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A clinical study of *PranadaGutika* and *ArshoghnaMahakashayaGutika* in the management of the *Arsha*

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ABSTRACT:

Introduction:Present time is the era of fast foods, irregularly food timing, changing Life style and stress, all these factors disturb the Gastrointestinal tract resulting *Mandagni* and constipation, resulting *Arsha*.

Aim:To assess the efficacy of *Pranada Gutika* and *Arshoghna Mahakashaya Gutika* in the management of the *Arsha*.

Materials and Methods: Total 30 patients were registered and randomly divided into two groups. Group A (trial) *PranadaGutika* and Group B (control) *ArshoghnaMahakashayaGutika*.

Assessment was done based on the subjective and objective parameters after 6 weeks of treatment, with a follow-up 1 month (once in weekly). The data obtained in clinical study was analyzed by using Wilcoxon test.

Results: Group-A and Group-B provided highly significant result ($P < 0.001$) symptoms *Mandagni* and *Vibandh*. In Group A, cured found in 3 patients (20%); markedly improvement in 01 patients (6.67%), moderately improvement in 09 patients (60%), mild improved in 2 patients (13.33%). In Group B, cured found in 4 patients (26.67%); markedly improvement in 01 patients (6.67%), moderately improvement in 08 patients (53.33%), mild improved in 2 patients (13.33%). No ADR found during clinical study.

Conclusion: *ArshoghnaMahakashayaGutika* given better result in *Mandagni* and *Vibandh*.

Key words: *Arsha, Mandagni, Pranadagutika, ArshoghnaMahakashayaGutika*

INTRODUCTION

In the present era of 21st century *Arsha* has become most common disease. According to Mayo's clinic, 3.4% of all the entered patients were

suffering from haemorrhoids.

Symptomatic haemorrhoids affect at least 50% of the population at the sometime during their lives with around 5% of the population suffering

at any given time^[1] However, the true age distribution was not estimated. The WHO has started celebrating the 20th Nov. of each year as "WORLD PILES DAY", which clearly indicates the infiltration of this disease all over the world and tremendous physical and mental sufferings of the mankind as result of this disease.

In *Ayurveda*, all *Acharya* have described *Arsha* in separate chapter, and *Acharyasushruta* and *Vagbhata* has described it under the heading of *Asthmahagada*.^[2]

AcharyaCharaka has given elaborate description about *Arsha*'s etiology, symptoms, pathogenesis and its management. He clearly says the involvement of all five subtypes of *Vata*, *Pitta*, *Kapha* in the *Samprapti* of *Arsha*.^[3]

Even *Sushruta* the father of surgery, has mentioned four lines of Management such as: *Aushadha*, *Kshara*, *Agni*, *Shastra*. He indicates the '*AUSHADH CHIKITSA*' as the first step in the management of *Arsha*.^[4] He further advocates the importance of '*Bheshaj Chikitsa*' (*Snehadikriya*) in comparison with the surgical treatment.

AIMS AND OBJECTIVES

To assess the efficacy of '*Pranada Gutika*' and '*Arshoghna Mahakashaya Gutika*' in the management of the *Arsha*.

MATERIALS AND METHODS

Selection of the patients

The patients from OPD & IPD of the Govt. Akhandanand Ayurved college and hospital, Ahmedabad and Shree Maniben Ayurved Hospita, Asarawa, have been selected. These patients have been divided into two groups with minimum 15 no. of patients in each group.

Ethical clearance

The present study has been cleared by Institutional Ethics Committee (IEC No. PGT/7-A/Ethics/2013-14/1767, dated 10/09/2013) and also registered in Clinical Trial Registry of India (CTRI/2014/02/004383, dated 06/02/2014). Written consent of the parents of each patient was taken before starting the treatment. Basic information of the disease and treatment was given to the patients.

Criteria for selection of patients

INCLUSION CRITERIA :

- 1ST and 2nd degree internal piles.
- Uncomplicated External pile mass.

- *Shuska* and *Aadra Arsha* both are selected.
- Classical signs described by *Acharya Sushruta*
 1. *Achirkalin* 2. *Alpdos-ling-upadrava*.

