



Research Article

AN OPEN LABELLED, PARALLEL ARM INTERVENTIONAL CLINICAL ASSESSMENT OF VASA (JUSTICIA ADHATODA L.) IN DADRU KUSHTHA (FUNGAL SKIN INFECTION)

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ABSTRACT

Vasa is a prime drug of respiratory disorders in Ayurveda. Seers of Ayurveda have also prescribed it as a single drug in *Kushtha Roga* in various dosage forms. It possesses *Tikta Rasa Pradhana-Kashaya Anurasa, Sheeta Virya, Laghu Guna* and *Kapha-Pitta Hara* properties. Many experimental studies like antitussive, bronchodilator activity, anti-asthmatic activities and clinical study were conducted to evaluate its *Kasahara, Shwasahara, Raktapittahara Karma*. But till date not a single study conducted to evaluate its *Kushthaghna* effect. Hence, an attempt was made to clinically compare Vasa with standard drug *Nimba* for its *Kushthaghna Karma*. **Aim:** To clinically assess the effect of Vasa in *Dadru Kushtha*. **Settings and Design:** Interventional, Open labeled, Randomized, Parallel arm. **Methods and Material:** Fresh leaves of Vasa were collected from periphery of Rajpipla, Gujarat. The patients were selected from Government Ayurved College & Hospital, Vadodara and grading analogue scale, general & physical examination was done as a screening. **Statistical analysis used:** Data were calculated by student 't' test for parametric data using Sigma stat 3.2. **Results:** Vasa showed statistically significant ($p < 0.001$) results in all symptoms of *Dadru Kushtha*. Group A- (*Nimba*) showed 75.83% and Group B- (*Vasa*) showed 78.54% improvement in all symptoms of *Dadru*. The chief complaint of *Dadru Kushtha* i.e., *Kandu* was better relieved by Vasa on the basis of percentage of relief i.e., 97.92% in comparison to *Nimba* i.e., 89.58. **Conclusion:** Vasa is effective in all the symptoms of *Dadru Kushtha*. Current study suggests that it can be effectively used in *Kapha pitta pradhana Kushtharoga*.

INTRODUCTION

Skin and its appendages are the most visible part of our body and any skin disease will create an emotional concern for an individual. The superficial fungal infections are the most common fungal infections observed in the society According to WHO prevalence rate of superficial mycotic infection is 20-25%.^[1] There is a detailed explanation of skin diseases in Ayurveda. *Kushtha* is also considered as one of the eight *Mahagada* (dreadful diseases).^[2]

There are eighteen types of *Kushtha roga* which are classified in to *Maha Kushtha* (major skin ailments) and *Kshudra Kushtha* (minor skin ailments)^[3].

Dadru is classified as a *Kshudra Kushtha* by *Acharya Charaka*. Clinical features of *Dadru Kushtha* are *Kandu* (itching), *Raga* (erythema or redness), *Pidika* (eruptions) and *Utsanna Mandala* (elevated circular skin lesion). It is a *Tridoshajavyadhi* with predominant vitiation of *Pitta* and *Kapha Dosha*^[4]. It can be very well co-related with fungal skin infection.

Ayurveda have many single herbs and formulations to cure or control the disease. But still nothing promising medication, has been assured to control / cure the disease so there is an urgent need to clinically prove single drug and its efficiency and capabilities based on the concepts of Ayurveda. *Nimba* is very versatile drug in Ayurveda and mostly all parts

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of *Nimba* have medicinal properties. *Bhavaprakasha Nighantu* also stated *Nimba* as *Sarva Kushthanuta*^[5] Owing to all these properties *Nimba* leaves is used in various skin related ailments in different dosage forms^[6] and considered as best armamentarium of physician. Considering all above information and background of the disease, *Vasa* is abundantly available and noncontroversial drug selected as trail drug owing properties like *Tikta Rasa Pradhan-Kashaya Anurasa, Sheeta Virya* and *Laghu Guna*^[7]. It has *Kapha -Pitta Nashana* properties, while it is indicated in the treatment of *Shwasa, Kasa, Jwara, Chhardi, Meha, Kushtha* and *Kshya*. Among all these information *Vasa* can be judged as a broad-spectrum action and seems to be a better option for the disease like *Dadru Kushtha*. Hence, considering this an attempt was made to evaluate clinical effect of *Vasa* in *Dadru Kushtha* where *Nimba* is taken as standard drug.

