



A PROSPECTIVE SINGLE ARM TRIAL TO EVALUATE THE COMBINED EFFICACY OF NEELITULSYADI KASHAYAM AND CHAKARMARDA GEL IN DUSHIVISHAJANYA DADRU

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ABSTRACT

Fungal infections pose a major challenge to physicians due to the higher recurrence rate and, if not treated early, result in development of more extensive disease ;Tinea being one of them.The conventional line of treatment is seen to have failed as recurrence is a common problem faced by the physicians worldwide. Hence, the need of the hour is to find an alternate line of treatment which not only cures the infection but also keeps a check on its recurrence. The symptoms of *Dadru* simulate with those of Tinea Corporis and hence both can be correlated. This Study comprises of identifying the etiological factors ,examining the sign and symptoms, elaborating the factors involved to establish appropriate treatment protocol. Hence, A Prospective Single Arm study comprising of a sample size of 100 patients was conducted at Bharti Vidyapeeth (Deemed-to-be) University, *Ayurved* hospital and Research Centre. *Neelitulsayadi Kshayam* with local application of *Chakramadra Gel* was found to be effective in alleviating the symptoms of *Dadru* which had *Dushivisha* as the prime etiological factor.

KEYWORDS *Chakramadra, Dadru, Dushivisha ,Neelitulsayadi Kshayam, Tinea corporis.*

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INTRODUCTION

The most important and largest sense organ of body is Skin, which has seven layers. It plays important role in protection and is crucial from the cosmetic point of view. In general practice 10-15% of all consultations are Skin diseases ^[1], in which 0.5% people are found to suffer from Tinea infection^[2]. Poor hygienic conditions are one of the important factors that account for Tinea infection. It appears in variety of forms; most easily identifiable are the enlarging raised red rings with a central area of clearing (*ringworm*)^[3]. Dermatophyte is a tiny fungus responsible for Tinea infection . 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. 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 [4]. On the basis of clinical appearance, *Dadru* mostly simulates with 'dermatophytosis' According to World Health Organization prevalence rate of superficial mycotic infection worldwide is 20%–25%. In this era, everybody is consuming *Viruddhahar* in one way or the other. According to Acharya *Vagbhat's* quotation, this *Viruddhahar* can be nomenclated as '*Garavisha*'. Similarly, when *Viruddhahar* is consumed consistently and for a long term it can result in the formation of *Dushivisha* which can also become an etiological factor of *Kushtha* [5].

Hence, besides *Nidan Parivarjan* it is important to eliminate (*Shodhan*) and pacify (*Shaman*) the systemic *Doshadushti* arising thereof. Its management is done by *Shodhana*, *Shamana* and *Bahiparimarjana* (topical) *Chikitsa*. Hence, *Neelitulasydi Kashayam* pacify the condition by its *Tikta Rasa*, *Vishaghna* and *Sroto-Shodhana* properties. The contents of this *Kashayam* are having *Kaphavatahara* (reduce *Kapha* and *Vata*), *Vishagna* (anti-toxic), *Kushtagna* (pacifies skin diseases), *Vedanasthapana* (reduce pain) and *Rakthaprasadana* (Purifies blood) properties [6].

Nidana Panchaka of Dadru Kushtha:

The details about *Nidana Panchaka* of *Dadru Kushtha* are in Table. 1

Samprapti Ghataka

Table 2 consists of information on *Samprapthi Ghataka* of *Dadru Kushtha*. *Acharya Charaka* and *Acharya Vagbhata* have laid emphasis on the role of *Agni* and *Viruddhahar* in the *Samprapti* of many ailments, *Kushtha* being one of them. This *Viruddhahar* is a causative factor of *Raktadushti* and *Kushtha* [7], with the latter also stated as one of *Raktapradoshaj Vyadhi's Lakshana*. As a result, *Viruddhahar* causes *Raktadushti*, which manifests as *Kushtha*, which is one of the eight *Mahagadas* *Dadru* is classified as a *Kshudra Kushtha* by *Charakacharya* and a *Maha Kushtha* by *Sushrutacharya* among the eighteen types of *Kushtha Roga* [8]. *Dadru* has been classified as a *Ksudra Kustha* by *Acharya Charaka* [6]. *Acharya Sushruta* has mentioned *Dadru* under *Maha Kustha* [9] and has classified it into two types i.e *Sitta* and *Asitta* by *Acharya Vagbhata* has also mentioned *Dadru Kushtha* under *Maha Kushtha* [10].

