

CLINICAL EFFICACY OF DINAMALLIKA (*Cestrum diurnum*) IN KITIBHA KUSTHA (PSORIASIS)

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Abstract

A non-native ornamental plant "*Cestrum diurnum*" know as Din-ka-raja or Dinamallika has been in use among some of the traditional Ayurvedic Vaidyas who by trial and error found out that the leaves of the plant are useful in the treatment of Kitibha Kushta. Further review of literature based on the methodology of anuktadravya, the drug has been found suitable for therapeutic use in skin ailments such as Kitibha Kustha (Psoriasis). Keeping in view, the burning problem of Psoriasis in the present era and its associated devastating disease, it has been decided to do research on Kitibha Kustha (Psoriasis) by using the oil prepared with "*Cestrum diurnum*" externally. As the drug does not have direct reference in Ayurveda to prove its action scientifically, there is a need to conduct appropriate clinical trials to establish the same. Further, as the plant is very easy to cultivate and the useful part being the leaves it is an ideal choice for therapeutic usage. Hence in the present study the drug "*Cestrum diurnum*" was selected to prove its efficacy clinically in Kitibha Kustha (Psoriasis).

Key words: Dinamallika; Kitibha Kustha; Psoriasis; *Cestrum diurnum*.

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INTRODUCTION

Skin disorders are one of the burning problems of modern scientific era. Kustha includes wide spectra of skin diseases, among them Kitibha Kustha can be correlated with Psoriasis based on similarity in etio-pathogenesis & symptomatology. It is one among the Kshudra Kustha which has dominance of Kapha & Vata Dosha in particular and Rakta in general are the vitiated dohas in its pathogenesis.^[1] Psoriasis is a common chronic non-infectious skin disease said to be idiopathic, characterized by well-defined slightly raised dry Erythematous lesions with silvery scales and typical extensor distribution.^[2] Comparing the features of Psoriasis & Kitibha lakshanas as per Susrutha Samhita, Caraka Samhita and Ashtanga Sangraha, both the diseases can be correlated to each other.

It is estimated that 2-3% of world population suffers from Psoriasis. Among them 35% of the people suffer from moderate to severe forms of Psoriasis. In the year 2008, National Psoriasis foundation did a survey of 426 Psoriasis sufferers, among them 71% reported that the disease was causing significant problem in day to day life.^[3] Patients with Psoriasis often experience a diminished quality of life. Itching and pain can interfere with basic functions such as self-care, walking and sleep. Psoriasis affects quality of life similar to other chronic diseases as HT, DM & Depression.

Treatment for Psoriasis in Allopathy is more palliative than curative. The First line of treatment for most of skin diseases is topical application which holds well in Psoriasis too. The topical applications such a Coal Tar, Dithranoll & Cortico steroids are the drug of choice. Most of them are messy, irritants, not suitable to apply in sensitive areas, having lot of side effects in a long run. With the limitations of these Allopathic procedures; a more skin friendly, non- irritant, long lasting,

easily available, economical and a potent therapeutic agent is the need of the hour.

Different treatment modalities, like Siravyada and Jaloaka which are not so friendly or easily acceptable by patient are described in literatures, which needs direct supervision by a Physician. Lepa, is one among the Bahya pradhana upakrama which could be easily employed with effective results.^[4] As it is the first line of treatment for Kustha, according to Susrutha many Lepa like Aragvadha Patra lepa,^[5] have been tried in Kitibha. Results have shown moderate to good response as high as 40% and 60%, but no total cure was observed in any of the studies.

Dinamallika leaves external application in different forms has been traditionally used by ancestors, vaidhyas and also very much in vogue in some parts of Andhra Pradesh. Direct references regarding the drug is not available in classics but it is not a new phenomenon to include new drugs into Ayurveda and under the category of “Anuktadravya” i.e., unlisted/non-narrated drugs (extra-pharmacopoeia medicine). However, before any such medicine which is already in use elsewhere or found to have merit by a Vaidya, is subjected to examination based on the fivefold basic parameters which qualify any substance before it is put to medicinal or edible use. The fivefold parameters are: a. rasa, b. guṇa, c. vīrya, d. vipāka and e. prabhāva.^{[6][7]} Ayurveda ka Vaijnanika Itihasa provides details of 121 new therapeutic entities, which were introduced to Ayurveda in different phases. Among the reported 54-plant drugs, 7-flowers, 26-fruits, 12-vegetables, 14-food grains, 8-animal origin ingredients. (PV Sharma, 1975: 338-372)

Keeping in view, the oil prepared out of the drug *Cestrum diurnum* (Dinamallika) was tried clinically to prove its effect in Kitibha Kustha (Psoriasis) externally.

