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A CLINICAL STUDY TO EVALUATE THE EFFECT OF DADRUGHNA PATRA TAILA IN DADRU KUSHTA

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ABSTRACT

Introduction: *All the skin diseases in Ayurveda have been classified under the broad heading, "Kushta". Dadru is one among Kushta. It involves the clinical features like kandu, raga, pidaka, utsannamandala. Dadru kushta mostly simulates with 'Dermatophytosis' commonly referred to as ringworm which is highly contagious. In this study an effort has been made to evaluate the Dadrughna karma (Antifungal activity) of the oil prepared from Dadrughna (Cassia alata Linn) leaves.*

Materials and methods: *In the present study, action of Dadrughna (Cassia alata Linn) patra taila on Dadru kushta was evaluated in 32 subjects who were treated with Dadrughna patra taila as an external application twice a day for 30 days and follow up was done on 45th day. Assessment was done for subjective parameter-itching and objective parameters-distribution of lesion, severity of inflammation, extent of lesion.*

Results: *The effect of therapy was assessed before treatment, 15th day, 30th day of treatment and follow up was done on 45th day. The results were statistically analyzed; it showed significant changes in subjective parameter-itching (p<0.001) and Objective parameters- distribution of lesion (p <0.001), severity of inflammation (p<0.001), extent of lesion (p <0.001).*

Discussion and conclusion: *The external application of Dadrughna patra taila applied for 30 days has helped in reduction of itching, distribution of lesion, extent of inflammation and severity of inflammation where the taila was found more effective in reducing itching when compared to other symptoms*

KEY WORDS: *Dadru kushta*, *Dermatophytosis*, *Dadrughna* (*Cassia alata* Linn), *Dadrughna patra taila*

INTRODUCTION

All the skin diseases in *Ayurveda* have been classified under the broad heading, "*Kushta*" which are further classified into *Mahakushta* and *Kshudrakushta*.[1] *Dadru* is one among *Kushta*. *Dadru kushta* is mentioned under both *Mahakushta* and *Kshudrakushta* by different *acharya*[2,3,4] It involves the clinical features like *kandu*, *raga*, *pidaka*, *utsannamandala* and it is also mentioned as *anushangini* [5]

On the basis of clinical appearance, *Dadru kushta* mostly simulates with 'Dermatophytosis' The Dermatophytes are a group of closely related fungi that have the capacity to invade keratinized tissue (skin, hair and nails) of humans and other animals to produce an infection, Dermatophytosis, commonly referred to as ringworm which is highly contagious. The infections caused by a dermatophyte (species of fungi belonging to the genera *Trichophyton*, *Microsporum* or *Epidermophyton*) are referred to as Tinea. Ringworm

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involving body, arms and legs is termed as Tinea corporis[6].

According to WHO, the prevalence rate of superficial mycotic infection worldwide has been found to be 20-25%. The Tinea infections are prevalent globally but they are common in tropics and may reach epidemic proportions in geographical areas with higher humidity, over population and poor hygienic living conditions[7].

In the context of *Dadru* Kushta, *Bahirparimarjana* type of *chikitsa*[8] is mentioned which includes *Taila kalpana* also. Fat/water soluble active constituents can be extracted easily in this method. Hence in the current study, *taila* of the leaves of Dadrughna (*Cassia alata* Linn) has been selected to assess the *Dadrughna* activity. *Dadrughna* botanically identified as *Cassia alata* Linn belonging to the family Caesalpiniaceae is an ornamental shrub, distributed from tropical America to India. It is commonly known as Ringworm senna. This plant is used as a folklore medicine for the treatment of skin diseases like Scabies, Eczema, Pruritus, Ringworm and other fungal infections.

AIMS AND OBJECTIVES

To evaluate the Dadrughna karma of Dadrughna (*Cassia alata* Linn) patra taila

MATERIALS AND METHODS

Source of data: Patients attending the Outpatient department (OPD) of Skin at a tertiary Ayurveda healthcare centre attached to a teaching institute, situated at the district headquarters in South India

Ethical Committee Approval Number - SDM/IEC/24/2019

Clinical Trial Registry of India - CTRI/2019/09/021113

CRITERIA OF EVALUATION

Diagnostic criteria

For diagnosis detailed medical history and physical examination was done according to both Ayurvedic and Modern clinical methods

Inclusion criteria

1. Patients clinically diagnosed with tinea infection.
2. Direct microscopy skin test positive.
3. Aged over 18 years and of any gender.
4. Patients who are willing to be a part of this study and sign the informed consent form.

