

RANDOMIZED CONTROLLED CLINICAL TRIAL OF SOORNADI MALAHARA (OINTMENT) IN THE MANAGEMENT OF ABHYANTARA ARSHA (INTERNAL HEMORRHOIDS)

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ABSTRACT

Ayurveda is an ancient vedic system for healing the human body internally. The word Ayurveda derived from two words – Ayur means life and Veda means science. So it is known as “Science of Life”.^[1] It is basic system to treat human body with Soul and Mind. The main principle of Ayurveda is based on three vital elements in human body, these vital elements are Vata, Pitta and Kapha.^[2] The main aim of Ayurveda is to make balance in this three vital elements.^[3] Ayurveda made up of Eight basic Angas (elements) known as Asthang Ayurveda, one of which Shalyatantra is described.^[4] Shalyatantra is a branch of Ayurveda represent the surgical field, deals with prevention and management of disease which rises from Nija Shalya and Agantuja Shalya.^[5] Now a day human society fighting with local as well as customized regional environment. Food is the basic need of life, which

directly affecting human physical, mental, as well as social well-being. But due to inadequate nutrients and eating habits, affects the human health. In Ayurveda, Acharyas mentioned “Agni”, which is the key centre of human's digestive system. Agni is described an important factor of digestion and metabolism of our body. It converts food in form of energy, which is responsible for all vital functions of our body. Therefore “Dehagni”, it is the cause of life, complexion, strength, health, nourishment, lusture, oja, teja(energy), and prana(life energy).^[6] In Ayurveda various treatment modalities are available for treatment of Arsha, like aushadhi, shashtra, kshar, agnikarma. Among which local application in the form of ointment is very effective in treatment of Arsha.^[7]

KEYWORDS: Internal hemorrhoids, Soornadi malahara (ointment), Pippalayadi malahara (ointment), Randomized clinical trial.

INTRODUCTION

Shalyatatra is the part of Asthang Ayurveda. Acharya Sushruta described Shalyatantra in detail, so that Sushruta Samhita is known as “Shalyatantra pradhan Grantha”.^[8] Ayurveda mention a group of life threatening disease which affect human health from vedic period, such group of disease is known as “Mahagada”.^[9] One of which Arsha mentioned. The Arsha means the abnormal fleshy growth originates from particularly ano-rectal region.^[10] Arsha is a prime important disease from Astamahagada. The ancient medicinal science of India has detail knowledge and description regarding Arsha. According to Ayurveda the Samprapti of Arsha is a Mithya Aahar-Vihar and a prime causative factor. A disease which tortures patients vital force (prana) as a enemy is called Arsha.^[11] The cause of Arsha is “Mandagni”. It leads to Dushti of Doshas at the site of Guda (anal region) which leads to Arsha.^[12] Neglect of proper diet and lifestyle habits ends in reducing digestive fire(Agni), or making it abnormal(Mandagni).^[13] It means inability to digest food material in proper pace and time leading to accumulation and stagnation of half digested food material(Aama), in form of stool inside or expelling it before time in watery or semisolid form which leads to Dushti of Doshas at anorectal region.^[14] In 20th Century Worldwide prevalence rate of haemorrhoids in general population is estimated to 4.4% (emedicinemedscape.com). Patients presenting with haemorrhoids are from higher socioeconomic as well as rural socioeconomic groups.^[15] In Ayurveda as well as Modern science having many treatment modalities has of been given. Many Ayurvedic Acharyas described the basic treatment for Arsha, among which Acharya Sushruta gives detail management of Arsha, which includes conservative as well as surgical.^[16] Basically treatment should non-invasive, easy for implement, no need of hospitalization, due to this Ayurveda mentioned some basic treatment modalities, one of which “Lepa kalpana” is described, which is first line treatment and easy for applicable.^[17] In Bhaishajyaratnavali, for treatment of Arsha some basic Lepa described one of which Soornadi Lepa is mentioned. For convenience of patient Lepa transformed into Malahara (ointment).which is first line treatment for Arsha.^[18] This Lepa contains Soorankanda, Haridra, Chitrakmula, Tankana, Guda and Kanji, these all drugs having Arshoghna properties. This Lepa transformed into Malahara(ointment), used as local application in internal haemorrhoids(Abhyantara Arsha).^[19]

AIM AND OBJECTIVES

AIM

Randomized clinical trial of Sooranadi Malahara in the Management of Abhyantara Arsha w.s.r. to Internal Haemorrhoids.”

OBJECTIVES

- To study Arsha in ancient and modern era
- To evaluate the efficacy of Sooranadi Malahara in management of Abhyantara Arsha.
- To evaluate the efficacy of Sooranadi Malahara.

DRUG REVIEW

- Soornadi Lepa– contains, Sooran, Chitrakmula, Tankan, Haridra, Guda, Kanji
- Pippalyadi lepa – contains, Pippali, Saindhava, Kushta, Shirisha, Snuhikshira / arkakshir
Laxative powder containing Trifgol (3 gm)
- Petroleum jelly (As a base)

Petroleum jelly is a semi-solid mixture of hydrocarbons originally promoted as a topical ointment for its healing properties.

MATERIALS AND METHODS

Modification of Lepa into Malahara (Ointment)

In Bhaishajya Ratnavali two Lepas described, which is Soornadi lepa and Pippalyadi lepa, both of these well -known preparation for treatment for Arsha. Due to inconvenience of Lepa application on mucosal part of anal canal, there is a need for pharmaceutical modification of the same for better enhancement of efficacy, shelf life and acceptability. Hence the study was undertaken with an effort to make a modification of Lepa into ointment form. The ointment was prepared as per the modern pharmaceutical principle using fine powder of ingredients along with white petroleum jelly was used as a base. Trituration method was adopted for preparation of ointment.

Preparation of Pippalyadi malahara (ointment)

Apparatus

- 1) Khalva
- 2) Water bath
- 3) Weighing machine
- 4) Spoon and stainless steel vessel

5) Empty tubes for feeling ointments.

The equipments needed for the preparation were given above. The ingredients with respective quantities taken had been given in table. The ratio of quantity of powdered drugs and liquid form drugs to petroleum jelly was taken as 1:4. in both groups.

Procedure

Ingredients was taken in equal parts. They was made into fine powder separately. All powdered drugs along with liquid drugs were mixed together. Petroleum jelly was taken in a stainless steel vessel. It was heated in a water bath while attaining 60-70, at which it liquefied. It was poured into a clean mortar. To this liquid petroleum jelly, the mixture of whole drugs was added little by little and stirrer well. It was kept undisturbed to obtain the ointment consistency. Total time taken for whole procedure was 1hr. 30 min.

