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# Clinical Study of *Brihatsindooradya Taila* and its *Malahar* on *Kustha* w.s.r. to Chronic Plaque Psoriasis

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**ABSTRACT:** 

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**Background:** In Ayurveda, skin ailments are categorized as "*kustha*." In skin diseases, external use of drugs is just as important as internal therapy because it may provide greater and faster symptom relief. Acharya Sushrut while prescribing the treatment for *kustha* according to *dhatugatawa*, mentioned *shodhan* and *alepana* as first choice of management for *twakgata kustha* hence *lepana* karma has been considered as an ideal therapeutic measure for these diseases.

**Aim:** The aim was to evaluate the role of Ayurveda treatment modalities in *Kushtha*. To conduct the pharmaceutical – analytical study on BST and its *malahar*. To study the comparative efficacy of *Brihatsindoordya Taila* (BST) and its *malahar* in the management of *kustha* w.s.r.to chronic plaque psoriasis.

**Materials and Methods**: The study was prospective, interventional with Randomized, Open labelled, Controlled trial and conducted in 30 clinically diagnosed patients with classical sign and symptoms of *kushtha*. The study was conducted on 30 clinically diagnosed patients of *Kushtha* divided into 2 groups having 15 patients in each group. Total 30 patients of *kushtha* w.s.r. to chronic plaque psoriasis had been randomly divided into two groups was given *Brihatsindoordya Taila* (BST) & *Brihatsindoordya Taila Malahar* (BSM) for topical administration, twice a day, for a duration of 30 days respectively.

**Results:** The observations and results concluded that drug i.e BST & BSM showed effective and highly significant results in signs and symptoms of *Kushtha* i.e (p<0.0001).

**Conclusion:** This case study revealed the efficacy of Ayurveda therapy, including external, for 1 month in the management of *Kushtha*. Keywords: Chronic plaque psoriasis, *Eka-Kushtha, Shamana, Shodhana*. The study reveals that combination of Ayurvedic modalities gives significant result in *lakshnas* (Symptoms) like *Aswedana, Mahavastu, MastyaShakalopama*. **Keywords:** *Kushtharoga, Maha Kushtha, Tri Dosha, Dhatugatawa, twakgata kustha, lakshnas, Aswedana, Mahavastu, MastyaShakalopama*.

## **INTRODUCTION**

The skin is the first organ of the body to come into contact with environmental factors like physical, chemical, and biological pollutants. Changes in external stimuli and the body's inherent ability to deal with these elements create spontaneous remissions and relapses. The skin serves as a



mirror, reflecting both internal and external pathology and thus assisting in the diagnosis of illness. Skin problems can affect persons of all ages, from infants to the elderly, and can cause deformity, disability, and other issues. In Ayurveda, skin ailments are categorized as "kustha." In skin diseases, external use of drugs is just as important as internal therapy because it may provide greater and faster symptom relief. In our literary classics, we have many medicines with proven efficacy in skin disorders.<sup>1</sup> In Ayurveda, almost all the skin diseases are described under Kushtha-Rogadhikara.<sup>2</sup> There are seven MahaKushtha (major variety of skin disorders) and eleven Kshudra Kushtha (minor variety of skin disorders).<sup>3</sup> EkaKushtha is one among all varieties of Kushtha, and it is main among the eleven Kshudra Kushtha, which is characterized by Aswedanam (dryness), Mahavastu (which covers entire body), and Matsyashakalawat Twacha (skin resembles scales of fish), which means Kushtha. Kushtha has also been included in list of Aupasargika Roga, which may spread from one person to the other.<sup>4</sup> According to commentator Gayadas there is severe and extensive vitiation of Doshas from the very beginning which penetrate the deeper tissues in Maha Kushtha, but there is no such severe and extensive vitiation of *Doshas* occurs in the Kshudra Kushtha from the beginning.