Exclusion criteria:

5. Patients associated with other types of *Kushta*.
6. Systemic disorders like uncontrolled Diabetes and uncontrolled hypertension
7. Use of corticoids, cytostatics, antibiotics or immune depressing drugs

STUDY DESIGN

The present study was an open label, single arm, clinical study conducted in a tertiary *Ayurveda* healthcare centre attached to a teaching institute, situated at the district headquarters in Hassan, Karnataka. 32 patients suffering from *Dadru kushta* who signed the informed consent form and who fulfilled the inclusion criteria for the study were selected using convenience / purposive sampling technique and treated with the external application of *Dadrughna*(*Cassia alata Linn.*) *patra taila*

DOSAGE AND DRUG ADMINISTRATION

Drug: Dadrughna patra taila
Dosage: Quantity sufficient
Mode of administration: External application
Duration: 30 days

ASSESSMENT CRITERIA

Assesment will be done on 15th, 30th and 45th day of the treatment. Assesment tables are given below

Subjective parameter: Assessment of itching as per pruritus severity scale

Sl No	Questions	Possible answers	Scorings
1.	How often did you feel pruritus within the last 3 days?	(i) All time (ii) All morning/afternoon/evening/night long itching episodes (iii) Occasionally short itching episode	3 points 2 points 1 point
2.	Did pruritus hinder your ability to do simply things, like watching TV, hearing music, etc.?	(i) Yes (ii) No	1 point 0 points
3.	Did you feel irritated or nervous because of your itching?	(i) Yes (ii) No	1 point 0 points

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4.	Did your pruritus cause you depressed?	(i) Yes (ii) No	1 point 0 points
5.	Did your pruritus impede your work or learning abilities?	(i) Yes (ii) No	1 point 0 points
6.	Did you scratch your skin because of itching?	(i) Yes (ii) No	1 point 0 points
7.	Did scratching bring you relief?	(i) Yes (ii) No	0 points 1 point
8.	Were you able to refrain from scratching?	(i) Yes (ii) No	0 points 1 point
9.	Did you wake up during last night because of pruritus?	(i) No (ii) Yes, 1-2 times (iii) Yes, 3-4 times (iv) Yes, 5 and more times	0 points 1 point 2 points 3 points
10.	Could you assess the severity of your pruritus within last 3 days?	(i) Very mild (ii) Mild (iii) Moderate (iv) Severe (v) Very severe	1 point 2 points 3 points 4 points 5 points
11.	Could you indicate pruritus location?	(i) Single locations of pruritus (ii) Large body areas (iii) Generalized pruritus	1 point 2 points 3 points
12.	Are excoriations or other scratch lesions present?	(i) Yes (ii) No	1 point 0 points

OBJECTIVE PARAMETERS

1. Distrubution of lesions:

1. Mild: involvement of only one region of the body
2. Moderate: involvement of more than one region of the body and less than or equal to three regions of the body
3. Disseminated: involvement of more than three regions of the body

2. Severity of lesions:

Sl No	Inflammation	Severity
1	Scaly plaque-like lesions with mild inflammation	1 point
2	Typical "ringworm" lesions with an annular appearance	2 points
3	Vesicular or exudative lesions with intense inflammation	3 points

3. Extent of lesions:

Sl No	Inflammation	Severity
1	Lesions < 3 cm in diameter	1 point
2	Lesions 3-6 cm in diameter	2 points
3	Lesions > 6 cm in diameter	3 points

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STATISTICAL ANALYSIS

- Friedman's test was applied to analyze the significance of change in Subjective and objective parameters (within the group)
- Wilcoxon's sign rank test was done for post Hoc analysis with Bonferroni correction on parameters which show significance in Friedman's test, to interpret the time of significant change

OBSERVATION

In the present study total 58 subjects were screened, out of which 35 subjects were registered for the study, among them 32 subjects completed the study and 3 were dropped out

Among 35 completed subjects maximum from the age group of 21-40 (n=20) and predominance of males (n=21) over females was found. Majority of the subjects were married (n=27). Diet wise distribution showed maximum were having non veg diet (n=33). Considerable number of subjects (n=19) were having family history

RESULTS

In the present study total 58 subjects were screened, out of which 35 subjects were registered for the study, among them 32 subjects completed the study and 3 were dropped out

32 subjects were given Dadrughna patra taila to apply externally twice a day for a period of 30 days

Friedman's test and Wilcoxon's sign rank test were conducted (Table 1- 8)

DISCUSSION

Effect of therapy on Subjective parameter:
Based on 12-item Pruritus severity scale

It's a validated scale created for the assessment of pruritus severity which consists of 12 questions. The questions are mainly related to pruritus intensity, pruritus extent and duration and influence of pruritus on concentration and patient psyche.