The observation during the preparation were given in Table no 2.

Sr.no	Ingredients	Quantity
1	Pippali	100gms
2	Saindhava	100gms
3	Kustha	100gms
4	Shirish	100gms
5	Snuhikshir	100ml
6	Petroleum jelly (As a base)	2000gms

Table No.2: Observation of the preparation of Pippalyadi ointment.

Time duration	Procedure	Change observed
2.30pm- 2.45am	All the apparatus was kept ready ingredients were measured.	
2.45pm- 3.00pm	100gm of fine powder each drug and 500ml of Snuhi kshir were mixed together.	Brown colored paste was obtained.
3.00pm-3.20pm	1500gm of white petroleum jelly was heated in water bath (temp: 65-70C).	Liquid in consistency for first 5 min. Color was changed to dark brown, Became thicker in consistency in last 15min.
3.40pm-4.00pm	Packing and labelling of the ointment.	About 200 g weight loss observed due to the adherence to the wall of container.

Preparation of Soornadi ointment

Ingredients was taken in equal parts. They were made into fine powder separately. All powdered drugs along with liquid drugs were mixed together. Petroleum jelly was taken in a stainless steel vessel. It was heated in a water bath while attaining 60-70, at which it

liquefied. It was poured into a clean mortar. To this liquid petroleum jelly, the mixture of whole drugs was added little by little and stirred well. It was kept undisturbed to obtain the ointment consistency. Total time taken for whole procedure was 1hr. 30 min. The observation during the preparation were given in Table no 2.

Table No.1: Ingredients with specific quantities of Soornadi ointment.

Sr no	Ingredients	Quantity
1	Soorana	100gms
2	Chitraka	100gms
3	Tankana	100gms
4	Haridra	100gms
5	Guda	100gms
6	Kanji	100ml
7	Petroleum jelly(As a base)	2000gms

Table No.2: Observation of the preparation of Soornadi ointment.

Time duration	Procedure	Change observed
4.30pm-4.45pm	All the apparatus was kept ready, ingredients was measured.	
4.45pm-5.00pm	100gms fine powder of each drug and 100ml of Kanji was taken and mixed together.	Brown colored paste was observed
5.00pm-5.20pm	2400 g of white petroleum jelly was heated in water bath (65-70C).	A whitish transparent liquid was obtained.
5.20pm-5.40pm	Liquefied white petroleum jelly was poured into a mortar powdered ingredients was added little by little and stirred well with a pestle kept undisturbed, weight was measured.	Liquid in consistency for 5 min. Then color was changed to brown and became thicker in consistency in last 15 min.

Laboratory analysis of Pippalyadi malahara (ointment)

Test	Specification	Result
Description	Dark yellowish brown colored greasy ointment with characteristics smell.	Light to dark brown colored greasy ointment.
L.O.D	8.75%	NMT 15%
Ash value	3.552% W/W	NMT 5% W/W
Water soluble extract	16.8745% W/W	NLT 15% W/W
Alcohol soluble extract	18.2254% W/W	NLT 15% W/W
Specific gravity at 25 d.c.	1.2548	1.2000 to 1.300

Laboratory analysis of Soornadi malahara (ointment)

Test	Specification	Value
Discription	Dark blackish brown colored greasy ointment with characteristic smell	Light to dark brown colored greasy ointment
L.O.D	7.53%	NMT 15%
Ash value	4.4621% W/W	NMT 5% W/W
Water soluble extract	18.4485% W/W	NLT 15% W/W
Alcohol soluble extract	16.1178% W/W	NLT 15% W/W
Specific gravity at 25 d.c.	1.2652	1.2000 to 1.3000.

MATERIALS

Well diagnosed and randomly selected total 60 patients of internal hemorrhoids (Abhyantara Arsha) for this study was selected irrespective of sex and divided into two groups.

Group A: Control group

Pippalyadi malahara (Ointment).

Group B: Trial group

Soornadi malahara (Ointment)

Laxative powder containing Isabgol in both groups.

Equipments/Instruments required:

- Proctoscope (Large, medium, small size.)
- Xylocaine jelly
- Cotton gauze.
- Torch.

METHODOLOGY

This was prospective, randomized, controlled clinical trial. They were randomly divided into two groups.

Trial group: In this group 30 patients were treated with the application of Soornadi malahara (ointment).

Control group: In this group 30 patients were treated with application of Pippalyadi malahara (ointment).