MATERIALS AND METHODS

All Ayurveda, Modern literatures and contemporary texts including the journals, Previous research works, websites etc. were reviewed pertaining to the drug and diseases in the intended study. The present study was conducted on 20 patients from OPD and IPD of Muniyal Institute of Ayurveda Medical Sciences and Hospital, Manipal and from referral sources and special camps. The data collected from the clinical trial were sorted out and processed further by subjection to varied statistical methods to find the significance.

Pharmaceutical procedure of the trial drug Dinamallika taila

Ingredients of Dinamallika taila are *Cestrum diurnum* leaves 1kg and coconut oil 4litres

The formulations selected for research work was prepared in the M.I.A.M.S pharmacy as per the Standard Operative procedures.

Method of preparation

Dinamallika patra are collected from healthy plants, cleaned and added into coconut oil till fully immersed and left in hot sun from sunrise to sunset for 7 days. Then squeezed, filtered, bottled and labeled.

Methods of collection of data

Sample size

A minimum of 20 patients fulfilling the diagnostic and inclusion criteria irrespective of their gender, caste, religion, education status and socio-economic status were taken for the study.

Study design

Single blind randomized clinical study

Patients of the trial group were treated with Dinamallika patra taila externally on affected areas twice daily for a period of 60 days. Observations were made and recorded before treatment. The changes with the treatment shall be observed and recorded on 15th, 30th and 45th day in the proforma of Case Sheet prepared for the study. A period of 30 days after the course of treatment was fixed for observation regarding the recurrences and also for total relief. The observations regarding recurrences if any were recorded in the proforma of Case Sheet.

Treatment period and Observation period

Patients were assessed clinically before treatment and on 15th, 30th and 45th day during treatment and 61st day (next day after stopping the treatment) and 90th day. The response of patient's disease condition to the drug was observed and recorded before, during and after the treatment in the specially designed case proforma which includes detailed history, physical examination, laboratory investigations and assessment based on objective and subjective parameters for which appropriate scoring pattern is adopted.

Diagnostic criteria

The main criterion of diagnosis of patients is based on cardinal and associated signs of the disease based on the Ayurvedic and modern texts. The main Diagnostic criteria were Ruksha (Dryness of the skin), Kinakharasparsha (Hard and torturous skin), Kandu (Itching), Parushya (Roughness), Asita (hyper pigmentation).

Inclusion criteria

- 1) Male and female patients aged 15 years or above.
- 2) Psoriasis involving arms / trunk / legs / scalp.
- 3) Patients were enrolled after informed consent.

4) Subjects who could be available for all study related visits.

Exclusion criteria

- 1) Patients with generalized pustular or erythrodermic exfoliative psoriasis, atopic dermatitis, seborrheic dermatitis or other inflammatory skin diseases.
- 2) Systemic anti psoriatic treatment or phototherapy within the last 6 weeks
- 3) Patients who used any topical antipsoriatic treatment on the body within the previous 2 weeks, except emollients.
- 4) Usage of corticosteroids for any reason within the last 6 weeks of the start of the Study.
- 5) Patients with planned changes in the concomitant medications (e.g. beta blockers, lithium etc.) that affect their psoriasis during the study period.
- 6) Subjects with uncontrolled metabolic diseases such as diabetes/hypertension, hyper or hypothyroidism.

Method

At baseline, informed consent was obtained after checking the inclusion and exclusion criteria and relevant medical history. All prior medications were stopped 2 weeks before the start of the study. The patients were asked to apply the oil twice daily. No concomitant drugs were allowed during the study. Total lesion severity scores (TLSS) and global assessment scoring systems are administered throughout the study. Patients are enquired about adverse events and compliance with the study medication on all follow ups. Statistical methods were employed to study the significance level from baseline to follow up

Assessment criteria

The following subjective and objective parameters were assessed using different grading and scoring methods before and after

treatment. Subjective parameters were Itching, Redness and burning, Size of lesion, Desquamation, Dryness and Epidermal Thickening. Objective parameters were Auspitz Sign, Candle Grease Sign, P.A.S.I Scoring, K A S I Scoring.

Diet and Regimen

The patients are strictly advised to follow the Pathyapathya of kustha Roga.

Drop-out Criteria

During treatment if any serious condition or serious adverse effects occur, or subject himself / herself wanted to withdraw from the study, such subjects were withdrawn from the study. The Ethical clearance has been obtained from the institutional ethical committee formulated in the college. However, consent was also taken from the patients before the treatment.

Scoring pattern

The improvement provided by the therapy was assessed based on relief in signs and symptoms of the disease and Dushti Lakshana of Dosh, Dushya etc. Routine hematological, urine, stool and biochemical investigations were repeated. All the signs and symptoms were assigned score depending upon their severity to assess the effect of the drugs objectively in Table 1 and Table 2.

