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# CLINICAL EVALUATION OF DANTADHYA LEPA (TOPICAL) AND KRISHNA TILA (ORAL) IN ARSHA (HAEMORRHOIDS)

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#### **ABSTRACT**

Arsha is a fairly common disease all over the world and is notorious due to its anatomical situation and it is a disease of guda which is a Marma and it is well known for its chronicity and is difficult to treat. Treatment of Arsha by Bhaiśaja does not produce the complications like putrification, pain and bleeding etc like the other modalities of the treatment. So Dantadhya lepa, indicated for the treatment of Arśha as local application and Black til, orally were selected for the present study. Patients were assessed on 7<sup>th</sup>, 14<sup>th</sup> and 21<sup>st</sup> day of treatment for the effect of the drugs. A maximum period of 21 days was kept for follow up study. The present study is first work on the effect of Dantadhya lepa, topically and Krishna til, orally in the management of Arśha at Rishikul State P.G. Ayurvedic College and Hospital, Haridwar, Uttarakhand Ayurved University, Dehradun, Uttrakhand.

Most of the patients 12(38.71%) (11 males,1 female) included in this study group were of 1° piles, while there were 11(35.48%)(10 males,1 female) patients with 2° piles. There were 7(22.58%)(6-males,1-female) patients of 3° piles. Only 1(3.23%) male patient of 4° piles alone was included in this study. Out of Total 31 patients treated in this study: 18(58.06%) patients were cured; 3(9.68%) patients showed marked improvement; 5(16.13%) patients showed moderate improvement; and 5(16.13%) patients showed mild improvement.

**KEYWORDS**: Arśha, Dantadhya lepa, Black til.

#### INTRODUCTION

Arsha is the disorder characterized by polypus or an abnormal fleshy growth (manskand) but is restricted to anorectal folds. Arsha is a clinical condition in which structural derangement those situated in takes place. The doşas are vitiated due to indulgence in etiological factors by the person that in turn leads to Agnimāndya that further hampers the functions of Apana Vayu. Normally, Apana Vayu contributes to evacuation of bowel but vitiated Apana Vayu leads to collection of faeces in gudavali, and eventually vitiates the other vāyus and Doshas, these vitiated Doshas get localized in the Mamsa and Meda of guda pradesha, which result into appearance of Mamsa prarohas or Arsha.

Haemorrhoid is a disease, which is very specific to human race only, due to its erect posture. Haemorrhoids are varicosity and dilatation of haemorrhoidal veins of anal-canal which are valve-less structures. Haemorrhoid is a fairly common disease all over the world.

#### **Selection of the Study**

Acharya Sushruta has depicted Arsha as Dirgha kalanubandhi, Dushchikitsya and Tridoshic. It becomes notorious disease due to its anatomical situation and it is a disease of guda; which is a Marma and it is well known for its chronicity and is difficult to treat. Among the different types of therapies mentioned for Arsha, the exclusion of therapy is to be graded on the basis of particular symptoms complex of the disease. Treatment of Arsha by Bhaiśaja does not produce the complications like putrification, pain and bleeding etc like the other modalities of the treatment. So Dantadhya lepa, indicated for the treatment of Arsha as local application and Black til, orally were selected for the present study. 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.

The present study is first work on the effect of Dantadhya lepa, topically and Krishna til, systemically in the management of Arsha at Rishikul State P.G. Ayurvedic College and Hospital, Haridwar, Uttarakhand Ayurved University, Dehradun, Uttrakhand.

AIMS AND OBJECTIVES- The main aim of the study is to validate the fundamental principle decscribed in various ayurvedic texts along with the evaluation of the therapeutic effect of Dantadhya lepa(applied topically) and Black til (sesamum) systemically in the management of Arsha (haemorrhoid).

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#### MATERIALS AND METHODS

The two drugs viz; Dantadhya Lepa and Black Tilwas taken for the present study. The Dantadhya Lepa is applied locally. It contains five ingredients viz; Danti roots (Baliospermum Montanam), Shyama (Black) Nisoth (Operculina turpethum), Amratasang (Tutiya, Tuttha, Copper sulphate), Pigeon's excreta (droppings) and Guda (Jaggery); Black Til - about 46grams given orally (in the form of modak) with cold water.

#### **Selection of patients**

Thirty-one clinically diagnosed patients of Haemorrhoids were selected from the O.P.D. and I.P.D. of Rishikul Government P.G. Ayurvedic College & Hospital, (U.K.) from department of Shalya Tantra (Surgery) on the bases of inclusion and exclusion criteria.