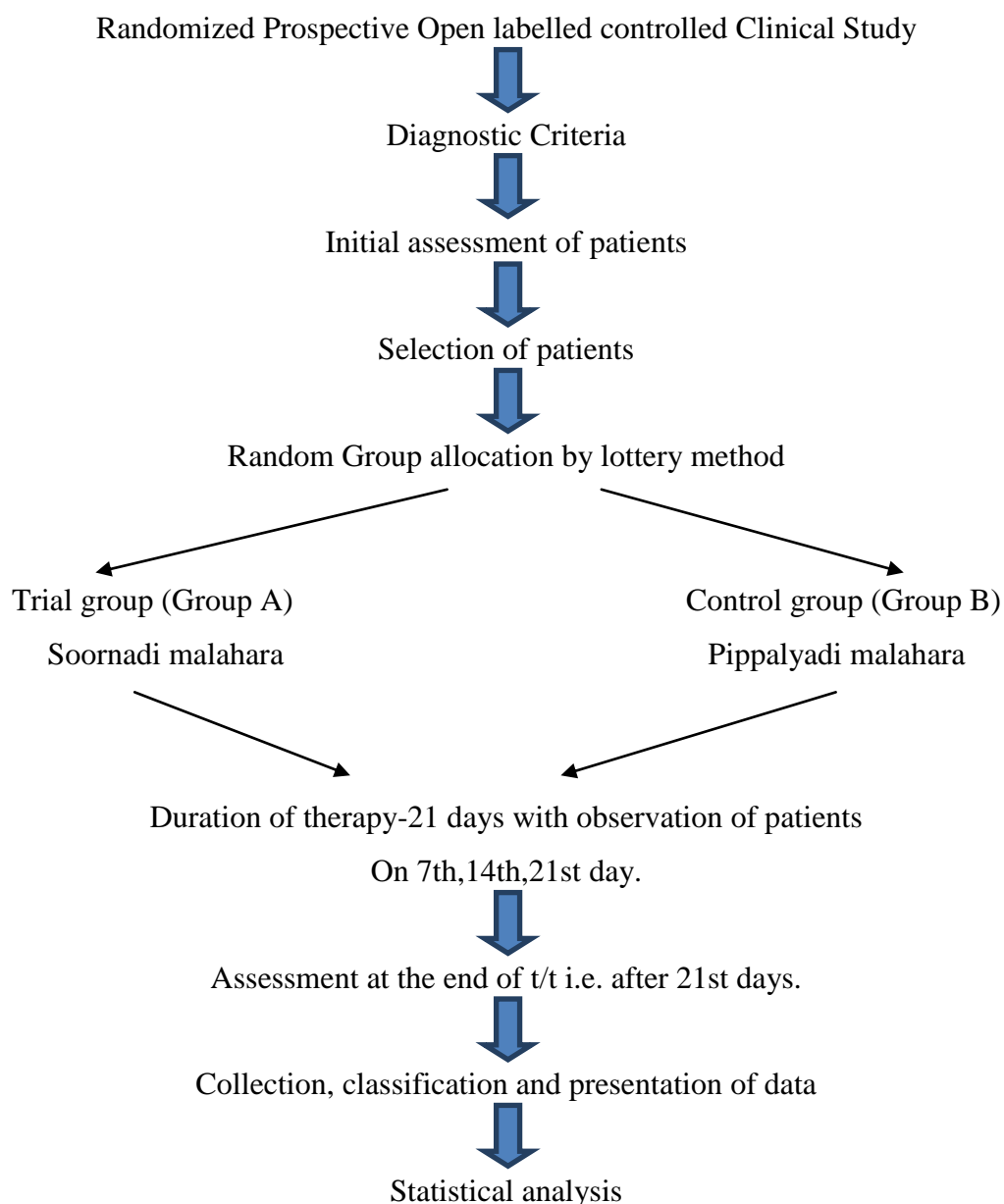
History of patients

Complete history of the patients with presenting complaints like protrusion of mass per rectum, bleeding, pruritis, duration and bowel habit was noted.

Local examination of patients

- Position- Patient was instructed to lie down in left lateral or lithotomy position.
- Inspection- Detail examination of perianal region or pile mass was carried out and positive findings were noted on case paper.
- Palpation- The palpation of perianal region or pile mass was done to determine tenderness and severity of that region
- Per rectal examination- It was carried out with well lubricated gloved finger and the severity of spasm of sphincter muscle, character of pile mass, any other growth is assessed. It was done by using digital examination with index finger or by proctoscope.

STUDY DESIGN



A) Inclusive criteria

- Patient of either sex will be selected for the study.
- Patient of age group between 18-60 years.
- Patient having 1st degree & 2nd degree internal hemorrhoids will be selected for study.

B) Exclusive criteria

- Prolapsed pile mass
- Haemorrhoid caused by other disease
- Carcinoma of rectum.
- Pregnancy
- Haemorrhoids with pelvi-rectal, ischio-rectal abscess.
- Patient suffering from any systemic disease e.g uncontrolled HTN, DM, TB, HIV +ve etc.
- Patient having HB% less than 10 gm.

C) Withdrawal criteria

The patient can be withdrawn from the trial if

- Occurrence of serious adverse events. If any complication occurred during treatment in any patient of both groups will be shifted on necessary treatment.
- The protocol has been violated or a patient has become uncooperative.
- The patient is not willing to continue the trial or to follow the assessment schedule.
- Occurrence of any other illness which may interrupt the treatment regime and efficacy of drug.

Investigations

- CBC
- BT
- CT
- BSL(R)
- HIV I AND II
- HBsAg.

Mode of Administration

The route of administration of Malahara (ointment) used Per rectally as a local application (for both groups).

Procedure of application of Pippalyadi malahara (ointment)

Proper position was given to patient i.e. left lateral or lithotomy position, per rectal examination was done by using index finger lubricating with xylocaine jelly, to assess spasm and palpation of pile mass. After assessment with use of Proctoscope, degree of haemorrhoid was diagnosed. Then Pippalyadi mahahara (ointment) directly applied on pile mass per rectally as a local application daily on two times a day.

The procedure carried out for 7 consecutive days. Bulk forming and stool softening agents like Isabgol along with identical dietary regime and sits bath had been advised to patients in both groups. After procedure, patients were advised for regular follow up on 7th, 14th and 21th day on which observe for both groups. Appropriate antibiotics and analgesic was given 5 days in both groups after procedure.

Procedure of application of Soornadi malahara(ointment)

Proper position was given to patient i.e. left lateral or lithotomy position, per rectal examination was done by using index finger lubricating with xylocaine jelly, to assess spasm and palpation of pile mass. After assessment with use of proctoscope, degree of hemorrhoid was diagnosed. Then Soornadi mahahara directly applied on pile mass per rectally as a local application daily on two times a day. After last follow of both groups a complete objective and subjective assessment was carried out to examine size, number of piles and bleeding per rectum.

Observational parameters

The criteria will be assessed in the manner stated below regarded to each patient as.

- **Haemorrhoids**

1st degree internal Hemorrhoids-

When Pile mass slightly projecting in lumen of anal canal during act of defecation only.

2nd degree internal Hemorrhoids-

When the haemorrhoidal mass protruded out of anal verge on straining, but returns spontaneously into anal canal when act of motion has been passed.

3rd degree internal hemorrhoids-

When the prolapsed haemorrhoid mass doesn't reduce spontaneously and require manual reduction even after cessation of defecation.

4th degree internal hemorrhoids-

Usually there are long standing & acquired a component of skin.

- **Pruritis**

Only subjective assessment will be possible in case of pruritis as per statement of patient regarding relief from above symptom hence subjective parameter as presence(+) or absence(0) of symptom before 7 after treatment.

- **Bleeding-**

1. Severe(+++)- It will be considered to be severe if bleeding is profuse in the form of stream or drops amounting more than 20 drops /bowel habit.
2. Moderate(++)- It will be considered moderate if the bleeding is in drop form amounting between 10-20 drops.
3. Mild(+)- It will consider being mild if the bleeding is streaking to stool or less than 10 drops.
4. Absent(0)- It will be considered to absent if the patient will have no bleeding during defecation.