MATERIALS AND METHODS

For this clinical study, patients fulfilling the diagnostic criteria of *Dadru Kushtha* were selected from O.P.D. of Dravyaguna department, Government Ayurved Hospital, Vadodara.

The study was started after obtaining the clearance from the Institutional Ethical Committee of Government Ayurved College, Vadodara (latter no. GAC/VAD/IEC/55/2019 Dt. 27/06/2019) and study was registered in CTRI (Ref. No. CTRI/2020/03/023990 Dt.16/03/2020) After getting the approval of IEC, Permission and NOC of the institutional ethical committee, all the patient was given the full idea about the clinical trial and after getting an information consent form (ICF) further process was started.

The uncomplicated cases with classical signs and symptoms of the *Dadru* were selected. They were selected irrespective of sex, religion, profession etc.

Fresh leaf of *Vasa* was collected from periphery of Rajpipla, Gujarat during August, 2020 (*Varsharitu*). The pharmacognostic study of the drug was done as macroscopy, microscopy study for authenticity of drug as per Ayurvedic Monographs. Other pharmacopeial standards, preliminary phytochemicals study was done to authenticate the drug. (Fig No. 1 & 2)

AIM AND OBJECTIVES

1. To clinically assess the effect of *Vasa* in *Dadru Kushtha*.

2. To categorize, classify, compare and generalize the conceptual textual data of *Vasa* and *Dadru Kushtha*.
3. To conduct pharmacognostic, phytochemical studies for correct identity of the herb.
4. To clinically evaluate effect of *Vasa* in *Dadru Kushtha*.

Inclusion Criteria

1. Patients between age group of 18-50 years.
2. Based on clear sign and symptoms of *Dadru Kushtha* fulfilling the diagnosis.

Exclusion Criteria

1. Patients having age less than 18 years and more than 50 years.
2. Uncontrolled clinical conditions like HTN, cancer, HIV, HBsAg, CKD, Liver cirrhosis, Cardiac failure, Stroke etc.
3. History of metabolic disorder.

Treatment Protocol

Patients were randomly divided into two groups by simple random method with the help of www.randomization.com. The physicians and patients were not blinded as no placebos were used. For the present clinical study, where the screened patients of *Dadru Kushtha* was randomly classified into two groups Group A & B.

Sample Size: Total-30 (15 patients in each group).

Posology (Fig No. 3)

Group-A: *Nimba Patra Yavkuta Churna* - 10gram for *Kashaya* Preparation and *Nimba Patra Sukshma Churna* for *Lepa* application for 21 days.

Group-B: *Vasa Patra Yavkuta Churna* - 10gram for *Kashaya* Preparation and *Vasa Patra Sukshma Churna* for *Lepa* application for 21 days.

Criteria for Assessment of the Treatment

Objective Criteria

- Investigations like routine haematological examinations like Hb, TC & ESR.

Subjective Criteria

- Assessment of sign and symptoms was done as per Grading Analog Scale (GAS) and was performed before, in-between and after the treatment.
- A scoring method was adopted for different sign and symptoms.

Table 1: Grading analog scale for *Dadru Kushtha*

No.	<i>Kandu</i> (Itching)	Grades
1	No <i>Kandu</i> (no itching)	0
2	<i>Ishatkandu</i> (mild itching: Which comes occasionally, does not disturb the mind, duration is 2/3 min; usually scratching is not required)	1
3	<i>Bahukandu</i> (moderate itching: Which occurs frequently disturbs the mind, lasts for longer time, scratching every time is essential, recurs 3/4 times in 12 hours)	2

4	<i>Ugrakandu</i> (severe itching: Frequently occurs, disturbs mind and sleep, lasts for 20/30 min, scratching very essential, recurs 8/10 times in 12 hours)	3
5	<i>Ugrakandu</i> (excessive itching: continuous itching, scratching marks present on body, drastically disturbs mind, sleep not possible.)	4
Raga (Skin Colour)		
1	Normal skin colour	0
2	Faint discolouration and near to normal skin colour	1
3	Blanching and red colour	2
4	Red colour	3
Pidika (Numbers of papules per Mandala)		
1	No papules per circular patch	0
2	1 to 3 numbers of papules in most of circular patches	1
3	4 to 6 numbers of papules in most of circular patches	2
4	More than 6 numbers of papules in most of circular patches	3
Utsanna Mandala (Numbers of elevated circular patch)		
1	No clear circular patch	0
2	4-6 numbers of circular patch	1
3	7-9 numbers of circular patch	2
4	More than 10 numbers of circular patch	3
Utasna Mandala (Size of elevated circular patch in cm)		
1	No clear circular patch.	0
2	Most of circular patches are less than 5cm in size.	1
3	Most of circular patches are 5-10cm in size.	2
4	Most of circular patches are more than 10cm in size.	3

Advice

- To avoid all causative factors of *Kushtha* according to Samhita.
- To avoid mental stress.
- To take light and easily digested food, regular lifestyle.