#### **Inclusion Criteria**

**The** Patients of first and second degree uncomplicated Haemorrhoids, third and fourth degree uncomplicated Haemorrhoids who do not want to undergo surgery and who are ready to participate in the trial.

#### **Exclusion criteria**

**The** patients with complicated Haemorrhoids, third and fourth degree Haemorrhoids who are willing for other therapeutic modalities.

#### Follow up

Patients were assessed on 7<sup>th</sup>, 14<sup>th</sup> and 21<sup>st</sup> day of treatment for the effect of the drugs. A maximum period of 21 days was kept for follow up study.

Table 1: Plan of work.

Name	Dantadhya Lepa	Krishna Til
Mode of Administration	Local Application	Oral
Preparation of drug	Lepa	Modak
Dose	As required	46 grams /day
Duration of Treatment	14 days (all patients daily)	21 days (all patients daily)

#### **Criteria for Assessment**

The result of therapy was assessed both by Ayurvedic and Modern system on the basis of observation of clinical improvement in the cardinal signs and symptoms before, during and after treatment. Laboratory investigations were done to rule out any associated ailment or other systemic disorders.

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The signs and symptoms were assessed by adopting suitable scoring pattern. The details of the scoring pattern are as:

**Table 2: Scoring pattern.** 

Symptoms	Score	Grade	Grading Criteria of Symptoms		
Bleeding	0	Absent	No complaint of bleeding per rectum		
	1	Mild	Bleeding per rectum after taking spicy food.		
	2	Moderate	Bleeding per rectum during almost every motion		
	3	Severe	Bleeding per rectum continuous.		
	0	Absent	No complaint of prolapse by the patient		
Prolapse of haemorrhoid	1	Mild Prolapsed of mass during defecation with insta			
	2	Moderate Prolapse of mass during defecation with digital reduction.			
	3	Severe	Prolapse of mass during defecation and can not be reduced.		
	0	Absent	No discharge of mucous.		
	1	Mild	Discharge of mucous before defecation.		
Mucous discharge	2	Moderate	After defecation discharge of mucous continuous for some time.		
	3	Severe	Discharge of mucous is continuous.		
	0	Absent	No Pruritis		
Pruritus ani	1	Mild	Pruritis Only present		
Fiuritus and	2	Moderate	Frequent Pruritis		
	3	Severe	Routine activities disturbed due to pruritus ani		

#### **Criteria for the Assessment of the Total Effect of Therapy:**

The total effect of therapy was assessed considering overall improvement in signs and symptoms after the therapies.

**Cured** : 100% relief in the complaints

Marked improvement : 76% to 99% relief in the complaints
 Moderate improvement : 51% to 75% relief in the complaints
 Mild improvement : 26% to 50% relief in the complaints
 Unchanged : 0% to 25% relief in the complaints.

#### **OBSERVATION AND RESULT**

Ahaarashakti of most of the patients was Mandagni: 29(93.55%).

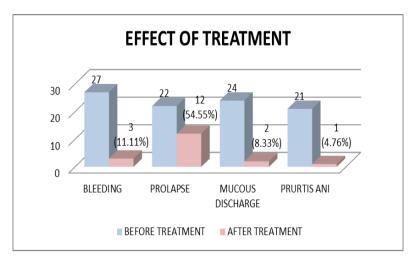


Figure 1: The effect of treatment.

Most marked effect was seen in Pruritis ani in which the symptom remained in only 1(4.76%) patient after treatment as compared to 21 patients before treatment, [Figure 1] Least effect was seen in Prolapse in which the symptom remained in 12(54.55%) patients after treatment as 22 patients before treatment.[Figure 1] Most of compared to the patients 12(38.71%)(11males,1 female) included in this study group were of 1° piles, while there were 11(35.48%)(10males,1female) patients with 2° piles. There were 7(22.58%)(6-males,1female) patients of 3° piles. Only 1(3.23%) male patient of 4° piles alone was included in this study. [Table 4] Out of Total 31 patients treated in this study: 18(58.06%) patients were cured; 3(9.68%) patients showed marked improvement; 5(16.13%) patients showed moderate improvement; and 5(16.13%) patients showed mild improvement. [Table 4].

Table 4: Result according to degree/grade of piles.

