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# A CLINICAL STUDY OF GUDADI GUTIKA IN THE MANAGEMENT OF ARSHA (HAEMORRHOIDS/PILES)

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### **ABSTRACT**

The purpose of present study was to evaluate the efficacy of *Gudadi Gutika* in the management of *arsha* (Piles). The study was carried out in 60 patients. 30 patients in Experimental group administrated *Gudadi Gutika* in the form of tablet of 250 mg while in control group 2 gm of Haritaki Churna, both in the morning and night after meal and administered along with warm water as an anupan up to 21 days. The drug is administrated to those patients suffering from *arsha* (piles) diagnosed by inspection, per-rectal examination and proctoscopy. The symptoms such as tenderness, burning pain, bleeding per-rectum, itching, anorexia, constipation & indigestion were taken for the subjective assessment of the disease. Recovery of patients was

assessed by the relief in the symptoms. According to observations and results obtained it was concluded that the treatment of *arshas* with *Gudadi Gutika* has given significant relief in the symptomatology of the disease.

**KEYWORDS:** Arsha, Piles, Gudadi Gutika, Haritaki churna.

## **INTRODUCTION**

The incidence of Anorectal disorders is increasing in population. due to sedentary life style, irregular food habits, physiological disturbances like depression and anxiety and excessive consumption of junk food etc. These factors cause *Mandagni* (indigestion) and chronic constipation because of diet irregularities and the low fiber diet respectively and cause

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diseases like *Arsha* etc. According to Ayurveda, *Mandagni* is considered as a main reason for the development of many diseases like *Arsha*, *Atisara*, *Grahani* etc.<sup>[1]</sup>

This mandagni further hampers the function of ApanVayu. Which leads to Malabaddhata & vitiates gudagat Doshas resulting in 'Arsha'. Anorectal disorders are most embarrassing disorder to any patient. The anal region is one of the most sensitive region in the body due to rich nerve supply. Thus even a mild form of disorder can produce major discomfort to the patient. It has been observed that patient does not consult the physician in the initial stage of the disease because they feel ashamed due to examination of private parts. Modern medicine has its own limitations in managing this type of disease. The present study has been planned to know the efficacy of the medicinal preparation *Gudadi Gutika* in the management of *Arsha* (piles).

### Aims

To study the effect of "Gudadi Gutika" in the management of Arsha (piles).

## **Objectives**

- 1) To discuss the concept of Arsha as per ancient and modern literature
- 2) To study internal use of Gudadi Gutika in detail.
- 3) To derive an easily accessible, cost effective and medical line of treatment.

## **Review of Literature**

## **Modern Aspect**

Haemorrhoids or piles can be correlated with the concept of Arsha in ancient literature which can be included as a lifestyle disorder caused due to sedentary lifestyle dietary regimen which is more spicy and unwholesome as well as *Viruddha Ahara* in nature is being adopted by the young generation of population. These are the clumps of dilated veins in the anus and lower rectum which become swollen and inflamed causing pain and rectal bleeding during defecation. Haemorrhoids can occur at any age and can affect both the sexes. A least 50% of individuals over the age of 50 years will have, at some point, experienced symptoms related to haemorrhoids.<sup>[2]</sup> There was high prevalence noted between the age group of 45-65 years in both sex with a subsequent decrease after age 65 years.<sup>[3]</sup> Haemorrhoid is a very common disease in Asian countries, more than 10 million cases per year seen in India The symptoms of haemorrhoids includes uneasiness, discomfort, pain and /or bleeding during defecation, constipation and tenesmus cause a great deal of discomfort. They are usually of two types;

external or internal with respect to their position with anal orifice. Internal haemorrhoids are further classified into four grades as:<sup>[4]</sup>

Grade 1: Non-prolapsing internal haemorrhoids.

Grade 2: Internal haemorrhoids that prolapse during defecation and spontaneously reduce.

Grade 3: Internal haemorrhoids that prolapse during defecation and must be manually reduced.

Grade 4: Internal haemorrhoids that are prolapsed and incarcerated.

