

**“A CONTROLLED CLINICAL STUDY OF HARIDRADI GUDA VARTI
(ANAL SUPPOSITORY) ON INTERNAL HAEMORRHOIDS (I⁰ & II⁰)”.**

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ABSTRACT

Aushadha, Shastra, Kshar and Agni are line of treatment of Arsha/haemorrhoids according to the Sushruta. Though abhyantar aushadha is important for treatment of Arsha, yet it has a limited scope. Shastrakarma also comes up with complication of incontinence and Agni karma is carrying fear in the patients mind hence the local application of Kshar for treatment of haemorrhoids is carrying great importance as per gradation of Haemorrhoids. Both in terms of patient convenience and result. Though modern medicine has their own suppositories like fensupp[®], Corect[®] yet they carries lot of adverse drug reaction hence in order to find out cheap, easily available effective, with minimum or no side effect and patient convenient drug. When I went through Ayurveda classics and I found that Haridradi

GUDA VARTI (ANAL SUPPOSITORY)⁷ mentioned by Charak in Arsha (chikitsa chapter 14) is very close to satisfying all the above mentioned criteria. Which contains Haridra (curcuma longa) and snuhi kshir (euphorbia neriifolia) and which is to be applied locally hence I have decided to do work on it.

KEYWORDS: Haemorrhoids, suppository, pile mass, Godavari.

INTRODUCTION

Nearly 1 million new cases are reported annually in United States of America, 47 per 1000 and increases with age, age group of 45-65yrs. It is estimated that 50-85% of people around the world have haemorrhoids. In India 75% of the population is estimated. Among this almost half million population are experiencing conditions that are related to haemorrhoids. Usually, many are not aware that they have the symptoms associated to this condition.^[1] Haemorrhoids are two types; the one which is placed inside is named as Internal Haemorrhoids and is structured just under the tissue that lines the inside of the rectum. They are not noticeable till they become big and will make them to prolapse and just out through the anus. On the other hand, the vein that forms outside the rectum and surround the anus is called the External Haemorrhoids. The main causes that alter into this painful position is hereditary, postponing of visits to toilet.^[4]

Current statistics suggest that almost half of people in their fifties have piles. Age is not the only factor though, and haemorrhoids can affect people of any age group or gender.^[5] Haemorrhoids can be correlated with Arsha in Ayurvedic classics. Ayurveda has described Arsha rightly that it troubles like enemy.^[6] Sushruta has also mentioned it in the Ashta mahagada. There are 4 types of treatments for Arsha mentioned by Sushruta. These are Aushadha, Shastra, Kshar and Agni.

Though abhyantar aushadha is important for treatment of Arsha, yet it has a limited scope. Shastrakarma also comes up with complication of incontinence and Agni karma is carrying fear in the patients mind hence the local application of Kshar for treatment of haemorrhoids is carrying great importance as per gradation of Haemorrhoids. Both in terms of patient convenience and result. Though modern medicine has their own suppositories like fensupp[®], Corect[®] yet they carries lot of adverse drug reaction hence in order to find out cheap, easily available effective, with minimum or no side effect and patient convenient drug. When I went through Ayurveda classics and I found that Haridradi GUDA VARTI (ANAL SUPPOSITORY)^[7] mentioned by Charak in Arsha (chikitsa chapter 14) is very close to satisfying all the above mentioned criteria. Which contains Haridra (curcuma longa) and snuhi kshir (euphorbia neriiifolia) and which is to be applied locally hence I have decided to do "A CONTROLLED CLINICAL STUDY OF HARIDRADI GUDA VARTI (ANAL SUPPOSITORY) ON INTERNAL HAEMORRHOIDS (I⁰ & II⁰)".

AIMS

1. To study effect of **HARIDRADI GUDAVARTI (ANAL SUPPOSITORY)** in treatment of internal haemorrhoids (Ist & IInd degree).
2. To study probable mechanism of action of **HARIDRADI GUDAVARTI (ANAL SUPPOSITORY)** in treatment of internal haemorrhoids (Ist & IInd degree).

OBJECTIVES

1. A controlled clinical study of **HARIDRADI GUDAVARTI (ANAL SUPPOSITORY)** (Per-rectally) in management of internal haemorrhoids (Ist & IInd degree).
2. To propose an alternative cost effective easy available herbal preparation in management of internal haemorrhoids.

MATERIAL AND METHODS**Consent**

A well informed written consent of all patients included in my study was taken before starting treatment.