- **Haemoglobin percentage Hb%**

For the sake of objective assessment of bleeding per rectum the HB% before treatment and the last follow up was recorded.

Criteria for overall assessment

1. Cured- Decrease in the degree of hemorrhoids after the treatment i.e. on the 7th or 14th day then the patient will be considered as cured.
2. Improved- Decrease in degree of Hemorrhoid after completion of treatment but significant decrees in bleeding, pruritis, then the patient will be considered as improved.
3. Non-improved- No any decrease in the degree of hemorrhoids then the patient will be considered as non-improved.
4. Complicated- Development of any complication such as Severe bleeding & pain along with hypersensitivity reaction to
5. Sooranadi Malhara then the patient will be considered as complicated.

OBSERVATION AND RESULT

60 patients of Arsha were registered for this clinical study. They were treated in two groups as Sooranadi Malhara(trial group) and Pipplyadi Malhara (control group).

The data collected from the study was analyzed under two headings:

1. Demographic Data
2. Clinical Data

1. Demographic data

Frequency analysis was done for the following data elements.

1. Age
2. Gender
3. Diet
4. Addiction
5. Habitat
6. Work

2. Clinical data

Frequency analysis was done for the following data elements.

1. Degree of Hemorrhoids
2. Per rectal Bleeding
3. Pruritis
4. Position of Hemorrhoid

Frequency Analysis

I. Age wise distribution of patient data.

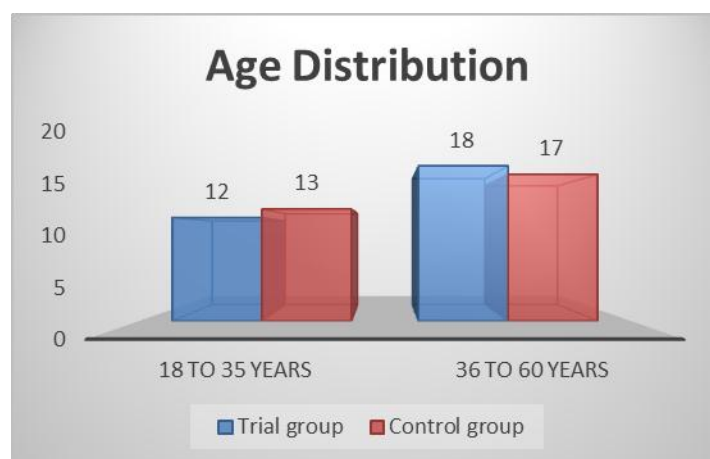
The patients were classified into 2 groups on the basis of their age.

1. Age ranges from 18 to 35 years
2. Age ranges from 36 to 60 years

Frequency calculation table is as below.

1. Age wise distribution of patient data.

Age	Control group		Trial group		Total	
	No. of patient	%	No. of patient	%	No. of patient	%
18-35 years	12	40%	13	43.33%	25	41.66%
36-60 years	18	60%	17	56.66%	35	58.33%
Total	30	100%	30	100%	100%	100%



Observation

1. In Trial Group

Age wise distribution of patients showing that 12(40%) patients were in the age group of 18 to 35 years and 18(60%) patients were in the age group of 36 to 60 years.

2. In Control Group

Age wise distribution of patients showing that 13 (43.33%) patients were in the age group of 18 to 35 years and 17(56.66%) of patients were in the age group of 36 to 60 years.

3. In both Group

Overall within 60 patients, 25(41.66%) patients were in the age group of 18 to 35 years and 35(58.33%) patients were in the age group of 36 to 60 years.

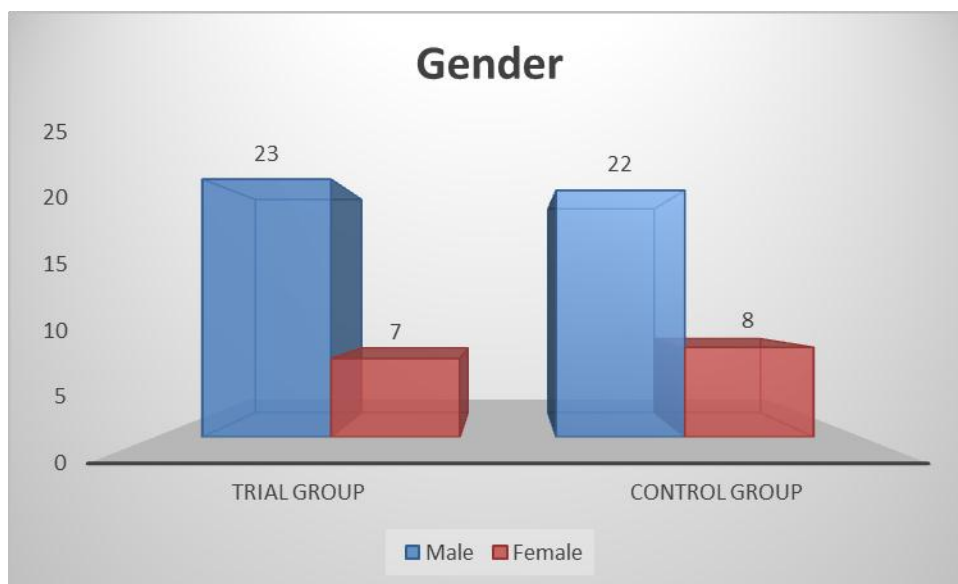
II. Gender wise distribution of patient data.

The patients were classified into two groups on the basis of gender

1. Male

2. Female

Gender	Trial group		Control group		Total	
	No. of patients	%	No. of patients	%	No. of patients	%
Male	23	76.666%	22	73.33%	45	75%
Female	07	23.33%	08	26.66%	15	25%
Total	30	100%	30	100%	60	100%



Observation

1. In Trial Group

In trial group, 23(76.66%) patients were male and 07(23.33%) patients were female.

2. In Control Group

In control group, 22(73.33%) patients were male and 08(26.66%) patients were female.

3. In Both Groups

Out of total 60 cases, incidence of Arsha is observed in 45(75%) male and in 15(25%) female patients.

3.A) Diet wise distribution of patient data.