EXCLUSION CRITERIA :

- 3rd and 4th degree internal piles.
- Thrombosed and prolapsed pile masses.
- Pappiloma, condyloma and sentinel tags
- Pile masses with excessive bleeding
- Malignancy involvement
- *Parikartika* (Fissure in Ano) and *Bhagandara* (Fistula in Ano) involvement

Grouping:

Selected patients were randomly divided into two groups by simple random method. In Group A (trial group) *PranadaGutika* and Group B (standard group) *ArshoghnaMahakashayaGutika* were administered.

Posology :

Dose : 4 gms daily (Each *Gutika* of 500 mg) in divided doses.

Anupan: *Ushnodaka*.

Duration : 6 weeks.

Follow Up : 1 month (Once in Every Week)

Criteria for Assessment:

The improvement achieved by the therapy was assessed on the basis of classical signs & symptoms of *Arsha*. The routine Pathological and Biochemical investigations were done before and after treatment.

All the signs & symptoms were assigned score depending upon their severity to assess the effect of the drugs objectively.

Subjective parameters:

Cardinal symptoms:

Mandagn (Indigestion),
Vibandh (constipation),
Raktastrava (bleeding p/r),
Arshabhransa (Protrusion of pile mass).

Associate symptoms:

GudaKandu (itching), *GudaVedana* (pain in ano), *GudaSrava* (Discharge)

The following pattern was adopted for the scoring:

	<i>Mandagn</i> (Indigestion)
0	No <i>Mandagni</i>
1	Indigestion of heavy food.
2	Indigestion of normal food and heaviness in abdomen

3	Indigestion of light food and sometimes digesting of heavy food and after complain of heaviness in abdomen.
4	Indigestion of all kind of food and heaviness and flatulence constant all throughout the day.

	of anal canal.
2	Pile mass protrude during defecation which reduced itself.
3	Pile mass protrude during defecation which replaced manually
4	Permanent protrusion of pile mass.

Vibandha(Constipation)	
0	Satisfactorily Soft stool passes daily
1	Passes Stool with strain, sometimes takes purgatives.
2	Passes Stool after more than 24 hrs frequently take purgatives.
3	Passes Stool After gap of one day, normal purgatives does not works.

Gudakandu(Itching per Rectum)	
0	No <i>Gudakandu</i>
1	Mild <i>Gudakandu</i>
2	Moderate <i>Gudakandu</i>
3	Severe <i>Gudakandu</i>

RaktaSrava(Bleeding per rectum)	
0	No Bleeding P/R
1	Occasionally bleeding P/R (> 1week)
2	Frequently bleeding P/R (2-4 times/week)
3	Regularly bleeding P/R

GudaVedana (Pain in ano)	
0	No pain
1	Occasionally mild Pain in ano which doesn't required any medication.
2	Pain in ano after defecation which required medication.
3	Severe Pain in ano which does not control with medication.

ArshaBhransha (Protrusion of pile mass)	
0	No protrusion
1	Pile mass protrude within lumen

Gudsrava(Discharge per Rectum)	
0	No <i>Gudsrava</i>
1	Mild <i>Gudsrava</i>
2	Moderate <i>Gudsrava</i>

3	Severe <i>Gudsrava</i>
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Laboratory Investigations:

(whenever possible)

- a) Haematological investigation
 - Hb %
 - Total leucocytes count and Differential count
 - ESR
- b) Stool examination-Routine and Microscopic
- c) Urine-Routine and Microscopic

Dietary advice

Pathya- Apathya:

The patients were allowed to take routine diet. But they were also advised to abstain from *AhitakaraAhar&Vihara* which leads to constipation and pathogenesis of *Arsha*.

Patients were advised to avoid the possible aggravating factors of *Arsha*.

Assessment of total effect of therapy:

The total effect of the therapy was assessed considering the following criteria.

- 1) **Cured** - 100% relief in the signs & symptoms was considered as cured.
- 2) **Markedly Improvement** - 76% to 99% relief in the signs & symptoms was considered as markedly

improvement.

- 3) **Moderately Improvement** - 51% to 75% relief was considered as moderate improvement in the signs & symptoms.
- 4) **Mild Improvement** - 26 to 50% relief in the signs & symptoms was considered as mild improvement.
- 5) **Unchanged** - Up to 25% relief was considered as unchanged.

Statistical analysis

Wilcoxon signed rank test was applied to evaluate the overall effect of therapy.

Selection of drug:

"PranadaGutika"^[5][Table 1] described in the *BhaishajyaRatnavali* *Arshaodhikar* has been taken as Test drug, and

"ArshoghnaMahakashayaGutika"^[6][Table 2] described in *Charaka Sutrasthana-4* has been taken as standard drug.