## **Ancient Aspect**

As per our ancient samhitas, Mandagni leads to all disorders. Among which gudgat rogas (anal disorders) are more common due to malabaddhata. Vitiation of ApanaVayu is the main factor responsible for this disease but other causative factors also play much more role in the disease formation like Vega-vidharana, Ati-Ushna-Tikshna and Mamsa Ahara, Utkutasana etc. There are six types of Arsha were mentioned according to Aacharya Charaka, Susrutha i.e. vataja, pittaja, kaphaja, sannipataja, raktaja, shushka Arshas. The pathophysiology i.e. Samprapti of arshas starts with nidana sevana causes the tridoshaj prakopa along with vitiation of twak, rakta, mamsa, medas leads to masankura in guda pradesha (anal region) called as arsha. Dosha involved are tridoshas. Dushyas are Twacha, Rakta, Mamsa, Meda. General line of treatment is explained as those suffering from piles should take food, drink and drug which is conducive for normalization of the course of vayu and stimulant for Agni (digestive fire). The arsh can be treated by 4 methods of treatment as Bheshaja, Kshara, Agni and Shastra. Bheshaja means Medical or conservative treatment which includes various Ayurvedic medicines which decrease intra-abdominal pressure, act as mild laxatives and thus give relief in the particular situation As Arsha is a Tridoshj disease and arises from Mandagni and Ama formation. In respect with the Bheshaj Chikitsa of Arsha, the Vatanuloman effect is desired, the principle of treatment of Arsha includes three chief clinical effects- (1) Agni Deepan, (2) Vatanuloman and (3) Raktasthambhan. Dushyas affected here are Twacha, Rakta, Mamsa and Meda. [5]

## Gudadi Gutika<sup>[6]</sup>

Gudadi Gutika internally is described to be useful in such condition. This is a herbal composition contains Maricha (Piper nigram), Pippali (Piper nigram), Suntha (Zingiber officinalis), Chitrak (Plumbago Zelamice), Suran (Amorphophylus companulatus) and Guda (Saccharum officinaru) These drugs used in this preparation are Dipaniya, Pachniya, Shool

prashamaniya & Arshoghna dravya. Thus the combination of these drug i.e. Gudadi Gutika does Agnivardhan, Pachana of Aahar thus relives malabaddhata and cures Arsha. Thus it is used as Experimental Drug. While Haritaki Churna is being used extensively in the management of Arsha in ayurveda, hence taken for control group.

### **MATERIAL AND METHODS**

The study is and open end clinical study where the 60 patients suffering from the disease *Arshas* (piles) irrespective to their sex, caste religion & occupation were selected for this study from the OPD and IPD of *Shalya Tantra* Department. The study was started after approval of Institutional Ethics Committee.

## Plan of Study

Patients selected as per inclusive criteria before the commencement of the therapy, general information both of the patients and the disease were recorded. A complete history of disease and complaints was recorded as per the specially prepared proforma for the ano-rectal disorders with the written consent of patient that includes the general, systemic and local examinations of the patient. The local examination procedures like inspection, palpation, digital examination and proctoscopy were performed to confirm the diagnosis. The Inclusion and Exclusion criteria and the general well-being of the patient a few laboratory investigations were also performed as follows:

### Laboratory investigations

- Blood investigations bio-chemical and pathological
- Bleeding time and clotting time.
- Stool and urine pathological examination of microscopic and routine

#### **Selection Criteria**

### **Inclusion criteria**

- Patient presenting with the Nidana, Lakshana & Samprapti of *Arsha*.
- Patient belongs to age group of 16-50 years.
- Patient who were suffering from 1st and 2nd degree internal piles were included.
- Patient having no other complications like diabetes, carcinomatous conditions etc. were selected for the study.

### **Exclusion criteria**

- Patients below 16 years of age and above 50 years of age are not included in the study.
- Patient having 3rd 4th grade piles were excluded.
- Patient having rectal prolapse were excluded.
- Patients suffering from chronic diseases like Carcinoma Anus & Rectum, Ulcerative colitis, Perianal Abscess, Proctitis, etc. other complications were not included
- Patient with any associated disease e.g. DM, HT, prolapsed rectum etc. were excluded.
- Patient associated with portal hypertension and Hepatitis B, Tuberculosis, HIV & VDRL positive cases were also excluded.

## Diagnostic Criteria

All the patients were diagnosed on the basis of symptoms local findings and P/S examination. In P/S (proctoscopic Examination) findings of piles (hemorrhoids) that are site, size, position and consistency were noted. The routine Haematological, Biochemical investigations were carried out to assess the patient.

