

**A COMPARATIVE CLINICAL EVALUATION OF SURAN PINDI & HARIDRADI LEPA
IN ARSHA W.S.R. TO HAEMORRHOIDS****Dr. Sanjay Kumar Agri^{*1}, Dr. Pankaj Kumar Sharma² and Dr. Ajay Kumar Gupta³**¹P.G. Scholar M.S. (Ay.) Rishikul Campus, U.A.U, Haridwar (U.K.).²Professor, P.G. Deptt. of Shalya Tantra Gurukul Campus, U.A.U, Haridwar (U.K.).³Professor, P.G. Deptt. of Shalya Tantra Rishikul Campus, U.A.U, Haridwar (U.K.).***Corresponding Author: Dr. Sanjay Kumar Agri**

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ABSTRACT

Arsha is one of the lifestyle disease which is Increasing at an alarming rate in our society due to sedentary life style, mental stress, over intake of fast food, lack of rest and physical exercise and careless attitude towards responding to natural urges such as suppression of defecation. In Ayurveda Acharya Sushruta (the pioneer of ancient Surgery) mentions this disease under the heading of Ashta Mahagadas. Arsha (Haemorrhoids) is an extremely common problem reported since thousands of years with a prevalence rate that is highest among all the ano-rectal disorders. The term Haemorrhoids is popularly used to refer for pathological varicosity of the haemorrhoidal veins due to increased pressure, and usually results by straining during defecation, chronic constipation or diarrhoea, pregnancy, etc. Arsha is treated by different modalities in modern science, but till today no single modality has proved to be complete cure for the disease. A clinical trial was conducted in this study in 2 groups of 15-15 patients each diagnosed with Arsha (Haemorrhoids). Patients were selected randomly irrespective of their religion, race, occupation etc. They were administered Suran Pindi & Haridradi Lepa, a herbal formulation. In group A, patients were administrated only Suran Pindi at a dose of 1gm Bid a day for two months and in group B, patients were administrated Suran Pindi oral administration and Haridradi lepa local application Bid a day for two months. Patients were monitored at every 15 days interval during the study period. Constipation, bleeding, pain or discomfort, itching, size of pile mass and prolapse of pile mass were observed over the treatment. Analysis of result showed improvement in Arsha (Haemorrhoid). Finally study concluded that Suran Pindi & Haridradi Lepa is effective for curing the patients of Arsha (Haemorrhoids).

KEYWORDS: Arsha, Haemorrhoids, Suran Pindi & Haridradi Lepa.**INTRODUCTION**

Arsha (Piles) is an extremely common problem reported since thousands of years with a prevalence rate that is highest among all the ano-rectal disorders. Arsha is a lifestyle disease which is increasing at an alarming rate in our society due to sedentary life style, mental stress, over intake of fast food, lack of rest and physical exercise and careless attitude towards responding to natural urges such as suppression of defecation. In Ayurveda Acharya Sushruta,^[1] (the pioneer of ancient Surgery) mentions this disease under the heading of Ashta Mahagadas. Arsha,^[2] (Haemorrhoids) is an extremely common problem reported since thousands of years with a prevalence rate that is highest among all the ano-rectal disorders. Manifestation of the disease occurs due to many factors eg. Improper diet intake, prolonged standing or sitting, faulty habits of defaecation, etc. which results in derangement of Jatharagni leading to vitiation of Tridosha, mainly Vata Dosha. These vitiated Doshas get localized in GudaVali and Pradhana

Dhamani which further vitiates Twak, Mansa, and Meda Dhatus due to Annavaha-sroto dushti leading to development of Arsha.^[3] The term Haemorrhoids is popularly used to refer for pathological varicosity of the haemorrhoidal veins due to increased pressure, and usually results by straining during defecation, chronic constipation or diarrhoea, pregnancy, etc. Arsha is treated by different modalities in modern science, but till today no single modality has proved to be complete cure for the disease. The word Arsha pertains to a disease occurring in Guda or anorectal region. It tortures the patient and may create hindrance in the function of anorectal region. In Ayurveda, fourfold management of Arsha has been indicated eg. Bhesajya, Kshar Karma, Agnikarma and Shashtra Karma, according to chronicity and presentation of the disease. As far as the modern modalities are concerned, the conservative treatment of piles consists of use of laxative and high-residual diet. But, not more than 80% of the hemorrhoidal symptoms can usually be controlled by non-excision techniques.