Pruritus intensity

All the 32 patients had the complain of pruritus with varying intensity. Assessment regarding severity of pruritus (*kandu*) was done before treatment and on 15^{th} day, 15^{th} & 30^{th} day, 30^{th} & 45^{th} day (follow up). On application of statistics Wilcoxon sign rank test with post hoc test with Bonferroni correction – 0.0125, the obtained result was statistically significant in all the 4 occasions with P value <0.001. No patients were distributed in positive rank in any of the occasions showed that there was no aggravation of *kandu*. Further on comparison of reduction in severity of *kandu* between before treatment and follow up, 32 patients were distributed in negative rank which shows that there was reduction in severity of *kandu* in all the patients after application of *Dadrughna patra taila*.

Pruritus Extent and Duration

Most of the patients had the complain of long itch episodes all morning/afternoon/evening/night. Assessment regarding extent and duration of pruritus (*kandu*) was done before treatment and on 15^{th} day, 15^{th} & 30^{th} day, 30^{th} & 45^{th} day (follow up). On application of statistics Wilcoxon sign rank test with post hoc test with Bonferroni correction – 0.0125, the results were statistically significant when compared to before treatment & 15^{th} day, 15^{th} day & 30^{th} day with p value < 0.001. When compared to 30^{th} day and follow up, there was reduction observed in extent and duration of *kandu* but statistically the result was non-significant with p value 0.025. However the result was significant when compared to before treatment and follow up with p value < 0.001 with 32 patients distributed in negative rank which shows that there was reduction in extent and duration of *kandu* in all the patients after application of *Dadrughna patra taila*.

As there is no classical reference available on *Rasapanchaka* of *Dadrughna* (*Cassia alata* Linn) *patra*, an attempt is made to discuss the results of present study with the help of previous supportive research studies.

The specific mechanism of itching due to dermatophytoses is still unknown. In general mechanisms of any infection induced itch can be direct through the neuronal recognition of PAMPs. Neuronal activation may also be indirect, in particular through immune cells that are activated during infection. These cells release cytokines, lipids and other inflammatory mediators in response to pathogens that then sensitize neurons. Pathogenic infections may also indirectly cause itch through other mechanisms such as the induction of oxidative stress. Recent work has shown that anti-oxidants are potent modulators of acute and chronic itch and thus could be useful in the treatment of infectious itch[9]. Previous research studies have been proved that Cassia alata leaf has strong inhibitory action against dermatophytes that cause ringworm. The phytoconstituents claimed to have antifungal properties are anthracene derivatives, chrysophanol, chrysophanic acid, crude anthraquinones, rhein and aloe-emodine. Thus *Dadrughna patra taila* is potential enough to reduce itching by inhibiting the activities of dermatophytes. Owing to the role of anti-oxidants in

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fungal infections, based on previous research study it is evidenced that the *Cassia alata* possess strong anti-oxidant activity, as it contains good quantity of phenols, vitamin-C, vitamin A, flavonoids, caretenoids and anthraquinone.[10]

Concentration and Patient Psyche

The questions based on concentration and patient psyche had covered the effect of pruritus on patient's learning ability, irritability, nervousness etc. Assessment was done before treatment and on 15th day, 15th & 30th day, 30th & 45th day (follow up). On application of statistics Wilcoxon sign rank test with post hoc test with Bonferroni correction – 0.0125, the results were statistically significant when compared to before treatment & 15th day with p value < 0.001. When compared to 15th and 30th day, 30th day and follow up, there was reduction observed but statistically the result was non-significant. However the result was significant when compared to before treatment and follow up with p value < 0.001 which shows that there was reduction in complains related to concentration, irritability, nervousness etc.

Itch is a complex sensory phenomenon that incorporates discriminative, cognitive, motivational and affective components. Recent studies have highlighted that most of the itchy skin conditions are associated with higher rates of stress, anxiety, depression leading to major deficits in quality of life. In turn, stress and anxiety exacerbate itch, leading to a vicious cycle that affects patient behavior (scratching) and worsens disease prognosis[11]. In the present study, there was significant result for the complaints related to stress and anxiety even on the 15th day of application of oil. This might be because of reduction of severity of itching in most of the patients on the 15th day of treatment as shown in the above results.