#### **Treatment Schedule**

The Selected patients were administered "Gudadi Gutika" as follows: (Ref: Ashtang Hridaya Cikitsasthana 8/ 157, Arshckikitsaadhyaya). The drug is a compound preparation with the following composition.

## **Ingredients**

Group 1 i.e. Experimental Group	Group 2 i.e. Control Group
Gudadi Gutika	Haritaki Churna
Maricha (Piper nigram) 1 part (20 gm)	
Pippali (Piper nigram) 2 part (40 gm)	
Suntha (Zingiber officinalis) 3 parts (60 gm)	
Chitrak (Plumbago Zelamice) 4 parts (80 gm)	Haritaki powder
Suran (Amorphophylus companulatus) 16 parts (320	Dose: 2 gm
gm)	Anupana: Warm water
Guda (Saccharum officinaru) 250 gm	Form of Medicine: Powder form
<b>Dose:</b> 250 gm	
Anupana: Warm water	
Form of Medicine: Tablet form	

Route of Administration: Oral route

**Kala** (**Time of administration**): *Pratahkala* i.e. before meal (morning and evening)

**Duration of Treatment**: 3 Weeks (21 days)

**Follow up:** 1 tablets thrice a day were advised to be taken for 3 weeks continuously with plain water before treatment, mid-treatment (7<sup>th</sup> day), during treatment (14<sup>th</sup> day) and after treatment (21<sup>st</sup> day). The follow up study of patients have conducted for 1 month after the completion of treatment.

#### Criteria of Assessment

The effect of treatment has been assessed on the basis of the relief of the major symptoms of the disease. This has done at a period of once in seven days. Scoring pattern was adopted to determine the relief in the cardinal symptoms as follows:

## Subjective criteria

## In each follow up Bleeding per rectum for each individual selected as subjective criteria and can be classified into following gradations

Grade 0	No bleeding	No bleed during defecation
Grade I	Mild bleeding	10 drops of blood per defecation or sometimes between 2-3 days
Grade II	Moderate bleeding	10-30 drops of blood per defecation
Grade III	Severe bleeding	Profuse bleeding or more than 50 drops of blood per defecation

## In each follow up Constipation for each individual selected as subjective criteria and can be classified into following gradations

Grade 0	No Constipation	No constipation
Grade I	Mild Constipation	Defecation between the gap of 1-1 day
Grade II	Moderate Constipation	Defecation between the gap of 2-2 day
Grade III	Severe Constipation	Defecation after using suitable virechak dravya

## Objective criteria

In each follow up hemoglobin percentage for each individual selected as objective criteria and can be classified into following gradations:

Grade –I	Hemoglobin percentage reduced
Grade 0	Hemoglobin percentage remain constant
Grade I	Hemoglobin percentage increases upto 0-0.5 gm
Grade II	Hemoglobin percentage increases upto 0.5-1 gm

#### **OBSERVATIONS AND RESULTS**

The above said subjective parameters of the study were recorded without any bias and the obtained results were tabulated and the results are assessed statistically and are expressed in terms of 'Z' value and 'p' values to show the significance of the study. The results of the study are as follows:

## (1) Bleeding per annum

In experimental group, out of 30 patients bleeding per rectum completely stopped in 17 patients (56.66%). In these patients 2 got completely relief from bleeding per rectum within 1 week while 7 patient got relief within 2 weeks while 8 has got relief after that. On the other hand remaining 13 (44.44%) were not get complete relief during therapy. In these patients 7

patients this symptom remains unchanged by treatment. In control group, out of 30 patients bleeding per rectum completely stopped in 6 patients (20%) while in 10 patients (33.33%) bleeding per rectum increases. In 6 patients symptoms bleeding increases in first week but after that bleeding proportion decreases but not completely stopped. Also in 2 patients bleeding per rectum remains constant.

Table No 1: Effect of Therapy on bleeding per annum by using Wilcoxon signed rank test.