Aacharya Sushruta first time clearly described the Anuvansika (Hereditary) and Krimija (Infectious) Nidana as a causative factor of Kushtha.<sup>5</sup> Sushruta has also explained the Dhatugatatva or Uttarotar Dhatu Pravesha of Kushtha Roga.<sup>6</sup> The number of Kushtha described by Sushruta are the same as that of Charaka but Dadru has been mentioned under Maha Kushtha and Sidhma under Kshudra Kushtha. There are also some differences of names. Vagbhata has followed Sushruta regarding classification of Maha Kushtha and Kshudrakushtha.<sup>7</sup> But Ekakushtha has been mentioned under Kshudrakushtha.<sup>8</sup>

#### **General** Samprapti of Kushtha<sup>9</sup>(Flow Chart Samprapti) General features of Kushtha

According to Acharya *Sushruta* the *Kushtha*, which makes blackish or reddish spots with discoloration of skin.<sup>10</sup> *Astanga Hridaya* has followed *Charaka* but has used the word *Mahashrayam* instead of *Mahavastu*.<sup>11</sup> In *Ekakushtha* lesions are *Chakrakara* (round) and with scaling like *Abhrakapatra* i.e.mica<sup>12</sup> *Acharya Kashyapa* has mentioned that cause of *EkaKushtha* is *visarpa* which is constantly spreading in the body & some discharge, pain, *krimi* are present in the lesion. *Aswedanam* means no sweating on the skin. According to *Chakrapani Mahavastum* means *Mahasthanam* i.e., the area of involvement of the lesion is vast & deeply rooted.<sup>13</sup> *Sighrakari Guna* of *Vayu* (Dosha) and *Rakta (Dushya)* is responsible for spreading of lesions of the body surface. *Charaka* says *Sapta Dravya* is causative factor for *Tvakasithilta* specifically lesions are produced at the site of engagement of *Doshas*.<sup>14</sup>

According to Charaka, chikitsa of Kushtha are Nidana Parivarjana, Apakarshana & Prakriti Vighata. Nidana Parivarjana stops the further progressive disease by restricting vitiation of Doshas. Vamana is to be applied in the treatment of Kapha predominant Kushtha, Virechana and Raktamokshana in the treatment of Pitta predominant Kushtha. Acharya Vagbhatta says that kushtha Rogi should be given Snehapana in the stage of Purvarupa Avastha. Swedana is generally done by Nadi Sweda or Bashpa Sweda. Sushruta has advised to carry out 'Ubhayato Samsodhana' even at the Purvarupa condition of Kushtha. Sushruta also advised Samsodhana in the treatment of Rasagata, Raktagata, Mamsagata and Medogata Kushtha.

#### METHODS

#### **Review Of Literature**

Psoriasis is defined as chronic relapsing disease of unknown etiology characterized by sharply defined dry scaling erythematous patches, covered with adherent silvery white scales. The eruption is usually symmetrical and most commonly affects elbows, knees, scalp, nails and the sacral regions.<sup>15</sup> Psoriasis is one of the most common dermatologic diseases, affecting up to 1 to 2 percent of the world's population. It occurs in all age groups and about equally in men and women. Psoriasis was included in *Kshudra Kushtha* by all study teams; more correlations were made with *Sidhma, Mandala, Kitibha*, and *Ekakushtha*.

Correlation between Ekakushtha & Psoriasis

- Matsya Shakalopamam
- Krishna Aruna Varna
- Aswedanam (Swedana Kshaya, Twaka Parushya)
- ➤ Mahavastu

According to *Charaka, Madhava and Vagbhata* the lesion like fish scale and according *Bhavprakash* the lesion like *Abhrakapatrasama* is produced. This symptom is similar to scaling which is also known as Hyperkeratinisation in psoriasis. The *Snigdhata* and *Slakshnata* of vitiated *Kapha* produce smooth and silvery skin. But due to vitiated Vayu lesions are not cent percent smooth and *Slakshna* because

Vayu produces a little roughness on lesions which gives appearance of *Matsya-Shakalopamam* 

#### AIMS AND OBJECTIVE

- 1- To evaluate the efficacy of BST in Patients of psoriasis.
- 2- To evaluate the efficacy of BSM in the patients of psoriasis.

