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ORIGINAL RESEARCH ARTICLE A COMPARATIVE CLINICAL STUDY OF KASISADI TAILA AND JATYADI TAILA IN THE MANAGEMENT OF ARSHA VIPUL PATEL¹ NEHA PARMAR²

ABSTRACT

Background: Acharya Susruta has described it under the heading of *ashtamahagada*- under the big umbrella of eight difficult to treat disorders and it is defined as violent as an enemy. **Aim and objectives:** The study was planned to compare the clinical efficacy of *Kasisadi taila* (Group I) with the *Jatyaditaila*(Group II) in the management of arsha with respect to haemorrhoids. **Methods and materials:** In Group-1 *-Kasisadi taila* (Test group) patients were pushed 10 ml *kasisadi taila* in the anal canal by rubber catheter no.9 and plastic syringe for 28 days. In Group-11 *-Jatyadi taila* – Control group patients were pushed 10 ml *jatyadi taila* in the anal canal by rubber catheter no.9 and plastic syringe for 28 days. **Results:** Group I- *kasisadi taila* provided highly significant relief in *raktasrava* (bleeding per rectum), *arshabhransha* (protrusion of mass), *gudavedana* (pain in ano) and *aniyatvibandha* (constipation). Group II – *jatyadi taila* provided significant relief in *raktasrava* (bleeding per rectum), *arshabhransha* (pain in ano) and aniyatvibandha (constipation). Group II – *jatyadi taila* provided significant relief in *raktasrava* (bleeding per rectum), *arshabhransha* (pain in ano) and aniyatvibandha (constipation). Group II – *jatyadi taila* provided significant relief in *raktasrava* (bleeding per rectum), *arshabhransha* (pain in ano) and aniyatvibandha (constipation). Group II – *jatyadi taila* provided significant relief in *raktasrava* (bleeding per rectum), *arshabhransha* (pain in ano) and aniyatvibandha (constipation). Conclusion:*Kasisadi taila* as local application with routine standard treatment is more effective than *jatyadi taila* in the 1st and 2nd degree of *arsha* (Haemorrhoids) because of its corrosive nature, *kasisadi taila* reduced the size of pile mass without hampering normal mucosa of anal canal. **Key words:** *Arshashatana*, Clinical study, *Jatyadi taila*, *Kasisaditaila*

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INTRODUCTION:

A healthy mind in a healthy body is the principle aim guiding all the prevailing systems of medicine. To achieve longevity of life, several scholars have made efforts since so many years. All the time Ayurveda has also the same implacability. Ayurveda is the natural healing system of medicine to maintain health of a healthy person and cure the ailments ailing person.

Present time is the era of fast foods, irregularity in food timing, changing food style and sedentary life and mental stress all these factors disturb the digestive system resulting into many diseases, among them one important group of diseases is that of anorectal disorders. Among these haemorrhoids commonly known as piles is quite common in the society. It is commonly seen in the people who work in sitting position for many hours such as driver, bank manager, tailor, shopkeeper, etc. Acharyas have described haemorrhoids as arsha in separate chapter, and AcharyaSusruta has described it under the heading of *ashtamahaqada*^[1](under the big umbrella of eight difficult to treat disorders) and it is defined as violent as an enemy.

Arsha is a clinical condition in which structural derangement take place. During process of pathogenesis, the *doshas* are vitiated due to indulgence in etiological factors by the person that in turn leads to *agnimandya* that further hampers the functions of *apanavayu*. Normally, *apanavayu* contributes to evacuation of bowel

but vitiated *apanavayu* leads to collection of faeces in *gudavali*, and eventually vitiates the other *vayus* and *doshas*, these vitiated *doshas* get localized in the *mamsa* and *meda* of *gudapradesha*, which result into appearance of *mamsapraroha* or *arsha*^[2].

According to modern surgery, haemorrhoids is varicosity and dilatation of haemorrhoidal veins of anal-canal. Hemorrhoid is commonly seen in human being due to valve- less structure of haemorrhoidal veins. Haemorrhoid is a disease, which is very specific to human race only due to its erect posture. Haemorrhoidal plexus drains into the internal pudendal veins and then into the internal iliac veins, thus providing a link between the portal and systemic venous circulation. In the management of hemorrhoids the procedures, which are in practice at present in modern surgery, are rubber band legation, cryo-surgery, dilatation, infra-red coagulation and haemorrhoidectomy, but not all of them have been uniformly successful^[3].