Other methods of treatments like sclerotherapy, rubber band ligation, infra-red photocoagulation, laser therapy, Lord's dilatation, cryosurgery, haemorrhoidectomy, stapled haemorrhoidectomy, etc. are in practice. Despite a range of treatment modalities, the options are limited in concern with their effectiveness. Among these, *Bheshaj Chikitsa* show wonderful results in management of *Arsha* because there is no complication, no fear for pain or bleeding or discomfort, etc. The patients were subjected for detail clinical examination and investigations. *Suran Pindi* and *Haridradi lepa* was taken for the present study. *Suran Pindi* has been described by *Acharya Sharangdhar* in his *Samhita's madhyam khand* and said that it is “*अर्शानाशनी पराम्*” and *Haridradi lepa* has been described by *Acharya Bhav prakash* in *chikitsa sthan* chapter 5 and said that it is “*अर्शसामन्ताकारक*”.

The present research work was planned for to find out an effective and safe modality of management of *Arsha* in early stage of disease. 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 treated by oral in-take of *Suran-Pindi* and Group-B patients were treated by oral in-take of *Suran-Pindi* and Local application of *Haridradi Lepa*.

Need For The Study

Arsha is treated by different modalities in modern science, but till today no single modality has proved to be complete cure for the disease. In today's modern field, *Arsha* is treated with many surgical and para-surgical procedure like haemorrhoidectomy, rubber-band ligation, cryosurgery, sclero-therapy, *Kshar-karma*, leech-therapy etc.

All of these procedures are not free of pain or discomfort, and most of the time complications may also occur. In Ayurveda, Bheshaj chikitsa is the first line of treatment for Arsha, in which many herbal formulations are mentioned for successful treatment of 1 and 2nd degree pile masses without known complications. Of these Suran Pindi and Haridradi lepa were selected for the present study.

Suran Pindi is described by Acharya Sharangdhar in his *Samhita's Madhyam khand* and *Haridradi lepa* has been described by Acharya Bhav prakash in *Chikitsa sthan* chapter 5.

➤ **Contents Of *Suran Pindi***

- 1- Suran
- 2- Chitrak mool
- 3- Shunthi
- 4- Kali Marich
- 5- Gud

Method of Preperation of Drug

नमः ६ इतः का &

'ए' 'उ' 'ऋ' 'ॠ' इ. एवम्; ऋधस्यप-ढङ्=अ' धादञ्च अ

ऋध्दथ्य॑ धल्क॒द इष॑छाए; 'ध्र.ऑ.६ ऋध्दथ्य॑ थ्य'ळ;ज॒अअ
 पृ॒ब्द ऋध्दथ्य॑द ज्झम्प;ध्दत्त न्धरु,ल्ल॒छ=९ ष॑ध्दत्तल्लअ
 सक्त्त॑ इत्त॒ङ्कव॑ध छःध्रम॑ध्दत्त ल्लत्ता त्थज॒अअ
 'ध॒- न॒द्धय॑ ज्;ज [६क]

First of all 32 parts of dry *Suran* was crushed into fine *Churna*, then 16 part of *Chitrak mool Churna*, followed by 4 parts of *Shunthi Churna* and 2 parts of *Kali Marich Churna* was taken together and 2 part of *Gud* (Jaggery) was mixed to form *Vati*.

