

# Clinical Efficacy of Amroid Tablet and Amroid Ointment in the Management of *Arsha* (Hemorrhoids) - A Single-Arm Open-Label Clinical Trial

Tukaram Sambhaji Dudhamal\*

## ABSTRACT

*Arsha* is very common anorectal disease presents with bleeding per rectum, pain in ano, peri anal inflammation, and itching per ano. In modern system, hemorrhoids is defined as abnormal engorgement of vascular anal cushions. Incidence of hemorrhoids increases day-by-day due to poor food habits and lifestyle. There are many medical and surgical methods available for hemorrhoids but now-a-days demand of Ayurvedic herbal preparation is increasing in the society. An open labeled single arm prospective trial were conduct to evaluate the efficacy of Amroid tablet and ointment in cases of *Arsha*, that is, hemorrhoids. Total 144 patients of 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup> degree hemorrhoids were treated with two tablets of Amroid orally thrice a day and Amroid ointment applied locally at per rectal before and after defecation for 4 weeks and patients were follow for 8 weeks. Highly significant ( $P < 0.0001$ ) results were found in Ano-rectal pain, inflammation, bleeding per ano, itching per ano, constipation, prolapsed of piles even after treatment of 1 week, and it sustained throughout follow-up of 8 weeks. This clinical trial concluded that Amroid tablet and Amroid ointment have been potential to cure hemorrhoid up to third degree.

**Keywords:** *Arsha*, Amroid tablet, Amroid ointment, Hemorrhoid  
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## INTRODUCTION

Acharya Sushruta enumerated 8 types of grave diseases, that is, *Ashtamahagad* among that *Arsha* is one of them which suggest importance of this disease.<sup>[1]</sup> *Arsha* occur at seat of Marma Pradesh, that is, Guda<sup>[2]</sup> that is also location of prana which require delicate and definite management. In modern system, *Arsha* is more or less can be correlated with hemorrhoids. It is a very common entity defined as the symptomatic enlargement and displacement of anal cushions. The exact prevalence rate of hemorrhoids is unknown but recent evidences suggested that improper day-to-day lifestyle is reason for increasing prevalence of disease over time. Incidence of hemorrhoids is peak in between 45 and 65 years of age in both sexes.<sup>[3]</sup> Several risk factors have been claimed to be the origin for disease but meanwhile conditions which related to increased intra-abdominal pressure, such as constipation and prolonged straining, are widely believed to cause hemorrhoids as a result of compromised venous drainage of hemorrhoid plexus. Some foods, including low fiber diet, spicy foods and alcohol intake, were reported to link with the development of hemorrhoids and the aggravation of acute hemorrhoid symptoms.

A number of para-surgical and surgical treatments right from medicinal treatment to the latest technology, that is, Doppler guided hemorrhoidal artery ligation are available options for the management of hemorrhoid in modern system.<sup>[4]</sup> Four types of explicit measures, that is, *Bheshaj Karma*, *Kshar Karma*, *Agnikarma*, and *Shashtra Karma* as per nature of disease narrated by Acharya Sushruta in the management of *Arsha*. In Sushruta Samhita mentioned that every attempt should be made to treat the disease with medicine.<sup>[5]</sup> Acharya Charak has given more emphasis on *Bheshaj Chikitsa*, that is, conservative treatment for that he given separate *Adhyay* as *Arsha chikitsa*.<sup>[6]</sup> Likewise due to fear of surgery and to avoid postsurgical complications in ano-rectal disease condition the demand from society is rising that disease should be treated with medicine. Hence, the study has been planned to evaluate the efficacy of Amroid tablet and ointment in cases of *Arsha*, that is, hemorrhoids.

Department of Shalya Tantra, Institute of Teaching and Research in Ayurveda, Jamnagar, Gujarat, India

**Corresponding Author:** Dudhamal Tukaram Sambhaji, Department of Shalya Tantra, Institute of Teaching and Research in Ayurveda, Jamnagar - 361 008, Gujarat, India. E-mail: drtsdudhamal@gmail.com

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## MATERIALS AND METHODS

This study was an open-label single-arm prospective interventional study of four weeks. Total 144 patients having complaints of ano-rectal pain, inflammation, bleeding per ano, itching per ano, constipation, prolapsed of piles were selected from the outpatient department of the study center. Detailed clinical history, physical and local per rectal findings was recorded in clinical research proforma.

## Ethical Clearance and CTRI

The study was initiated after approval of Institutional Ethics Committee, vide letter no. PGT/7/-A/Ethics/2018-19/2638, Dated 18/12/2018 and CTRI number of trail is CTRI/2019/02/017584 [Registered on: 12/02/2019].