RESULTS AND OBSERVATION

Statistical Analysis

All the BT score of all symptoms of a patient were added. All the AT score of every symptom of that patient were added. The information gathered based on observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation.

Table 1: Symptoms and scoring pattern

Sl.No:	Symptoms	Parameters	Score
1	Itching / kandu	No itching	0
		Mild itching-only aware of itching as times, when relaxing	1
		Intermediate itching - (1 to 3)	2
		Moderate itching-sometimes disturbed the sleep and day time activity	3
		Intermediate-between 3 to 5	4
		Severe-constant itching, frequent sleep disturbed	5
2	Erythema	Normal colour	0
		Near to normal, this looks like normal colour	1
		Light reddish colour	2
		Moderate red colour	3
		Bright red colour	4
		Dusky to deep red colour	5
3	Desquamation	No scaling	0
		Minimal -(occasional fine scale over < 5% of lesion)	1
		Mild-(fine scale predominant)	2
		Moderate – (coarse scale predominant)	3
		Marked -(thick non tenacious scale predominant)	4
		Severe-(very thick tenacious scale predominant)	5
4	Dryness	No line on scrubbing with nail	0
		Faint line on scrubbing with nail	1
		Lines and even words can be written on scrubbing with nail	2
		Excessive rukshata leading to kandu	3
		Rukshata leading to crack formation	4
		No thickening	0
5	Epidermal thickening	Mild thickening	1
		Moderate thickening	2
		Very thick	3
		Very thick with indurations	4
		No burning sensation	0
		Mild burning sensation	1
6	Burning sensation	Moderate burning sensation	2
		Severe burning sensation	3
		Severe burning sensation affecting sleep	4
		No Srava	0
7	Srava (Discharge)	Mild Srava	1
		Moderate Srava	2
		No elevation	0
8	Unnati	Slight elevation that cannot be felt	1
		Elevation can be felt but depressed in middle	2
		Elevation in all lesions but soft	3
		Elevation in all lesions and hard	4
9	Joint involvement	No arthritis	0
		Slight pain	1
		Pain present but do not hinder activity	2
		Pain with deformity	3
10	Jvara	Pain with deformity affecting activity & sleep	4
		No fever	0
		Occasional fever subsides by itself	1
		Occasional fever subsides by drug	2
		Remittent fever	3
		Continuous fever	4
11	Pitting	No Pitting	0
		Pitting in 1 finger only	1
		Pitting in few fingers	2
		Uncountable pitting	3
		Uncountable Pitting with nail pathology	4

Table 2: Sign and Scoring pattern

Sl.No.	Sign	Scoring
1	Candle grease sign	Absent 0
	When a psoriatic lesion is scratched with the point of a dissecting forceps, candle grease like scale can be repeatedly produced even from the non-scaling lesions. This is called the candle grease sign (Tache de bougie).	Improvement 1
		Present 2
2	Auspitz sign: This sign occurs only in psoriasis. Psoriasis can be diagnosed when there is a classical silvery white scaling and the Auspitz sign. When hyperkeratosis scale is mechanically removed from a psoriatic plaque by scratching, within few minutes, small blood droplets appear on erythematous surface. This phenomenon is called Auspitz sign.	No Bleeding 0
		Mild Bleeding 1
		Moderate Bleeding 2
		Severe Bleeding 3
3	PASI SCORING REFERENCE	0% of involved area. 0
	Calculation: The body is divided into 4 sections (head (H) (10% of a person's skin), arms (A) (20%), trunk (30%), legs (40%). Each of these areas is scored by itself, and then the four scores are combined for the final PASI. For each section, the percent of area of skin involved, is estimated and then transformed into a grade from 0 to 6. Within each area, the severity is estimated by three clinical signs, erythema (redness), indurations (thickness) and desquamation (scaling). Severity parameters are measured on a scale of 0 to 4, from none to maximum. The sum of all three severity parameters is then calculated for each section of skin, multiplied by the area score for that area and multiplied by weight of respective section. (0.1 for head, 0.2 for arms, 0.3 for body and 0.4 for legs).	<10% of involved area 1
		10-29% of involved area 2
		30-49% of involved area 3
		50-69% of involved area 4
		70-89% of involved area 5
		90-100% of involved area 6

For all symptoms in both group name of test applied is Kruskal wallis test with Dunns multiple comparison test. It is non-parametric, one-way ANOVA test. The obtained results were interpreted as: NS - not significant- $p > 0.05$; *-significant- $p < 0.01$; **-more significant- $p < 0.001$; ***-highly significant- $p < 0.0001$

