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A clinical study to evaluate the efficacy of Chincha Kshar malhar (locally) along with Suranpindi vati (internally) in the management of abhyantar Gudarsha w.s.r. to Grade I & II internal Haemorrhoids

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#### **Abstract**

**Background:** Internal haemorrhoid can be correlate with *Abhyantar Gudarsha*. The symptoms of *Gudarsha* are *ankura* in guda vali region along with pain in anal region and *raktasrava* through anal opening and *kosthabaddhata* and it has been included in *Ashtamahagada*. Sushruta described various types of treatment modalities in the management of *Gudarsha* such as *Bheshaja*, *Ksharkarma*, *Agnikarma* and *Shastrakarma*. *Kshar chikitsa* is effective second line of treatment for *Gudarsha*.

**AIM:** To evaluate the efficacy of *Chincha Kshar malhar* (locally) along with suranpindi vati (internally) in the management of *Abhyantar Gudarsha* w.s.r to grade I and II internal haemorrhoids.

**Methods:** This is a single arm clinical interventional study. Total 50 patients of grade I & II internal haemorrhoid were selected for this study. Patients were treated with *Chincha Kshar malhar* (locally) for 7 days along with *Suranpindi vati* (orally) for 30 days. The parameters such as pain, per rectal bleeding, Constipation, Colour of Pile pedicle and Size of Pile pedicle were observed before, during and after treatment by video proctoscope.

**Results:** Before start treatment on 1<sup>st</sup> day median value of pain was 2.00, which was completely relieved on 7<sup>th</sup> day. On 1<sup>st</sup> day median value of p/r bleeding, constipation, colour of pile pedicle and size of pile pedicle were 2.00, however it showed that on 15<sup>th</sup> day these all parameters were completely relieved and the median value was reduced to 0.

**Conclusion:** This prescribed combination therapeutic intervention proved effective in reducing symptoms of *Abhyantara Gudarsha* such as pain, per rectal bleeding, constipation, colour of pile pedicle, Size of pile pedicle

Keywords: Haemorrhoid, Gudarsha, Chincha Kshar, Suranpindi vati



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#### INTRODUCTION

Haemorrhoids, also called Piles are masses or clumps of tissues which consist of muscle and elastic fibres with enlarged, bulging blood vessels and surrounding supporting tissues present in the anal canal of an individual.<sup>[1]</sup> It is a condition characterized by the prolapsed of an anal cushion that may result in bleeding and pain. In modern medical science, haemorrhoids are managed by least intrusive procedures of surgery like Haemorrhoidectomy extending to procedures such as Band ligation, Sclerotherapy, Laser therapy, Cryosurgery etc. <sup>[2]</sup>

According to ancient Ayurvedic medical science, haemorrhoids can be correlate with Gudarsha. Gudarsha is the common Ano-rectal disease found in the proctology run through. A Gudarsha Ankuras i.e., nodular swelling in the anal area is the characteristic of this disease. Though not disastrous, *Gudarsha* is very distressing for patients and hence called *Mahagada*. Acharya Sushruta has included *Gudarsha* in *Ashtamahagada*.<sup>[3]</sup> Sushruta says that, if nonself-possessed person continuously practices unsalutary lifestyle, use of incompatible foods, continuous siting on hard surface, overeating, indulge strenuous work-exercise, siting on one heel, which leads vitiation *Vata dosha* and derangements of *Jattharagni*, 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 pradhana dhamani (arteries-blood vessels)in the downward direction reaching the guda(rectum) and produce sprouts muscle in gudavali which result into appearance of Gudarsha. [4] The basic lakshana of Gudarsha is ankura in guda vali region along with pain in anal region and raktasrava through anal opening and kosthabaddhata. Great Indian surgeon Acharya Sushruta known as father of surgery narrated four-fold of treatment modalities such as Bheshaja, Kshara, Agni & Shastra for the disease of Gudarsha.<sup>[5]</sup>

