



A Clinical Study Of *Pranada Gutika* And *Kasisadi Taila* In The Management Of *Arsha Roga* With Special Reference To Hemorrhoids.

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Abstract

Context: *Ayurveda* is a science of life and more than just a medical system. *Ayurveda* has taken the foremost place in the management of crippling disease. *Arsha* is one of the prime important disease from *Ashta Mahagada*. *Ayurveda*, the ancient science of medicine of India has detail information and description of *Arsha*. According to *Ayurvedic Samprapti Mithya Aahara-Vihara* is one of the important etiological factors of it. *Arsha Roga*, which can be compared with hemorrhoids due to its clinical appearance. *Arsha* is more than another anorectal ailment, near about one third of population suffering from anorectal diseases.

Aims: To study the efficacy of *Pranada Gutika* and *Kasisadi Taila* in the management of *Arsha Roga* (Hemorrhoids).

Materials and Methods: 30 clinically diagnosed patients were selected and administered *Pranada Gutika* 2 tab. (each tablet 500 mg) three times in a day with lukewarm water, after meal for 30 days and *Kasisadi Taila Pichu Dharana* for 7 days.

Study design- Single centre and open label clinical study.

Results: Statistically highly significant result was found in *Mandagni* (Indigestion), *Vibandha* (Constipation), *Raktastrava* (Bleeding per rectum), *Arshabhransa* (Protrusion of pile mass), *Guda Kandua* (Itching), *Guda Vedana* (Pain in ano), *Guda Srava* (Discharge per rectum) and also in Hb %, ESR and symptoms of *Arsha Roga*.

Conclusions: Therapy in the form of administration of *Pranada Gutika* and *Kasisadi Taila* was effective in the management of *Arsha Roga*.

CC License CC-BY-NC-SA 4.0	(Hemorrhoids). Key words- <i>Arsha Roga, Ashta Mahagada, Pranada Gutika, Kasisadi Taila, Hemorrhoids.</i>
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INTRODUCTION –

Ayurveda is not merely a system of medicines but it also imparts the knowledge to masses about the art of living a healthy life without suffering from various ailments. In the present era our society has changed a lot with technological advancement life style has become sedentary and food habits have become unhealthy. The culture of fast-food, eating outside, eating preserved, canned and precooked food, and erratic schedule of sleeping and waking has been pervading our society very subtly. These dietetic and life style indiscretion vitiate the *Agni*. According to *Acharya Vagbhatta Mandagni* is the prime cause of all disease. [1] *Arsha* has become most common and distressing disease. In *Sushruta Samhita* the author has describe concept of *Ashta Mahagada* i.e. eight such disorders which are considered to be incurable. [2] The *Arsha Vyadhi* (Haemorrhoids) has been classified under *Ashta Mahagada* Thus main cause of anorectal disorders is the irrationality of *Jatharagni (Mandagni)* leading to *Vibandha* (Constipation), which is considered as the root cause of *Arsha*. Constipation exerts pressure on haemorrhoid veins situated in anal canal that induce its dilation. This dilated mass is considered as piles. Perianal skin is one of the most pain sensitive region of the body owing to the presence of rich nerve ends. Thus, only a moderate type of illness may bring a great deal of pain to the individual. The problem just seems to get worse over time and age.

Acharya Charaka clearly divided *Arsha* into two types while describing the treatment modality i.e. *Shushka* and *Stravi*. *Shushka Arsha* i.e. *Vata Kapha* dominance & *Stravi Arsha* i.e. *Rakta Pitta* dominance occurs. [3] According to the Bailey and Love's Short Practice of Surgery, Haemorrhoids are dilated, tortuous or varicose veins arising in relation to the anus and originating from the epithelial plexus produced by radicals of the superior, middle and inferior rectal veins. Some scientists find this to be the displacement of anal cushions. [4] According to Park's, Haemorrhoids are the secular dilation of the terminal portion of the haemorrhoidal venous plexus located in the sub mucosa of the upper anal canal just above the muco-cutaneous junction. [5] Highly vascularized "cushions" incorporated discreet masses of dense submucosa containing blood vessels, smooth muscle and elastic & connective tissue within the normal anal canal. These are found in the left lateral, right anterior and right posterior canal quadrants to assist in anal continence. The word "Haemorrhoids" should be limited to clinical condition in which these "cushions" are irregular and cause symptoms.

Symptomatic hemorrhoids affect at least 50% of the population at some phase during their lives with around 5% of the population suffering at any given time. Such clinical manifestation is humiliating to the user. These anorectal conditions are usually associated with psychiatric symptoms due to their position and impaired suffering that impacts the quality of life. The altered lifestyle is the leading cause significant rise in the incidence of this disorder.