➤ **Contents Of *Haridradi Lepa***

1. Haridra
2. Kritvedhan Churna
3. Katu Taila

Method of Preperation of Drug

हरिद्राजालनी चूर्ण कटु तैल समन्वितम् ।

एष लेपो वरः प्रोक्तो ह्यर्शसामन्ताकारक ॥

(भाव प्रकाश चिकित्सा प्रकरण-५/५७ अर्श रोगाधिकार)^[5]

The *Churna* of *Haridra* and *Kritvedhan* was mixed properly with *Katu Taila* to form *Lepa*. This *Lepa* was used locally over *Arsha*.

MATERIAL AND METHODS

Plan of Study

- Criteria of selection of patient
- Criteria for diagnosis
- Criteria for assessment

- **Selection of patients**
- Two trial groups of 15-15 patients of *Arsha* were selected randomly from OPD and IPD of *Shalya Tantra, Rishikul Campus Hospital, U.A.U., Haridwar, U.K.* for present clinical trial.
- The study was conducted on the basis of criteria of inclusion and exclusion with detailed clinical history and physical examination and other necessary/ desired investigations.

Selection Criteria

The patient were diagnosed on the basis of *Ayurvedic* as well as Modern parameters /examination like –

- Symptomatology
- History of the patient
- Local examination-Inspection, palpation, digital per rectal examinations, proctoscopy.

Diagnostic Criteria

Patient having sign and symptoms of *Arsha* (Haemorrhoids) as follows

- Constipation
- Bleeding per rectum
- Pain in anus
- Pruritus ani

- Mucus discharge
- Prolapse of pile mass
- Anemia

Examination:- Following examination were performed on each patient

- Inspection of the Anal region
- Digital examination
- Proctoscopy

Investigations

- Haemogram :- Hb%, TLC, DLC, ESR, CT, BT
- Blood sugar- RBS
- HIV, HCV, HBsAg
- Urine:-routine and microscopy
- Stool:- ova and cyst

Assessment Criteria:- Assessment was done on subjective & objective criteria before & after the treatment.

Subjective Criteria:

- Constipation
- Pain in anal region
- Itching in anal region

Objective Criteria:-

- Number of pile mass
- Size of Pile mass
- Prolapse of pile mass
- Bleeding per rectum

Grading of Assessment Criteria

Subjective criteria

1. Constipation:-

- G₀ – Easy evacuation of stool
- G₁- Hard stool once a day
- G₂- Hard stool after 2 days
- G₃- Hard stool after more than 2 days

2. Pain:- Assessed by MRC (Medical Research Council) scale.

- G₀- Absence of pain.
- G₁ –Mild pain- that can easily be ignored
- G₂- Moderate Pain- that can't be ignored, interferes with function, and needs treatment from time to time
- G₃- Severe pain – That is demanding constant attention

3. Itching

- G₀ -No itching
- G₁- Once or twice a day
- G₂- Often in a day and discomfort
- G₃- Severe itching and discomfort whole day

Objective Criteria

1. Number of pile mass

G₀- No pile mass

G₁- one pile mass
G₂- two pile mass
G₃- three pile mass

2. Size of pile mass

G₀- Almost none

G₁- Size of the tip of little finger (approx 0.5cm)

G₂- Size of the tip of index finger (approx 0.5cm to 1.0cm)

G₃- Size of the tip of thumb (approx 1.0cm to 1.5cm)

3. Prolapse of pile mass

G₀- No prolapse of pile mass

G₁- Pile mass prolapse during defecation & reduces itself

G₂- Pile mass prolapse during defecation & require manual reduction

G₃- Permanent prolapse of pile mass

4. Bleeding

G₀- No bleeding

G₁- Mild bleeding with defecation (1-5 drops occasionally)

G₂- Moderate bleeding (6-12 drops)

G₃- Profuse bleeding

Inclusion Criteria

- Any age group.
- Patients who are suffering from *Arsha* (1st , 2nd and 3rd degree piles)
- Irrespective of sex.