## Inclusion Criteria

Patients of either gender between age of 18 years and 60 years having 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> degree of hemorrhoids and pre surgical patient of hemorrhoid were included in the study.

## Exclusion Criteria

Patients having congenital hemorrhoids, fibrotic anal stenosis, 4<sup>th</sup> degree hemorrhoids and complicated hemorrhoids viz thrombosed piles, etc., were excluded from the study. Patients of hemorrhoid with fistula-in-ano or ano rectal abscess were excluded from the study. Patients with severe anemia (Hb% < 7 g%) and having concomitant severe systemic disease (cardiovascular, renal, hepatic, endocrine, hematological, neurological, and immunological) were excluded. Unwilling patient also not included in this study.

## Investigations

Complete blood count, random blood sugar, blood urea, serum creatinine, serum bilirubin, serum glutamic pyruvic transaminase, serum glutamic oxaloacetic transaminase, alkaline phosphatase and lipid profile as well as urine (Routine and Microscopic), stool (Routine and Microscopic) were done at baseline and at the end of the study.

## Ingredients of Trial Drugs

The study drugs Amroid Tablets and Amroid Ointment were supplied by AIMIL Pharmaceuticals (India) Ltd. A-13/2 Naraina Industrial Area, Phase- I, New Delhi - 110028.

## Drug's Administration (Dose and Duration)

### Tablet

Two tablets 3 times a day with plain water orally 1 h after food for 4 weeks.

### Ointment

Per rectal local applications of ointment with applicator or finger before and after defecation in sufficient quantity or maximum 10 g.

### Does and Don't

Patients were advised to consume fiber rich diet, green vegetables, plenty of water, and buttermilk. Patients were advised to avoid spicy, non-vegetarian diet, oily and junk foods.

## Assessment Criteria

The assessment of the efficacy was carried out at the end of every week during study period and patient were followed up to 8 weeks of treatment as reduction in intensity of following signs and symptoms such as ano-rectal pain, inflammation, bleeding per ano, itching per ano, constipation, prolapsed of piles based on gradation (Tables 1-5).

## Overall Assessment

1. Complete remission: 100% improvement in sign and symptoms
2. Marked improvement: >75–99% in sign and symptoms
3. Moderate improvement: >50–75% in sign and symptoms

**Table 1:** Ano-rectal pain (VAS)

Ano-rectal pain	Grade	VAS
No pain	0	0
Mild pain relieved within 1hr after defecation	1	1–3
Moderate pain relieved within 4-5 hr after defecation	2	4–7
Severe pain present whole day	3	8–10

**Table 2:** Inflammation

Inflammation	Grade
No inflammation	0
Only congestion of the anal mucosa	1
Moderate inflammation and no discharge	2
Severe inflammation and discharge	3

**Table 3:** Bleeding per ANO

Bleeding per ano	Grade
No bleeding	0
0–10 drops occasionally	1
11–20 drops	2
Profuse bleeding	3

**Table 4:** Itching per ANO

Itching per ANO	Grade
No itching	0
Once or twice in a day	1
Often in a day and discomfort	2
Severe and constant itching whole day	3

**Table 5:** Constipation

Constipation	Grade
Absent	0
Present	1

4. Mild improvement: >25–50% in sign and symptoms
5. Unchanged: up to 25% improvement in sign and symptoms.

## Statistical Analysis

Obtained results were analyzed through Wilcoxon sign rank test then final conclusion was drawn.

## OBSERVATIONS AND RESULTS

In this study, out of 144 patients, maximum 131 patients were males because male predominance was found higher might be due to reporting of more male patients to the anorectal department. 114 patients were between 30 and 50 years of age group which showed that most of the patients were of middle age group. Presence of family history was noted by patients. Out of 144 patients 135 patients had poor appetite, 80 patients complained of bleeding per ano which brought the patient to hospital, 86 patients had burning type of pain and 35 patients had pricking type of pain while 102 patients had complained of constipation. The constipation is the main etiological factor of hemorrhoids.

On local per rectal examination, 85.41% patients had unhealthy peri-anal skin. Among all patients, 74.31% patients were diagnosed as a case of internal pile mass, 4.86% patients had external piles and 20.83% patients had interno-external piles. Patients with 2<sup>nd</sup> degree piles were observed maximum 65.20% and 25.69% were observed 1<sup>st</sup> degree pile mass because in the

2<sup>nd</sup> degree pile mass patient suffered from per rectal bleeding as well as congestion of the piles may lead to anorectal discomfort which brings the patients to surgeon. At base line 85.41% patients had complaint of pain in ano, 55.56% patients had complaint of bleeding per rectum and 56.25% patients had complaint of itching per ano and 71.53% patients had perianal inflammation.

