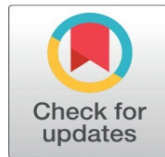
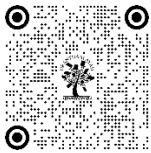


# A CLINICAL STUDY TO EVALUATE THE EFFICACY OF DARUHARIDRA-NIMBA MALHAR (LOCALLY) ALONG WITH PANCHASAMCHURNA-VATI (INTERNALLY) IN THE MANAGEMENT OF ABHYANTAR GUDARSHA W.S.R. TO GRADE II INTERNAL HAEMORRHOIDS

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## ABSTRACT

Haemorrhoid is one of the prime important diseases of ano rectal disorder. In Ayurveda, it can be co-related with Gudarsha. In modern science, haemorrhoids are managed by lifestyle-diet modification, topical preparations, internal medicines and surgical procedures like Sclerotherapy, rubber band ligation, Laser therapy, Haemorrhoidectomy etc. with varied prognosis and complications. Acharya Sushruta has mentioned four different treatment modalities for management of Arsha (Haemorrhoids). Further, Bhashaj Chikitsa (Palliative medicine) is used for conservative management of Grade II Internal Haemorrhoids effectively. Hence, to establish a palliative treatment for Abhyantar Gudarsha, the open single arm clinical study had been carried on 50 patients. These patients were treated with specific regimen- Daruharidra-Nimba Malhar (Locally) at anal region twice daily for 15 days along with Panchasamchurna-Vati (Internally) for 28 days. Therapeutic efficacy of the regimen was evaluated by assessing the parameters such as Pain, Bleeding per rectum, Constipation, Colour and Size of pile pedicle before, during and after the treatment.

The present clinical study revealed that, the prescribed combination therapy proved effective in reducing symptoms of Abhyantar Gudarsha such as pain, per rectal bleeding, constipation, colour and size of pile pedicle in desired 28 days.

**Keywords:** Haemorrhoids, Gudarsha, Panchasam churna, Daruharidra, Nimba

## 1. INTRODUCTION

Haemorrhoids are the common ano-rectal disease found in the proctology. In Ayurveda, it can be co-related with Gudarsha. Acharya Sushruta has included Gudarsha under Ashtamahagada vyadhi [1]. Haemorrhoids are masses or clumps of tissues which consists of muscles and elastic fibre with enlarged, bulging, blood vessel and surrounding supporting tissues present in the anal canal of an individual [2]. The symptoms includes prolapsed of an anal cushion with bleeding and pain at anal region. The causative factors are congenital, anatomical, pregnancy, sedentary lifestyle, constipation, enlarge prostate, asthma, irregular diet, prolonged standing or sitting, certain psychological disturbance

etc[3,4]. Haemorrhoids are one of the most common anorectal disorders with a reported prevalence of 4.4% up to 36.4% of general population [5]. The peak prevalence occurs between 40 and 65 years of age [6, 7].

The modern treatment includes diet and lifestyle modification, internal medicines, topical preparation and Surgical procedure such as rubber band ligation, sclerotherapy, cryosurgery, LASER treatment Haemorrhoidectomy, DGHAL etc in advanced stage with varied prognosis and untoward effects [8]. Moreover, Haemorrhoid surgery also have high recurrence rate, fear of bleeding, faecal incontinence and poor acceptability amongst the patients [9].

According to Sushruta, if non self-possessed person continuously practices unsalutary lifestyle, use of incompatible foods, continuous sitting on hard surface, overeating, indulge strenuous work-exercise, which leads vitiation Vata dosha and Jatharagni, this vitiated Vata gets aggravated either individually or in combination of two or all three or together with blood, spread out and travels through the Pradhan dhamani in the downward direction reaching the guda and produce mamspraroha in gudavali i.e. Gudarsha[10]. Acharya Sushruta has advocated four different treatment modalities such as Bhesha, Ksharkarma, Agni karma and Shastrakarma [11]. Various Ayurvedic anecdotal studies on conservative management of internal hemorrhoids have been conducted which includes various internal herbal preparations aiming to pacify like Agnimandya along with Vatanuloman, Malasarak drugs and local ointments or Basti Chikitsa, however they have varied prognosis and certain limitations [12, 13].