Exclusion Criteria

- 4th degree piles.
- Thrombosed & Strangulated piles.
- Rectal prolapse.
- Haemorrhoids associated with fissure and fistula in ano.
- Rectal polyp.
- Pregnant women.
- Patient with known systemic disorder like HTN, DM, Malignancy, etc.
- Hepatitis B, HIV, HCV positive cases.

• **Drug Dose:-** *Suran Pindi* tablets (500 mg each) were given orally, two tablets twice in a day, after meal with Luke warm water, and *Haridradi lepa* was locally applied after warm sitz bath.

Study Design

Group	Drug	Dosage	Duration	Route of Administration
A	Suran Pindi	1gm BD	60 Days(maximum)	Oral administration(tab)
B	Suran Pindi With Haridradi Lepa	1gm BD(oral) Lepa(L/A)	60 Days(maximum)	Oral administration(tab) &Local application(Lepa)

Criteria for Overall Assessment of Therapy

1. Complete remission: 100% improvement.
2. Marked Improvement: 75% to <100% improvement.
3. Moderate Improvement: 50% to <75% improvement.
4. Mild Improvement: 25% to <50% improvement.
5. Unchanged: less than 25% improvement.

Total Effect in Group A

Group A	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Constipation	2.43	1.08	-4.156 ^a	0.01	86.7	Highly Significant
Pain	2.37	1.39	-4.138 ^a	0.05	60.0	Significant
Itching	2.25	1.23	-4.153 ^a	0.05	60.9	Significant
Bleeding	2.50	1.13	-4.141 ^a	0.01	84.3	Highly Significant
Number of pile mass	2.48	1.15	-4.141 ^a	0.01	84.0	Highly Significant
Size of Pile Mass	2.40	1.27	-4.199 ^a	0.05	65.0	Significant
Prolapse of pile mass	2.39	1.28	-4.172 ^a	0.05	64.3	Significant

Since observations are on ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From above table we can observe that P-Values for all parameters are less than 0.05. Hence we conclude

that effect observed is highly significant result was found in Constipation, Bleeding and Number of pile mass and statistically significant result was found in Pain, Itching, size of pile mass and prolapse of pile mass.

Total Effect in Group B.

Group B	Median		Wilcoxon Signed Rank W	P-Value	% Effect	Result
	BT	AT				
Constipation	2.98	1.02	-4.263 ^a	0.01	85.5	HS
Pain	2.23	1.75	-4.738 ^a	0.05	78.8	Significant
Itching	2.10	1.03	-4.252 ^a	0.01	86.8	HS
Bleeding	2.18	1.07	-4.238 ^a	0.01	85.5	HS
Number of pile mass	2.17	1.09	-4.238 ^a	0.01	85.2	HS
Size of Pile Mass	2.83	1.13	-4.122 ^a	0.01	87.5	HS
Prolapse of pile mass	2.53	1.00	-4.122 ^a	0.01	87.5	HS

Since observations are on ordinal scale (gradation), we have used Wilcoxon Signed Rank test to test the efficacy. From above table we can observe that P-Values for all parameters are less than 0.001. Hence we

conclude that effect observed is highly significant result found in Constipation, itching, bleeding, number, size and Prolapse of pile mass and statistically significant result was found in Pain.

➤ Comparison Between Group A And Group B.