It is *Raktapradoshaja Vyadhi* having *Kapha*, *Pitta* dominance with characteristic features such as presence of *Srava* (*Utsan Mandal* (elevated circular skin lesion), *Kandu* (itching), *Raga* (erythema), and *Pidaka* (eruptions). Due to similarity of all symptoms *Dadru* can be very well correlated with *Tinea corporis* which is a fungal infection especially caused due to poor hygienic conditions. It is a *Chirkalaja* (chronic) *Vyadhi* with vitiation of *Pitta* and *Kapha Dosha* predominantly [6].

The *Dadru Kustha* has the appearance like the colour of the linseed flower or are copper-coloured, and are full of eruptions with slow spread. In India, 5 out of 1000 people, suffer from *Tinea* infections [9]. *Neelitulasyadi Yoga* is one such commonly practiced formulation mentioned in the management of spider poisoning. This formulation contains 14 ingredients which are easily available [11].

Properties and action of ingredients of Neelitulsyadi Kashayam ^[12].

S. N O	INGREDIENS	ACTION
1	<i>Nili Moola</i>	<i>Kaphavatahara</i> (reduce <i>Kapha</i> and <i>Vata</i>) <i>Vishagna</i> (anti-toxic), <i>Kushtagna</i> (pacifies skin diseases), <i>Vedanasthapana</i> (reduce pain) <i>Rakthaprasadana</i> (Purifies blood)
2	<i>Tulasi</i>	<i>Kaphavatahara</i> , <i>Vishagna</i> , <i>Twakdosahara</i> , <i>Vedanasthapana</i> , <i>Rakthaprasadana</i>
3	<i>Ishwarmuli</i>	<i>Kaphavatahara</i> , <i>Vishagna</i> , <i>Vedhanasthapana</i> , <i>Sophahara</i>
4	<i>Sariva</i>	<i>Tridoshagna</i> , <i>Vishagna</i> , <i>Kushtagna</i> , <i>Rakthasodhana</i>
5	<i>Nirgundi</i>	<i>Kaphavatahara</i> , <i>Kushtagna</i> , <i>Vedanasthapana</i> , <i>Rakthaprasadana</i>
6	<i>Rasona</i>	<i>Kaphavatahara</i> , <i>Kushtagna</i> , <i>Vedanasthapana</i> , <i>Sophahara</i> (reduce swelling)
7	<i>Kushtha</i>	<i>Kaphavatahara</i> , <i>Kushtagna</i> , <i>Vedanasthapana</i>
8	<i>Yashtimadhu</i>	<i>Vatapittahara</i> (pacifies <i>Vata</i> and <i>Pitta</i>), <i>Kandughna</i> , <i>Vedanasthapana</i> , <i>Sophahara</i>
9	<i>Chandan</i>	<i>Kaphapittahara</i> , <i>Vishagna</i> , <i>Kushtagna</i> , <i>Raktasodhana</i>
10	<i>Tagar</i>	<i>Kaphavatahara</i> , <i>Vishagna</i> , <i>Kushtagna</i> , <i>Vranaropanam</i>
11	<i>Nagar</i>	<i>Kaphavatahara</i> , <i>Kushtagna</i> , <i>Vedanasthapana</i> , <i>Sophahara</i>
12	<i>Maricha</i>	<i>Kaphavatahara</i> , <i>Kushtagna</i> , <i>Vedanasthapana</i> , <i>Sophahara</i>
13	<i>Pippali</i>	<i>Kaphavatahara</i> , <i>Kushtagna</i> , <i>Vedanasthapana</i> , <i>Sophahara</i>
14	<i>Ashwagandha</i>	<i>Kaphavatahara</i> , <i>Kushtagna</i> , <i>Vedanasthapana</i> , <i>Sophahara</i>

Materials and Methods

Aim: To evaluate the efficacy of *Neelitulsyadi Kashayam* with local application of *Chakramarda Gel* in *Dushivishajanya Dadru*

Objectives

1. Study the prevalence of *Viruddhahar* as an etiological factor of *Dadru*
2. Enlist the factors that trigger *Dushivisha* to manifest as *Dadru*
3. Evaluation of the utility of a formulation indicated in *Luta VishaChikitsa* in alleviation of *Dadru*
4. Utilization of a gel based topical application.
5. To record the untoward effect if any during the study

Study design

Type of study: Prospective, Single Arm Clinical Trial

Place of study: BVMF's Ayurved hospital and Research centre, Katraj-Dhankawadi, Pune 43.

