rank test, we get p - value < 0.0001 and hence we reject H₀. Therefore we can say that the treatment i.e. *Arshohar malhar* is not much effective in reducing size of pile pedical.

No. of Patients	0 Day	7 th DAY	14 th DAY	21 st DAY	28 th DAY
1	1	1	1	1	1
2	1	1	1	1	1
3	2	2	2	2	2
4	1	1	1	1	0
5	1	1	1	1	1
6	1	1	1	1	1

7	2	2	2	2	2
8	1	1	1	1	1
9	1	1	1	1	0
10	2	2	2	2	1
11	1	1	1	1	1
12	1	1	1	1	1
13	1	1	1	0	0
14	3	3	3	3	2
15	1	1	1	1	1
16	2	2	2	2	1
17	3	3	2	2	2
18	1	1	1	1	1
19	2	2	1	1	1
20	1	1	1	1	1
21	1	1	1	1	1
22	1	1	1	0	0
23	2	2	2	2	2
24	3	3	2	2	2
25	1	1	1	1	0
26	1	1	1	1	1
27	2	2	2	2	2
28	2	2	2	2	2
29	1	1	1	1	0
30	1	1	1	1	1

Table 7: Assessment of size of pile pedicle (on proctoscopy) in 30 patients

4. Colour of pile pedicle

The Statistical analysis shows that in case of colour of pile pedical the mean before treatment was 2.9333 and was reduced to 1.2 after 60 days.

H₀: No significant difference due to the effect of *Arshohar malhar* in of colour of pile pedical.

H₁: Significant difference due to the effect of *Arshohar malhar* in of colour of pile pedical.

Decision criterion: Reject H₀ if p value is less than 0.05

After applying the Wilcoxon signed rank test, we get p - value < 0.0001 and hence we reject H₀. Therefore we can say that the treatment i.e. *Arshohar malhar* is effective in reducing of colour of pile pedicle.

No. of Patients	0 Day	7 th DAY	14 th DAY	21 st DAY	28 th DAY
1	3	3	2	2	1
2	3	3	2	2	1

3	3	3	3	2	2
4	3	3	2	2	2
5	2	2	1	1	0
6	3	3	2	2	2
7	3	3	2	2	2
8	3	2	1	1	1
9	3	2	2	2	2
10	3	2	2	1	1
11	3	2	1	1	1
12	2	2	1	1	1
13	4	4	4	3	3
14	2	2	2	1	1
15	3	2	1	1	0
16	3	3	2	2	2
17	4	4	3	3	2
18	3	3	2	1	1
19	3	2	2	1	1
20	3	3	2	1	0
21	3	2	2	2	1
22	2	2	1	1	1
23	3	2	2	2	1
24	4	4	3	3	2
25	3	2	2	2	1
26	3	2	1	1	0
27	3	2	2	2	1
28	3	2	2	2	1
29	3	2	2	2	1
30	2	2	2	1	1

Table 8: Assessment of colour of pile pedicle (on proctoscopy) in 30 patients

DISCUSSION

The study was conducted to evaluate the therapeutic efficacy of *Arshohar Malhar* in the management of *Abhyantar Gudarsh* w.s.r. to 1st and 2nd degree internal haemorrhoids.

In this study it was observed that maximum patients who had *Arsha* were of VataPitta and VataKapha Prakruti.

Arsha disease affects persons, irrespective of sex. In this study we found more male

patients than female i.e. Male-21 (70%) and Female-9 (30%). Further, 2 female patients were seen affected with piles due to multiparity.

As far as age is concerned, this study revealed that occurrence of the *Arsha* is very common in age group 25yrs to 35 yrs.

Amongst most of the patient there was history of consuming junk food.

Arshohar Malhar has been proved, cost effective and user friendly (convenient for

patient to apply) in internal piles even during out patient basis with significant result with less complication or minimal complications (sometimes local edema observed if applied on external haemorrhoids i.e. below dentate line).

CONCLUSION

In two symptom i.e. bleeding and colour of pilemass better result was observed, so we can conclude that treatment given in trial group is equally efficient on bleeding and colour of pile mass. The Statistical analysis showed that in case of per rectal bleeding the mean before treatment was 3 and was reduced to 0.733 after 30 days. For colour of pile pedicle, the mean before treatment was 2.9333 and was reduced to 1.2 after 60 days. In case per rectal discharge, the mean before treatment was 6.933 and was reduced to 0.5 after 60 days. Further, size of pile pedical before the treatment was 1.4666 and after treatment was 1.0666. After applying the Wilcoxon signed rank test, we got p - value < 0.0001.

Therefore, we can say that the treatment i.e. *Arshohar malhar* proved effective in reducing symptoms such as per rectal bleeding, discharge and colour of pile pedical. Similarly, the drug did not showed any untoward effects and is quite safe and easy to apply.

From the socio-economic view the drug is relatively cheap, easy to prepare and can prove one of the good ambulatory type of treatment.

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