Result According To Degree/Grade Of Piles						
Grade			Improvemen			
	Cured	Marked	Moderate	Mild	Uncured	Total
1°	11(35.48%)	1(3.23%)	0	0	0	12(38.71%)
2°	7(22.58%)	2(6.45%)	2(6.45%)	0(3.23%)	0	11(35.48%)
3°	(0%)0	0	3(9.68%)	4(12.90%)	0	7(22.58%)
4°	0	0	0	1(3.23%)	0	1(6.45%)
TOTAL	18(58.06%)	3(9.68%)	5(16.13%)	5(16.13%)	0	31(100%)

#### STATISTICAL OBSERVATIONS

Statistical Technique Adopted For Data Analysis: Paired-t test was applied using SPSS software.

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Table 5: Statistical observations of the study.

	Bleeding	Prolapse	Mucous discharge	Pruritis ani
Mean before treatment	1.0968	1.129	0.8065	0.6774
Mean after treatment	0.0968	0.4194	0.0645	0.0323
Mean difference	1.000	0.7097	0.7419	0.6452
% relief	91.176%	62.857%	92.00%	95.238%
Correlation	0.558	0.776	0.095	0.126
Significance of Correlation	0.001	0.000	0.610	0.499
Mean	1.000	0.6774	0.7419	0.6452
<b>Standard Deviation</b>	0.4472	0.5408	0.5755	0.4864
Standard error	0.08032	0.09713	0.1034	0.08736
t-value	12.450	6.974	7.178	7.385
P-value	0.000	0.000	0.000	0.000
Significance	Highly significant	Highly significant	Highly significant	Highly significant

#### IMPROVEMENT IN BLEEDING

The mean of degrees of bleeding before treatment is 1.0968, while mean of degrees of bleeding after treatment is 0.0968, Thus the difference of mean before and after treatment is 1.00, resulting in percentage relief of 91.176%. The t-value after applying paired t-test is 12.450, with corresponding P-value <0.001, which is highly significant.[Table 5].

#### **PROLAPSE**

The mean of degrees of bleeding before treatment is 1.129, while mean of degrees of bleeding after treatment is 0.4194, Thus the difference of mean before and after treatment 0.7097, resulting in percentage relief of 62.857%. The t-value after applying paired t-test is 6.974, with corresponding P-value <0.001, which is highly significant[Table 5].

#### **MUCOUS DISCHARGE**

The mean of degrees of bleeding before treatment is 0.8065, while mean of degrees of bleeding after treatment is 0.0645, Thus the difference of mean before and after treatment is 0.7419, resulting in percentage relief of 92.00%. The t-value after applying paired t-test is 7.178, with corresponding P-value <0.001, which is highly significant. [Table 5].

#### **PRURITIS ANI**

The mean of degrees of bleeding before treatment is 0.6774, while mean of degrees of bleeding after treatment is 0.0323, Thus the difference of mean before and after treatment is

0.6452, resulting in percentage relief of 95.238%. The t-value after applying paired t-test is 7.385, with corresponding P-value <0.001, which is highly significant[Table 5].

#### **DISCUSSION**

Arsha is a clinical condition in which structural derangement takes place. During process of pathogenesis, the doşas are vitiated due to indulgence in etiological factors by the person that in turn leads to Agnimāndya that further hampers the functions of Apaana Vāyu. The vitiated Apaana Vāyu is responsible to get localized in the Mamsa and Meda of guda pradesha, which result into appearance of Mamsa prarohās or Arsha.

The Ahaarashakti of most of the patients was Mandagni: 29(93.55%) Mandagni Ahaarashakti is the prime etiological factor in Arsha. Bleeding was present in 27 patients before starting treatment and after completion of treatment bleeding was still present in 3(11.11%) patients, though it was reduced. Thus bleeding was eliminated in 24(88.89%) patients. Ruksha, shita, gunas, kasaya rasa, shita virya have stambhan property that helps in reducing bleeding. Before treatment Prolapse (protrusion of mass) was present in 22(70.97%) patients and after completion of treatment remained in 12(54.55%), thus protrusion was cured in 10(45.45%) patients. Laghu, Vishad, Tikshana, gunas and kashaya rasa have lekhana property which helps in reducing the prolapse. It was observed that treatment reduced mucous discharge by 91.67% i.e. mucous discharge which was present in 24 patients before treatment was reduced to 2(8.33%) patients after completion of treatment. The best response was seen with Pruritis ani, in which Pruritis ani was left in only a single (4.76%) patient on completion of treatment out of 21 patients before starting of therapy. Thus 20(95.24%) patients got relieved of Pruritis ani, which was statistically significant (P<0.01). After the application of lepa, the size of the pile masses got reduced and went inside the anal canal (reduction in the degree of the pile mass) and it was noticed that there was no mucous discharge outside the anal verge. As the reduced mass did not moist the the outside vicinity of the verge, there was reduction in the itching symptom of the patients (Kapkhadosaha).