Hence, the present clinical study was carried out to evaluate the therapeutic efficacy of Daruharidra-Nimba Malhar (locally) and Panchasamchurna Vati (internally) in the management of Abhyantar Gudarsha w.s.r to Grade II Internal Haemorrhoids.

## 2. MATERIALS AND METHODS

This was an open, single arm, prospective clinical study. The study had been carried on selected total 50 patients who were diagnosed with Grade II Internal Haemorrhoids. The source of data was taken from D.Y Patil Ayurvedic Hospital, Navi Mumbai, OPD No- 03, Shalyatantra department. Ethical clearance had been taken from ethical committee of D.Y Patil Ayurvedic Hospital. The CTRI registration was done prior to enrol the patients for this study. An understanding was given to the patients about trial and an informed written consent had been taken from the patient prior to participate in the study. The patients had also understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

### 2.1. SELECTION OF CRITERIA

We had included the patients who were randomly selected and diagnosed with second degree Internal Haemorrhoids, the age group between 25-60 years (irrespective of gender) and all cases were fresh/new who didn't receive any local treatment. We had excluded patients having 3rd degree prolapsed thrombosed haemorrhoid piles, patients having diabetes, malignancies, HIV, HBsAg and VDRL positive, post-operated (post haemorrhoidectomy) patients, pregnant women and the patient diagnosed with Ca Rectum.

### 2.2. TRIAL DRUG AND DOSE WITH DURATION

- Local application of Daruharidra-Nimba Malhar with the help of applicator BD for 15days(In the morning post defecation and at night)
- Panchasamchurna-vati - 4 tablet (500mg each) BD for 28 days with Luke warm water after food.

Total duration of study was 28 days.

**Dietary regimen:** Diet plays a very important role in development of haemorrhoid. All patients were advised to take plenty of water and high fibrous diet. Patients were also advised to avoid spicy food, bakery food items etc.

**Diagnostic criteria:** The patient was clinically diagnosed with the help of video proctoscope.

**Laboratory investigations:** Before starting the treatment, essential blood investigation were carried out such as CBC, Blood Sugar (Fasting & Post Prandial), BT, CT, LFT, HIV and HBsAg.

**Follow-up:** Patients were called for follow-up on day 1st, 3rd, 5th, 7th, 14th, 21st and 28th day of treatment.

**CTRI registration number:** CTRI/2023/05/053298

**Assessment parameter:** The therapeutic evaluation was done by assessing parameter such as pain, P/R bleeding, constipation, colour of pile pedicle and size of pile pedicle. The assessment parameters are mentioned in following table.

**Table 1** Assessment Parameter

PARAMETER	GRADATION	SCORE	
PAIN (As per VAS Scale)			
	No Pain	0	0
	Mild	1-3	+
	Moderate	4-6	++
	Severe	7-10	+++
CONSTIPATION			
	Minimal or no effort to defecate	0	0
	Mild effort or straining required to defecate	1	+
	Moderate or straining required to defecate	2	++
	Unable to defecate despite maximum effort or straining	3	+++
P/R BLEEDING			
	Baseline	+++	
	50% of baseline	++	
	75% of baseline	+	
	No bleeding	0	
SIZE OF PEDICLE			
	Size resembling the of groundnut or larger than groundnut	+++	
	Size resembling the size same as pea nut	++	
	Size resembling the size smaller than peanut	+	
	No of pile visualized	0	
COLOUR OF PILE PEDICLE			
	Bluish or Blackish colour	+++	
	Reddish colour	++	
	Pinkish colour	+	
	Colour resembling that of Mucosa	0	

### 3. OBSERVATION

This single arm prospective clinical study was carried out on total 50 patients by simple random method of selection. Abhyantar Gudarsha was seen more common in age group between 41 -50 years, where as it was less common in the age group of 25-30 years. The incidence of haemorrhoid was seen more in male i.e. 62 % whereas considerably less in females i.e. 38%. Maximum patients were belonging to service class i.e. 66%, having mixed diet i.e.78% and 56% were of Pitta Pradhan Kapha prakruti. In this clinical study, maximum patient (42%) were having mild to moderate pain at anal region during defecation,46% were having moderate per rectal bleeding whereas 44% patients having severe bleeding. The number of patients having mild constipation were 16%, moderate constipation 56% and 28% patient were having severe constipation .Further, the number of patients were having size of haemorrhoid same as peanut (78%) while maximum number of patients (66%) were having reddish colour of pile pedicle.