The treatment modalities for *Arsha* have been split into four sections in *Bhaishajya Ratnavali*. These are *Bheshaja Karma* (Medical treatment), *Kshara Karma* (Caustic Therapy), *Agni Karma* (Thermal cautery therapy), *Shashtra Karma* (Surgery). [6]

AIMS & OBJECTIVES:

1. Conceptual & Clinical study to review *Arsha Roga* w.s.r. to Haemorrhoids.
2. To evaluate the efficacy of *Pranada Gutika* and *Kasisadi Tail* in the management of *Arsha Roga* w.s.r. to Haemorrhoids.

MATERIALS & METHODS:

SELECTION OF PATIENT-

The study was conducted on 30 clinically diagnosed and confirmed patients of *Arsha Roga* (Haemorrhoids) from the *Kayachikitsa & Shalyatantra* OPD and IPD of M.M.M. Government Ayurveda college, Udaipur, Rajasthan. A careful history, physical examination and necessary investigations were performed as per proforma prepared for the trial.

INCLUSION CRITERIA-

1. The patients between the age group of 20 to 60 years in either sex presenting with clinical features of *Arsha Roga*.
2. Diagnosed patients of *Arsha Roga*.
3. Chronicity less than 5 years.
4. Patients willing to sign the consent forms.

EXCLUSION CRITERIA-

1. Patients of *Arsha*, age less than 20 years and more than 60 years.
2. Chronicity of *Arsha Roga* more than 5 years.
3. Patients with other systemic illness like uncontrolled Diabetes mellitus, Hypertension, Malignancy, Hepatitis B, Tuberculosis and Retrovirus positive.
4. Complicated external piles and other associated Ano-rectal diseases like *Parikartika* (Fissure in Ano) and *Bhagandara* (Fistula in Ano).
5. Thrombosed or Strangulated pile mass.
6. Infective and Neoplastic conditions of rectum, Rectal prolapse.
7. Pelvic pathology and Pregnancy.
8. Patients who have completed participation in any other clinical trial during the past six months.

GROUPING & DRUG ADMINISTRATION-

30 clinically diagnosed and registered patients of *Arsha Roga* (Haemorrhoids) treated by *Pranada Gutika* 2 tab. (each tablet 500 mg) three times in a day with lukewarm water, after meal for 30 days and *Kasisadi Taila Pichu Dharana* for 7 days.

Pathya-Apathya was advised as per *Ayurvedic* classics.

WITHDRAWAL CRITERIA:

The participant did withdraw from the trial if-

1. She/he developed any serious adverse effect (necessitating hospitalization).
2. There is non-compliance of the treatment regimen (minimum 80% compliance is essential to continue in the study).

DRUGS & METHOD OF ITS PREPARATION-***Pranada Gutika* [7]-**

The proposed formulation *Pranada Gutika* selected in this trial was chosen from the *Chakradatta* in *Arshorogadhikara* & Contents of *Pranada Gutika* are *Shringabera* (*Zingiber officinale*), *Maricha* (*Piper nigrum* Linn.), *Pippali* (*Piper longum* Linn.), *Chavya* (*Piper retrofractrum* Vahl), *Talishapatra* (*Abies webbiana* Lindl), *Nagakesara* (*Mesua ferrea*), *Pippalimoola* (*Piper longum* Linn), *Tejapatra* (*Cinnamomum tamala*), *Sookshma Ela* (*Elettaria cardamomum*), *Twak* (*Cinnamomum verum*), *Khasa* (*Vetiveria zizanioides*) and *Guda* (Jaggery) were taken according to quantity mentioned in classical text *Chakradatta*. All drugs were powdered and mixed with *Guda* and *Vati* (each tablet 500 mg) was made. This trial drug was prepared in the pharmacy.

***Kasisadi Taila* [8]-**

The *Kasisadi Taila* was chosen from the *Sharangadhara Samhita Madhyama Khanda*. The ingredients of *Kasisadi Taila* are mineral drugs *Kasisa* (Ferrous sulfate (FeSO_4)), *Danti* (*Baliospermum montanum* Muell.), *Saindhava Lavana* (Sodium chloridum), *Ashwamara* (*Nerium indicum* Soland), *Chitraka* (*Plumbago Zeylanica* Linn), *Snuhi dugdha* (*Euphorbia neriifolia* Linn.) and *Tila Taila* (*Sesamum indicum* Linn.). Boil the *Tila Taila* till it become free of froath. Add 4 parts of *Kwatha* along with *Kalka* (paste) of specified drugs. Boil it on moderate heat till the oil became free from water, hence *Taila paka* was done. This *Taila* was prepared in pharmacy according to instructions given in *Sharangadhara Samhita Madhyama Khanda Taila Kalpana*.