**Effect of Therapy**

Pain in ano was reduced by 38.26% after 1<sup>st</sup> week and 55.21% relief in pain by the 2<sup>nd</sup> week and at the end of 4<sup>th</sup> week 89.56% relief was found in pain. At the end of follow-up, patients had 100% relief in ano rectal pain (Table 6). After first week of treatment, 34.16% relief was seen in peri-anal inflammation and on 2<sup>nd</sup> week 55.27%, 3<sup>rd</sup> week 87.57% and after 4 week 96.27% and at end of 60 days follow-up 99.37% which are all highly significant reduction in inflammation was observed (Table 7). Bleeding per rectum was reduced by 43.19% after the 1<sup>st</sup> week and by 92.90% after 4 weeks. After 2 months of follow-up 98.81% improvement observed in cessation of bleeding per rectum (Table 8). Itching per ano was decreased in 36.36% after 1 week of treatment. On 2<sup>nd</sup> week 53.03%, 78.78% in 3<sup>rd</sup> week after 4 weeks 89.39% relief in itching per ano. At the end of follow-up of 2 months, 93.18% patients had improvement in itching per ano (Table 9). Constipation was

reduced by 24.81% after 1<sup>st</sup> week and at the end of 4 weeks 87.59% patient got complete relief from constipation. On 2 months of follow-up 93.43% significant improvement in constipation (Table 10). Prolapse of piles was reduced by 14.15% at the end of 1<sup>st</sup> week and 34.90% at the end of 2<sup>nd</sup> week. On third week 59.43%, 4 weeks 63.20% and after 2 months of follow-up 80.18% improvement observed in prolapse of piles (Table 11).

**Overall Assessment**

Overall effect of therapy showed that 29.16% patients got complete remission and 63.89% patients showed marked improvement. Moderate improvement was found in 5.56% patients while 1.39% noted with mild improvement. Hence, it can be said that the patients of 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> degree piles is managed with Amroid tablet and ointment (Table 12).

**DISCUSSION**

The present study of Amroid tablet and Amroid ointment was designed to evaluate the efficacy of dual treatment in management of hemorrhoids. The study planned with polyherbo-mineral tablet and ointment which had been used to treat hemorrhoids systematically and locally. The herbs which are

**Table 6:** Effect of therapy on ANO-rectal pain: (n=123)

Assessment Days	Mean score		% Relief	SD	SE	W	p	Significance
	BT	AT						
On 7 <sup>th</sup> day	1.61	1.007	38.26%	0.63	0.05	2850	<0.0001	HS
On 14 <sup>th</sup> day	1.61	0.72	55.21%	0.64	0.05	5671	<0.0001	HS
On 21 <sup>st</sup> day	1.61	0.39	76.96%	0.67	0.05	7875	<0.0001	HS
On 28 <sup>th</sup> day	1.61	0.17	89.56%	0.64	0.05	8778	<0.0001	HS
				Follow up				
On 15 <sup>th</sup> day	1.61	0.37	81.30%	0.71	0.06	7682	<0.0001	HS
On 30 <sup>th</sup> day	1.61	0.19	91.73%	0.69	0.06	8719	<0.0001	HS
On 45 <sup>th</sup> day	1.61	0.10	97.82%	0.64	0.05	8778	<0.0001	HS
On 60 <sup>th</sup> day	1.62	0.03	100.00%	Table 0.58	0.04	9453	<0.0001	HS

**Table 7:** Effect of therapy on peri anal inflammation (n=103)

Assessment Days	Mean score		% Relief	SD	SE	W	P	Significance
	BT	AT						
On 7 <sup>th</sup> day	1.132	0.74	34.16%	0.50	0.04	1540	<0.0001	HS
On 14 <sup>th</sup> day	1.132	0.51	55.27%	0.55	0.04	3655	<0.0001	HS
On 21 <sup>st</sup> day	1.132	0.14	87.57%	0.52	0.04	7750	<0.0001	HS
On 28 <sup>th</sup> day	1.132	0.04	96.27%	0.51	0.04	8686	<0.0001	HS
				Follow up				
On 15 <sup>th</sup> day	1.132	0.25	78.26%	0.55	0.05	6441	<0.0001	HS
On 30 <sup>th</sup> day	1.132	0.06	94.40%	0.51	0.04	8515	<0.0001	HS
On 45 <sup>th</sup> day	1.132	0.02	98.13%	0.50	0.04	8911	<0.0001	HS
On 60 <sup>th</sup> day	1.132	0.01	99.37%	0.50	0.04	9045	<0.0001	HS