There have been many anecdotal studies conducted at various Ayurvedic institutes on conservative management of internal haemorrhoids such as internal herbal preparation aiming to pacify *Agnimandya* (diminished digestive fire), *Vatanuloman* (bowel motality) and *malasarak* (laxative) drugs. <sup>[6,7]</sup> Simillarly, various local treatment such as *Basti chikitsa* (medicated enema) and *arshoghna lepa/malhar* (paste or ointment), however they have varied prognosis and certain limitations. Thus, as there is no assured established palliative management which is unanimously accepted nationwide, this gives us scope for further research in conservative Ayurvedic treatment for internal haemorrhoid. The 2<sup>nd</sup> line of treatment is *Kshar chikitsha*. <sup>[8]</sup> Hence concept of application of *Kshar* by patient himself was presumed and for this purpose ointment of *Chincha Kshar* was selected as *Kshar* ingredient to treat *Gudarsha*. <sup>[9]</sup> The product was named as "*Chincha Kshar malhar*". <sup>[10]</sup> Similarly, in the early stage of the disease, conservative management by local drug administration along with established herbal formulation- *Suranpindi vati* internally is more acceptable palliative treatment. <sup>[111]</sup>

## Aim and Objective



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To evaluate the efficacy of *Chincha Kshar malhar* (locally) along with *Suranpindi vati* (internally) in the management of *Abhyantar Gudarsha* w.s.r to grade I and II internal haemorrhoids.

# **Materials and Methods**

# **Selection of patients**

The patient with grade I & II internal haemorrhoid were registered randomly from Out Patient Department of Shalyatantra, D.Y Patil Ayurvedic hospital. Written informed consent was taken from all patients prior to embarking on the examination and treatment. Findings in each case were recorded over a follow-up of 30 days. A total number of 50 cases were selected irrespective of age, sex, occupation and religion. The study was approved by Institutional Ethics committee. This CTRI registration was done prior enrol these patients for this study. Drug authentication, HPTLC test and antimicrobial test were done.

Inclusion criteria were having Patient of first- and second-degree internal haemorrhoid, age group between 18-60 years and fresh/new cases who didn't receive any local treatment.

Exclusion criteria were having grade III internal haemorrhoid, thrombosed piles and Carcinoma of Rectum Patients having underlying systemic diseases such as Diabetes, Malignancies, HIV, HBsAG and VDRL positive, Post haemorrhoidectomy, Fissurectomy, fistulectomy, Pregnant women and Patient receiving any other local treatment for haemorrhoids.

Withdrawal criteria were development of severe drug reactions, profuse bleeding or any other severe illness.

## Trial drug and duration

Chincha Kshar malhar (locally) once daily after defecation for seven days.

Suranpindi Vati 500mg (internally) 4 tablets twice daily with luke warm water for 30 days.

This clinical treatment period was of 30 days.

# Dietary regimen

Diet plays an important role in development of haemorrhoid. All patients were advised no to intake of spicy food like hot chili, pepper etc. Eating right amount of fibre helps stool from being too hard and causing constipation.

**Diagnostic criteria -** Clinical diagnosis was done with the help of video proctoscope.

**Laboratory investigations -** CBC, Fasting blood sugar, post prandial blood sugar, BT, CT, LFT were carried out before start treatment.

**Follow-up** - Patients were called for follow-up from day 1 to 7<sup>th</sup> day daily and then 15<sup>th</sup>, 22<sup>nd</sup> and 30<sup>th</sup> Day.

## Assessment parameter

For the therapeutic evaluation parameter such as pain, p/r bleeding, constipation, colour of pile pedicle and size of pile pedicle mentioned in table no 1, 2,3, 4 & 5.