Duration of clinical trial and follow up study-

1. 30 days for oral drug.
2. All patients will be followed up fortnightly for 1 month.

CRITERIA FOR ASSESSMENT:**1. Subjective parameters-**

Clinical features of *Arsha Roga* which mention in *Ayurveda* classics-

1. *Mandagni* (Indigestion)
2. *Vibandha* (Constipation)
3. *Raktastrava* (Bleeding per rectum)
4. *Arshabhransa* (Protrusion of pile mass)
5. *Guda Kandu* (Itching)
6. *Guda Vedana* (Pain in ano)
7. *Guda Strava* (Discharge per rectum)

2. Objective parameters-

1. Haemoglobin (Hb)
2. Erythrocyte Sedimentation Rate (ESR)
3. Total Leucocyte Count (TLC)

Assessment of sign and symptoms was done pre and post trial on severity grading scale for various aspects of disease as follow-

Table No. 1: Grading of *Mandagni* (Indigestion):

Sr. No.	Symptoms	Grading
1	No <i>Mandagni</i> /Indigestion	0
2	Indigestion / prolongation of food digestion period occasionally related to heavy meal	1
3	<i>Avipaka</i> occurs daily after each meal takes four to six hour for <i>Udagara shuddhi</i> etc <i>Lakshana</i>	2
4	Eat only once in a day and does not have hungry by evening	3
5	Never gets hungry always feeling heaviness in abdomen	4

Table No. 2: Grading of *Vibandha* (constipation):

Sr. No.	Symptoms	Grading
1	Satisfactorily Soft stool passes daily	0
2	Passes Stool with strain, sometimes takes purgatives.	1
3	Passes Stool after more than 24 hrs frequently take purgatives.	2
4	Passes Stool after gap of one day, normal purgatives does not work.	3

Table No. 3: Grading of *Raktastrava* (Bleeding per rectum):

Sr. No.	Symptoms	Grading
1	No bleeding per rectum	0
2	Occasionally bleeding per rectum (>1week)	1
3	Frequently bleeding per rectum (2-4 times/week)	2
4	Regularly bleeding per rectum	3

Table No. 4: Grading of *Arshabhransa* (Protrusion of pile mass):

Sr. No.	Symptoms	Grading
1	No protrusion	0
2	Pile mass protrude within lumen of anal canal	1
3	Pile mass protrude during defecation which reduced itself	2
4	Pile mass protrude during defecation which replaced manually	3
5	Permanent protrusion of pile mass	4

Table No. 5: Grading of *Guda Kandu* (Itching):

Sr. No.	Symptoms	Grading
1	No <i>Guda Kandu</i>	0
2	Mild <i>Guda Kandu</i>	1
3	Moderate <i>Guda Kandu</i>	2
4	Severe <i>Guda Kandu</i>	3

Table No. 6: Grading of *Guda Vedana* (Pain in ano):

Sr. No.	Symptoms	Grading
1	No pain	0
2	Occasionally mild pain in ano which doesn't required any medication	1
3	Pain in ano after defecation which required medication	2
4	Severe Pain in ano which does not control with medication	3

Table No. 7: Grading of Guda Strava (Discharge per rectum):

Sr. No.	Symptoms	Grading
1	No <i>Guda Strava</i>	0
2	Mild <i>Guda Strava</i>	1
3	Moderate <i>Guda Strava</i>	2
4	Severe <i>Guda Strava</i>	3

STUDY DESIGN:**Study type:** Single center, Interventional**Purpose:** Treatment**Masking:** Open label**Duration of clinical trial:** Total duration of clinical trial was 30 days.**No. of group:** 1**OBSERVATION & RESULTS:**