According to ayurveda the disease comes under the heading of *maharogas* because of it is *dirghakalanubandhi*, *duschikitsya* in nature and involves the *marma*.^[4]*Arsha* occurs in *gudabhaga*, which is undoubtedly a *marma* and it is well known for its chronicity and difficulty to treat. In ayurvedic treatise, several methods of treatments like *bhaishajakarma*, *shastrakarma*, *ksharakarma*, *agnikarma*, and *raktamokshana* etc. are advised for *arsha* among them, *bhaishajakarma* is the first line of treatment because there is no fear of complication, putrefaction and bleeding in comparison of others. *Kasisaditaila* indicated for the treatment of *arsha* as local application^[5] was selected for the present study. *Kasisaditaila* is also mentioned in *bhaishajyaratnavali*^[6] for the management of *arsha* as *arshashatanayoga*(have suppression property towards the piles), and it is mentioned that it destroys the *arsha* as like *kshara* without hampering the normal structure of *guda*.

Any drug has no importance if it is not tested for a particular disease and the results are not drawn from that study. The drug has no use in the clinical practice if its efficacy pertaining to any particular disease is not known to the administrator. Hence prior to the use of any drug, it's in vitro and in vivo studies must be carried out to ensure the safety of that drug and the results drawn from such scientific methods should be presented before world. Only after passing through these ordeals the drug becomes suitable for clinical practice. The properties and actions of ayurvedic drugs are already enumerated in the classics, but it's a need of the hour to prove their actions and properties in the light of modern scientific parameters. Envisaging these points, the selected drug kasisaditaila was screened here for their arshashatana karma through clinical point of view. Arsha is the commonest ailments afflicting after the age of fifty up to 50% of world's population. Taking а lead from the ayurvedicdescription of *arsha*, it can be correlated with haemorrhoids or bleeding piles. Both streams i.e. Ayurveda & modern have been searching for a good remedy and the easy and simple medication for *arsha* is still the requirement of the world.

AIMS & OBJECTIVES

To study the clinical efficacy of *kasisaditaila* and compare with the *jatyaditaila* in the management of *arsha* with respect to haemorrhoids.

MATERIALS AND METHODS:

KasisaditailahavingKasisa(FeSO4,7H2O),Hartala(AS2S3),Vidanga(EmbeliaribesBrum.f.),Karavira(NeriumindicumMill.),Karanja(PongamiapinnataPierre.),Saindhava(Rock salt),Jambu(SyzygiumcuminiLinn.skeels),Kritvedhana(Luffaacutangula.L.Roxb.),(PlumbegozeylanicaLinn.),Dantimoola

(*Baliospermummontanum*Wild.Moll.Arg.),*Arkaksh ira*(latex of *Calotropisprocera*(Aiton) Dryand.) *Snuhikshira*(latex of *Euphorbia nerifolia*Auct.Non Linn.), *Tilataila* (Sesame oil)^[7].

Jatyadi taila consists Jatipatra (JasminumgrandiflorumL.), Nimbpatra (AzadirachtaindicaA.Juss.), Patolapatra (TricosanthesdioicaRoxb.), Naktamalapatra (PongamiapinnataOierre.), Siktha (Honey bee wax), Madhuka (GlycyrrhizaglabraLinn.), Kustha (SaussurialappaDecne.Sch. Bip.), Nisha (Curcuma Linn.) Katurohini longa , (PicrorhizakurroaRoyleexBenth), Manjistha

(RubiacordifoliaL.) Padmaka (PrunuspuddamFranch), Lodhra (SymplocosracemosaRoxb.), Abhaya (TerminaliachebulaRetz), Nilotpala (NelumbiumspeciosumWild.), Tuttha Copper (sulphate), Sariva (HemidesmusindicusL. R.Br.), Naktamalabija (PongamiapinnataPirre.), Tilataila(Sesame oil)^[8].

Both *tailas* were prepared in the pharmacy unit of Gujarat Ayurved university, Jamnagar. The drugs were checked for their quality and used for preparation. Raw drugs were washed and grinded, prepared the *snehakalpana* according to *sharangdharsamhita*^{[9].}

The present study is first work on the effect of *kasisaditaila* in the management of *arsha*at I.P.G.T. & R.A., Gujarat Ayurveda University, jamnagar. The present research work was planned with the aim to find out a useful and easy remedy for the *arsha* in the initial stage which can be helpful for the patients suffering from it.

CLINICAL STUDY:

Research design: Interventional, randomized, open-labelled clinical trial.

Study Population: Patients with classical sign and symptoms of *arsha* (haemorrhoids) visiting O.P.D. & I.P.D. of *Shalya Tanta*; department of I.P.G.T. & R.A., Hospital, Jamnagar were selected for the present study in the year between 2006-2007.

Sampling: Simple random sampling technique was followed and Randomization sequence was generated with the help of coin method.

Study sample: Previously known or freshly identified patients of *arshas* from in and around Jamnagar.

Sample size: A total of 28 patients of *arshas* willingly participating in the study from in and around Jamnagar after a preliminary screening.

Determination of sample size was not done priory as this was a pilot scale study.