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# Table 1: PAIN (Visual Analogue Scale)

PARAMETER	GRADATION	SCORE					
PAIN (As per VAS	No pain	0	0				
Scale)	Mild	1-3	+				
	Moderate	4-6	++				
	Severe	7-10	+++				

# **Table 2:** Per rectal bleeding as per patient complaints

PR bleeding	Grade
Severe bleeding (Baseline)	+++
Moderate bleeding (50% relief)	++
Mild bleeding (75% relief)	+
Complete relief	0

# **Table 3:** Size of pedicle (on proctoscopy)

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

# Table 4: Colour of pedicle

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

# Table 5: CONSTIPATION (VICTORIA BOWEL PERFORMANCE SCALE)

PARAMETER	GRADATION	SCORE



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Control constipation	Minimal or no effort to defecate	0	0
	Mild effort or straining	1	+
	required to defecate		
	Moderate or straining required	2	++
	to defecate		
	Unable to defecate despite	3	+++
	maximum effort or straining		

# **Observation**

Amongst Patients in this clinical study, the incidence of *Gudarsha* disease is more among the age group of 31-40 years, male, serviceman, Hindus, mixed dietary habits, *pitta pradhana vata*, *mandagni* with moderate constipation and in the individuals indulging sedentary life style.

In this present study maximum 42% patient were having mild to moderate pain at anal region during defectaion, 46% patients were having moderate bleeding, 56% were having moderate constipation and 28% patient were having severe constipation, maximum number of patients were having size of haemorrhoid same as peanut and 66% patients were having reddish colour of pile pedicle.

## **Results**

The assessment of the results was made by adopting the standard methods of scoring the signs and symptoms of *Arshas*. [Table 6]

**Table 6:** Shows overall statistical analysis of all parameters

Parameters	G 1	Chincha Kshar malhar along with Suranpindi Vati										
	Statical Analysis	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 15	Day 22	Day 30	AT
PAIN	Median	2.00	1.00	1.00	1.00	0.5	0	0	0	0	0	0
	Range	0-3	0-3	0-3	0-2	0-2	0-2	0-2	0-1	0-1	0-0	0-0
	Total	84	81	63	40	29	27	26	3	1	0	0
	Score											
	No. of	50										
	Pairs											
	P Value	P<0.0	001, Hi	ghly sig	nificant							
PR Bleeding	Median	2.00	2.00	2.00	1.00	1.00	1.00	1.00	.00	.00	.00	.00
	Range	1-3	0-3	0-3	0-3	0-2	0-2	0-2	0-1	0-1	0-0	0-0
	Total	117	114	89	58	39	36	36	4	1	0	0
	Score											
	No. of	50			•					•		
	Pairs											
	P Value	P<0.0001, Highly significant										



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Constipation	Median	2.00	2	1	1	1	1	1.00	.00	.00	.00	.00
	Range	1-3	1-3	0-3	0-2	0-2	0-2	0-2	0-2	0-2	0-1	0-1
	Total	106	106	67	58	58	58	58	18	18	2	2
	Score											
	No. of	50										•
	Pairs											
	P Value	P<0.00	001, Hi	ghly sig	nificant							
Colour of Pile	Median	2.00	2.00	2.00	1.00	1.00	1.00	1.00	.00	.00	.00	.00
Pedicle	Range	1-3	1-3	1-2	0-2	0-2	0-2	0-2	0-1	0-1	0-0	0-0
	Total	115	115	80	65	64	64	64	19	08	00	00
	Score											
	No. of	50										
	Pairs											
	P Value	P<0.00	001, Hi	ghly sig	nificant							
Size of Pile	Median	2.00	2.00	2.00	1.00	1.00	1.00	1.00	.00	.00	.00	.00
Pedicle	Range	1-3	1-3	1-3	0-2	0-2	0-2	0-2	0-1	0-1	0-0	0-0
	Total	110	110	106	60	57	55	51	18	10	00	00
	Score											
	No. of	50										
	Pairs											
	P Value	P<0.0001, Highly significant										

On first day, minimum range of pain was 0, maximum range 3 and median is 2.00 On day 7<sup>th</sup> of treatment, minimum range of pain was 0, maximum range of pain is reduced to 2 and median value is 0. After completion of treatment on 30<sup>th</sup> day minimum range of pain is 0, maximum range of pain was completely reduced to 0 and median value is to 0.