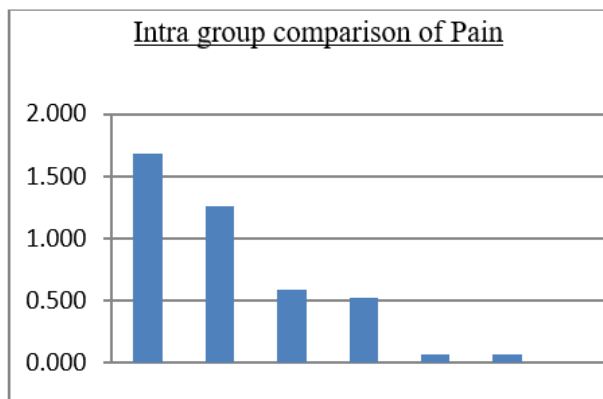
### 4. RESULTS

During study, the obtained data was an ordinal scale (i.e. base on gradation) observed at specific interval of time. So, for overall intragroup comparison, we had used Friedman test and for pair wise comparison, Wilcoxon signed-ranks test had been used statistically to observe the efficacy of Daruharidra Nimba Malhar (Locally) and Panchasamchurna Vati (Internally) in the management of Abhyantar Gudarsha w.s.r. to Grade II Internal Haemorrhoids.

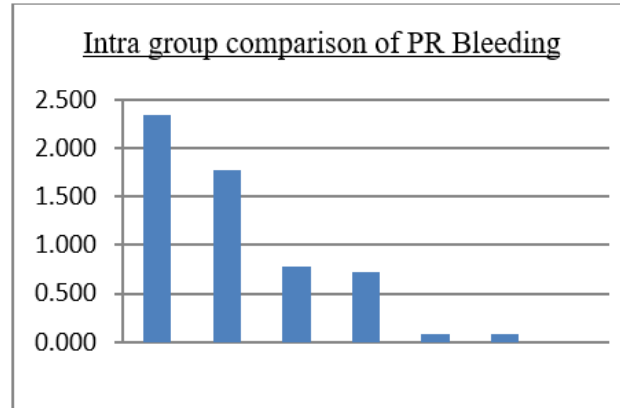
**Table 2:** Shows statistical analysis of all parameters.

PARAMETER	Statistical Analysis	DARUHARIDRA –NIMBA MALHAR & PANCHASAMCHURNA VATI						
		Day 1	Day 3	Day 5	Day 7	Day 14	Day 21	Day 28
PAIN	Median	2.00	1.00	1.00	0.00	0.00	0.00	0.00
	Range	0-3	0-3	0-2	0-2	0-1	0-1	0-0
	No. of Pairs	50						
PR Bleeding	Median	2.00	2.00	1.00	1.00	0.00	0.00	0.00
	Range	1-3	0-3	0-2	0-2	0-1	0-1	0-0
	No. of Pairs	50						
Constipation	Median	2.00	1.00	1.00	1.00	0.00	0.00	0.00
	Range	1-3	0-2	0-2	0-2	0-2	0-2	0-1
	No. of Pairs	50						
Colour of Pile Pedicle	Median	2.00	2.00	1.00	1.00	0.00	0.00	0.00
	Range	1-3	1-2	0-2	0-2	0-1	0-1	0-0
	No. of Pairs	50						
Size of Pile Pedicle	Median	2.00	2.00	1.00	1.00	0.00	0.00	0.00
	Range	1-3	1-3	0-2	0-2	0-1	0-1	0-0
	No. of Pairs	50						