Effect of therapy on Objective Parameters
Distribution of lesion

Majority of patients were having distribution of lesions in more than 1 region and less than or equal to 3 regions of the body. Assessment regarding distribution of lesions was done before treatment and on 15th day, 15th & 30th day, 30th & 45th day (follow up). On application of statistics Wilcoxon sign rank test with post hoc test with Bonferroni correction – 0.0125, the result was non-significant when compared to before treatment and 15th day with p value 0.317 and no patient was distributed in negative rank hence there was no reduction in the distribution of lesions in any of the patients. When compared to 15th day and 30th day, there was reduction observed and 5 patients were distributed in negative rank but the result was statistically non significant with p value 0.025. Further the obtained results were statistically significant when compared to 30th day and follow up, before treatment and follow up with p value <0.001 , 8 and 13 patients were distributed in negative rank respectively which shows that there was reduction in distribution of lesions after application of *Dadrughna patra taila*

In the present study, the results were non-significant for 30 days of treatment and even after treatment only 13 patients showed the reduction of distribution of lesions. As the disease is contagious in nature, the important factor in the spread of this infection is the scratching which develops due to the local reaction between the fungus and the body's immune system. Whenever a patient scratches the lesion, some fungal particles stick to the fingers or the instruments used for scratching and get dislodged to a new site where the person touches after that. This may be considered as one of the reasons for delay in cure of the dermatophytoses.

Severity of Inflammation

All the 32 patients had typical ringworm lesions with annular appearance. Assessment was done before treatment and on 15th day, 15th & 30th day, 30th & 45th day (follow up). On application of statistics Wilcoxon sign rank test with post hoc test with Bonferroni correction – 0.0125, the result was non- significant when compared to before treatment and 15th day with p value 1.000 and no patient was distributed in negative rank hence there was no reduction in the distribution of lesions in any of the patients. When compared to 15th day and 30th day, there was reduction observed and 10 patients were distributed in negative rank but the result was statistically non significant with p value 0.002. Further the obtained results were statistically significant when compared to 30th day and follow up, before treatment and follow up with p value <0.001 , 12 and 21 patients were distributed in negative rank respectively which shows that there was reduction in severity of inflammation after application of *Dadrughna patra taila*.

Previous research studies have revealed that *Cassia alata* leaves extract have been proven to have effective anti-inflammatory action. Rhein is one of the major chemical constituents found in *Cassia alata.* According to a previous study pre-treatment with rhein on t-BHP induced inflammation in human keratinocytes showed that the chemical constituent could diminish the inflammatory responses such as production of TNF-α and IL-8 and these effects occurred via suppression of ROS production[12], thus

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supporting the anti-inflammatory action of *Dadrughna patra taila*.

Extent of Lesion

Majority of patients had lesions measuring 3cm – 6cm. Assessment was done before treatment and on 15th day, 15th & 30th day, 30th & 45th day (follow up). On application of statistics Wilcoxon sign rank test with post hoc test with Bonferroni correction – 0.0125, the result was non- significant when compared to before treatment and 15th day with p value 1.000 and no patient was distributed in negative rank hence there was no reduction in the extent of lesions in any of the patients. Further the obtained results were statistically significant when compared to 15th day & 30th day, 30th day & follow up, before treatment & follow up with p value < 0.001 and in the last occasion 31 patients were distributed in negative rank which shows that there was reduction in extent of lesion after application of *Dadrughna patra taila*.

The dermatophyte invades the uppermost non-living keratinized layer of the skin namely the stratum corneum, produces an exoenzyme keratinase and induces inflammatory reaction at the site of infection. Inflammation causes the pathogen to move away from the site of infection and take residence at a new site. This movement of the organism away from the infection site produces classical ringed lesion[13]. The diameter of the lesion varies according to strength of the infecting dermatophyte and immunity of the host. In the present study the reduction in the size of the lesion is due to anti-fungal and anti-inflammatory action of phytoconstituents present in *Cassia alata* as explained previously. But there was delay in the reduction of size of the lesions or no complete reduction in the majority of patients. The reason may be the chronicity of the infection in many of the patients and also due to application of steroid creams previously. Steroid creams can temporarily reduce ringworm symptoms like itching and redness, but they don't kill the dermatophyte. These creams also can make ringworm worse because they weaken the skin's defenses.[14]