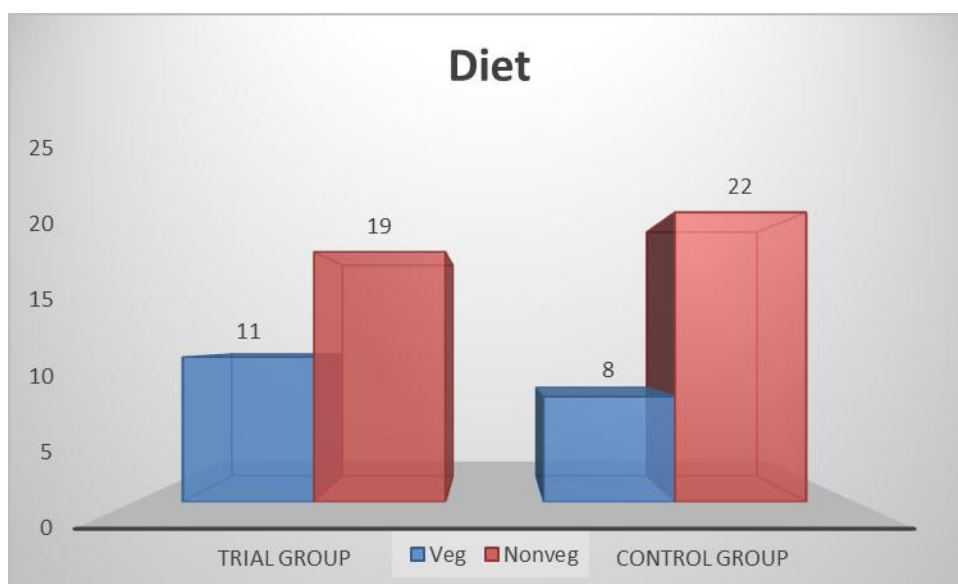
The patients were distributed in two groups as.

A. Veg and Nonveg

B. Spicy and Nonspicy

Table no. Showing Veg non veg diet wise patient data.

Veg/Non ve	Trial group		Control group		Total	
	No. of patients	%	No. of patients	%	No. of patients	%
Veg	11	36.66%	08	26.66%	19	31.66%
Non vegetarian	19	63.33%	22	73.33%	41	68.33%
Total	30	100%	30	100%	60	100%

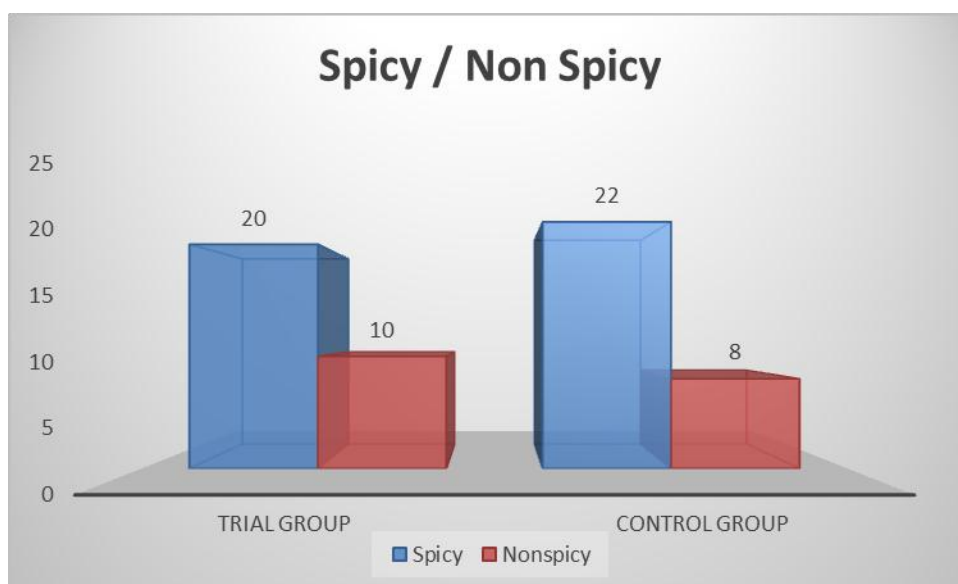


Observation

1. In Trial Group
 2. In trial group, 11(36.66%) patients were vegetarian and 19(63.33%) patients were Non-vegetarian.
 3. In Control Group
 4. In control group, 08(26.66%) patients were vegetarian and 22(73.33%%) patients were non-vegetarian.
 5. In Both Groups
 6. Out of total 60 cases, 19(31.66%) patients were vegetarian and 41(68.33%%) non-vegetarian patients.
- b) Diet wise distribution of patient data.

Table no: Showing Spicy / nonspicy diet wise patient data.

Spicy/Non spicy	Trial group		Control group		Total	
	No.of patients	%	No. of patients	%	No. of patients	%
Spicy	20	66.66%	22	73.33%	42	70%
Non spicy	10	33.33%	08	26.66%	18	30%
Total	30	100%	30	100%	60	100%



Observation

1. In Trial Group

In trial group, 20(66.66%) patients were taking spicy diet and 10(33.33%) patients were taking non spicy diet.

2. In Control Group

In control group, 22(73.33%) patients were taking spicy diet and 08(26.66%) patients were taking nonspicy diet.

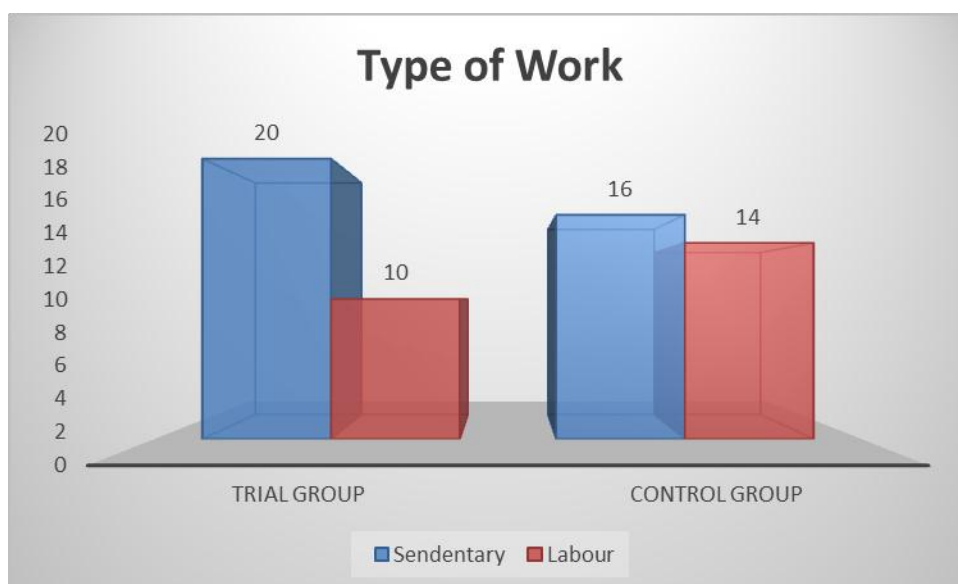
3. In Both Groups

4. Out of total 60 cases, 42(70%) patients were taking spicy diet and 18(30%) patients were taking non spicy diet.

4.Type of work wise distribution of patient data.