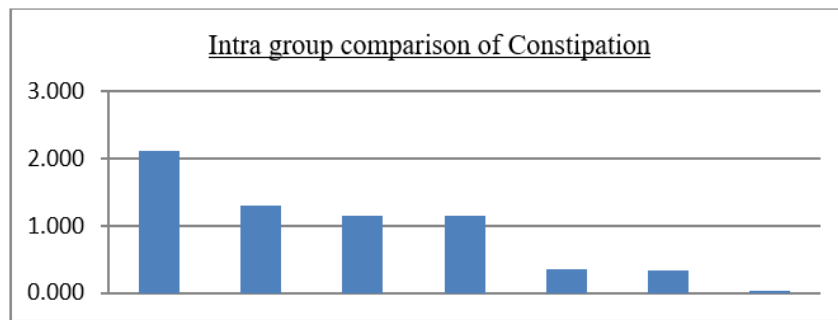
**Graph 1** Intra group comparison of Pain



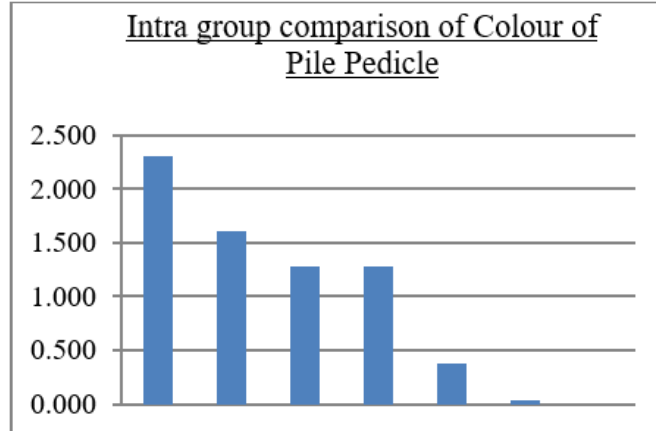
**Graph 2** Intra group comparison of PR Bleeding



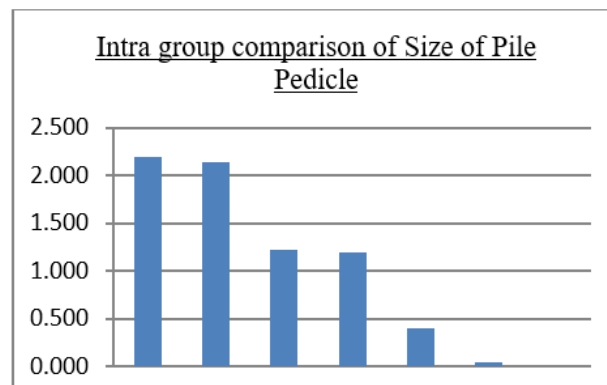
**Graph 3** Intra group comparison of Constipation



**Graph 4** Intra group comparison of Colour of Pile Pedicle



**Graph 5** Intra group comparison of Size of Pile Pedicle



**Table 3** Overall assessment of all parameters

PARAMETER	RANGE		MEAN VALUE		MEDIAN VALUE		P VALUE
	BEFORE TREATMENT	AFTER TREATMENT	BEFORE TREATMENT	AFTER TREATMENT	BEFORE TREATMENT	AFTER TREATMENT	
PAIN	0-3	0-0	1.680	0.000	2.000	0.000	0.000** Highly Significant
P/R BLEEDING	1-3	0-0	2.340	0.000	2.000	0.000	0.000** Highly Significant
CONSTIPATION	1-3	0-1	2.120	0.040	2.000	0.000	0.000** Highly Significant
COLOUR OF PILE PEDICLE	1-3	0-0	2.300	0.000	2.000	0.000	0.000** Highly Significant
SIZE OF PILE PEDICLE	1-3	0-0	2.200	0.000	2.000	0.000	0.000** Highly Significant

On first day, minimum range of pain was 0; maximum range 3 and median was 2.00. On 14th day, minimum range of pain was 0, maximum range of pain was reduced to 1 and median value was 0. After completion of treatment on 28th day minimum range of pain was 0, maximum range of pain was completely reduced to 0 and median value was to 0.

On first day, minimum range of P/R Bleeding was 1, maximum range 3 and median was 2.00. On 14th day, minimum range of P/R Bleeding was 0, maximum range of P/R Bleeding was reduced to 1 and median value was completely reduced to 0. After completion of treatment on 28th day minimum range of P/R Bleeding was 0, maximum range of P/R Bleeding was completely reduced to 0 and median value was to 0.