Type of study: Open Controlled study.

No. of patients

Group A - 30

Group B - 30

Drug used

Group A: HARIDRADI GUDAVARTI (ANAL SUPPOSITORY)

Composition -Haridra churna snuhi kshir bhavit– 1gm

Ghruta - 3gm

Hard wax - 1gm

Group B: Corect suppository

Duration of Treatment for group A and B: 15 days

Dose: one HARIDRADI GUDAVARTI (ANAL SUPPOSITORY) daily after defecation.

Follow up: Once a week for 4 week.

METHOD OF PREPARATION OF DRUG

Group A: HARIDRADI GUDAVARTI (ANAL SUPPOSITORY) will prepared as per standard method described in Ayurvedic Text in the Department of Ras-Shastra of standard Medical College of Ayurveda.

Composition- Haridra churna snuhi kshir bhavit–1gm.

Ghruta- 3gm.

Hard wax- 1gm.

First I Prepared snuhi kshir bhavit Haridra as per Standard Bhaishajaratnawali siddhant. Then I siddha Go-Ghrut from snuhi kshir bhavit Haridra. After adding Hard wax & Molding Haridradi gudavarti suppository prepared.

Group B: Drug was purchased from standard pharmaceutical company

Route of Administration: Per rectum.

INCLUSION CRITERIA

- 1) 1st & 2nd degree internal haemorrhoids.
- 2) Both male and female patients.
- 3) Patients of age group 15 to 50 years old.

EXCLUSION CRITERIA

- 1) 3rd and 4th degree haemorrhoids.
- 2) Thrombosed haemorrhoids.
- 3) Haemorrhoids with ulcerative colitis.
- 4) HIV Patient
- 5) Prolapse of Rectum
- 6) Patient with hepatic disorder
- 7) Diabetic patient
- 8) Tuberculosis patient
- 9) External haemorrhoids.
- 10) Fissure in ano

Withdrawal criteria

Patients suffering from any adverse effect during study, was withdrawn & was shifted for further management.

INVESTIGATIONS

- **Blood: CBC,ESR,BT,CT**

- **BSL**

a) Fasting

b) Post prandial

- **Urine**

a) Routine

b) Microscopic

- **HBsAg**

- **HIV I and II**

Observations and Results

Observations were recorded and noted as follows

- 1) Total number of patients recruited in the study- 60
- 2) No of patients who completed study- 60
- 3) No of patients who received Haridradi Gudavarti- 30
- 4) No of patients who received Corect[®] suppository- 30

No of patients enrolled in the trial in the beginning and no of patients dropped out afterwards are tabulated below accordingly.

Group	A	B	Total
No of patients in the beginning	30	30	60
Patients dropped out	0	0	0
Patients remaining till end of trial	30	30	60

Table showing classification of patients according to sex

	MALE	%	FEMALE	%	TOTAL
GROUP A	18	60%	12	40%	30
GROUP B	19	63.33%	11	36.66%	30

As far as sex is concerned no. of male patients is high in each group. Above table shows that out of total 60 patients there are total of 37 male patients and 23 female patients. Statistically, the distribution of patients according to sex in both groups is insignificant. Hence, both groups are homogenous.

Table showing classification of patients according to age

AGE GROUP	15-30	%	31-40	%	41-50	%
GROUP A	10	33.33%	11	36.66%	9	30%
GROUP B	12	40%	10	33.33%	8	26.66%

Above table shows that there are total 22 patients of age group 15-30 year of age, 21 patients of age group between 31-40 years and 17 patients of age group between 41-50 years.

Statistically, the distribution of patient according to age in above three groups is insignificant. Hence, three groups are homogenous.

Table showing distribution of patients according to Marital Status

	Married	%	Unmarried	%
GROUP A	26	86.67%	4	13.33%
GROUP B	24	80%	6	20%

Distribution of patients according to religion

Religion	Hindu	Muslim	Christian	Others
Group A	26	3	1	0
Group B	26	4	0	0

Above table shows that in group A there were 26 Hindu patients, 3 Muslim patients and 1 Christian patient. In group B there were 26 Hindu, 4 Muslim patients.

Distribution of patients according to diet

	VEG	%	MIXED	%
GROUP A	6	20%	24	80%
GROUP B	9	30%	21	70%

Above table shows that there were 24 patients having mixed diet in group A and 6 patients with veg diet. In group B 21 patients were having mixed diet and 9 patients with veg diet.