The study had shown that 16 patients in age group of 21-35 years & 14 patients in age group of 36-60 years were found; it shows overall 60% patients belong to 3rd to 5th decade of life. Incidence of disease is found notably higher in males (53.33%) than in females (46.66%), majority of the patients (90%) belong to Hindu religion; 82% patients were married. Out of which, maximum 80% patients belong to middle class, followed by 15% patients belong to poor class. Maximum 45% patients of *Vata-Pittaja Prakriti*, followed by 40% patients of *Vata-Kaphaja Prakriti*, 57% patients were of *Madhyama Sara*, 66% were having *Madhyama Samhanan*, 64% patients with *Madhyama Satmya*, 90% patients with *Madhyama Satva*, 60% patients showed *Avara Ahara Shakti* then 40% patients showed *Madhyama Ahara Shakti*, 50% patients showed *Madhyama Vyayama Shakti* then 40% patients showed *Avara Vyayama Shakti*, 65% patients of showed *Krura* nature of *Koshtha* whereas 25% patients with *Madhyama Koshtha*, all 100% patients were related to *Mandagni*. In this type of *Koshtha* & *Agni* has predominance of *Vata Kapha Dosha* & associated *Pitta Dosha*, which may play important role in developing the pathogenesis of *Arsha Roga*, maximum addicted 90% patients found were tea addiction, maximum 55% patients found duration of illness <2 years, followed by 15% patients found duration of illness 4 years. Maximum patients were found *Ati guru Ahara* 76% then *Singdha Ahara* 76.66%, *Ati Ushna Ahara* 53.33%, *Atidrava Ahara* 50%, *Abhishyandi Ahara* 80%, *Adhyashana* 76.66%, *Vishamashana* 70%, *Divasvapna* 76.66%, *Ratri Jagarana* 63.33%, *Vishama Shayya* 36.66%, *Chinta* 60.33%, *Bhaya* 16.66%, *Shoka* 10% and 100% patients had *Mandagni* (Indigestion), 90% patients of *Vibandha* (Constipation), 73.33% patients had *Raktastrava* (Bleeding per rectum), 60% patients had *Arshabhransa* (Protrusion of pile mass), 80% patients had *Guda Kandru* (Itching), 100% patients had *Guda Vedana* (Pain in ano), 53.33% patients had *Guda Strava* (Discharge per rectum).

RESULTS:

All the results calculated by using In Stat Graph Pad 3 software.

- For nonparametric data **wilcoxon matched-pairs signed ranks test** was used while for parametric data **paired 't' test** was used and results was calculated in group.

Effect of therapy in subjective parameters-**Table No. 8: Showing effect of therapy in subjective parameters (wilcoxon matched paired single ranked test)**

Variable	(n)	Mean		Mean Diff.	% Relief	SD±	SE±	P	S
		BT	AT						
<i>Mandagni</i> (Indigestion)	30	2.85	1.00	1.85	64.91	0.37	0.08	<0.001	HS
<i>Vibandha</i> (Constipation)	27	2.00	0.63	1.37	68.50	0.8087	0.1477	<0.0001	HS
<i>Raktastrava</i> (Bleeding per rectum)	22	1.47	0.13	1.34	91.15	0.8841	0.1614	<0.0001	HS
<i>Arshabhransa</i> (Protrusion of pile mass)	18	2.33	1.00	1.33	57.08	0.6065	0.1107	<0.0001	HS
<i>Guda Kandru</i> (Itching)	24	1.60	0.23	1.37	85.62	0.8087	0.1477	<0.0001	HS
<i>Guda Vedana</i> (Pain in ano)	30	2.43	0.70	1.73	71.19	0.7397	0.1350	<0.0001	HS
<i>Guda Srava</i> (Discharge per rectum)	16	1.81	0.50	1.31	72.41	0.48	0.12	<0.001	HS

(BT: Before Treatment, AT: After Treatment, HS: Highly Significant)

30 patients were treated with *Pranada Gutika* 2 tab. (each tablet 500 mg) three times in a day with lukewarm water, after meal for 30 days and *Kasisadi Taila Pichu Dharana* for 7 days that showed highly significant results regarding subjective parameters i.e. *Mandagni* (Indigestion), *Vibandha* (Constipation), *Raktastrava* (Bleeding per rectum), *Arshabhransa* (Protrusion of pile mass), *Guda Kandua* (Itching), *Guda Vedana* (Pain in ano), *Guda Strava* (Discharge per rectum) with % relief of 64.91%, 68.50%, 91.15%, 57.08%, 85.62%, 71.19% & 72.41% respectively.

Effect of therapy in objective parameters (Lab investigations)-

Table No. 9: Showing effect of therapy on Lab investigations (Paired 't' test)

Variable	No. of patients (n)	Mean		Mean Diff.	% Relief	SD±	SE±	t	P	S
		BT	AT							
Hb% (gm%)	30	12.86	13.28	0.42	3.26	0.8405	0.1535	2.737	<0.05	S
ESR	30	26.30	19.20	7.10	26.99	17.562	3.206	2.214	<0.05	S
TLC	30	7505	7123.3	381.67	5.08	1362.2	248.70	1.535	>0.05	NS

(Hb- Haemoglobin; TLC- Total Leucocytes Count; ESR- Erythrocyte Sedimentation Rate

S- Significant, NS- Highly Significant)

In objective parameters, Hb% have shown significant results ($P < 0.05$) with an improvement of 3.26 % & ESR have shown significant results ($P < 0.05$) an improvement of 26.99%, respectively, while in case of TLC has shown non significant results ($P > 0.05$) with an improvement of 5.08%.