On first day, minimum range of constipation was 1, maximum range 3 and median was 2.00. On 14th day minimum range of constipation was 0, maximum range of constipation was 2 and median value was completely reduced to 0. After completion of treatment on 28th day minimum range of constipation was 0, maximum range of constipation was reduced to 1 and median value was to 0.

On first day, minimum range of colour of pile pedicle was 1, maximum range 3 and median was 2.00. On 14th day minimum range of colour of pile pedicle was 0, maximum range of colour of pile pedicle was reduced to 1 and median value was completely reduced to 0. After completion of treatment on 28th day minimum range of colour of pile pedicle was 0, maximum range of colour of pile pedicle was completely reduced to 0 and median value was 0.

On first day, minimum range of size of pile pedicle was 1, maximum range 3 and median was 2.00. On 14th day minimum range of size of pile pedicle was 0, maximum range of size of pile pedicle was reduced to 1 and median value was completely reduced to 0. After completion of treatment on 28th day minimum range of size of pile pedicle was 0, maximum range of size of pile pedicle was completely reduced to 0 and median value was to 0. [Figure 1 – Case 1 before & after treatment]

A highly significant result was obtained when the Wilcoxon signed-ranks test was statistically applied for pair wise comparison and the p value was less than 0.0001.



**Figure 1** Case before & after treatment

## 5. DISCUSSION

In Ayurveda, Haemorrhoid can be co-related with Gudarsha and it is the most common ano rectal disease. Arsha is a very distressing for patient and poor prognosis, Acharya Sushruta has included Gudarsha in Ashtomahagada vyadhi. The established modern treatment includes diet and lifestyle modification, sclerotherapy, rubber band ligation, LASER treatment, and surgical alternative such as Haemorrhoidectomy etc. with varied prognosis. Similarly, Ayurvedic treatment includes Agnideepan, Pachan, Vatanuloman, Raktastambhak and Malasarak chikitsa. Moreover, there is no assured and unanimously established palliative line of treatment for Arsha. Hence, we had prepared Daruharidra-Nimba Malhar as per snehpak kalpana and malhar kalpana [14,15,16] for local application adjuvant to Panchasamchurna vati – internally. This combination treatment helped to reduce P/R bleeding, reduce the size of pile pedicle, and colour of pile mass changed to normal. Similarly, the internal medicine pacified Agnimandya and helped in smooth defecation. Thus, proved an effective, safe and user-friendly, affordable and acceptable regimen [17].

In the present study, the incidence of Gudarsha disease was found more among the age group of 41-50 years, male patients, occupation wise in-service people, Hindu religion, patients having mixed dietary habits, Pitta Pradhan Kapha prakruti with mandagni, moderate constipation and in the individuals indulging in sedentary life style.

In this clinical study, maximum patients (42%) were having mild to moderate pain at anal region during defecation. Due to Vednasthapan, shothaghna properties of Daruharidra Nimba malhar, it helps to reduce the size of pile mass and inhibits pain sensation. Similarly, the oral medicine Panchasamachurna vati helps in smooth evacuation of stools and reduces pain.

In this present study, maximum patients (46%) were having moderate bleeding whereas 44% patients having severe per rectal bleeding. Daruharidra-Nimba malhar reduces bleeding due to its Raktastambhana, Shothahara, Vranashodhana and Vranaropana properties. Panchasamchurna vati helps in relieving constipation and Agnimandya which further helps to avoid the excessive pressure on haemorrhoidal cushion.

In this present study, maximum numbers of patients (56%) were having moderate constipation and 28% patients were having severe constipation and 16% patient having mild constipation. Unsalutary food habits, sedentary life style; suppression of natural urges, Virudhaahara, Adhyashana etc. leads to Agnimandya which results in constipation.

In this present study, maximum numbers of patients were having size of haemorrhoid same as peanut (78%) while maximum number of patients (66%) were having reddish colour of pile pedicle. This study was related only Grade II Internal Haemorrhoids. Thus, no other degrees of haemorrhoid masses were to be found in these patients. Daruharidra-Nimba malhar has shothahara, Vranashodhana and Vranapachana properties which help to reduce size and colour of pile pedicle.