On initial day, minimum range of p/r bleeding was 1, maximum range 3 and median was 2.00. Further, on day 7<sup>th</sup> of treatment, minimum range of p/r bleeding is 0, maximum range of p/r bleeding is reduced to 2 and median value is subsided to 1.00 After completion of treatment on 30<sup>th</sup> day minimum range was 0, maximum range was completely reduced to 0 and median value was 0.

Before starting treatment on first day, minimum range of constipation was 1, maximum range 3 and median is 2.00. On day 7<sup>th</sup> of treatment, minimum range of constipation is 0, maximum range of constipation is reduced to 2 and median value is completely reduced to 0. After completion of treatment on 30<sup>th</sup> day minimum range of constipation is 0, maximum range of constipation is reduced to 1 and median value is to 0.

On first day, minimum range of colour of pile pedicle was 1, maximum range 3 and median is 2.00. On day 7<sup>th</sup> of treatment, minimum range of colour of pile pedicle is reduced to 0, maximum range of colour of pile pedicle is 2 and median value is reduced to 1.00. After



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completion of treatment on 30<sup>th</sup> day minimum range of colour of pile pedicle is 0, maximum range of colour of pile pedicle is completely reduced to 0 and median value is to 0.

On first day, minimum range of size of pile pedicle was 1, maximum range 3 and median is 2.00. However, on day 7<sup>th</sup> of treatment, minimum range of size of pile pedicle is reduced to 0, maximum range of size of pile pedicle is reduced to 2 and median value is reduced to 1.00. After completion of treatment on 30<sup>th</sup> day minimum range of size of pile pedicle is 0, maximum range of size of pile pedicle is completely reduced to 0 and median value is to 0. [Figure 1 & 2]

Figure 1 – Case 1 before & after treatment



Figure 2: Case 2 before & after treatment



# Discussion

In this present study maximum patient (42%) were having mild to moderate pain at anal region during defecation. It is commonly found that internal haemorrhoid is painless still clinically



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patient observed mild to moderate pain specially while straining during defecation. *Chincha Kshar malhar* cauterizes and induce fibrosis in mucosa thus, reduce the size of pile mass and inhibits pain sensation. Similarly, the oral medicine *Suranpindi 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. P/R bleeding associated with bowel movements is the cardinal features of *Gudarsha*. *Chincha kshar malhar* cauterizes the pile mass and ceased the oozing of blood by its sclerosing effect of the *Kshara*.

In this present study, maximum number of patients (56%) were having moderate constipation and 28% patient were having severe constipation. Constipation is the cardinal symptoms of this disease. It is due to *mandagni*, insufficient dietry fibre, rectal mucosal prolapse, Psychiatric disorder, suppression of natural urges, *virudhahara*, *virudhadhyasana*, *avara jarana shakti*. The relief in constipation was assessed via gradation of this symptoms and accordingly it was noted via clinical data in present study. Local application of *Chincha Kshar malhar* starts immediately after contact with tissue of piles. *Kshara* coagulate the protein tissue which in fact causes the local necrosis of pile mass and ultimately, the necrosed tissue leads to fibrosis and thus controls engorgement by fixing mucosa. which resulting in relaxation of anal canal and there was reduction in constipation and thereby straining. Similarly, the ingredient of *Suranpindi vati* such as *Suran*, *sunthi*, *maricha* has *anulomana* action, which support for relieving constipation.

In this present trial maximum number of patients were having size of haemorrhoid same as peanut. This study was including first- and second-degree internal haemorrhoid only, thus no other degree of haemorrhoid masses are to be found in these patients. *Kshar* present in *Chincha Kshar malhar* has properties like *chedana*, *bhedana*, *lekhana* and *tridoshaghna*, *shothahara* which further reduces the size of pile pedicle. Similarly, *Suranpindi vati* has *Ushna*, *tikshna guna* which also helps to reduce the size of *Gudarsha*.