Observations

The observations made in this aspect lead to the conclusions that maximum number of patients i.e. 43.33% belonged to the age group of 31-45 years. More number of male patients i.e. 80% reported in the study than female patients. Maximum number i.e. 33.33% of patients were

serviceman. Maximum i.e. 50% patients were having *KrooraKostha* and 40% patients were having *MadhyamKostha*. Maximum number of patients i.e. 86.67% had hard consistency of stool.

In Present Study, All the patients in the present study reported *Mandagni* (Indigestion) are found 100%, *Vibandha* (Constipation) was observed in 96.67%, Protruding of pile mass outside to anal canal (self reducing) or within lumen (during proctoscopy) was observed in 70%, *RaktaSrava* (Bleeding per rectum) was observed in 70% of patients. [Table 3] *GudaVedana* (Pain in Ano) was observed in 30% of patients, *Gudakandu* was found 66.67% and *GudaSrava* Found 33.33%. [Table 4]

RESULTS

Effect of therapy:

Test group provided statistically highly significant results were obtained in the three chief complaints i.e. in *Mandagni*, *Vibandha* (Constipation), *RaktaSrava* (Bleeding per rectum) which were relieved by 60.5%, 60%, 100% respectively at the level of $p < 0.001$. Whereas statistically significant results were obtained in symptom *ArshaBhransa* (Protrusion of mass) at

the level of $p < 0.05$ and percentage wise improvements were observed in 55%. Statistically highly significant ($p < 0.001$) result was obtained in the complaint of *Gudkandu* which was relieved by 92.9%. Whereas statistically significant results were obtained in two symptoms like viz. *Gudvedana* and *Gudsrava* at the level of ($p < 0.05$) but percentage wise improvements were observed as 100% and 100% respectively. [Table 5, 6]

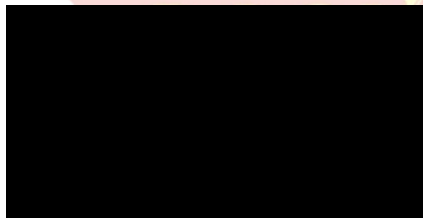
Standard group provided Statistically highly significant results were obtained in the two chief complaints i.e. in *Mandagni*, *Vibandha*, which were relieved by 80% and 100% respectively at the level of $p < 0.001$. Statistically significant results were also obtained in the symptoms of *RaktaSrava* (Bleeding per rectum) but relieved 100% respectively level of $p < 0.004$, *ArshaBhransa* (Protrusion of mass) which was relieved by 36.40% at the level of $p < 0.125$ (significant). Whereas statistically significant results were obtained on symptom *Gudasrava* at the level $p < 0.016$. Percentage wise improvements were observed which was relieved by 100%. Statistically insignificant results were obtained in two symptoms

GudaKandu and *GudaVedan* which were relieved by 60% and 75% respectively at the level of p 0.250 and p 0.250. [Table 7, 8]

Overall effect of therapy

Overall effect of *Pranada Gutika* shows that 26.67% of the patients got cured, 33.33% showed marked improvements, 26.67% of the patients obtained moderate improvements and rest of 13.33% patients obtained improvement in the various clinical manifestations of *Arsha*. [Table 9]

Overall effect of *ArshoghnaMahakashayaGutika* shows 26.67 % of the patients got cured, 6.67% showed marked improvement, 53.33% moderately improved in the clinical manifestations and 13.33% of the patients attained mild improvement in the clinical conditions. [Table 10]



DISCUSSION

The subject concerned here is *Arsha*. As described in all the *Ayurvedic* classics, it is very clear that

Arsha is a disease that arises from *Mandagni*. The drug which is to be used in the management of *Arsha* must possess the *Deepan, Pachan, Anulomanam, Samsha mana* and *RaktaSangrahi* properties.