	Group	B.T.	7 <sup>th</sup> day	14 <sup>th</sup> day	A.T.
Mean	Experimental	1.76	1.53	1.23	0.76
	Control	1.9	2.1	1.93	1.5
S.D.	Experimental	0.568	0.889	0.935	1.07
	Control	0.60	0.66	0.69	1.04
S.E.	Experimental	0.10	0.164	0.170	0.195
	Control	0.110	0.120	0.126	0.190
Z value	Experimental	-	1.460	2.818	3.241
	Control	-	1.604	0.399	1.007
P value	Experimental	-	P>0.05	P<0.01	P<0.01
	Control	_	p>0.05	p>0.05	p>0.05

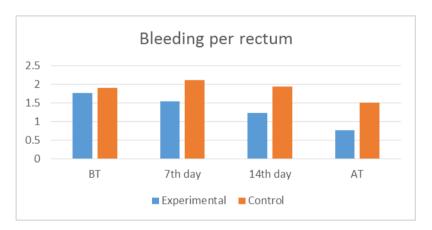


Table No 2: Comparison of bleeding per annum by using Wilcoxon rank sum test (Mann Whitney's test).

Follow up	Experimental	Control	7 volue	Dyoluo	Significance	
Follow up	Mean±S.D.	Mean±S.D.	Z value	r value	Significance	
7 <sup>th</sup> day	0.23±0.85	0.2±0.86	2.137	P>0.05	Significant	
14 <sup>th</sup> day	0.53±0.93	0.033±0.81	2.736	P<0.01	Highly Significant	
A.T.	1±1.34	0.26±1.23	2.350	P>0.05	Significant	

As per the above tables, in experimental group p value < 0.01 shows highly significant result while control group p value > 0.05 shows non-significant results. Thus the above findings

indicates that experiment group i.e. patients given *Gudadi Gutika* shows more significant results in bleeding per annum than that of control group i.e. patient given *Haritaki churna*.

## (2) Constipation

In experimental group, out of 30 patients constipation completely cure in 22 patients (56.66%). In these patients 17 got completely relief from constipation within 1 week while 4 patient got relief within 2 weeks and 1 has got relief after that. On the other hand, in control group 23 patients gets completely relief from constipation where 16 patients gets relief within 1 week while 4 patients gets relief from constipation after complete treatment.

Table No 3: Effect of Therapy on Constipation by using Wilcoxon signed rank test.

	Group	B.T.	7 <sup>th</sup> day	14 <sup>th</sup> day	A.T.
Mean	Experimental	1.96	0.6	0.4	0.33
	Control	2.1	0.66	0.46	0.266
S.D.	Experimental	1.0662	0.770	0.674	0.6064
	Control	0.9595	0.8.22	0.6814	0.5208
S.E.	Experimental	0.194	1.140	1.123	1.110
	Control	0.175	0.146	0.124	0.520
Z value	Experimental	-	4.244	4.564	4.559
	Control	-	4.259	4.724	4.790
P value	Experimental	-	P<0.001	P<0.001	P<0.001
	Control	-	P<0.001	P<0.001	P<0.001

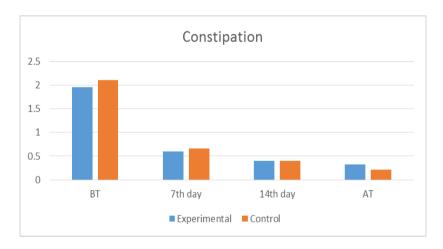


Table No 4: Comparison of bleeding per annum by using Wilcoxon rank sum test (Mann Whitney's test).

Follow up	Experimental	Control	Z value P value		Cianificance	
Follow up	Mean±S.D.	Mean±S.D.	L value	r value	Significance	
7 <sup>th</sup> day	0.0033±0.09	$0.02\pm0.29$	1.1314	p>0.05	Non-Significant	
14 <sup>th</sup> day	0.046±0.199	$0.036\pm0.088$	2.1690	p<0.01	Significant	
A.T.	0.16±0.29	0.053±0.15	3.3865	p<0.001	Highly Significant	

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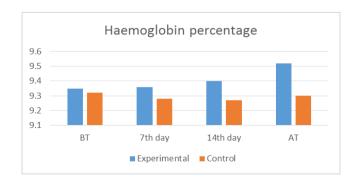
As per the above tables, in experimental group as well as in control group p value < 0.001 shows highly significant results. Thus the above findings indicates that experiment group i.e. patients given *Gudadi Gutika* as well as control group i.e. patient given *Haritaki churna* shows significant results in bleeding per annum.