In treatment group, for the symptom itching mean was 3.2 and after treatment 0.6, whose 'p' value is highly significant ($p < 0.0001$). In symptom redness before treatment, mean was 3.3 and after treatment 0.6, where p value is highly significant ($p < 0.0001$). In symptom burning mean was 1.95 and after treatment mean was found 0.45, where p value is highly significant ($p < 0.0001$). In Desquamation mean was 3.3 and after treatment mean was found 0.55, where p value is highly significant ($p < 0.0001$). In Dryness mean was 2.5 and after treatment mean was found 0.45, where p value is highly significant ($p < 0.0001$). In Epidermal thickening before treatment mean was 2.25 and after treatment mean was found 0.4, where p value is highly significant ($p < 0.0001$). (Table 3)

In Auspitz sign mean was 1.35 and after treatment mean was found 0.4, where p value is highly significant ($p < 0.0001$). In Candle grease sign mean was 1.9 and after treatment mean was found 0.4, where p value is highly significant ($p < 0.0001$). In Pasi score mean was 17.9 and after treatment mean was found 2.42, where p value is highly significant ($p < 0.0001$). In Kasi score mean was 31.11 and after treatment mean was found 0.6, where p value is highly significant ($p < 0.0001$). (Table 4)

DISCUSSION

External application of Dinamallika leaves in different forms has been traditionally used. It is interesting to note that Ayurvedic practitioners employ the leaves of this plant in the treatment of different skin ailments, of which it is found to be effective in the treatment of Psoriasis on external application. In the present study dinamallika taila was prepared and used. In this regard, a study was planned with Dinamallika taila in Kitibha Kustha patients.

Table 3: Effect on cardinal symptoms

Symptoms	Mean		Median		Std. Deviation		Std. Error		Sum		P value
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	AT
Itching	3.2	0.6	3	1	0.7678	0.5026	0.1717	0.1124	64	12	***
Redness	3.3	0.6	4	1	0.9787	0.5026	0.2188	0.1124	66	12	***
Burning	1.95	0.45	2	0	0.9445	0.5104	0.2112	0.1141	39	9	***
Desquamation	3.35	0.55	3	1	0.6708	0.5104	0.15	0.1141	67	11	***
Dryness	2.5	0.45	3	0	0.8885	0.5104	0.1987	0.1141	50	9	***
Epidermal thickening	2.25	0.4	2	0	0.7864	0.5026	0.1758	0.1124	45	8	***

[*** - Highly significant - p<0.0001]

Table 4: Effect on various signs in psoriasis

Symptoms	Mean		Median		Std. Deviation		Std. Error		Sum		P value
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	AT
Auspitz sign	1.35	0.4	1	0	0.4894	0.5026	0.1094	0.1124	27	8	***
Candle grease sign	1.9	0.4	2	0	0.8522	0.5026	0.1906	0.1124	38	8	***
Pasi score	17.9	2.42	12	2.3	17.15	1.964	3.835	0.4391	358	48.4	***
Kasi score	31.11	4.465	18	4	32.59	3.076	7.288	0.6878	622.2	89.3	***

[*** - Highly significant - p<0.0001]

Dinamallika (*Cestrum diurnum*) has utility in the treatment of Psoriasis and other skin ailments. The leaves of *Cestrum diurnum* are known to contain Calcitriol a naturally occurring active form of vitamin D3 and have been used for topical psoriasis therapy in Europe and other parts of the world. Further, Calcitriol 3 microg/g ointment has been extensively evaluated for the treatment of chronic plaque-type psoriasis and has been shown to be effective, safe and well-tolerated in a number of short-term and long-term clinical trials. Pharmacokinetic studies in patients with psoriasis and healthy control subjects have demonstrated that topical calcitriol ointment produces little systemic absorption of calcitriol and does not alter systemic calcium homeostasis significantly even when applied to approximately one third of the body surface area. Calcitriol ointment is associated with a low rate of cutaneous irritation and does not increase the sensitivity of treated skin to phototoxicity following treatment with ultraviolet treatment. Further, the efficacy of utilizing naturally occurring calcitriol from *Cestrum diurnum* L. in the treatment of psoriasis has been ascertained clinically.

In the present study 14 patients got 80-100% relief from symptoms and 6 subjects obtained 60-80% relief. Results of the present study are encouraging and looking to the importance of emerging problem of Psoriasis. Particularly in Indian society, there is need to conduct long duration study on Psoriasis with large sample size and wide range of assessment parameters.

CONCLUSION

In the present study Dinamallika (*Cestrum diurnum*) taila had good action in Kitibha Kustha (Psoriasis). Yet the study should be conducted in large sample size. Detailed pharmacognostical and analytical studies should be conducted.

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