	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Constipation	Group A	15	12.90	193.50	158.000	0.003
	Group B	15	22.10	331.50		
	Total	30				
Pain	Group A	15	13.50	202.50	190.000	0.002
	Group B	15	20.50	307.50		
	Total	30				
Itching	Group A	15	13.00	195.00	175.000	0.005
	Group B	15	20.00	300.00		
	Total	30				
Bleeding	Group A	15	13.50	202.50	175.000	0.005
	Group B	15	21.00	315.00		
	Total	30				

Size of Pile Mass	Group A	15	12.60	189.00	170.000	0.004
	Group B	15	21.00	315.00		
	Total	30				
Prolapse of Pile Mass	Group A	15	13.60	204.00	170.000	0.004
	Group B	15	21.00	315.00		
	Total	30				

For comparison between Group A and Group B, we have used Mann Whitney U test. From above table we can observe that P-Values for all parameters are less than 0.05. Hence we conclude that there is significant difference observed between effect of Group A and Group B. Further we can observe that mean rank for Group B is greater than Group A. Hence we conclude that effect observed in Group B is more than Group A.

Total effect of therapy

➤ Group A-

In present study 5 (33.33%) patients were marked improved, 7 (46.66%) patient were moderate improved and 3 (20%) mild improved while no case in unchanged category.

➤ Group B-

In present study 9 (60%) patients were marked improved, 5 (33.33%) patient were moderate improved and 1 (6.66%) mild improved while no case in unchanged category.

DISCUSSION

- Maximum number of patients in the present study belonged to the age group 31-40 years (36.66%), Male (63.33%), Resident of rural area (60%), Muslim (56.66%), Middle class (46.66%), Serviceman (26.66), Married (63.33%) and Literate (83.33%).
- Maximum numbers of patients were having addiction of both Tea and alcohol (83.33% & 53.33% resp.), sedentary life style (40%), and *Madhyam* body built (80%).
- Maximum patients were practiced to Mixed diet (86.66%), Hard stool consistency (73.33%), Hard irregular bowel habit (53.33%), Decreased appetite (63.33%), *Adhyashan* dietetic habit (40%), Chronicity of less than 3 months were present in 43% patients and 26.66% were having family history.
- Maximum number of patients were having *Pitta-Kapha prakriti* (50%), 56.66% were noted of *Avara Sara*, *Madhyama Samhanan* (70%), *Madhyama Satva* (53.33%), *Sarva rasa satmaya* (100), *Madhyama praman* (70%), *Sadharana Desha* (100%), *Madhyama Ahar Shakti* (53.33%), *Madhyama Vyayam Shakti* (70%), *Madhyama Abhyavaran Shakti* (53%), *Avara Jarana Shakti* (83.33%).
- 100% patients complained of Constipation, 100% patients complained of pain, 100% patients complained of itching, 66.66% patients complained of bleeding and prolapse of pile mass 73.33%.

- There was no adverse effect observed in any patients during the trail of Drugs as well as follow up.
- Suran Pindi & Haridradi lepa* are the economical and effective herbal formulation for manament of *Arsha*.

1. Percentage relief in Symptom

	Group A	Group B
1. Constipation	86.7%	85.5%
2. Pain	62%	78%
3. Itching	60.9%	86%
4. Bleeding	84%	85%
5. Number of pile mass	84%	85%
6. Size of pile mass	65%	87.5%
7. Prolapse of pile mass	64.3%	87.5%

Here, it is observed that the trial drug Group B (*Suran Pindi & Haridradi lepa*) is more effective to cure *Arsha* disease rather than Group A (only *Suran Pindi*).

Effect of Therapy

1. Effect on Constipation

Group A- The mean rank of constipation was 2.43 which got reduced in 15 days to 1.98 then after 30 days 1.68 and in 45 days to 1.28 and in 60 days it was reduced to 1.08. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.00001$) was found (%age relief-86.7%). The initial mean score of the symptom constipation was 2.43 which was reduced to 1.08 at the completion of the therapy.

Group B- The mean rank of constipation was 2.98 which got reduced in 15 days to 2.56 then after 30 days 1.95 and in 45 days to 1.28 and in 60 days it was reduced to 1.02. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.00000$) was found (%age relief-85.5%). The initial mean score of the symptom constipation was 2.98 which was reduced to 1.02 at the completion of the therapy.

From above, we can observe that P-Values for Group A and Group B are less than 0.05 hence we conclude that there is significant change observed in both groups.