PROBABLE MODE OF ACTION

According to a previous research study, the inhibition of tested clinical dermatophytes by *Cassia alata* leaf extract confirmed their antifungal activity and this is most likely due to the action of different phytoconstituents present in the leaf extract and a wide range of physiological activity of saponins, alkaloids, carbohydrates, flavonoids, anthraquinones, steroids and tannins.[15]

Anthraquinones, the quinines are aromatic rings with two ketone substitutions. They are ubiquitous in nature and are characteristically highly reactive. The switch between hydroquinone and quinone occurs easily through redox reactions. In addition to providing a source of stable free radicals, quinines are known to complex irreversibly with nucleophilic amino acids in protein often leading to inactivation of the protein and loss of function thus acting as anti-fungal.

Tannins are found in almost every part: bark, wood, leaves, fruits and roots of *Cassia alata*. The tannins present in the leaf extract of Cassia alata were believed to act on skin infections by coagulating the cell wall proteins. According to number of studies, Tannins can be toxic to filmentous fungi, yeast, bacteria.

Saponins are the surface active agents which interfere with or alter the permeability of the cell. Saponins were reported as major components acting as antifungal secondary metabolite.

Flavonoids are phenolic in nature and acts as cytoplasmic poisons. Flavonoids are also hydroxylated phenolic substances but occur as a C6-C3 unit linked to an aromatic ring. Their activity is probably due to their ability to complex with extracellular and soluble proteins and to complex with fungal cell walls.[16]

A previous research study confirms that there are antifungal properties in the crude extract of Cassia alata leaf and this activity may be due to the presence of chrysophanol in the leaf extract. The study states that the reduction in the growth of dermatophytes (3 *Trichophyton spp*, *Microsporum gypsum, and Microsporum canis*) was possibly due to interference by active principles of the extract. Such interference may be at the biosynthetic level. Dermatophytes parasitize keratinized tissue such as the horny layer of the epidermis, hair and nails. It exists in either a hyphal form or conidial form. Therefore in this the susceptibilities of the conidia to drugs were examined. Under a light microscopy study, control or untreated culture showed many smooth walled and regularly shaped macroconidia, whereas the treatment culture showed the shrunken and collapsed macroconidia. This phenomenon could be due to the leakage of the cell wall or perhaps some alteration in the membrane permeability and resulting in the loss of cytoplasm. This could lead to loss in rigidity of the macroconidia and finally cause the death of the cells, thus proving the fungicidal activity of *Cassia alata*.[17]

Thus a handful of research studies provide an insight into the usage of the plant *Cassia alata* in

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traditional treatment of diseases associated with fungal infections.

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Table: 1 Friedman test for subjective parameter Pruritus
Statistical assessment on questionnaire of 'Pruritus severity scale'

Parameters	Day	N	Mean rank	Chi Square(x^2)	P value	Remarks
'How often did you feel Pruritus within last 3 days'?	D1	32	3.88	77.410	<0.001	Significant
	D15		2.52			
	D30		1.92			
	D45(FU)		1.69			
Did pruritus hinder your ability to do simple things like watching TV, hearing music,etc?'	1	32	3.69	68.348	<0.001	Significant
	15		2.44			
	30		1.94			
	Follow up(45)		1.94			
'Did you feel irritated or nervous because of your itching?'	1	32	3.36	51.814	<0.001	Significant
	15		2.30			
	30		2.17			
	Follow up(45)		2.17			
'Did your pruritus cause you depressed?' Table: 43 Friedman test	1	32	3.05	33.324	<0.001	Significant
	15		2.36			
	30		2.30			
	Follow up(45)		2.30			
'Did your pruritus impede your learning abilities?'	1	32	3.55	63.676	<0.001	Significant
	15		2.23			
	30		2.11			
	Follow up(45)		2.11			
'Did you scratch your skin because of itching?'	1	32	3.80	73.457	<0.001	Significant
	15		2.48			
	30		1.92			
	Follow up(45)		1.80			
'Did scratching bring you relief?'	1	32	2.81	18.545	<0.001	Significant
	15		2.44			
	30		2.38			
	Follow up(45)		2.38			
'Were you able to refrain from scratching?'	1	32	2.69	12.000	<0.001	Significant
	15		2.44			
	30		2.44			
	Follow up(45)		2.44			
'Did you wake up during last night because of pruritus?'	1	32	3.86	77.927	<0.001	Significant
	15		2.67			