From the present study, it can be concluded that 58.06% were cured, 9.68% patients showed marked improvement, 16.13% patients showed moderate improvement, and 16.13% patients showed mild improvement. None of the patients remained unchanged /uncured in the treatmentgroup.

In the present study, one of the trial drug is Dantadhya lepa. Except indication in treatment of Arsha there is no reference of Rasa, Guna, etc. of this drug. Hence the Rasa, Guna etc. whatever described of individual drug was mentioned to get an overall idea of the main formulation i.e. Dantadhya lepa. To understand this scientifically, we should consider the related basic fundamental. The drugs are active due to their own inherent constituent (Dravya Prabhava), properties (Guna Prabhava) and both combined (Dravyaguna Prabhava) together in particular time, on reaching particular site with particular mechanism and objective.

Table 6: Properties of Dantadhya lepa contents as per various ayurvedic texts.

	Danti	Nisoth	Tutha	Gud	Kapot pureesh	Krishna til
Rasa	Katu	Katu, Tikta	Madhur, Kashaya	Madhur	Madhur, Kashaya	Madhur
Guna	Guru, Tikshna	Laghu, Ruksha, Tikshna	Laghu	Guru, Kashaya, Snigdha	Laghu, Ruksha, Vishad	Guru, Snigdha
Veerya	Ushna	Ushna	Sheeta	Ushna	Sheeta	Ushna
Vipaka	Katu	Katu	Madhur	Madhur	Madhur	Madhur
Dosha- karma	Kapha- pittahar	Kapha- pittahar	Kapha- pittahar	Vata- pittahar	Kapha- pittahar	

On the basis of above analysis it can be concluded that the Dantadhya lepa used in the present project has the properties of Ropana, Stambhana, Vilayana, Pachana, Shodhana and Lekhana.

Since a clear cut description about pharmaco-dynamic action of Dantadhya lepa is not available in the classics, but an attempt is made for the same on the basis of symtomatological relief obtained from clinical trials. Dantadhya lepa is mentioned in Charaka samhita for the management of Arśha, and wrote that it destroys the Arśha but not affect the normal structure of guda. Probably, there may be reduction in size of haemorrhoids by the local application of Dantadhya lepa due to its corrosive effect on the wall of affected veins by acidic nature (pH – 3.3) as well as Ropana, Stambhana, Vilayana, Pachana, Shodhana and Lekhana properties of Dantadhya lepa. Ushna, Tikshana guna of Dantadhya lepa may correct the Vāta duşti and regulate the function of Apāna Vāyu which breaks Samprāpti and cure the disease Arśha. Laghu guna of Nisoth, Kapot-pureesh, and Tuttha: acts as Vrana pachan, Ropana, and Lekhan. Ruksha guna of Nisoth and Kapot-pureesh acts as Stambhana and Lekhan. Tikshna guna of Nisoth and Danti: acts as Vathar, Sodhan and Lekhan. Vishad guna of Kapot-pureesh: acts as Ropana and Lekhan. Katu, Tikta rasa of Nisoth and Katu

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rasa of Danti: acts as Sodhan and Pachan. Kashaya Rasa of Gud, Kapot-pureesh, Tuttha: acts as Sodhan, Ropan, Stambhana, and Lekhan. Ushna-virya of Nisoth, Danti, and Gud: acts as Pachana, Vilayan.

Sheeta-virya of Kapot-pureesh and Tuttha: acts as stambhana.

Krishna Til is Vatashamak, due to Guru, Snigdha, Madhur and Ushna guna. Black til is Pachak due to Ushna-virya property, so it is useful in Agni mandhya, which is a prime etiological factor in Arsha and it is Rakta stambhak due to Madhur, Kashaya rasa.

#### **CONCLUSION**

The present study conclude that the drugs viz; Dantadhya lepa and Krishna tila can be a best combination in the management of Arsha. It helps in releiveing the symptoms of Arshas like bleeding, prolapsed, mucous discharge and pruritis ani. This study was conducted only in a limited number of patients and follow-up was of limited period, thus a longer duration study with inclusion of larger number of patients should be done for better evaluation of this drug combination.

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