Criteria for Assessment

Improvement in condition was assessed on the basis of changes in scoring pattern developed for grading of these clinical factors. Special clinical proforma was designed to record the demographic data, history of present illness, personal history, and examination of *Dashavidha-Bhava* and change in assessment parameters.

Assessment of Overall Effect of Therapy

- The overall improvement in symptoms was assessed after the completion of treatment course. Total effect was assessed in following categories.

Table 2: Overall Effect of Therapy

No change.	Less than 25% changes in the sign and symptoms
Mild improvement	26-50% changes in the signs and symptoms
Moderate improvement.	51-75% changes in the signs and symptoms
Marked improvement.	76-99% changes in the signs and symptoms
Complete remission.	100% changes in the signs and symptoms

Statistical Analysis

- Obtained data were calculated by student 't' test for parametric data in single group as well as in comparison.
- Test was performed by using Sigma Stat^[8] 3.2 software.
- A level of P value <0.005 was considered as statistically significant, P < 0.001 were considered as highly significant.

Observation on Demographic Data

Total 50 patients were screened who appeared the O.P.D. of Dravyaguna, Government Ayurved Hospital, Vadodara. Among them 36 patients were fulfilled inclusion criteria of study so they were enrolled and randomly allocated into Group A and Group B. 2 patients were dropped out in Group A and Group B.

Among 36 patients, 41.67% of patients were of 18-29 years of age group, followed by 30.56% belonged to age group of 30-39 years while 27.78% patients were from 40-50 years of age group.

Table 3: Distribution of 36 patients of *Dadru Kushtha* based on age

Age (in years)	No. of Patients (n=36)		Total	Percentage
	Group A	Group B		
18-29	8	7	15	41.67
30-39	5	6	11	30.56
40-50	5	5	10	27.78

Table 4: Distribution of 36 patients of *Dadru Kushtha* based on sex

Sex	No. of Patients (n=36)		Total	Percentage
	Group A	Group B		
Male	8	8	16	44.44
Female	10	10	20	55.56

Table 5: Distribution of 36 patients of *Dadru Kushtha* based on religion

Religion	No. of Patients (n=36)		Total	Percentage
	Group A	Group B		
Hindu	13	13	26	72.22
Muslim	5	5	10	27.78

Table 6: Distribution of 36 patients of *Dadru Kushtha* based on nature of diet

Nature of Diet	No. of Patients (n=36)		Total	Percentage
	Group A	Group B		
Vegetarian	12	12	24	66.67
Mixed	06	06	12	33.33

Table 7: Distribution of 36 patients of *Dadru Kushtha* based on dietary pattern (*Aharavidhi*)

<i>Aharavidhi</i>	No. of Patients (n=36)		Total	Percentage
	Group A	Group B		
<i>Viruddhasana</i>	8	13	21	58.33
<i>Vishmasana</i>	3	1	4	11.11
<i>Samasana</i>	0	0	0	0
<i>Adhyasana</i>	7	4	11	30.56

Table 8: Distribution of 36 patients of *Dadru Kushtha* based on dominant *Rasa* in diet

Dominant <i>Rasa</i>	No. of Patients (n=36)		Total	Percentage
	Group A	Group B		
<i>Madhura</i>	17	15	32	88.89
<i>Amla</i>	16	12	28	77.78
<i>Lavana</i>	3	5	8	22.22
<i>Katu</i>	14	17	31	86.11
<i>Tikta</i>	0	1	1	2.78

Table 9: Distribution of 36 patients of *Dadru Kushtha* based on *Koshtha*

<i>Koshtha</i>	No. of Patients (n=36)		Total	Percentage
	Group A	Group B		
<i>Mrudu</i>	0	2	2	5.56
<i>Madhyama</i>	16	12	28	77.78
<i>Krura</i>	2	4	6	16.67

Table 10: Distribution of 36 patients of Dadru Kushtha based on Sharira Prakruti

Sharira Prakruti	No. of Patients (n=36)		Total	Percentage
	Group A	Group B		
Vata-Pitta	7	6	13	36.11
Pitta-Kapha	8	7	15	41.66
Vata-Kapha	3	5	8	22.22