#### **Study Design**

The study was prospective, interventional with Randomized, Open labelled, Controlled trial and conducted in 30 clinically diagnosed patients with classical sign and symptoms of *kushtha*. The study was conducted on 30 clinically diagnosed patients of *Kushtha* divided into 2 groups having 15 patients in each group. Total 30 patients of *kushta* w.s.r. to chronic plaque psoriasis had been randomly divided into two groups was given *Brihatsindoordya Taila* (BST) & *Brihatsindoordya Taila Malahar* (BSM) for topical administration, twice a day, for a duration of 30 days respectively.

**Ethical Committee Approval**: IEC/ACA/2019/147 Dated 28/05/2019.

**CTRI NO** : CTRI/2020/09/027611 [Registered on: 04/09/2020].

**Selection Of The Patients:** Clinical study has been conducted on patients in the OPD/IPD of NIA hospital Jaipur, fulfilling the criteria of diagnosis with irrespective of their age, sex, religion etc. The selection of cases was based on clinical features and laboratory findings. A written information and consent form were given to the patients and were explained about the purpose, procedures and possible side-effects of the trail. Total 30 patients were selected and registered for the study.

#### A) Inclusion criteria:

- 1. Patients with the classical features of *Kustha* (chronic plaque psoriasis) between 18 to 60 years of age.
- 2. Patients willing to provide consent for trial.

#### **B)** Exclusion criteria:

- 1. Patients suffering from systemic disorders as cardiac problem, uncontrolled diabetes mellitus, uncontrolled hypertension, paralysis, malignancy, HIV, leprosy.
- 2. Patients suffered from psoriatic arthritis.
- 3. Patients taking any other medicine for *kustha* (chronic plaque psoriasis)

#### **Criteria For Diagnosis**

#### A) Subjective Parameters

1. MandalRoopa (Erythema lesion)

- 2. Vedana (Pain)
- 3. Aswedanan (Prespiration)
- 4. Daha (Burning sensation)
- 5. Matasyashakalopam (Scaling)
- 6. Kandu (Itching)
- 7. Sukla Rakta Spot (Erythematous Plaques)

B) **Objective Parameters:** CBC, ESR, SGOT, SGPT, Blood Urea, Serum Creatinine, Routine Examination was done to exclude any other pathology. The assessment of the clinical response in the total number of patients have been made on the basis of-  $\succ$  Primary outcomes- Changes in psoriasis area and severity index (PASI)

Secondary outcomes- Changes in dermatology life quality index (DLQI)

#### ADMINISTRATION OF DRUG

The patients were randomly divided and studied under the two group Viz. Group A and Group B. Each group having 15 patients.

#### Group A - Brihatsindoordya Taila

Name/Code - BST

Dose - As Per Requirement of Individual Patients.

Route Of Administration - Topical Dosage - Twice a day Treatment Period - 30 days

Table 1. Showing the ingredients of BrihatsindoordyaTaila<sup>16</sup> (Yogaratnakar, Kustha Chikitsa shlok no. 186-189 edi19)

Group B - Brihatsindoordya Malahar

Name/Code - BSM

Dose - As Per Requirement of Individual Patients.

Route Of Administration - Topical Dosage - Twice a day Treatment Period - 30 days

Modified dosage form of *Brihatsindoordya Malahar* will be prepared using *Brihatsindoordya Taila* along with other ingredients as listed in the table below.

Table no.2 showing ingredients of the *Brihatsindoordya Malahar*.