2. Effect on pain in ano-rectal region

Group A- The mean rank of pain was 2.37 which got reduced in 15 days to 2.37 then after 30 days 1.98 and in 45 days to 1.62 and in 60 days it was reduced to 1.39.

Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically Significant result ($p < 0.0000122$) was found (%age relief=60%). The initial mean score of the symptom pain was 2.37 which were reduced to 1.39 at the completion of the therapy.

Group B- The mean rank of pain was 2.23 which got reduced in 15 days to 1.82 then after 30 days 1.43 and in 45 days to 1.20 and in 60 days it was reduced to 1.09. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically Significant result ($p < 0.000063$) was found (%age relief=78.88%). The initial mean score of the symptom pain was 2.23 which were reduced to 1.09 at the completion of the therapy.

From above, we can observe that P-Values for Group A and Group B are less than 0.05 hence we conclude that there is significant change observed in both groups.

3. Effect on itching in ano-rectal region

Group A- The mean rank of itching was 2.25 which got reduced in 15 days to 2.02 then after 30 days 1.95 and in 45 days to 1.45 and in 60 days it was reduced to 1.23. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically Significant result ($p < 0.000052$) was found (%age relief=60.9%). The initial mean score of the symptom itching was 2.25 which was reduced to 1.23 at the completion of the therapy.

Group B- The mean rank of itching was 2.10 which got reduced in 15 days to 1.88 then after 30 days 1.56 and in 45 days to 1.20 and in 60 days it was reduced to 1.03. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.0015$) was found (%age relief=86%). The initial mean score of the symptom itching was 2.25 which was reduced to 1.03 at the completion of the therapy.

From above, we can observe that P-Values for Group A and Group B are less than 0.05 hence we conclude that there is significant change observed in both groups.

4. Effect on Bleeding

Group A- The mean rank of bleeding was 2.50 which got reduced in 15 days to 1.83 then after 30 days 1.65 and in 45 days to 1.45 and in 60 days it was reduced to 1.13. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.000016$) was found (%age relief=84.0%). The initial mean score of the symptom bleeding was 2.48

which were reduced to 1.13 at the completion of the therapy.

Group B- The mean rank of bleeding was 2.18 which got reduced in 15 days to 1.81 then after 30 days 1.46 and in 45 days to 1.29 and in 60 days it is reduced to 1.07. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.0024$) was found (%age relief=85%). The initial mean score of the symptom bleeding was 2.18 which were reduced to 1.09 at the completion of the therapy. From above, we can observe that P-Values for Group A and Group B are less than 0.05 hence we conclude that there is significant change observed in both groups.

5. Effect on Number of pile mass

Group A- The mean rank of number of pile mass in ano-rectal region was 2.48 which got reduced in 15 days to 1.83 then after 30 days 1.65 and in 45 days to 1.45 and in 60 days it was reduced to 1.15. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.000016$) was found (%age relief=84.0%). The initial mean score of the symptom number of pile mass in ano-rectal region was 2.48 which was reduced to 1.15 at the completion of the therapy.

Group B- The mean rank of number of pile mass in ano-rectal region was 2.17 which got reduced in 15 days to 1.81 then after 30 days 1.46 and in 45 days to 1.29 and in 60 days it was reduced to 1.09. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.0024$) was found (%age relief=85%). The initial mean score of the symptom number of pile mass in ano-rectal region was 2.17 which were reduced to 1.09 at the completion of the therapy.

From above, we can observe that P-Values for Group A and Group B are less than 0.05 hence we conclude that there is significant change observed in both groups.

6. Effect on size of pile mass in ano-rectal region

Group A- The mean rank of size of pile mass was 2.73 which got reduced in 15 days to 1.83 then after 30 days 1.65 and in 45 days to 1.38 and in 60 days it was reduced to 1.27. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.0000001$) was found (%age relief=65.00%). The initial mean score of the symptom size of pile mass was 2.73 which was reduced to 1.27 at the completion of the therapy.