Table showing distribution of patients according to addict and non-addict

	ADDICT]	%	NON ADDICT	%	TOTAL
A GROUP	15	50%	15	50%	30
B GROUP	14	46.66%	16	53.33%	30

Above table shows the no. of addicts and non-addicts. In Group A 15 patients are addict and 15 are non-addict. In Group B 14 patients are addict and 16 are non-addict. Statistically both the groups are homogenous.

Table showing the type of addiction to which the patients are addicted

Addiction	Alcohol	Tobacco chewing	Smoking	Total
Group A	7	3	5	15
Group B	7	2	5	14
Total	14	5	10	29

Above table shows there were total 14 patients addicted to alcohol 10 patients were addicted to smoking and 5 patients were addicted to tobacco chewing.

Table showing classification according to occupation-

Occupation	Job	Hous2e wife	Labour	Student
Group A	13	8	6	3
Group B	12	5	5	8

Above table shows distribution of patients according to their occupation. There were total 25 patients who were having office job as occupation, 13 were housewives, and 11 were labours and 11 were students.

Table showing distribution of patients according to effect of treatment

Effect	CURED	IMPROVED	MARKEDLY IMPROVED	UNCHANGED
GROUP A	4	1	25	0
GROUP B	0	24	6	0

The above table shows total effect of treatment in group A i.e. Haridradi Gudavarti there were 4 patients who were cured, 25 patients showed markedly improvement and 1 patient was improved. In group B there were 24 patients who showed improvement, and 6 patients were markedly improved, while no patient was cured. In both the group no patient was unchanged.

Total effect of therapy in Group - A

Sr. No.	R.N.	BT	AT	diff	%	REMARK
1	4646	7	2	5	71.42857	Markedly improved
2	3608	8	2	6	75	Markedly improved
3	8969	6	1	5	83.33333	Cured
4	8830	8	3	5	62.5	Markedly improved
5	10608	8	2	6	75	Markedly improved
6	9085	8	2	6	75	Markedly improved
7	9140	8	3	5	62.5	Markedly improved
8	9149	7	2	5	71.42857	Markedly improved

9	1801	8	3	5	62.5	Markedly improved
10	4463	9	3	6	66.66667	Markedly improved
11	9098	8	2	6	75	Markedly improved
12	54104	8	3	5	62.5	Markedly improved
13	42073	6	0	6	100	CURED
14	50172	5	1	4	80	Markedly improved
15	32834	10	3	7	70	Markedly improved
16	32814	8	3	5	62.5	Markedly improved
17	32181	7	2	5	71.42857	Markedly improved
18	31414	6	2	4	66.66667	Markedly improved
19	4708	7	3	4	57.14286	Markedly improved
20	4711	10	4	6	60	Markedly improved
21	4718	8	3	5	62.5	Markedly improved
22	4821	11	4	7	63.63636	Markedly improved
23	4988	8	4	4	50	Improved
244	5041	6	0	6	100	CURED
25	5181	7	2	5	71.42857	Markedly improved
26	5218	5	0	5	100	Cured
27	5308	6	2	4	66.66667	Markedly improved
28	5322	9	3	6	66.66667	Markedly improved
29	5378	7	2	5	71.42857	Markedly improved
30	5414	7	2	5	71.42857	Markedly improved

Total effect of therapy in Group - B

Sr.	OPD no	BT	AT	diff	%	REMARK
1	3936	5	2	3	60	Markedly improved
2	3622	5	4	1	20	Improved
3	9000	7	3	4	57.14286	Markedly improved
4	9122	6	3	3	50	Improved
5	9120	8	4	4	50	Improved
6	6925	8	4	4	50	Improved
7	5460	7	3	4	57.14286	Markedly improved
8	35245	6	4	2	33.33333	Improved
9	26406	10	7	3	30	Improved
10	37692	7	3	4	57.14286	Markedly improved
11	9080	9	6	3	33.33333	Improved
12	6628	6	4	2	33.33333	Improved
13	59144	7	5	2	28.57143	Improved
14	48791	9	5	4	44.44444	Improved
15	53628	6	3	3	50	Improved
16	7198	7	5	2	28.57143	Improved
17	8188	9	7	2	22.22222	Improved
18	6844	8	6	2	25	Improved
19	6811	10	6	4	40	Improved
20	4107	9	7	2	22.22222	Improved
21	7812	9	5	4	44.44444	Improved
22	6186	10	6	4	40	Improved
23	6081	9	7	2	22.22222	Improved

24	4809	4	1	3	75	Markedly improved
25	6178	9	6	3	33.33333	Improved
26	6180	6	3	3	50	Improved
27	6124	9	5	4	44.44444	Improved
28	6211	11	8	3	27.27273	Improved
29	6282	7	3	4	57.14286	Markedly improved
30	6488	5	3	2	40	Improved

Statistical Analysis of effect of therapy of group A by Wilcoxon signed rank test.