Design of the study (Grouping with Dose, Duration and *anupana* in therapy)

28 patients were randomly divided into two groups:-

- Group-I -Kasisaditaila Test group
 In this group, patients were pushed 10 ml
 kasisaditaila in the anal canal by rubber
 catheter no.9 and plastic syringe for 28 days.
- Group-II- Jatyaditaila Control group
 In this group, patients were pushed 10 ml
 jatyaditaila in the anal canal by rubber
 catheter no.9 and plastic syringe for 28 days.

Selection criteria

- All the patients were diagnosed & assessed thoroughly on the basis of Ayurvedic& modern classical signs & symptoms of *arsha*& examined on the basis of specially prepared proforma. A detailed history was taken.
- The routine haematological, urine, stool & biochemical investigations were also carried out to exclude any other pathology.

Exclusion criteria:

The following patients having thrombosed piles, piles with fistula in ano,piles with ulcerative colitis and 3rd&4th degree hemorrhoids were excluded from study.

Ethical considerations:

Ethical clearance was obtained from the institutional ethics committee (IEC) of IPGT & RA, Gujarat Ayurved University, Jamnagar. Informed consent was obtained from the participating patients.

Assessment criteria:-

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

- Cured 100% relief in the signs & symptoms was considered as cured.
- Markedly Improvement 76% to 99% relief in the signs & symptoms was considered as markedly improvement.
- Moderately Improvement 51% to 75% relief was considered as moderate improvement in the signs & symptoms.
- 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

Subjective parameters: - Bleeding per rectum, constipation, itching, burning sensation, protrusion of mass during defecation.

Objective parameters: - Degree of hemorrhoids, size and shape of pile mass.

OBSERVATIONS:

Total 28 patients were registered for the present study i.e. 15 patients in *kasisaditaila* group and 10 patients in *jatyaditaila*. In *kasisaditaila* group, out of 15 patients, 5 patients left against medical advice and 10 completed the treatment. In *jatyaditaila* group, out of 13 patients, 5 patients left against medical advice and 8 completed the treatment.

Maximum number of patients i.e. 75.00% were from urban and 25.00% patients were from rural area. This may be due to the location of the hospital where the study was performed. However, the urban distributions *arsha* can be attributed to over busy and sedentary life.

Faulty dietary habits like eating junk fast foods also add to this problem. Maximum number i.e. 35.72 % of patients were businessman, 28.57 % of patients were servicemen. 17.86% of patients were housewives; the prevalence indicates that business rivalry and heavy work load in offices which is main cause for untimely food intake have largely contributed towards the manifestations of the disease. Maximum i.e. 53.58 % patients hailed from lower middle class; followed by 32.14% patients from middle class. 07.14% patients were from poor and upper middle class. This represents that the people from the lower middle class are highly prone to this disease due to untimely food habits as all the day they are indulged in earning more and more money without giving proper attention to timely food habits. Maximum 57.14% of patients were having irregular bowel habit while 42.86 % of patients were having regular bowel habit. This indicates that irregular bowel habits lead to constipation and hard stool the main source of *arsha*. Maximum number of patients i.e. 82.14% had hard consistency of stool and 17.86% of patients had bulky consistency of stool. This suggests that hard stool give raise a much more pressure on the valve less blood vessels of rectum during defecation. Habits as all the day they are indulged in earning more and more money without giving proper attention to timely food habits.

Maximum 57.14% of patients were having irregular bowel habit while 42.86 % of patients were having regular bowel habit. This indicates that irregular bowel habits lead to constipation and hard stool the main source of *arsha*. Maximum number of patients i.e. 82.14% had hard consistency of stool and 17.86% of patients had bulky consistency of stool. This suggests that hard stool give raise a much more pressure on the valve less blood vessels of rectum during defecation.

In group-I as shown table- 1, statistically highly significant results were obtained in the four chief complaints i.e. In raktasrava (bleeding per rectum), arshabhransha (protrusion of mass), qudavedana (pain in ano), and aniyatvibandha(constipation), which were relieved by 66.67%, 56.62%, 53.63%, and 70.83% respectively at the level of p < 0.001. This may be due to kasisaditaila reduction in the pressure coming on rectal veins during defecation. While statistically significant results were obtained in the reduction size of pile mass i.e. 50.00%, at the level of p <0.01 due to lekhana (corrosive) effect of acidic nature of kasisaditaila. Statistically moderately significant (51 - 75%) results were obtained in aniyatvibandha (constipation) relived by 52.53% at the level of p < 0.01, due to vatanulomana action of oil.