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	30		1.95			
	Follow up(45)		1.52			
'Could you assess the severity of pruritus within last 3 days?'	1	32	4.00	92.584	<0.001	Significant
	15		2.97			
	30		1.80			
	Follow up(45)		1.23			
'Could you indicate pruritus location?'	1	32	2.59	9.000	<0.001	Significant
	15		2.59			
	30		2.41			
	Follow up(45)		2.41			

Friedman test for objective parameters

Table: 2 Distribution of lesions

Parameters	N	Mean rank	Chi Square(x^2)	P value	Remarks
Distribution of lesions D1	32	2.80	26.745	<0.001	Significant
Distribution of lesions D15		2.73			
Distribution of lesions D30		2.48			
Distribution of lesions FU		1.98			

Table: 3 Severity of inflammation

Parameters	N	Mean rank	Chi Square(x^2)	P value	Remarks
Severity of inflammation BT	32	2.98	50.020	<0.001	Significant
Severity of inflammation D15		2.98			
Severity of inflammation D30		2.38			
Severity of inflammation FU		1.66			

Table: 4 Extent of lesion

Parameters	N	Mean rank	Chi Square(x^2)	P value	Remarks
Extent of lesions BT	32	3.33	77.504	<0.001	Significant
Extent of lesions D15		3.33			
Extent of lesions D30		1.95			
Extent of lesions FU		1.39			

Table: 5 Wilcoxon sign rank test for questionnaire of 'Pruritus severity scale'

Parameters	Day	Negative ranks			Positive ranks			Ties	Total	Z value N	P value MR	R SR
		N	MR	SR	N	MR	SR					
'How often did you feel Pruritus within last 3 days'?	D1-D15	25	13.00	325.00	0	.00	.00	7	32	-5.00	<0.001	S
	D15-D30	11	6.00	66.00	0	.00	.00	21	32	-3.31	<0.001	S
	D30-FU	5	3.00	15.00	0	.00	.00	27	32	-2.23	>0.001	NS
	D1-FU	32	16.50	528.00	0	.00	.00	0	32	-5.18	<0.001	S
Did pruritus hinder your ability to do simple things	D1-D15	20	10.50	210.0	0	.00	.00	12	32	-4.47	<0.001	S
	D15-D30	8	4.50	36.00	0	.00	.00	24	32	-2.82	<0.001	S
	D30-FU	0	.00	.00	0	.00	.00	32	32	.000	>0.001	NS
	D1-FU	28	14.50	406.00	0	.00	.00	4	32	-5.29	<0.001	S