Effect of Therapy on Lakshana

Nimba Churna relieved *Kandu* 89.58% in patients and *Vasa Churna* provided 97.92% relief in *Kandu*. The results observed in both groups were highly significant statistically (<0.001). The drug, *Nimba Churna* provided relief in others features of *Dadru Kushtha* like *Raga* (67.70%), *Pidika* (78.13%), *Utasna Mandala* (numbers) (71.88%), *Utasna Mandala* (size) (71.88%). The results observed were highly significant statistically (<0.001). (Fig. No. 4)

Table 11: Effect of Nimba Churna in classical symptoms of Dadru Kushtha

Main Symptoms	N	Mean score of BT	Mean score of AT	Df in mean score	Change in %	SD (±)	T	P	Significance
<i>Kandu</i>	16	2.87	0.31	2.56	89.58	0.51	20.006	<0.001	HS
<i>Raga</i>	16	2.56	0.81	1.75	67.70	0.33	12.12	<0.001	HS
<i>Pidika</i>	16	2.18	0.5	1.68	78.13	0.70	9.59	<0.001	HS
<i>Utasna Mandala</i> (Number)	16	2.25	0.63	1.63	71.88	0.72	9.043	<0.001	HS
<i>Utasna Mandala</i> (Size)	16	2.25	0.63	1.63	71.88	0.72	9.043	<0.001	HS

All the other features of *Dadru Kushtha* relieved in the group treated with *Vasa Churna* also i.e., *Raga* (70.83%), *Pidika* (82.29%), *Utasna Mandala* (numbers) (68.75%), *Utasna Mandala* (size) (72.92%). The results were also highly significant statistically (<0.001). (Fig. No. 5)

Table 12: Effect of Vasa Churna in classical symptoms of Dadru Kushtha

Main Symptoms	N	Mean score of BT	Mean score of AT	Df in mean score	Change in %	SD (±)	T	P	Significance
<i>Kandu</i>	16	2.87	0.063	2.81	97.92	0.40	27.908	<0.001	HS
<i>Raga</i>	16	2.31	0.63	1.68	70.83	0.79	8.51	<0.001	HS
<i>Pidika</i>	16	2.06	0.31	1.75	82.29	0.68	10.25	<0.001	HS
<i>Utasna Mandala</i> (Number)	16	2.38	0.63	1.75	68.75	0.70	10.24	<0.001	HS
<i>Utasna Mandala</i> (Size)	16	2.5	0.69	1.81	72.92	0.54	13.33	<0.001	HS

Nimba Churna relief on associated symptoms, e.g. in *Vibandha* (100%), *Alasya* (0%), *Adhmana* (0%), *Urodaha* (100%). Among the patients treated with *Vasa Churna* relief on associated symptoms, e.g. in *Vibandha* (66.67%), *Urodaha* (83.33%) were observed.

The comparative value is statistically significant in some symptoms. *Kandu* was better relieved by *Vasa Churna* on the basis of percentage of relief i.e., 97.92% than by *Nimba Churna* i.e., 89.58%. This comparative data is statistically highly significant ($p < 0.001$). The comparative *Vasa Churna* showed better percentage of relief *Raga* i.e., 70.83% when compared with the group i.e. 67.71% to relieve. While better percentage of relief was found in Group B in *Pidika* 82.29%, as compared to Group A i.e., 78.13%. On relieving *Utasna Mandala* (numbers) Group A showed better result i.e., 71.88%, than that of Group B which is 68.75%. On relieving *Utasna Mandala* (size), Group B showed better result i.e., 72.92%, than that of Group A which is 71.88%. (Fig. No. 6)

Table 13: Comparison in between two group in classical symptoms of Dadru Kushtha

Main symptoms	% Relief		SD		T	P	A vs B
	A	B	A	B			
<i>Kandu</i>	89.58	97.92	0.51	0.40	-1.73	0.104	NS
<i>Raga</i>	67.71	70.83	0.58	0.79	0.32	0.751	NS
<i>Pidika</i>	78.13	82.29	0.70	0.68	-0.25	0.806	NS
<i>Utasna Mandala</i> (Number)	71.88	68.75	0.72	0.70	-0.24	0.817	NS
<i>Utasna Mandala</i> (Size)	71.88	72.92	0.72	0.54	-0.82	0.423	NS