We see the chief ingredient for *PranadaGutika* is *Gud*, which is certainly *VatakaphaNashak, Vatanulomak*. Most of drugs i.e. *Maricha, Pippli, Pippalimool, Chavya, Talishpatra, Twakand Ala* possess *Tikshna, Laghu* and *Ruksha* properties and *Katu Rasa, Katu Vipaka* with *UshnaVirya*. This functional complex in *PranadaGutika* targets its action on *Mandagni* mainly. Its *Tikshna, Laghu* and *Ruksha* properties acts on *Pitta* and lessen the *dravatva* in it which in turn promotes the *Mandagni*. This series of actions and reactions streamlines the *Samana* and *Apanavayu*. The function of rest of three *Vayu* mostly depends upon the normal function of these two *Vayu*. Ingredient *Haritaki* is *vatpittaghna*, can be used in *Tridoshaj* disease, and *Arsha* is among one them. Therefore the normalization of *Samana* and *Apana* ultimately corrects the remaining threes. This proper functioning of the *PanchatmaMaruta*

relieves the pressure on the valve less rectal veins thereby leaving them in normal i.e. Pre *Arsha* position (normalised anal cushions). As mentioned earlier the fine quality of *Dhatus* does not allow the faecal matter to form more in quantity. This also contributes to the less pressure on the valve less rectal veins.

Simultaneously to the above operation *Nagkesar* and *Amrunal* act on *Raktasrava* and *Acharyacharaka* indicated *Nagkesara* in bleeding piles.

Vatanuloman is also easily achieved by *Haritaki* and *Gud*, which is also an ingredient of this formula. So, "***Vatanuloman***" and "***Agni balvirdhi***" effect was desired for each patient.

In *ArshoghnaMahakashayaGutika* most of the drugs that are used are *Katuvipaki*, *Ushanvirya* and *Katu-Tikta-Kashaya Ras* dominance and in addition they do possess *UshnaGuna* too.

Haritaki and *BilvaFalmajjais* well known *Anolomaka* drugs. They help the digestion process and facilitate the *Vatanuloman* in the body.

The therapeutic effect of *Deepana-Pachana* is achieved by *Chitraka*, *Chavya*, *Dhanvayasaka* and *Nagara*.

Kutaja is *VyadhiPratyanik* drugs of piles and It is the drug of choice in *AadraArsha* (*Bleeding piles*).

Ativisha act as a *Deepana*, *Pachan*, *Sangrahi* and *Krumihara dravya*. Where as *Daruharidra* act as a *Dosashodhaka* Drug.

To summaries we can say that some ingredients directly dissolve the pathology of piles. This entire drugs together acts specifically at various levels with a single aim of treating various clinical manifestations of piles.

CONCLUSION

The therapeutic effect of both the formulations was observed as *Dipan-Pachan*, *Vatanulomya*, *Kandughna*, *RaktaStambhaka*, *Vedanashamak* and hence *Arshaoghna.PranadaGutika* and *ArshoghnaMahakashayaGutika* statistically highly significant results were obtained in the two chief complaints i.e. in *Mandagni* & *Vibandha*, but percentage wise relieved of *Arshoghna Mahakashaya Gutika* given better result than *Pranada Gutika*. Further, the treatment is cost effective and devoid of side effects, so it can be applied in the community.

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[6] Ibidem[2] (*CharakaSamhita*, *Sutra Sthana* 4/12)

Table 1. Ingredient of *PranadaGutika*

SR. NO.	Name of the drug	Part used	Proportion
1.	<i>Haritki</i>	<i>Phala</i>	3 part
2.	<i>Maricha</i>	<i>Phala</i>	4 Part
3.	<i>Pippali</i>	<i>Phala</i>	2 Part
4.	<i>Chavya</i>	<i>Phala</i>	1 Part
5.	<i>Talispatra</i>	<i>Patra</i>	1 Part
6.	<i>Nagkesar</i>	<i>Punkesar</i>	½ Part
7.	<i>Pippalimoola</i>	<i>Moola</i>	2 Part
8.	<i>Ala</i>	<i>Phala</i>	¼ Part
9.	<i>Twak</i>	<i>Twaka</i>	¼ Part
10.	<i>Amrunal</i>	<i>Moola</i>	¼ Part
11.	<i>Guda</i>	—	30 Part