**Table 8:** Effect of therapy on Bleeding per rectum: (n=80)

Assessment Days	Mean score		% Relief	SD	SE	W	p	Significance
	BT	AT						
On 7 <sup>th</sup> day	1.19	0.67	43.19%	0.68	0.57	1904	<0.0001	HS
On 14 <sup>th</sup> day	1.19	0.43	63.90%	0.67	0.06	4095	<0.0001	HS
On 21 <sup>st</sup> day	1.19	0.24	78.29%	0.75	0.06	5050	<0.0001	HS
On 28 <sup>th</sup> day	1.19	0.08	92.90%	0.81	0.07	5356	<0.0001	HS
				Follow up				
On 15 <sup>th</sup> day	1.19	0.21	82.24%	0.87	0.07	4606	<0.0001	HS
On 30 <sup>th</sup> day	1.19	0.08	93.49%	0.86	0.07	5573	<0.0001	HS
On 45 <sup>th</sup> day	1.19	0.06	94.67%	0.82	0.07	5727	<0.001	HS
On 60 <sup>th</sup> day	1.19	0.01	98.81%	0.80	0.07	5995	<0.001	HS

**Table 9:** Effect of therapy on itching per ano-rectum: (n=81)

Assessment Days	Mean score		% Relief	SD	SE	W	p	Significance
	BT	AT						
On 7 <sup>th</sup> day	0.93	0.59	36.36%	0.51	0.04	1081	<0.0001	HS
On 14 <sup>th</sup> day	0.93	0.44	53.03%	0.59	0.04	2216	<0.0001	HS
On 21 <sup>st</sup> day	0.93	0.19	78.78%	0.63	0.05	4278	<0.0001	HS
On 28 <sup>th</sup> day	0.93	0.10	89.39%	0.69	0.05	4873	<0.0001	HS
				Follow up				
On 15 <sup>th</sup> day	0.93	0.23	71.21%	0.74	0.06	4003	<0.0001	HS
On 30 <sup>th</sup> day	0.93	0.10	85.60%	0.63	0.05	5151	<0.0001	HS
On 45 <sup>th</sup> day	0.93	0.04	90.90%	0.65	0.05	5799	<0.0001	HS
On 60 <sup>th</sup> day	0.93	0.02	93.18%	0.64	0.05	5886	<0.0001	HS

**Table 10:** Effect of therapy on constipation: (n=102)

Assessment Days	Mean score		% Relief	SD	SE	W	p	Significance
	BT	AT						
On 7 <sup>th</sup> day	0.99	0.73	24.81%	0.47	0.04	666	<0.0001	HS
On 14 <sup>th</sup> day	0.99	0.47	52.55%	0.57	0.04	2704	<0.0001	HS
On 21 <sup>st</sup> day	0.99	0.25	74.45%	0.56	0.04	4959	<0.0001	HS
On 28 <sup>th</sup> day	0.99	0.13	87.59%	0.55	0.04	6124	<0.0001	HS
				Follow up				
On 15 <sup>th</sup> day	0.99	0.26	73.72%	0.61	0.05	2614	<0.0001	HS
On 30 <sup>th</sup> day	0.99	0.15	85.40%	0.56	0.04	3570	<0.0001	HS
On 45 <sup>th</sup> day	0.99	0.08	92.70%	0.56	0.04	4283	<0.0001	HS
On 60 <sup>th</sup> day	0.99	0.07	93.43%	0.56	0.04	4376	<0.0001	HS

**Table 11:** Effect of therapy on prolapse of piles: (n=91)

Assessment Days	Mean score		% Relief	SD	SE	W	P	Significance
	BT	AT						
On 7 <sup>th</sup> day	0.75	0.64	14.15%	0.32	0.26	136	<0.0001	HS
On 14 <sup>th</sup> day	0.75	0.48	34.90%	0.49	0.04	742	<0.0001	HS
On 21 <sup>st</sup> day	0.75	0.30	59.43%	0.52	0.04	1953	<0.0001	HS
On 28 <sup>th</sup> day	0.75	0.27	63.20%	0.55	0.04	2145	<0.0001	HS
				Follow-up				
On 15 <sup>th</sup> day	0.75	0.26	65.09%	0.60	0.05	2491	<0.0001	HS
On 30 <sup>th</sup> day	0.75	0.21	72.64%	0.60	0.05	2935	<0.0001	HS
On 45 <sup>th</sup> day	0.75	0.20	72.69%	0.65	0.05	2940	<0.0001	HS
On 60 <sup>th</sup> day	0.75	0.14	80.18%	0.60	0.05	3582	<0.0001	HS