Table no. Showing work wise patient data.

Type of work	Trial group		Control group		Total	
	No. of patients	%	No. of patients	%	No. of patients	%
Sedentary	20	66.66%	16	53.33%	36	60%
Labour	10	33.33%	14	46.66%	24	40%
Total	30	100%	30	100%	60	100%



Observation

1. In Trial Group

In trial group, 20(66.66%) patients were doing sedentary type of work and 10(33.33%) patients were doing labour type of work.

2. In Control Group

In control group, 16(53.33%) patients were doing sedentary type of work and 14(46.66%) patients were doing labour type of work.

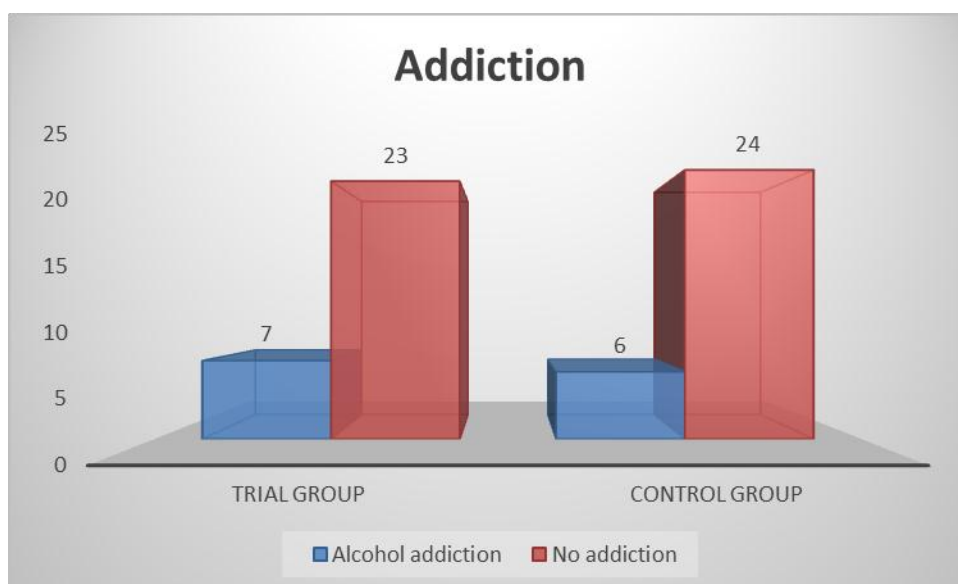
3. In Both Groups

Out of total 60 cases, 36(60%) patients were doing sedentary type of work and 24(40%) patients were doing labour type of work.

5.A) Addiction wise distribution of patient data.

Table no. Showing alcohol addiction wise patient data.

Addiction	Trial group		Control group		Total	
	No. of patients	%	No. of patients	%	No. of patients	%
Alcohol addiction	07	23.33%	06	20%	13	21.66%
No addiction	23	76.66	24	80%	47	78.33%
Total	30	100%	30	100%	60	100%



Observation

1. In Trial Group

In trial group, 07(23.33%) patients were alcohol addicted and 23(76.66%) patients were non alcoholic.

2. In Control Group

In control group, 06(20%) patients were alcohol addicted and 24(80%) patients were non alcoholic.

3. In Both Groups

Out of total 60 cases, 13(21.66%) patients were alcohol addicted and 47(78.33%) patients were non alcoholic.

1. B) Addiction wise distribution of patient data

Table no. Showing tobacco addicted patient data.

Addiction	Trial group		Control group		Total	
	No. of patients	%	No. of patients	%	No. of patients	%
Tobacco	14	46.66%	18	60%	32	53.33%
No addiction	16	53.33%	12	40%	28	46.66%
Total	30	100%	30	100%	60	100%

Observation

1. In Trial Group

In trial group, 14(46.66%) patients were tobacco addicted and 16(53.33%) patients were having no addiction.

2. In Control Group

In control group, 18(60%) patients were tobacco addicted and 12(40%) patients were having no addiction.

3. In Both Groups

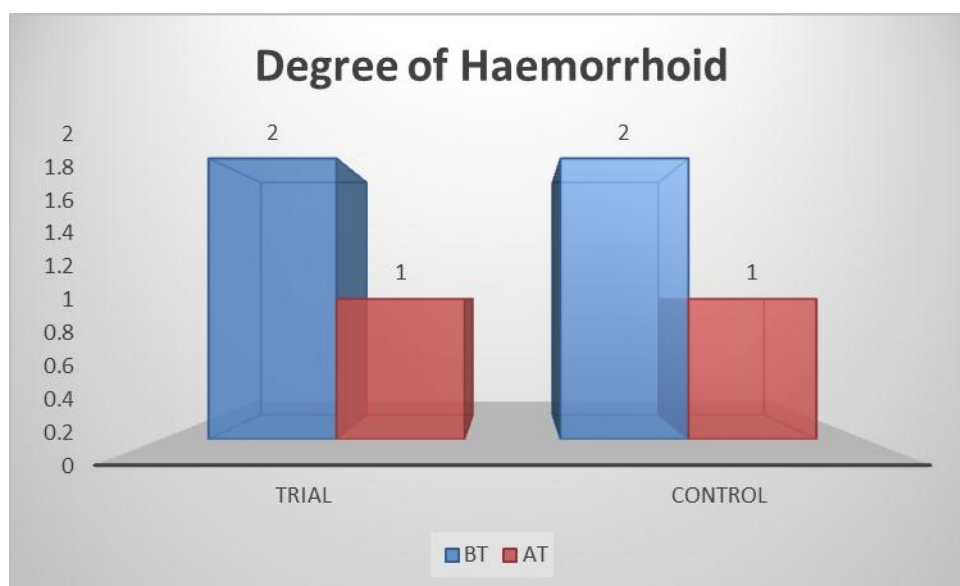
Out of total 60 cases, 32(53.33%) patients were tobacco addicted and 28(46.66%) patients were having no tobacco addiction.