#### RESULTS

All the Results are calculated by using Software: In Stat Graph Pad 3. For Nonparametric Data Wilcoxon matchedpairs signed ranks test is used while for Parametric Data Paired 't' Test is used and results Calculated in each group. For calculating the Inter group comparison, Mann-Whitney Test and Unpaired 't' Test was used.

Table no.3 Showing effect of therapy on Subjective Parameters (Wilcoxon Matched Pairs Single Ranked Test)

**Effect of therapy on PASI score** : The p value is < 0.0001

is statistically extremely significant which indicates that there is significant statistically difference in efficacy of both treatments on PASI score.

**Effect of therapy on DLQI score** : The p value is < 0.0001 is statistically extremely significant which indicates that there is significant statistically difference in efficacy of both treatments on DLQI score.

# Table no.4 Intergroup Comparison in SubjectiveParameters of both groups: (Mann -Whitney test)

The data shows that GROUP A had mean PASI score 16.727 before treatment which was decreased to11.720 after treatment with the mean difference was 8.693 (42.58%) with p < 0.0001 which is extremely significant. GROUP B had mean PASI score 20.413 before treatment which was decreased to 8.207 after treatment with the mean difference was 8.520 (50.90%) with p < 0.0001 which is also extremely significant.

The data shows that GROUP A had mean DLQI score was 9.600 before treatment which was decreases to 4.800 after treatment with the mean difference was 4.800 (50.00%) with p < 0.0001 which is extremely significant. In GROUP B had mean DLQI score was 9.333 before treatment which was decreases to 4.667 after treatment with the mean difference was 4.667 (50.05%) with p < 0.0001 which is extremely significant.

# Table no.6 Showing overall effect of treatment of PASIscore.

In Group A out of 15 patient, 03 patients showed No effect, 07 patient showed small effect, 4 Moderate effect, 01 Very large effect after Treatment.

In Group B out of 15 patient, 08 patients showed small effect, 07 Moderate effect after treatment.

#### DISCUSSION

Clinical study was done taking 15 patients in each two group (A & B group). Maximum patients registered were of (18- 30 yrs.) age group (46.66.%), Male (66.66%), Hindu (93.33%), Married (36.66%), Middle class (80%), Addiction Tea (76.66%) Vegetarian (70%), *Kandu* (100%) i.e., present in all patients etc.

We started 28 days trial giving 50 ml BST to the patients of Group A & 50 g BSM to the patients of Group B. The patients were asked to apply the medicine twice daily on the lesion of *Kustha*. Follow up study was done on every 15 days.

The data shows that GROUP A had mean PASI score was 16.727 before treatment which was decreases to 8.520 (42.58%) after treatment followed by BSM with p < 0.0001

which is extremely significant. In GROUP B had mean PASI score was 20.413 before treatment which was decreases to 11.720(50.90%) after treatment followed by BST with p < 0.0001 which is extremely significant.

The data shows that GROUP A had mean DLQI score was 9.600 before treatment which was decreases to 4.800 (50.00%) after treatment followed by BST with p < 0.0001 which is extremely significant. In GROUP B had mean DLQI score was 0.8666 before treatment which was decreases to 4.667 (50.05%) after treatment followed by BSM with p < 0.0001 which is extremely significant.

Drug Absorption Through Skin According to Acharya Sushruta explains, Tiryaka Dhamani divides into hundred and thousand times and become innumerable forming a network over body. They have their openings in the Lomakoopa when the Dravya applied over the skin got absorbed through these openings and undergo Pachana by the help of Bhrajaka Pitta. The principle fence for absorption of exogenous materials through the skin is Stratum Corneum. The physiological factors that affect per cutaneous absorption include hydration, occlusion, age, intact versus disrupted skin, temperature and anatomical site. Absorption depends upon lipid solubility of the drug since the epidermis act as a lipid barrier. The dermis however is freely permeable to many solutes. Suspending the drug in an oily vehicle can enhance absorption through the skin. Because hydrated skin is more permeable than dry skin. The drug used in present study is oil preparation. Acharyas have advised use of Kharapaka Sneha for Abhyanga procedure. Kharapaka indicates that the preparation predominantly contains lipid soluble material for easy absorption.