### (3) Haemoglobin percentage

In experimental group, out of 30 patients hemoglobin percentage of 8 patients (26.66%) increase in per week while in 6 patient it remain constant in 1<sup>st</sup> week but after that it increases where as in 3 patients hemoglobin remain constant for 2 week but after that it increases. In 2 patients hemoglobin percentage decreases in 1<sup>st</sup> week then increases in 2<sup>nd</sup> week but after treatment hemoglobin remain same as before. In 2 patients hemoglobin level decreases in 1<sup>st</sup> week and remain constant upto the end of the treatment. On the other hand in control group, 3 patients hemoglobin percentage reduced in 1<sup>st</sup> week then after it remains constant. In 2 patients hemoglobin percentage raises in 1<sup>st</sup> week then it remains constant. In 2 patients hemoglobin percentage remain constant in 1<sup>st</sup> week and after that it raises continuously, in 2 patients hemoglobin percentage increases continuously during whole treatment.while in 2 patients hemoglobin percentage remain constant during whole treatment.

Table No 5: Effect of Therapy on Haemoglobin percentage by using Students paired t test.

	Group	B.T.	7 <sup>th</sup> day	14 <sup>th</sup> day	A.T.
Mean	Experimental	9.35	9.36	9.40	9.52
	Control	9.32	9.28	9.27	9.3
S.D.	Experimental	1.85	1.83	1.81	1.79
	Control	1.74	1.75	1.78	1.78
<b>S.E.</b> Experimental		0.339	0.334	0.331	0.327
	Control	0.318	0.320	0.325	0.326
t value	Experimental	-	0.1827	1.2810	3.0781
At 29 d.f.	Control	-	0.5639	0.8874	4.902
P value Experimental		-	P>0.05	P>0.05	P<0.05
	Control	-	p>0.05	p>0.05	p>0.05



**Experimental Control** Follow up Z value P value **Significance** Mean±S.D. Mean±S.D. 7<sup>th</sup> day  $0.0033\pm0.09$  $0.02\pm0.29$ 1.1314 P>0.05 Non-Significant 14<sup>th</sup> day 0.046±0.199  $0.036 \pm 0.088$ 2.1690 P<0.01 Significant A.T.  $0.16\pm0.29$  $0.053\pm0.15$ 3.3865 P > 0.05**Highly Significant** 

Table No 6: Comparison of Haemoglobin (gm/dl) by using unpaired t test.

As per the above tables, in experimental group p value < 0.05 shows highly significant results while control group p value > 0.05 shows non-significant results. Thus the above findings indicates that experiment group i.e. patients given *Gudadi Gutika* shows more significant results of hemoglobin percentage than that of control group i.e. patient given *Haritaki churna*.

## (4) Mucous discharge

In experimental group, out of 30 patients 4 patients were had complaints of mucous discharge which gets relief in all patients after treatment. In control group, out of 30 patients 5 patients were had complaints of mucous discharge which does not get relief in any patients after treatment.

## (5) Kandu (Itching)

In experimental group, out of 30 patients 4 patients were had complaints of itching which gets relief in all patients after treatment. In control group, out of 30 patients 4 patients were had complaints of mucous discharge which does not get relief in any patients after treatment.

### **DISCUSSION**

Management of *Arsha* (hemorrhoids) has been a challenge for physicians of all the system of medicines. *Sushruta* has described the anatomy and physiology of *Guda* as well as contribute separate chapters for its diagnosis and management. *Sushruta* narrated it under the "*Ashta Mahagadas* (eight grave diseases)." *Sushruta* has mentioned four types of treatment of *Arsha* and has given more emphasis on *Bhaisajya Chikitsa*. In *bhaishajya chikitsa*, *Sanrakshan Chikitsa* i.e. Conservative treatment plays an important role in 1<sup>st</sup> and 2<sup>nd</sup> degree piles. In *Ashtang hridaya*, some of the important compositions are mentioned that can be used in piles treatment. One of them is *Gudadi Gutika* which is mentioned in *Ashtang hrudaya* by *Acharya Vagbhata* in *Arshodhyaya*. Thus the clinical study was performed to evaluate the efficacy of *Gudadi Gutika* in 1<sup>st</sup> and 2<sup>nd</sup> degree piles. This study was conducted among 60 patients, in which *Gudadi Gutica* given in randomly selected 30 patients while other 30 patient belongs