STATISTICAL ANALYSIS

1. Degree of haemorrhoids

Degree of haemorrhoid	Median		Wilcoxon signed Rank W	P value	% Effect	Result
	BT	AT				
Trial	2	1	-4.838 ^a	0.000	54%	Significant
Control	2	1	-5.112 ^a	0.000	50.9	Significant

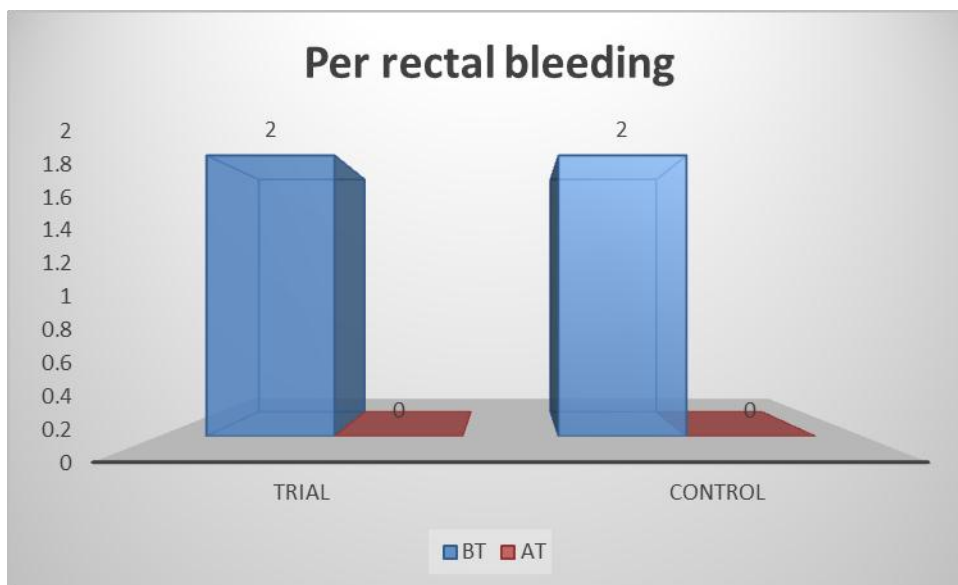
Since observations are on ordinal scale, we have used Wilcoxon Signed Rank test to test the efficacy in Trial Group and Control Group. From above table we can observe that P-Values for Trial Group and Control Group are less than 0.05 hence we conclude that effect observed in both groups are significant.



2. Per rectal bleeding

Per rectal bleeding	Median		Wilcoxon signed Ranked W	P value	% Effect	Result
	BT	AT				
Trial	2	0	-4.939 ^a	0.000	87.0	Significant
Control	2	0	-4.966 ^a	0.000	95.5	Significant

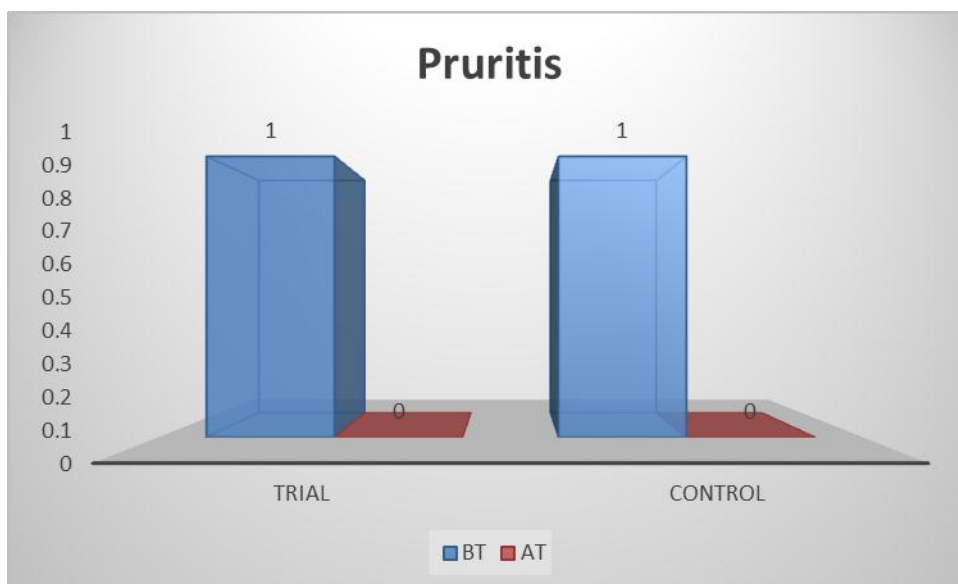
Since observations are on ordinal scale, we have used Wilcoxon Signed Rank test to test the efficacy in Trial Group and Control Group. From above table we can observe that P-Values for Trial Group and Control Group are less than 0.05 hence we conclude that effect observed in both groups are significant.



3. Pruritis

Pruritis	Median		Wilcoxon signed Rank W	P value	% Effect	Result
	BT	AT				
Trial	1	0	-4.899 ^a	0.000	100.0	Significant
Control	1	0	-4.690 ^a	0.000	100.0	Significant

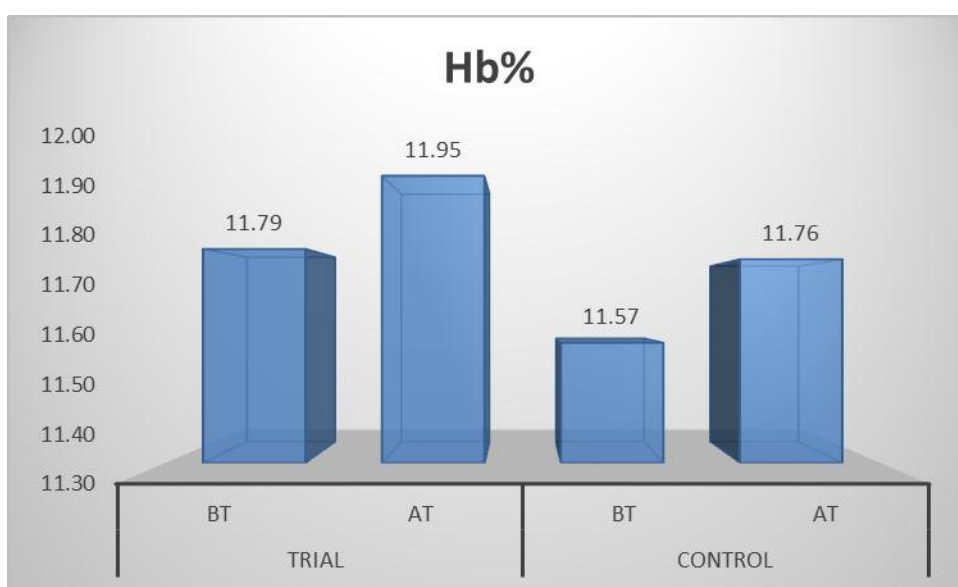
Since observations are on ordinal scale, we have used Wilcoxon Signed Rank test to test the efficacy in Trial Group and Control Group. From above table we can observe that P-Values for Trial Group and Control Group are less than 0.05 hence we conclude that effect observed in both groups are significant.