#### **Discussion on BST and BSM**

*Kushtha* disease occurs due to vitiation of *Kapha* and *Vata Dosha* is understood that the drug should possess the *Kapha-Vata shamak* effect. Thus, *Sarshapa Taila* was *Kapha-Vata shamak* property.

#### **Probable Mode Of Actions Of The Drug**

When *Taila* and *Malahar* are applied over the surface of skin opposite to the direction of hairs on it, through proper base, the active principles of the ingredients of *Taila* and *Malahar* are released into that base. After that this combination enters the *Romkupa* & further gets absorbed through the *Swedavaha srotas* and *siramukh*. However, it should be kept in mind that the pilosebaceous uptake i.e., absorption of *Taila* and *Malahar* differs as per the site variation, skin condition & more important is the base through which it is applied.

#### CONCLUSION

Literature review suggested that BST is mentioned in Yogratnakar, Bhaishjya Ratnavali, Gada nighraha, Vanga sena, Vrindh madhav, Chakradatta, Vrihat Nighantu Ratnakar, Yoga Chintamani, Yoga tarangini, Vrihat yoga Tarngini and Rasa Kamdhenu in kushtha roga. According to Samhita, Kustha is one of the Asthamahagada, even in modern advanced era by its prevalence, chronic nature & relapse it has recurrent to concluded that Kushtha(Psoriasis) is still like a one of Mahagada. There is no any single disease in Ayurveda which can be exactly corelated as Psoriasis. The formula BST consisits of 24 ingredients viz. Sindoor, RaktaChandana, Jatamansi, Vidang, Haridra, Daruharidra, Priyangu, Padyamaka, Kushtha, Man jishtha, Khadir, Vacha, Jati, Arka, Trivrit, Nimba, Karanj, Vatsnabha, Pippali, Chitraka, Lodhra, Chakramarda and sarshapaTaila. Which are easily available and cost effective. For the study of Brihatsindooradya Taila, the formulation was selected from Yogaratnakar, Kustha Chikitsa, shlok no.186-189.Brihatsindooradya Taila (BST) can be used for the indications Kushtha rog like pama, vicharchika, kachhoo, visharapa etc. The Plaque Psoriasis can be correlated with Kushtha and above case study concludes that the Kushtha can be successfully treated with the BST & BSM.

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#### **Flow Chart Samprapti**

Vitiated Vata-Kapha Dosha along with Aama

( by Tiryaka.Sira )

Got settled to the Twaka & Mamsa along with vitiated Rakta & Lasika



Obstruction in Rasavaha, Raktavaha, Mamsavaha & Svedavaha Srotas



(symptoms like Aswedana, Twaka Vaivarnyama, Mahavastum etc.)

S. No	Ingredients	English Name	Part used	Quantity
1	Shuddh Sindoor	Lead oxide		1 part
2	RaktaChandana	Pterocarpus santalinus	heartwood	1 Part
3	Jatamansi	Nordostachys jatamansi	Mool	1 Part
4	Vidang	Embelia ribes	Fruit	1 Part
5	Haridra	Curcuma longa	Kanda	1 Part
6	Daruharidra	Berberis aristata	Kanda	1 Part
7	Priyangu	Callicarpa macrophylla	Flower	1 Part
8	Padyamaka	Prunus cerasoides	Twak	1 Part
9	Kustha	Sausserea lappa	Mool	1 Part
10	Manjishtha	Rubia cordifolia	Mool	1 Part
11	Khadir	Acacia catechu	Twak	1 Part
12	Vacha	Acarus calamus	Mool	1 Part
13	Jati	Jasminum officinale	Leaf	1 Part
14	Arka	Calotropis procera	Leaf	1 Part
15	Trivrit	Operculina terpentum	Mooltwak	1 Part
16	Nimba	Azardiarachta indica	Leaf	1 Part
17	Karanj	Pongamia pinnata	Leaf	1 Part
18	Vatsnabha	Aconitum ferox	Mool	1 Part
19	Pippali	Piper longum	Fruit	1 Part
20	Chitraka	Plumbago zeylanica	Mool	1 Part
21	Lodhra	Symplocos racemosa	Twak	1 Part
22	Chakramarda	Cassia tora	Seed	1 Part
23	Mustard oil	Brassica nigra	Seed oil	4 Part
24	Jala	Water		16 Part