Group B- The mean rank of size of pile mass was 2.83 which got reduced in 15 days to 2.45 then after 30 days 1.60 and in 45 days to 1.35 and in 60 days it was reduced to 1.13. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.00000$) was found (%age relief=87.5%). The initial mean score of the symptom size of pile mass was 2.83 which was reduced to 1.13 at the completion of the therapy.

From above, we can observe that P-Values for Group A and Group B are less than 0.05 hence we conclude that there is significant change observed in both groups.

7. Effect on prolapse of pile mass in ano-rectal region

Group A- The mean rank of prolapse of pile mass was 2.68 which got reduced in 15 days to 1.87 then after 30 days 1.68 and in 45 days to 1.47 and in 60 days it was reduced to 1.28. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.0000001$) was found (%age relief=64.3%). The initial mean score of the symptom size of pile mass was 2.68 which were reduced to 1.20 at the completion of the therapy.

Group B- The mean rank of prolapse of pile mass was 2.53 which got reduced in 15 days to 1.95 then after 30 days 1.55 and in 45 days to 1.22 and in 60 days it was reduced to 1.00. Since the data is on ordinal scale (gradation), observed at specific interval of time, we have used Friedman's Test (Non parametric Repeated measures ANOVA). Statistically highly Significant result ($p < 0.000028$) was found (%age relief=87.5%). The initial mean score of the symptom size of pile mass was 2.53 which were reduced to 1.00 at the completion of the therapy.

From above, we can observe that P-Values for Group A and Group B are less than 0.05 hence we conclude that there is significant change observed in both groups.

Probable mode of action of formulation:- *Arsha* (Haemorrhoid) is a troublesome ano-rectal condition of the society. The probable mode of action of formulation is discussed as mentioned below based on the result of therapy and its interpretation by Ayurvedic as well as modern pharmacology.

While selecting the formulation, a hypothesis was made that as per etio-pathogenesis of *Arsha* described in Ayurvedic classics and equivalent pathology described in modern texts for Haemorrhoid, there is deranged function of *vayu*, particularly *apana vayu* which is the prime causative factor and this perturbed *vata* with *pitta* and *kapha* manifest *Agnimandya*, *vibandh* and bleeding.

So, the drugs which have *vata-pitta-kaphahara* properties like *Agnideepak*, *Anulomak* and *Raktstambhak* were selected, these properties helps to crack the *samprapti* of *Arsha* as well as pathophysiology of Haemorrhoid.

Mode of action of *Suran Pindi* and *Haridradi Lepa*

The important factor which develops *Arsha* is *Agnimandya* and *vibandh*. In such situation, a drug which work as *Agnideepak*, *Anulomak* and *Raktstambhak* is more suitable. Here *Suran Pindi* and *Haridradi Lepa* have been selected for the present study due to having the same properties.

Relief in symptoms

Reduction in degree of constipation, pain, itching, bleeding, number, size and prolapse of pile mass

Provides healthy cushions for haemorrhoidal vessels/mass

Shrinkage of pile masses and decrease congestion of sub mucosal structure as well as mucous membrane

Easy evacuation of faeces with reduction in overall symptomatology.

➤ Discussion on drug action of *Suran Pindi*

- *Suran-kand* has special property as *Arshoghna*⁶ (*Prabhav*). So it is the classical drug of choice in *Arsha*. As it is *ushna*, *tikshna guna* helps *rakta dhatu* to flow in regular manner without any congestion at *rakta-vahi sira* and hence *shotha* (inflammation) decrease and size of pile mass seems to be decreased as *ushna guna* dilates the channel of *raktavaha srotas*.
- All ingredients' (*Suran Chitrak*, *kali marich*, *Sunthi*) in this formulation are *katu ras pradhan*⁷ and *ushna virya* so they help in reducing the blood accumulation as they are said to be having action as "*Shonit Sanghat Bhinnati*". It is stated that *Arsha* is the congestion of vein and *katu ras* dissolve the congestion.
- The main cause of *Arsha* is *Mandagni* and *Vibandh*. So *chitrak*, *kali marich* and *Sunthi* are having *Deepan*, *pachan* and *vataanulomak guna* due to its *ushna virya* and *katu vipak*.