Sr. No	Criteria of Pain		B.T	A.T	Diff	Sum Of All Signed Ranks (W)	No Of Pairs	Z VALUE	P Value
1	PR Bleeding	Mean	1.900	0.5333	1.367	465	30	4.78	<0.0001 Extremely Significant
		SD	0.7589	0.5713	0.4901				
		SE	0.1385	0.1043	0.08949				
2	Itching	Mean	1.767	0.5000	1.267	465	30	4.78	<0.0001 Extremely Significant
		SD	0.7289	0.5724	0.4498				
		SE	0.1329	0.1045	0.08212				
3	Pile Mass	Mean	1.900	0.4667	1.433	435	30	4.47	<0.0001 Extremely Significant
		SD	0.7120	0.5713	0.5683				
		SE	0.1300	0.1043	0.1038				

- 1) For PR bleeding before treatment mean is 1.900, Std. deviation is 0.7589 and std. error is 0.1385. after treatment mean is 0.5333, std. deviation is 0.5713 and std. error is 0.1043, Sum of all signed ranks is 465, no of pairs is 30, z value is 4.78 and p is <0.0001 which is extremely significant hence the drug is effective in stopping PR bleeding.
- 2) For Itching before treatment mean is 1.767, Std. deviation is 0.7289 and std. error is 0.1329. After treatment mean is 0.5000, std. deviation is 0.5724 and std. error is 0.1045, Sum of all signed ranks is 465, no of pairs is 30, z value is 4.78 and p is <0.0001 which is extremely significant hence the drug is effective in Itching.
- 3) For Pile Mass before treatment mean is 1.900, Std. deviation is 0.7120 and std. error is 0.1300 after treatment mean is 0.4667, std. deviation is 0.5713 and std. error is 0.1043, Sum of all signed ranks is 435, no of pairs is 30, z value is 4.47 and p is <0.0001 which is extremely significant hence the drug is effective in reducing Pile Mass.

Statistical Analysis of effect of therapy of group B by Wilcoxon signed rank test.

Sr. No	Criteria of Pain		B.T	A.T	Diff	Sum Of All Signed Ranks (W)	No Of Pairs	Z VALUE	P Value
1	PR Bleeding	Mean	2.133	1.567	0.5667	153	17	3.62	<0.0001 Extremely Significant
		SD	0.7303	0.6789	0.5040				
		SE	0.1333	0.1240	0.09202				
2	Itching	Mean	1.733	0.9667	0.7667	231	21	4.01	<0.0001 Extremely Significant
		SD	0.7397	0.6687	0.5683				

		SE	0.1350	0.1221	0.1038				Significant
3	Pile Mass	Mean	2.000	1.300	0.7000	210	20	3.92	<0.0001
		SD	0.7878	0.8367	0.5350				Extremely
		SE	0.1438	0.1528	0.09767				Significant

- 1) For PR bleeding before treatment mean is 2.133, Std. deviation is 0.7303 and std. error is 0.1333. after treatment mean is 1.567, std. deviation is 0.6789 and std. error is 0.1240, Sum of all signed ranks is 153, no of pairs is 17, z value is 3.62 and p is <0.0001 which is extremely significant hence the drug is effective in stopping PR bleeding.
- 2) For Itching before treatment mean is 1.733, Std. deviation is 0.7397 and std. error is 0.1350. After treatment mean is 0.9667, std. deviation is 0.6687 and std. error is 0.1221, Sum of all signed ranks is 231, no. of pairs is 21, z value is 4.01 and p is <0.0001 which is extremely significant hence the drug is effective in Itching.
- 3) For Pile Mass before treatment mean is 2.000, Std. deviation is 0.7878 and std. error is 0.1438. after treatment mean is 1.300, std. deviation is 0.8367 and std. error is 0.1528, Sum of all signed ranks is 210, no of pairs is 20, z value is 3.92 and p is <0.0001 which is extremely significant hence the drug is effective in reducing Pile Mass.