Table 2 Ingredients of *ArshoghnaMahakashayaGutika*

Drug Name	Latin Name	Part used	Proportion
<i>Kutaja</i>	<i>HolarrhenaAntidysentrica</i> Linn.	<i>Twak</i>	1 Part
<i>Bilva</i>	<i>AegleMarmelos</i> Corr.	<i>PhalaMajja</i>	1 Part
<i>Chitraka</i>	<i>Plumbagozylenicum</i>	<i>Moola</i>	1 Part
<i>Nagara</i>	<i>Zingiberofficinale</i>	<i>Kanda</i>	1 Part
<i>Ativisha</i>	<i>Aconitum hetrophyllum</i>	<i>Kanda</i>	1 Part
<i>Abhaya</i>	<i>Terminaliachebula</i>	<i>Phala</i>	1 Part
<i>Dhanvayasakah</i>	<i>Fagoniacretica</i>	<i>Panchang</i>	1 Part
<i>Daruharidra</i>	<i>Berberisaristata</i>	<i>Kanda</i>	1 Part
<i>Vacha</i>	<i>AcorusCalamus</i>	<i>Kanda</i>	1 Part
<i>Chavya</i>	<i>Piper retrofractum</i>	<i>Moola</i>	1 Part

Table 3 Presence of the Cardinal symptoms of *Arsha* in 30 patients

Symptoms	GROUP-A	GROUP-B	Total	Percentage
<i>Mandagni</i>	15	15	30	100
<i>Vibandha</i>	14	15	29	96.67
<i>RaktaSrava</i>	12	09	21	70.00
<i>ArshaBhransha</i>	13	08	21	70.00

Table 4 Presence of Associated symptoms of *Arsha* in 30 patients

Associated symptom	GROUP-A	GROUP-B	Total	Percentage
<i>Gudkandu</i>	12	06	20	66.67
<i>Gudvedana</i>	06	03	09	30.00
<i>Gudsrava</i>	07	04	11	33.33

Table 5 Effect of *PranadaGutika* on Cardinal symptoms of 15 patients.

Chief Complaints	'n'	Mean score		Diff.	%	W	P
		BT	AT				
<i>Mandagni</i> (Indigestion)	15	2.2	0.87	1.33	60.5	105	<0.001
<i>Vibandha</i> (Constipation)	14	2.14	0.87	1.29	60	105	<0.001
<i>Raktstrava</i> (Bleeding per rectum)	13	1.08	0.00	1.08	100	78	<0.001
<i>ArshaBhransa</i> (Protrusion of mass)	13	1.54	0.69	1.08	55	55	0.002

Table 6 Effect of *PranadaGutika* on associated symptoms of 15 patients

Chief Complaints	'n'	Mean score		Diff.	%	W	P
		BT	AT				
<i>GudKandu</i>	12	1.17	0.08	1.08	92.9	78	<0.001
<i>GudVedana</i> (Pain in Ano)	6	1.00	0	1	100	21	0.031
<i>GudSrava</i>	7	1.00	0	1	100	28	=0.016

Table 7 Effect of *ArshoghnaMahakashayaGutika* on cardinal symptoms in 15 patients

Chief Complaints	'n'	Mean score		Diff.	%	W	P
		BT	AT				
<i>Mandagni</i> (Indigestion)	15	1.73	0.33	1.40	80.8	120	<0.001
<i>Vibandha</i> (Constipation)	9	1.00	0.00	1.00	100	91	<0.001
<i>Raktstrava</i> (Bleeding per rectum)	9	1.00	0.00	1.00	100	45	0.004
<i>ArshaBhransa</i> (Protrusion of mass)	8	1.38	0.88	0.50	36.40	10	0.125

Table 8 Effect of *ArshoghnaMahakashayaGutika* on associated symptoms in 15 patients

Associated Complaints	'n'	Mean score		Diff.	%	W	P
		BT	AT				
<i>GudKandu</i>	5	1.00	0.4	0.6	60	6	0.250
<i>GudVedana</i> (Pain in Ano)	3	1.33	0.33	1.00	75	6	0.250
<i>GudSrava</i>	3	1.00	0.00	1.00	100	-28	0.016

Table 9 Overall effect of *PranadaGutika* 15 patients of *Arsha*

Total Effect	Percentage	No. of pts	Percentage
Cured	100%	03	20%
Markedly Improved	76 – 99%	01	6.67%
Moderately Improved	51 – 75%	09	60%
Mild Improved	26 – 50%	02	13.33%
Unchanged	< 25%	00	00.00 %

Table 10 Overall effect of *ArshoghnaMahakashayaGutika* on 15 patients of *Arsha*

Total Effect	Percentage	No. of pts	Percentage
Cured	100%	04	26.67%
Markedly Improved	76 – 99%	01	6.67%
Moderately Improved	51 – 75%	08	53.33.%
Mild Improved	26 – 50%	02	13.33%
Unchanged	< 25%	00	00

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