In present clinical data, the relief in constipation was assessed via gradation of symptoms and noted accordingly. Panchsama churna vati contain Shunthi, Pippali and Haritaki which has Deepana, Pachana, and Anuloman properties helps to relieve Agnimandya which is the root cause of haemorrhoid. Further, Haritaki has Mrudu rechak and Trivrit has Sukhavirechan properties which helps in smooth act of defecation.



### **Probable mode of action of intervention**

#### **1) Daruharidra -Nimba Malhar**

The main ingredients used in Daruharidra-Nimba Malhar are Daruharidra kand and Neem leaves. Daruharidra has tikta- kashaya rasa, ushna veerya, katu vipaka and Raktastambhana, Shothahara, Vedanasthapana, Vranashodhana, and Vranaropana properties [18], it helps in reducing P/R bleeding, pain and size and colour of the pile pedicle. Ushna veerya helped in reducing blood accumulation and helps in prevention of further dilatation of veins and prevents prolapse of regional mucosa of anal canal. Eventually, it helped to reduce size and colour of pile mass.

Similarly, Nimba has tikta-kashay rasa, sheeta veerya and Vranashodhana, Vranapachan Dahaprashaman and Kandughana properties [19], it reduces P/R bleeding, pain and itching at anal region. Similarly, due to sheeta veerya it also helps to heal the mucosa of anal canal.

#### **2) Panchasamchurna-vati**

The ingredients of Panchasamchurna-vati are Shunthi, Haritaki, Pippali, Trivrit and Sauvarchala lavana. Shunthi has katu rasa, ushna veerya and madhur vipaka with arshoghna, deepan-pachan, rochan, shooleprashaman, vatanuloman, aampachak properties [20]. Haritaki is panchrasatmak (Kashaya Pradhan) with ushna veerya. It has deepana pachana, anuloman, and krimighna and Mrudurechan properties [21]. Pippali has katu rasa, teekshna guna; Anushna veerya with madhur vipaka and vatanuloman, krimighna, and raktashodhak properties [22]. Trivrit has tikta-katu rasa and ushna veerya and acts as Sukhavirechan [23]. Sauvarchala lavana has laghu -vishad guna, ushna veerya and katu vipaka and ruchipradm and deepaniya properties [24].

Due to deepana, pachana, vatanuloman properties of Panchasamchurna-vati, it helps to relieve Agnimandya and Constipation which is the root cause of Gudarsha, to break the pathogenesis(samprapti).

It is stated that Arsha is congestion of vein &Katu rasa relieves its congestion. Ushna veerya, laghu and tikshna guna helps the blood to flow in a regular manner without any congestion at veins and reduce inflammation. Hence, it helps to reduce colour and size of pile pedicle [25].

## **6. CONCLUSION**

In this clinical study, 50 patients clinically diagnosed with Grade II Internal Haemorrhoid were treated with special combination regime i.e. Daruharidra –Nimba malhar locally for 15 days and Panchasamchurna vati 500 mg 4 tablets BD for 28 days.

The combination treatment proved efficacious in reducing symptoms of Grade II Internal Haemorrhoid such as pain 98%, P/R bleeding100%, constipation 96 %, colour and size of pile pedicle100% completely in maximum 28 days.

Further, Daruharidra-Nimba malhar proved disposable, safe, cost effective, user-friendly formulation for local application in Grade II Internal Haemorrhoid. Similarly, adjuvant Panchasamchurna vati helped in decreasing the size of haemorrhoidal mass, relieved Agnimandya and Constipation which is the important cause of Gudarsha.

The overall assessment revealed that Daruharidra-Nimba malhar locally along with Panchasamchurna-Vati internally is found to be significantly effective in the management of Grade II Internal Haemorrhoids. However, the study on larger sample size, histo-pathological study to know exact action of malhar on mucosa, effect of Daruharidra-Nimba oil for Matrabasti, and adding Kshar for improving its potential can be undertaken for further future study.

## **CONFLICT OF INTERESTS**

None.

## **ACKNOWLEDGMENTS**

None.



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