➤ Discussion on drug action of *Haridradi Lepa*

- In this formulation, the main ingredients are *Haridra*,^[8] which is *ruksha*, *laghu*, *ushna virya* and *kapha-vata shamaka* properties. It is *shothhar* due to its *Ushna Virya*. It contains curcumin, curcumenone, curcane, cineole which have anti-bacterial, anti-fungal, anti-tumor, anti-inflammatory activity.
- *Haridra* have anti-bacterial and anti-inflammatory properties and can help heal haemorrhoids when used topically.

- Other ingredients Krtvedhan,^[9] and Sarsap,^[10] also have Ushna virya so it also helps in contraction of pile mass.
- *Krtvedhan* contains cysteine, glutamic, leucine which has anti-bacterial, anti-fungal, anti-inflammatory activity.
- *Sarsap* contains sulforaphane, glucosinolate, 3, 3-diinodolylmethane which have anti-bacterial, anti-fungal, anti-carcinogenic, anti-inflammatory activity.
- All ingredients have anti-inflammatory activity so this *lepa* help in reduce the size and prolapse of pile mass and maintain the local hygiene due to its anti-bacterial, anti-fungal activity hence itching is reduced.

CONCLUSION

- *Arsha* is a common ano-rectal disorder irrespective of sex. In this clinical study most of the patients were 31-40 years of age group in both groups.
- It's important to know this disease's etiological factors because it's the half of the treatment.
- In Ayurveda, the main treatment for 1st and 2nd degree pile mass is Bheshaj chikitsa (conservative treatment) which is very effective.
- Present western lifestyle, cola culture and fast food, and day to day sedentary regimen gives rise to *Mandagni* which leads to *Arsha*. Irregular and hard bowel habit along with prolong sitting has a significant role in development of *Arsha*.
- The disease can be diagnosed on the basis of chief complaints like bleeding, constipation, and prolapse pile mass in ano-rectal region.
- In present study maximum patients have addictions like tea & alcohol. These are also to be considered for causative and aggravating factors the disease. Apart from the above factors socio - economic condition, mental stress and sedentary life style play an important role in causing and aggravating the disease.
- **In group A-** Oral medication of *Suran pindi* is more effective in treating the constipation, bleeding and number of pile masses. Constipation is root cause of *Arsha* (Haemorrhoids).
- **In group B-** Oral medication of *Suran pindi* and local application of *Haridradi lepa* is more effective in curing constipation, itching, bleeding, number of pile masses, Size and prolapse of pile masses.
- *Suran-kand* has special action (*Prabhav*) as *Arshoghna*. The root cause of *Arsha* is *Mandagni* and *Vibandh*. So *chitrak*, *kali marich* and *Sunthi* are having *Deepan*, *pachan* and *vataanulomak guna* due to its *katu vipak* and *ushna virya*.
- In *Haridradi lepa* all ingredients have anti-inflammatory activity so this *lepa* helps in reducing the size and prolapse of pile mass and maintains the local hygiene due to its anti-bacterial, anti-fungal activity, hence itching is reduced.

- Finally it can be concluded that *Suran Pindi* and *Haridradi Lepa* is more effective in curing the cases of *Arsha*.
- It is a low cost effective and it may be recommended for practice in case of *Arsha* successfully.

Thus, these classical preparations can very well be advised as a curative, cost effective, conservative remedy for patients of *Arsha* (Haemorrhoids). Moreover, no adverse effects of the medication were observed during and after completion of the clinical study.

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