**Table 1. Showing the ingredients of** *Brihatsindoordya Taila*<sup>16</sup> (*Yogaratnakar, Kustha Chikitsa shlok no. 186-189 edi19*)

S. No.	Ingredients	Percentage %
1	Distil water	55-75 %
2	Emulsifiers	02-06 %
3	Emollients	10-35 %
4	Thickeners	0.1-2 %
5	Active ingredients (BST)	01-40 %
6	Fragrances	0.1-1 %
7	Preservatives	0.1-1 %

Table no.2 showing ingredients of the Brihatsindoordya Malahar.

Table no.3 Showing effect of therapy on Su	ubiaatiya Danamatana (Wilaayan	Matched Dairs Single Danked Test
Table no.5 Showing effect of therapy of S	ublective rarameters (whotxon	(Matcheu Fairs Single Kaikeu Test)

Para meter s	Mean		Mea	%			w	ʻp' Value	s
	вт	AT	n Diff.	Relie f	SD ±	SE ±	value	value	
PASI Sc	ore	·		•					
Group A	20.413	11.720	8.69 3	42.58 %	7.328	1.892	120.0	< 0.0001	ES
в	16.727	8.207	8.52 0	50.90 %	7.721	1.993	120.0	< 0.0001	ES
DLQI		•							•
Group A	9.600	4.800	4.80 0	50.00 %	1.859	0.4801	120.0	< 0.0001	ES
в	9.333	4.667	4.66 7	50.05 %	2.059	0.5315	120.0	< 0.0001	ES

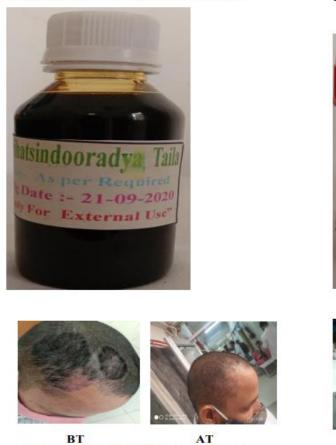
Para meter s	Mean		Mea	%	SD ±	SE ±	W	ʻp' Value	s
	BT	AT	Diff.	Relief	50 ±	SE ±	value	Value	5
PASI Sc	ore					•	•	•	
Group A	20.4 13	11.72 0	8.693	42.58 %	7.328	1.892	131.0	< 0.0001	ES
В	16.7 27	8.207	8.52 0	50.90 %	7.721	1.993	131.0	< 0.0001	ES
DLQI									
Group A	9.60 0	4.800	4.80 0	50.00%	1.859	0.480 1	131.0	< 0.0001	ES
В	9.33 3	4.667	4.66 7	50.05 %	2.059	0.531 5	131.0	< 0.0001	ES

Table no.0 Showing over an effect of treatment of rASI score.					
Question	Group A	Group B			
No effect at all on patient's life	3	0			
Small effect on patient's life	7	8			
Moderate effect on patient's life	4	7			
Very large effect on patient's life	1	0			
Extremely large effect on patient's life	0	0			

#### Table no.6 Showing overall effect of treatment of PASI score.

### BRIHATSINDOORADYA TAILA

#### BRIHATSINDOORADYA TAILA MALAHAR







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Date : 08-10-2020

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