Plan of work:

- Patients suffering from skin manifestations were screened at the OPD level.
- Those diagnosed with *Dadru* were shortlisted.
- These patients were given a specially designed questionnaire to confirm *Viruddhahar (Dushivisha)* as the etiological factor.
- Patients suffering from two or more repeated incidences of *Dadru*.
- Patients diagnosed with *Dushivishajanya Dadru* were selected for the study.
- A specially designed case proforma was used to record all relevant details of patients eligible to be included as participants in the clinical trial.
- The ethical clearance for the clinical study was taken from the I.E.C. (Institutional Ethics Committee).
- Informed consent of patient was taken prior to commencement of clinical trial.
- Duration for drug administration was 28 days, which was based on a pilot study conducted on similar lines.
- Regular follow-up visits were taken on Day 7(± 2 days), Day 14(± 2 days), Day 21(± 2 days), Day 28(± 2 days) and Day 42(± 3 days).
- Patients were administered *Neelitulasyadi Kashayam* at *Prata* and *Sandhya Kala* in a dose of 20ml twice a day.
- Topical application of *Chakramarda Gel* was done daily(applied such that it covered the affected area).
- Patients were advised medications for 28 days after which a fortnightly follow-up without medications was recorded.

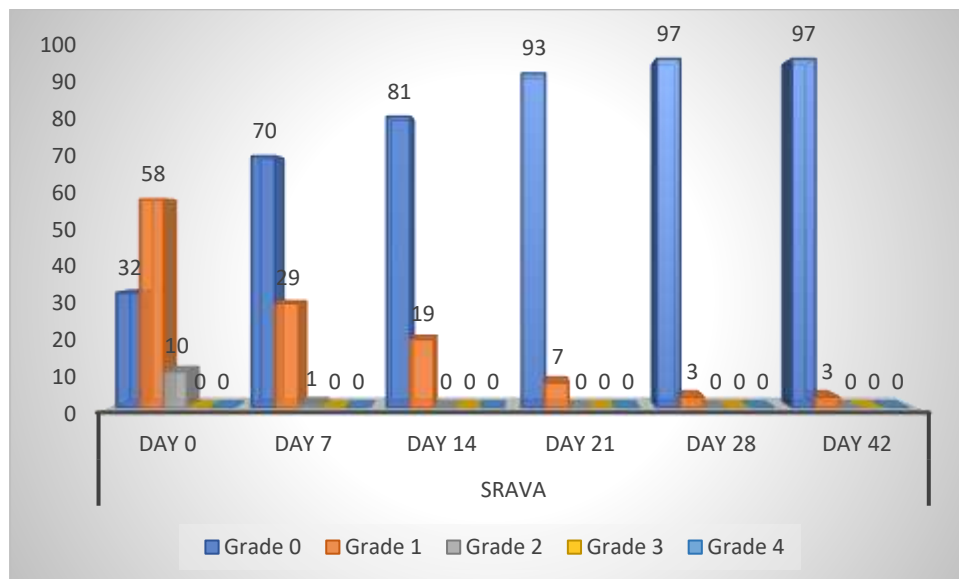
Observation and Results

1. Demographic Data

- Maximum patients belonged to the age group of 18-27 Years in our study
- In the study no specific occupation was predominant. However students(25%) were found to be maximum in number.
- It was seen that all the patients consumed *Madhur Rasatmak Dravyas* in the end of the meal inspite of the fact that, Ayurved promotes its consumption in the beginning. Thus leading to delay and alteration in *Samanya Pachan Kriya*.
- In this study two provoking factors ,which are *Ritu Viparit Bhojan* and untimely meals were seen
- *Paka Viruddha* type of Ahar was consumed by 90% of the patients.
- 55% of the patients consumed Snigdha and Guru Ahar
- 45% of the patients were found to suffer from Alpa Nidra whereas 25% had *Khandit Nidra*