**Table 12:** Overall assessment of patients (n=144)

Improvement	No. of patients	Percentage
Complete cured	42	29.16
Marked improvement	92	63.89
Moderate improvement	8	5.56
Mild improvement	2	1.39
Unchanged	0	0

included in Amroid tablet and ointment are having analgesic, anti-inflammatory, antioxidant and astringent potential. Statistically highly significant results were obtained in patients of first-, second- and third-degree hemorrhoids. In maximum patients' relief in ano-rectal pain, peri-anal inflammation, and peri-anal itching was observed after four weeks of management. In cases of internal piles highly significant result was seen in features of bleeding per rectum irrespective of the decrease in size of piles. In efficacy parameters, the relief was 92.90% in bleeding per rectum, 89.56% in ano-rectal pain, 87.59% in constipation, 89.39% in itching per ano, 96.27% in peri-anal inflammation and 63.20% in prolapsed piles. Overall effect of Amroid tablet and ointment was highly significant in hemorrhoids. Amroid tablet contains extract of several herbs, mineral components and oils which have potential actions such as hemostatic, anti-inflammatory, laxative, anti-microbial and metabolic regulation. All these combined

actions work systematically and improve microcirculation, capillary flow, vascular tone and strengthen connective tissue of a peri-anal region. Amroid ointment act as local astringent by virtue of that it strengthens the veins and reduces the bleeding. The hemostatic properties of herbs in ointment cause coagulation of proteins in the cells of lining of anal canal which subsequently help in relieving pain, burning and itching.

### Mode of Action of Amroid Tablet

*Nagakesar* (*Mesua ferrea* Linn.) and *Indrajav* (*Holarrhena antidystrica* Linn.) component in Amroid ointment having multiple actions like antibacterial, antifungal, antioxidants, analgesic and hemostatic. By virtue of all these actions it relieved inflammation and helps in cessation of bleeding in hemorrhoids.<sup>[7,8]</sup> *Triphala* by its quercetin, gallic acid and chebulinic acid contents reduces oxidative stress in body and thus reduces perianal inflammation. With high level of flavonoids *Triphala* reduces constipation while improving the frequency and consistency of stool.<sup>[9]</sup> *Chitrak* (*Plumbago zylanica* Linn.), *Snuhi* (*Euphorbia nerifolia* Linn.) and *Bhallataka* (*Semicarpus anacardium* L.f.) work as *Amadoshahara* by means of their *Dipan - Pachan* properties thus it regulates metabolism as well as bowel regulation which help in reduction of perianal inflammation and prolapsed pile mass.

*Trivrut* (*Operculina turpenthum* L.) facilitates in *Pitta Virechan* with this action indirectly it decreases bleeding per ano and itching in ano. In origin of hemorrhoid main reason is *Mandagni* so here in Amroid tablet all the herbs and mineral mainly work on *Agni* and thus correcting metabolism in body all other symptoms relieved significantly.

### Mode of Action of Amroid Ointment

Amroid ointment contains antiseptic herbs such as *Haridra* (*Curcuma longa* L.), *Nimba* (*Azadirachta indica* A. Juss.), *Karanj* (*Millettiapinnata* L.) with these ingredients, ointment locally reduces infection and prevent the chances of further bacterial or fungal infection.<sup>[10,11]</sup> Along with this, they act as anti-inflammatory. *Durva* (*Cynodon dactylon* Linn.) and *Lodhra* (*Symplocos racemosa* Roxb.) effective as local hemostat by constricting blood capillaries at ano-rectal region. *Haridra* due to large content of curcumin effective in congestion of piles. *Ghririkumari* (*Aloe barbadensis* Miller.) consist large number of polysaccharides which helpful to relieve burning pain in ano and itching in ano simultaneously provides soothing effect at peri anal region.<sup>[12]</sup> Thus, Amroid ointment work as anti-inflammatory, antifungal, antibacterial, analgesics and hemostatic locally at peri anal region and thus help in curing hemorrhoids.

### CONCLUSION

The study was concluded that Amroid tablet and Amroid ointment has potential to cure hemorrhoids up to third degree. The formulation is easy to use and convenient for consumption without any untoward effect.

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