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like watching TV, hearing music,etc?'												
'Did you feel irritated or nervous because of your itching?'	D1-D15	17	9.00	153.00	0	.00	.00	15	32	-4.12	<0.001	**S**
	D15-D30	2	1.50	3.00	0	.00	.00	30	32	-1.41	>0.001	**NS**
	D30-FU	0	.00	.00	0	.00	.00	32	32	.000	>0.001	**NS**
	D1-FU	19	10.00	190.00	0	.00	.00	13	32	-4.35	<0.001	**S**
'Did your pruritus cause you depressed?' Table: 43 Friedman test	D1-D15	11	6.00	66.00	0	.00	.00	21	32	-3.31	<0.001	**S**
	D15-D30	1	1.00	1.00	0	.00	.00	31	32	-1.00	>0.001	**NS**
	D30-FU	0	.00	.00	0	.00	.00	32	32	.000	>0.001	**NS**
	D1-FU	12	6.50	78.00	0	.00	.00	20	32	-3.46	<0.001	**S**
'Did your pruritus impede your learning abilities?'	D1-D15	21	11.00	231.0	0	.00	.00	11	32	-4.583	<0.001	**S**
	D15-D30	2	1.50	3.00	0	.00	.00	30	32	-1.414	>0.001	**NS**
	D30-FU	0	.00	.00	0	.00	.00	32	32	.000	>0.001	**NS**
	D1-FU	23	12.00	276.0	0	.00	.00	9	32	-4.79	<0.001	**S**
'Did you scratch your skin because of itching?'	D1-D15	21	11.00	231.00	0	.00	.00	11	32	-4.58	<0.001	**S**
	D15-D30	9	5.00	45.00	0	.00	.00	23	32	-3.00	<0.001	**S**
	D30-FU	2	1.50	3.00	0	.00	.00	30	32	-1.41	>0.001	**NS**
	D1-FU	32	16.50	528.00	0	.00	.00	0	32	-5.65	<0.001	**S**
'Did scratching bring you relief?'	D1-D15	6	3.50	21.00	0	.00	.00	26	32	-2.449	>0.001	**NS**
	D15-D30	1	1.00	1.00	0	.00	.00	31	32	-1.000	>0.001	**NS**
	D30-FU	0	.00	.00	0	.00	.00	32	32	.000	>0.001	**NS**
	D1-FU	7	4.00	28.00	0	.00	.00	25	32	-2.646	<0.001	**S**
'Were you able to refrain from scratching?'	D1-D15	4	2.50	10.00	0	.00	.00	28	32	-2.000	>0.001	**NS**
	D15-D30	0	.00	.00	0	.00	.00	32	32	.000	>0.001	**NS**
	D30-FU	0	.00	.00	0	.00	.00	32	32	.000	>0.001	**NS**
	D1-FU	4	2.50	10.00	0	.00	.00	28	32	-2.000	>0.001	**NS**
'Did you wake up during last night because of pruritus?'	D1-D15	23	12.00	276.00	0	.00	.00	9	32	-4.70	<0.001	**S**
	D15-D30	13	7.00	91.00	0	.00	.00	19	32	-3.60	<0.001	**S**
	D30-FU	10	5.50	55.00	0	.00	.00	22	32	-3.16	<0.001	**S**
	D1-FU	32	16.50	528.00	0	.00	.00	0	32	-5.09	<0.001	**S**
'Could you assess the severity of pruritus within last 3 days?'	D1-D15	32	16.50	528.00	0	.00	.00	0	32	-5.578	<0.001	**S**
	D15-D30	30	15.50	465.00	0	.00	.00	2	32	-5.477	<0.001	**S**
	D30-FU	17	9.00	153.00	0	.00	.00	15	32	-4.12	<0.001	**S**
	D1-FU	32	16.50	528.00	0	.00	.00	0	32	-5.08	<0.001	**S**
'Could you indicate pruritus location?'	D1-D15	0	.00	.00	0	.00	.00	32	32	.000	>0.001	**NS**
	D15-D30	3	2.00	6.00	0	.00	.00	29	32	-1.732	>0.001	**NS**
	D30-FU	0	.00	.00	0	.00	.00	32	32	.000	>0.001	**NS**
	D1-FU	3	2.00	6.00	0	.00	.00	29	32	-1.732	>0.001	**NS**

Table: 6 Wilcoxon sign rank test for Distribution of lesions

Parameters	Negative ranks			Positive ranks			Ties	Total	Z value	P value	R
	N	MR	SR	N	MR	SR					
D1-D15	0	.00	.00	0	.00	.00	31	32	-1.000	>0.001	NS
D15-D30	5	3.00	15.00	0	.00	.00	27	32	-2.236	>0.001	NS
D30-FU	8	4.50	36.00	0	.00	.00	24	32	-2.828	<0.001	S
D1-FU	13	7.50	97.50	1	7.50	7.50	18	32	-3.207	<0.001	S

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Table: 7 Wilcoxon sign rank test for Severity of inflammation

Parameters	Negative ranks			Positive ranks			Ties	Total	Z value	P value	R
	N	MR	SR	N	MR	SR					
D1-D15	0	.00	.00	0	.00	.00	32	32	.000	>0.001	NS
D15-D30	10	5.50	55.00	0	.00	.00	22	32	-3.162	<0.001	S
D30-FU	12	6.50	78.00	0	.00	.00	20	32	-3.217	<0.001	S
D1-FU	21	11	231.00	0	.00	.00	11	32	-4.291	<0.001	S

Table: 8 Wilcoxon sign rank test for Extent of lesion

Parameters	Negative ranks			Positive ranks			Ties	Total	Z value	P value	R
	N	MR	SR	N	MR	SR					
D1-D15	0	.00	.00	0	.00	.00	32	32	.000	>0.001	NS
D15-D30	22	11.50	253.00	0	.00	.00	10	32	-4.690	<0.001	S
D30-FU	9	5.00	45.00	0	.00	.00	23	32	-3.000	<0.001	S
D1-FU	31	16.00	496.00	0	.00	.00	1	32	-5.568	<0.001	S