to control group administrated by oral administration of *Haritaki churna*. These patient were ask for regular follow up in each week upto 3 weeks and also before and after treatment condition were noted. In experimental group, out of 30 patients bleeding per rectum completely stopped in 17 patients (56.66%). In these patients 2 got completely relief from bleeding per rectum within 1 week while in control group, out of 30 patients bleeding per rectum completely stopped in 6 patients (20%) while in 10 patients (33.33%) bleeding per rectum increases. It indicates that patients given Gudadi Gulika shows more significant results in bleeding per rectum than that of control group. In experimental group, out of 30 patients constipation completely cure in 22 patients (73.33%). In these patients 17 (56.66%) got completely relief from constipation within 1 week while in control group constipation is completely cured 23 patients (76.66%). In these patients, 16 (53.33%) got completely relief from bleeding per rectum within 1 week. Also by applying Wilcoxon ranked sign test to both criteria i.e. bleeding per rectum and constipation, Gudadi Gutika shows the significant improvements in both criteria. Hemoglobin percentage for each individual selected as objective criteria to prove the efficacy of Gudadi Gutika in piles. Here in 17 patients (56.66%) out of 30 patients in experimental group has increase in hemoglobin percentage while in control group it raises in just 4 patients. Thus by applying paired t test, Gudadi Gutika shows significant improvement in hemoglobin percentage than control group. The patients having symptoms of mucous discharge and kandu, all gets relief by the administration of Gudadi Gudika. This data shows that Gudadi Gutika formulation has potency to cure 1<sup>st</sup> and 2<sup>nd</sup> degree internal piles. Almost all the symptoms studied have shown significant results and relief in the symptoms of piles.

### Probable mode of Gudadi Gutika

According to Ashtang Hrudaya, Gudadi Gutika is mentioned under Arshorogadhikar. Its ingredients are- Maricha (Piper nigram), Pippali (Piper nigram), Suntha (Zingiber officinalis), Chitrak (Plumbago Zelamice), Suran (Amorphophylus companulatus) and Guda (Saccharum officinaru) These drugs used in this preparation are Dipaniya, Pachniya, Shool prashamaniya & Arshoghna dravya, etc. Almost all of these drugs are having the property of Deepan, Pachana, Vatanulomana, ushna guna hence will have shulaprashamana or the pain relieving activity and are said to be the best appetizers. Suran has special effect (Prabhav) as Arshoghna. So it is the pathya in all Arsha. As it is Kashaya rasapradhana, it is useful to stop bleeding in Raktarsha, because of ushna and tikshna guna. Also ushna, tikshna guna helps rakta dhatu to flow in regular manner without any congestion at veins and hence shotha

(inflammation) decreases and size of pile mass seems to be decreased as ushna guna dilates the channel of raktavaha strotas. Most of the ingredients of Gudadi Gutika formulation are katu rasapradhana and they help in reducing the blood clotting or accumulation as they are said to be having action as "Shonit Sanghata Bhinnati". It is stated that Arsha is the congestion of veins and katu rasa dissolve the congestion. The root cause for Arsha is Mandagni, due to which production of ama increases and such continuous production of ama leads to malasanchaya. This large quantity of mala is loaded in colon for long duration. Absorption of fluids from *faeces* occurs in large quantity resulting in hard stool passage. To pass such hard stool, patients undergoes straining (pravahana) during defaecation, finally resulting in dilated rectal plexus and mamsankur (Arsha) utpatti occurs. So from above pathological process most of the Ayurvedic texts gives more concentration for deepana (increasing jatharagni) and digestion of ama i.e. pachana chikitsa respectively effects on mandagni and ama. Charakacharya mentioned most of the ingredients in deepaniya, Arshoghna and shulaprashamana gana while Sushrutacharya explained in pippalyadi gana which acts as deepana, pachana, vatanuloman, shulaprashaman, kaphaghna. Thus the Chikitsa with Gudadi Gutika disturbs pathological process of Arsha and ultimately patients get relief from signs and symptoms of Arsha.

### **CONCLUSION**

From the above study it can be concluded that the drug *Gudadi Gutika* proves to be one of the best drugs in the management of *Arsha*. It helps in relieving the symptoms of the *Arshas* like bleeding, constipation, etc. As the study was conducted only in a limited set of conditions, the results must to be evaluated in a large population to prove its efficacy.

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