2. Subjective Parameters

2.1 SRAVA



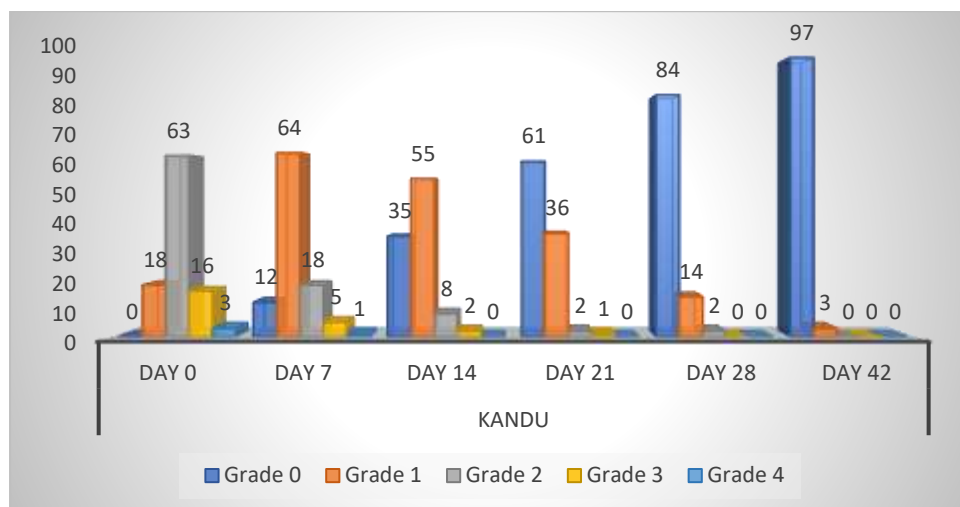
There were 0 patients who reported with grade 4 and grade 3 severity for the symptom of Srava. However it was found in 10 patients with grade 2 severity and 58 patients with grade one severity which reduced to 1 and 29 respectively by day 7. There were 19 patients left with grade 1 severity by day 14 which further reduced to 7 by day 21 and 3 by day 28.

The symptom of *Srava* showed Grade 0 Severity in 97 patients and Grade 01 Severity in 3 Patients, Which remained the same on day 42.

<i>Srava</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	0.78	1.00	0.61	-7.900 ^a	0.000	96.15	Sig

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Srava* is significant. Effect observed in *Srava* is about 96.15%.

2.2 KANDU



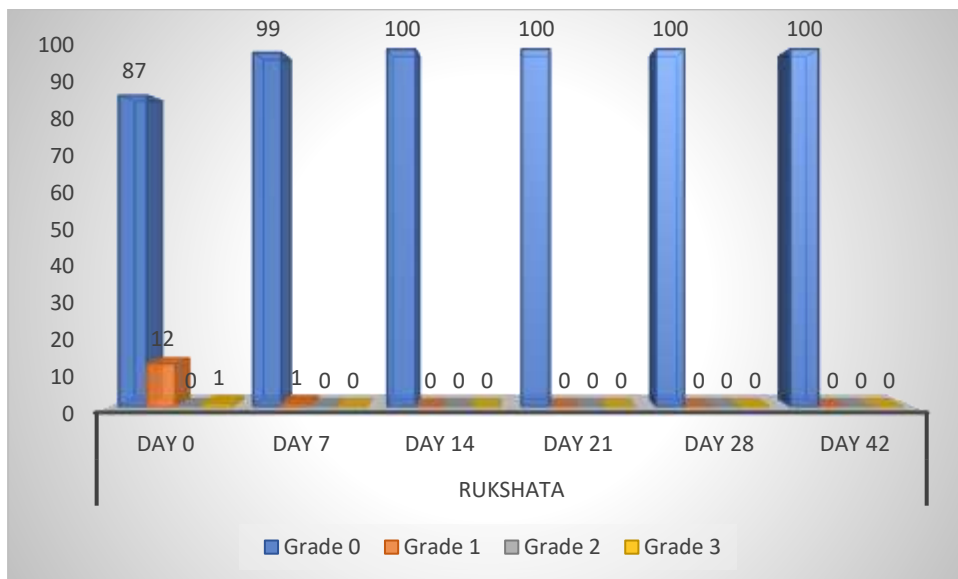
The symptom of *Kandu* was seen in 3 patients with grade 4 severity, 16 patients with grade 3 severity, 63 patients with grade 2 severity, 18 patients with grade 1 severity which reduced to 1 patient, 5 patients, 18 patients, 64 patients respectively by day 7. The severity further reduced to 2 patients with grade 3 severity, 8 patients with grade 2 severity and 55 patients with grade 1 severity by day 14.

By day 21, there was one patient with grade 3 severity, 2 patients with grade 2 severity and 36 patients with grade 1 severity which further reduced to 2 patients with grade 2 severity and 14 patients with patients with grade 1 severity by day 28.

<i>Kandu</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	2.04	2.00	0.68	-9.054 ^a	0.000	91.18	Sig
AT	0.18	0.00	0.44				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Kandu* is significant. Effect observed in *Kandu* is about 91.18%.