DISCUSSION:

Probable mode of action of *Pranada Gutika*-

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 *Deepana*, *Pachana*, *Anulomana*, *Samshamana* and *Rakta Sangrahi* properties. [9] The chief ingredient for *Pranada Gutika* is *Guda*, which is certainly *Vatakaphashamaka*, *Vatanulomaka*. Most of drugs i.e. *Maricha*, *Pippali*, *Pippalimoola*, *Chavya*, *Talishapatra*, *Twak* and all possess *Tikshna*, *Laghu* and *Ruksha* properties and *Katu Rasa*, *Katu Vipaka* with *Ushna Virya*. This functional complex in *Pranada Gutika* 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 *Apana Vayu*.

The function of rest of three *Vayu* mostly depends upon the normal function of these two *Vayu*. Ingredient *Haritaki* is *Vatapittaghna*, can be used in *Tridoshaja* disease, and *Arsha* is among one them. Therefore the normalization of *Samana* and *Apana* ultimately corrects the remaining threes. This proper functioning of the *Panchatma Maruta* 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 *Dhatu*s does not allow the fecal matter to form more in quantity. This also contributes to the less pressure on the valve less rectal veins. Simultaneously to the above *Nagakesara* and *Amrunala* act on *Raktastrava* and *Acharya Charaka* indicated *Nagakesara* in bleeding piles. *Vatanulomana* is also easily achieved by *Haritaki* and *Guda*, which is also an ingredient of this formula. So, "*Vatanulomana*" and "*Agni balavridhi*" effect was desired for each patient.

Probable mode of action of *Kasisadi Taila*-

The most of the ingredients of *Kasisadi Taila* have *Ushna*, *Tikshna*, *Lekhana* and *Shodhana* properties. These properties helped to scraping out the slough and dead tissue as well as reduce the inflammation. *Kasisa* (Ferrous sulfate- FeSO_4) have *Krimighana* (antimicrobial) property which helped to control the infection and also for wound contraction (in bleeding piles). [10] *Manahshila* (Arsenic Sulphide) has *Katu- Tikta* and *Snigdha-Usna-Guru Guna* which exhibits *Lekhana* property. [11] *Kasisa*, *Kushtha* and *Chitraka* [12] have *Lekhana* properties so slough, pus, unhealthy granulation tissue is debrided and wound become healthy with revascularization and normal granulation. *Karavira* have *Vrana Laghavakara* property. [13] *Vidanga* have *Krimigna* property so wound become free from any outside of bacteria. [14] So chance of wound infection was minimized at which promote the wound healing. *Chitraka* and *Danti* have also *Krimighna* property. [15,16] In nutshell it can be hypothesized that all ingredients of *Kasisadi Taila* play combine effect of *Shodhana*, *Lekhana* and *Ropana* activity and wound healed without recurrence. In *Ayurved* classic the *Kasisadi Taila* is indicated in the management of *Arsha* (Piles) & it has been also shown the healing potential in *Dushta Vrana*. [17]

CONCLUSION:

- On the basis of *Rogaprakriti*, *Adhishtana* and *Samutthana* as well as on the basis of their clinical manifestations, *Arsha Roga* has very close resemblance with the disease Haemorrhoid.
- Dearranged status of *Agni i.e. Mandangi* is the main causative factor in the *Samprapati* of *Arsha Roga*.
- *Pranada Gutika* play major role to establish the *Jatharagni* in normal state.
- *Kasisadi Taila* possesses *Shodhana* (Cleaning), *Lekhana* (Scraping/debride), *Ropana* (healing) properties.
- *Pranada Gutika* and *Kasisadi Taila* have provided better relief in most of the cardinal features like *Mandagni* (Indigestion), *Vibandha* (Constipation), *Raktastrava* (Bleeding per rectum), *Arshabhransa* (Protrusion of pile mass), *Guda Kandu* (Itching), *Guda Vedana* (Pain in ano), *Guda Strava* (Discharge per rectum) and Hb% of the disease at highly significant level ($P < 0.005$).
- No adverse or side effects were encountered during the course of the study.

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