4.Hb percentage

HB %		Mean	N	SD	SE	t- value	p- value
Trial	BT	11.79	30	1.32	0.24	-4.264	0.000
	AT	11.95	30	1.38	0.25		
Control	BT	11.57	30	1.09	0.20	-3.001	0.005
	AT	11.76	30	1.15	0.21		

Since observations are quantitative, we have used paired t-test to test the efficacy in Trial Group and Control Group. From above table we can observe that P-Values for Trial Group and Control Group are less than 0.05 hence we conclude that effect observed in both groups are significant.



DISCUSSION

Total 60 well diagnosed patients suffering from Ist and IInd internal hemorrhoids were included in the study. The maximum incidence of Arsha in men of age 18-35 and 36-60 years was observed i.e more prevalent in adult and old age group. The male sex prevalence may be due to hemorrhoid disease precipitating dietary habit and addiction. Only 15 female patients were participated out of 60 patients, the less number of female patients could be due to ignorance and shyness.

As regards of diet, those patients taking mix and spicy diet were suffered than taking vegetarian and non spicy diet. This may because of nonveg and spicy food more prone to develop constipation, eventually leads to pressure on anal vascular system, provoking dilatation of hemorrhoidal vessels. Hard stool having fraction of anal congested hemorrhoid mass and produces symptomatic mass and thus produces symptomatic hemorrhoid. Regularization of dietary habit along with avoidance of constipation and friction by stool softening agent is having their own importance. Therefore ideal dietary regimen and stool softening agents advised in both groups. The patients were also included according to Habit, out of 60 patients 32 patients had tobacco chewing addiction, 13 patients had alcohol consumption, 12 patients had both tobacco and alcohol addiction and 15 patients had no any type of addiction. This observation shows that those patients having same type of habit were more prone to develop internal hemorrhoid.

The cases also analysed according to type of work is suggest that those patients having sedentary type of work or lifestyle were more prone to internal hemorrhoid than those having non sedentary or labour work. The sedentary worker having maximum prevalence because they have more tendencies to develop 'Habitual constipation', therefore change in lifestyle was advised to these patients. Observation regarding no. of hemorrhoid and position of hemorrhoid shows that maximum patients having one and two on hemorrhoid and and 11 o'clock was the most common position of hemorrhoid. As per present clinical study was carried out between two well established and accepted modalities. The statistical analysis of the observational parameters clears that both the modalities decreases size, per rectal bleeding.

Mode of action of both the treatments**Pippalyadi malahara(ointment)**

Pippalyadi malahara is an effective Ayurvedic regimen as far as the management of Abhyantara Arsha was considered the probabal mode of action of drugs due to its ingradients such as Pippali, Sandhava, Kustha, Shirish, Snuhikshir. These all ingradients works as per its Rasa, Virya, Vipaka, and its Guna, Karma. Pippali having Katu rasa causes Lekhan, Kshanan, and Kshapan properties reduces the size of pile mass. The medicinal patency of these drugs can be enhance by synergistic drug Saindhava having Sukshma Srotogamitva and Vikasi properties help in proper application and action of drug. Kushtha drug having Katu rasa help as Lekhana karma reduces size of pile mass, also having Raktashodhakn karma help in purification of blood. Shirisha having Tikta rasa having Shodhana property, also Kandughna karma relieves priritis. Snuhikshir is effective as per its Raktashodhana, Lekhaniy, Vedanasthapan karma reduces pile mass, localized infection and pain.

So all these drugs togatherally help like reduces pile mass, pruritis and per rectal bleeding. And very effective as a local application in the form of of Malahara (ointment).

Soornadi malahara(ointment)

Soornadi malahara was prepared by ingradients such as Soorana, Haridra, Tankana, Guda and Kanji. Soorana is very effective as its Arshoghna property. Soorana is Katu rasatmak having Lekhaniya, Pachaniya, Dipaniya and Krimighna karma in reduction of dilatation of veins and pile mass. Haridra (Rajni), is a Tikta rasatmaka having raktadoshahara, Shothahara, Vranaropana, Dipana, Vishaghna, relieves Raktadushti, reduces localized pile mass infection and relieves pruritis and also stop per rectal bleeding. Chitraka is a Katurasatmaka having Lekhaniya, Pachaniya, Shothahara properties help in reduction of pile mass. Tankana (Borax) is mineral component is Katu, Ushna, Tikshana, properties help in reduction of pile mass. Guda and Kanji having Raktshodhan Properties.

In both group for preparation of malahara (ointment) Petroleum jelly was used as a base to make topical ointment.

In overall assessment reduces digree of haemorrhoids, per rectal bleeding and pruritis in both modality treatment was equally effective.

Both the modalities reduce PR bleeding and significantly reduces on 0- 21th day. Therefore the overall effect of Pippalyadi and Soornadi malahara improved the HB% of patient by reducing per rectal bleeding. The effect of both drugs having healing and local soothing action over the tissue. As per as pruritis in ano considered it was reduced significantly on 2nd and 3rd follow up in both groups.

According to result of treatment in group i.e Pippalyadi malahara(ointment) 17 patients were completely cured, 10 patients having improvement and 03 patients were uncured. In group i.e Soornadi malahara(ointment) 19 patients were completely cured, 08 patients showed improvement and 03 patients were uncured out of 30 patients.

CONCLUSION

There is significant improvement in all the objective parameters in both the groups. But there is no significant difference between two groups. But degree of hemorrhoid is significantly reduced by Soornadi malahara (ointment) Finally it is concluded that Soornadi malahara and Pippalyadi malahara is equally effective on internal hemorrhoids.



Image no.1 (Before treatment)



Image no.2 (After treatment)

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