Comparison between Group A and Group B drugs by Man Whitney Test.

Sr. no	Parameters	Mean		S.D.		U	U'	R	R'	p
		A group	B group	A group	B group					
1	PR Bleeding	1.367	0.5667	0.4901	0.5040	161.50	738.50	1203.5	626.50	<0.0001 Extremely significant
2	Itching	1.267	0.7667	0.4498	0.5683	261	639	1104	726	0.0044 Very significant
3	Pile Mass	1.433	0.7000	0.5683	0.5350	189.50	710.50	1175.5	654.5	<0.0001 Extremely significant

By Man Whitney Test

- 1) In PR bleeding and Pile Mass p value is <0.0001 which is extremely significant i.e. group A drug is more effective than group B in reducing PR bleeding and Pile Mass.
- 2) In Itching p value is 0.0044 which is very significant hence group A drug is more effective than group B in reducing Itching.

DISCUSSION

Total effect of therapy

In group A, 4 patients cured, 25 patients improved markedly and 1 patient was improved according to accepted assessment criteria. In group B, 24 patients improved and only 6 patients showed marked improvement but no patient was cured according to accepted clinical assessment criteria. From this data it can be said that Haridradi gudavarti is more effective conservative mode of management than Corect suppository in 1st and 2nd degree internal haemorrhoids.

Probable action of Haridradi gudavarti

Haridradi gudavarti reduces per-rectal bleeding probably due to anti-inflammatory and haemostatic action of Haridra. Anti-inflammatory and wound healing property of Snuhi and soothing action of Go-grut.

Haridradi gudavarti reduces itching probably due to antiviral and antibacterial action of Haridra and Snuhi and soothing action of Go-grut.

Size of pile pass is reduced by Haridradi Gudavarti probably due to antitumor action of Haridra, hepatoprotective action of Haridra and Snuhi and lubricating action of Go-grut.

CONCLUSION

- ✓ Haridradi gudavarti & Corect suppository both have good efficacy in reducing pile mass size and management of itching and per-rectal bleeding in anorectal diseases.
- ✓ Haridradi gudavarti also cures other associated symptoms like anal pain & burning. It also acts as a cooling & soothing agent as Go-Ghrut was used in it. While Corect suppository does not relief pain & burning.
- ✓ During study no side effects or adverse effects of Haridradi gudavarti were noted, whereas in control group side effects like urticaria, headache & G.I.problems were observed.
- ✓ During study when applying Haridradi gudavarti, some patients, got relief up to 10-12 hrs in itching & burning of the haemorrhoids and in control group itching relieved up to 3-4 hrs only.
- ✓ Apart from decrease in pile mass size, itching, Per-rectal bleeding and burning, in some cases I observed that Haridradi gudavarti has mild laxative effect. It was not found in correct suppository.

- ✓ Corect suppository needs deep refrigeration, without this it melts & cannot be inserted. While Haridradi gudavarti remains intact without refrigeration.
- Therefore after conducting this study I came to a conclusion that Haridradi gudavarti is effective in decreasing the pile mass size, reduces itchings and Per-rectal bleed besides these it also has a soothing and mild laxative action. This study was carried out in limited patients a large scale study can also be untaken in future to undertaken to conduct huge data based study.

REFERENCES

- 1) WûËUSiÉcÉÑhÉi xÉÇrÉÑ£Çü xÉÑkÉÉæÉÏUÇ mÉësÉåmÉlÉqÉÇ | xiÉÇpÉ µÉrÉjÉÑ MÇüQÒû ÀliÉi zÉqÉlÉÉxiÉâXûzÉixÉÉÇ qÉiÉÉ: || (cÉ. ícÉ. 14 /52,58)
- 2) Sushrut Samhita Purvardha-DR. Anantram Sharma Chaukhamba publication Varanasi 2000
- 3) Vd. D. S. Yalmar – Thesis in University of Mumbai (A Clinical Study of Haridradi Malahara in Bahya Arsha July 2000).
- 4) Vd. Kedar M. Nita- Thesis in Government Ayurveda Medical College, Nagpur 2003, MUHS in Nashik. (Clinical Evaluation of Haridradi Lepa in Arsha.
- 5) A controlled study of Apamarga Kshar pratisaran on internal haemorrhoids (2nd degree), (2008-2009) muhs.