The present study was assessed as complete remission, markedly improved, moderate Improved, mild improved and no changed. The overall effect of the therapy on 34 patients of *Dadru Kushtha* in both groups has been evaluated 12.5% of patients in Group A were remission completely. 56.25% of patients in Group B and 37.5% of patients in Group A were markedly improved. 43.75% of patient in Group B and Group A were moderately improved. While 6.25% patient mildly improved in Group A. (Fig. No. 7)

Table 14: Effect of Therapies

Improvement	Group A (<i>Nimba</i>)		Group B (<i>Vasa</i>)	
	No. of Pts.	Percentage	No. of Pts.	Percentage
Complete cure	2	12.5	0	0
Marked improvement	6	37.5	9	56.25
Moderate improvement	7	43.75	7	43.75
Mild improvement	1	6.25	0	0
No change	0	0	0	0
Overall effect	75.83%		78.54	

Clinical Observations of Patients after Follow-up

After accomplishment of the clinical trial of 21 days, the patients were followed up for further 14 days at regular interval of 7 days. They were evaluated for recurrence or aggravation of symptoms. In follow up study no patient had complaint of recurrence of symptoms within 14 days.

Probable Mode of Action of Drug

Effect of *Vasa* can be justified because of *Samprapti Vighatana* of *Dadru Kushtha*. This can be explained on the bases of *Rasa, Guna, Virya, Vipaka and Prabhava* of *Dravya*. *Vasa* has *Tikta-Kashaya Rasa, Katu Vipaka, Sheeta Virya*, and *Kapha-Pitta hara* qualities which helps to resolve *Samprapti*.

Vasa possess mainly *Tikta rasa*. Acharya Charaka has mentioned that *Tikta Rasa* is having *Kandughna, Kleda, Puya* and *Kaphashoshna* pharmacological properties.^[9] *Tikta Rasa* is a combination of *Vayu* and *Akasha Mahabhuta*.^[10] These two *Mahabhuta* are having qualities opposite to *Kapha*.^[11] The additional *Rasa* in *Vasa* is *Kashaya*^[12] it has properties like *Sleshma-Rakta-Pitta Prashamana*, and it has also quality of drying *Kleda*.^[13] This *Rasa* is formed by *Vayu* and *Prithivi Mahabhuta*^[14] having properties opposite to *Kapha* and *Pitta* by these properties it eases *Kandu* as well as reduces *Raga* and *Pidika*. *Vasa* possess *Laghu* and *Sara Guna*. By the virtue of this property this may pacify vitiated *Kapha* and *Kleda* and as *Kandu* is chief complain of *Dadru Kushtha* and *Kandu* is mainly due to *Kapha*.^[15]

As *Vasa* is *Katu Vipaka Dravya* it has properties like *Baddhavinmutra, Vatala, Shukraha*^[16] so it decreases *Kapha*. That's why the role of *Katu Vipaka* can be justified to pacify symptoms of *Dadru Kushtha*.

Action as per modern pharmacological activity:

The modern technology has proved that *Vasa* has antibacterial, antimicrobial activity and antifungal activity and immunomodulatory activity^[17] by which it kills the causative microorganism i.e., *Trichophyton, Microsporum*, and *Epidermophyton* and reduces inflammation. By its immunomodulatory activity it will positively modulates the immunity of the host. The strong antibacterial activity was exhibited by vasicine at 20µg/ml dose against *E. coli* and also demonstrated maximum antifungal activity against *C. albicans* at the dose of >55µg/ml.^[18] There is maximum percentage of Vasicine (1.74%w/w) and Vasicinone (1.24%w/w) in *Vasa Kwatha* (Decoction) than raw *Vasa* drug (1.17%w/w and 1.126%w/w simultaneously)^[19]. In one of the research study Vasicine percentage in *Vasa* powder observed was 1.69% (%w/w)^[20]. Hence, these studies support the antifungal activity of *Vasa* in current research work based on obtained data of both the dosage forms i.e., *Kwatha* and *Lepa*.

CONCLUSION

In the end significant improvement was observed in almost all the symptoms in Group B- *Vasa* (*J. adhatoda*). On comparing the trial drug with standard drug statistically insignificant difference was observed. Group B- *Vasa* had shown better effect than

group A – *Nimba* (*A. indica*) in overall effect of therapy i.e., Group – A (75.54%), Group – B (78.54%).

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Fig. No. 4 : Effect of therapy of group A – *Nimba* (*A. indica*) in *Dadru Kushtha* (Fungal Skin Infection)



Fig. No. 5 : Effect of therapy of group B- *Vasa* (*J. adhatoda*) in *Dadru Kushtha* (Fungal Skin Infection)