In this present study maximum number of patients (66%) were having reddish colour of pile pedicle. *Chincha kshar malhar* coagulate the haemorrhoid plexus or cauterizes the pile mass, necrosis of tissue with obliteration of haemorrhoidal radicles followed by fibrosis and scar formation which helps to turn the black and reddish colour of pile pedicle to mucosa colour.

## • Probable mode of action of Chincha kshar malhar

Main ingredient used in *Chincha kshar malhar* is *Chincha Kshar*. Chincha kshar is high alkaline in nature having ph 13. Ripen *phal twak* was used to prepare *Chincha kshar*. *Pakwa phala* of *Chincha* has properties like *madhuramla rasa, amla vipak & Ushna virya, tridoshanashak*. It causes cauterization of haemorrhoid plexus and necrosis of tissue followed by fibrosis of plexus, adhesion of mucosal, submucosal coat, which helps in prevention of further dilatation of veins and prevents prolapse of regional mucosa of anus. This makes permanent radical obliteration of Haemorrhoids.

## • Mode of action of Suranpindi vati



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Amongst all ingredient of *Suranpindi vati, Suran has higest in part i.e 8 bhag. Suran* is a very effective herbal drug to treat *Gudarsha*. So, it is the drug of choice in *Gudarsha*. It has properties like *Ushna virya* with *laghu* and *tikshna guna*, which helps the blood to flow in a regular manner without any congestion at veins, reduce inflammation.<sup>[13]</sup>

Ingredients present in this formulation are *Katu ras pradhan* and *ushna virya*, *so they help in* blood accumulation. It is stated that *Arsha* is congestion of vein & *Katu ras* dissolve its congestion. *Chitrak*, *Shunthi* & *maricha are having deepan*, *pachan and vatanulomak guna* due to its *Katu*, *Vipak* and *Ushna virya*. [14]

#### **CONCLUSION**

The disease described as *Gudarsha* in Ayurvedic literature can be regarded as haemorrhoid in modern medical science. The brief description of anatomy and physiology of anorectal region is also found in ancient Ayurvedic literature.

The prescribed combination therapeutic intervention proved effective, cost effective and selfed application of pratisaraneeya kshar by patient. Simillarly, Suranpindi vati which was known as Arshonashini param given orally for 30 days, its rich dietary fibre reduce constipation and improve metabolism. The incidence of *Gudaarsha* disease is more among the age group of above 31-40 years, male, serviceman, Hindus, mixed dietary habits, pittapradhana vata, mandagni with moderate constipation and in the individuals indulging sedentary life style. In this study we used video proctoscope for observation of therapeutic result. It helps us in better visual assessment of treatment. Application of Chincha Kshar malhar was advanced, sterile, cost effective, disposable, safe use of pratisaraneeya Kshar, user-friendly and ambulatory technique. Oral medication of Suranpindi vati having ushna tikshna guna which help to regulate rakta dhatu to flow in regular manner without any congestion at veins and decrease in size of haemorrhoidal mass. Kapha-Vata shamaka properties normalizing the vitiated doshas and thereby alleviating the cause of Raktarsha. This therapeutic intervention (Chincha Kshar malhar locally along with Suranpindi vati orally) of present study proved efficacious result in reducing symptoms of internal haemorrhoid such as pain, p/r bleeding, constipation, colour of pile pedicle, size of pile pedicle completely in maximum 30 days.

**Ethical approval -** The study was approved by Institutional ethical committee of D.Y Patil Ayurvedic hospital.

CTRI registration was done with no CTRI/2022/04/041782.

#### **Declaration of patient consent**

The authors certify that they have obtained patient consent for images and other clinical information to be reported in the journal. The patients 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.

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**Conflicts of interest -** There are no conflicts of interest.



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