Symptoms	B.T.	A.T.	%	±SD	±SE	't'	' p'
Raktasrava(Bleeding per rectum)	2.10	0.70	66.67	0.88	0.29	4.80	<0.001
Arshabhransha (Protrusion of mass)	2.30	1.00	56.62	0.85	0.28	4.64	<0.001
Gudavedana(Pain in Ano)	1.90	0.90	53.63	0.92	0.31	3.22	<0.001
Aniyatvibandha (Constipation)	2.40	0.70	70.83	0.83	0.29	5.16	<0.001
Size of pile mass	1.8	0.90	50.00	0.88	0.28	3.20	<0.01

Table-1 Effect of therapy in Group-I(Kasisaditaila)

All the data presented in Mean ± SEM

While in group-II as shown table- 2, statistically significant results were obtained in the *raktasrava* (bleeding per rectum), *arshabhransha* (protrusion

of mass), *gudavedana* (pain in ano), 47.06%, 46.66% and 43.75% respectively at the level of p < 0.05. Whereas statically insignificant results were

were obtained in the reduction of size of pile

obtained in the reduction in the size of pile mass i.e. 23.07% at level of p <0.10, due to soothing effect of *jatyaditaila*. Statically insignificant results

'ť Symptoms B.T. % ±SD ±SE ' p' A.T. Raktasrava(Bleeding per rectum) 1.70 0.90 47.06 0.64 0.25 3.20 <0.05 Arshabhransha (Protrusion of mass) 0.80 46.66 0.59 0.23 3.05 <0.05 1.50 *Gudavedana*(Pain in Ano) 0.90 43.75 0.75 0.27 <0.05 1.60 2.59 Aniyatvibandha (Constipation) 2.10 1.00 52.35 0.90 0.32 3.44 <0.01 Size of pile mass 1.3 1.00 0.52 23.07 0.18 1.66 <0.10

Table-2 Effect of therapy in Group-II(Jatyaditaila)

mass.

All the data presented in Mean ± SEM

Group I- *kasisaditaila* provided highly significant relief in *raktasrava* (bleeding per rectum), *arshabhransha* (protrusion of mass), *gudavedana* (pain in ano) and *aniyatvibandha* (constipation). But significant relief obtained in the reduction in size of pile masses. Group II – *jatyaditaila* provided significant relief in *raktasrava* (bleeding per rectum), *arshabhransha*(protrusion of mass), *gudavedana* (pain in ano) and *aniyatvibandha* (constipation). But insignificant relief obtained in

the reduction in size of pile masses. In the both groups, not a single patient got complete cure in the *kasisaditaila* group, two patients got marked improvement (76 – 99%) and five patients got moderate improvement. In *jatyaditaila* group, three patients got moderate improvement and three patients got improvement. Result is depending upon time factor which is related to chronicity and severity of the disease. Results are shown in table 3.

Table-3 Comparative effect of therapy (Total patient =18)

		Kasisadit	aila	Jatyditaila			
		(grou	ıp-1)	(group-2)			
Symptoms	Mean Score		I.M.P.	Mean Score		I.M.P.	
	B.T	A.T	%	B.T	A.T	%	
Raktasrava(Bleeding per rectum)	2.22	0.33	85.14	2.17	0.80	63.13	
Arshabhransha(Protrusion of mass)	2.11	0.33	84.36	1.67	0.67	59.88	
Gudavedana(Pain in Ano)	2.67	0.22	91.76	2.17	0.67	69.12	
Aniyatvibandha (Constipation)	2.78	0.22	92.08	2.33	0.33	85.83	
Size of pile mass	2.00	0.56	72.00	1.67	1.33	20.36	

DISCUSSION:

Since a clear cut description about pharmacodynamic action of *kasisaditaila* is not available in the classics, but an attempt is made for the same on the basis of symtomatological relief obtained from clinical trials. *kasisaditaila* is mentioned in *bhaişjyaratnavali* for the management of *arsha* as *arshashatan yoga*, and wrote that it destroys the *arsha* as a *kshara* but not affect the normal structure of *guda*.

Probably, there may be reduction in size of haemorrhoids by the local application of *kasisaditaila* due to its corrosive effect on the wall of affected veins by acidic nature $(ph - 3.7)^{[10]}$ as well as *Lekhana* property of contents of *kasisaditaila*. Pain and bleeding may be reduced due to decreased pressure of stool on veins and sphincters by soothing effect of *kasisaditaila*. *ushna, tikshana, and snigdhaguna* of *kasisaditaila* may correct the vatadusti and regulate the function of *apanavayu* which breaks *samprapti* and cure the disease *arsha*.

CONCLUSION:

In this clinical study, it can be concluded that *kasisaditaila* as local application with routine standard treatment is more effective than *jatyaditaila* in the 1st and 2nd degree of *arsha* (haemorrhoids) because of *Kasisaditaila* is mentioned in *Bhaishjyaratnavali* for the management of *arsha* as *arshashatanayoga*, and wrote that it destroys the *arsha* as a *kshara* but not affect the normal structure of *guda*.

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