2.3 RUKSHATA

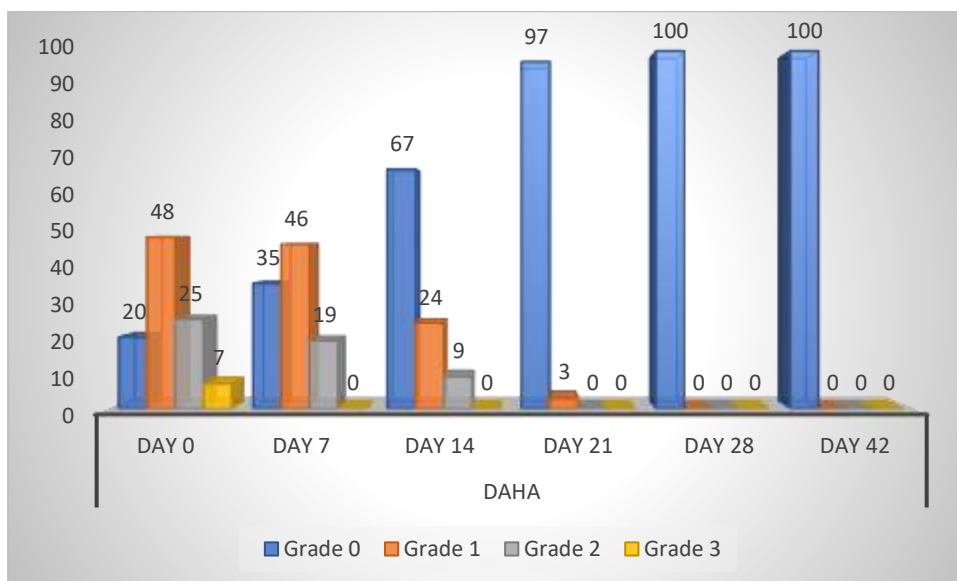


Rukshata was seen in 1 patient with grade 3 severity on day 0 which reduced to grade 0 by day 7. There were 0 patients with grade 2 severity. 12 patients with grade 1 severity reported on day 0 which reduced to 1 patient by day 7 and 0 patient by day 14.

<i>Rukshata</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	0.15	0.00	0.44	-3.500 ^a	0.000	100.00	Sig
AT	0.00	0.00	0.00				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Rukshata* is significant. Effect observed in *Rukshata* is about 100%.

2.4 DAHA

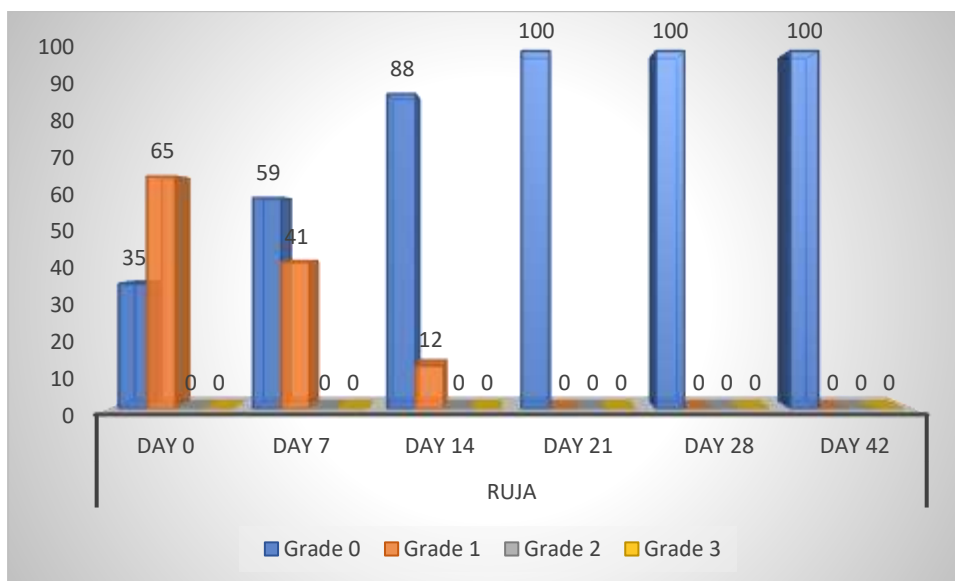


The symptom of *Daha* was seen in 7 patients with grade 3 severity, 25 patients with grade 2 severity and 48 patients with grade 1 severity on day 0 which reduced to 0 patients, 19 patients, 46 patients respectively by day 7. On day 14, there were 9 patients with grade 2 severity and 24 patients with grade 1 severity which reduced to 0 patient and 3 patients respectively by day 21. By day 28 there were 0 patients who reported the symptom.

<i>Daha</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	1.19	1.00	0.84	-8.017 ^a	0.000	100.00	Sig
AT	0.00	0.00	0.00				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Daha* is significant. Effect observed in *Daha* is about 100%.

2.5 RUJA

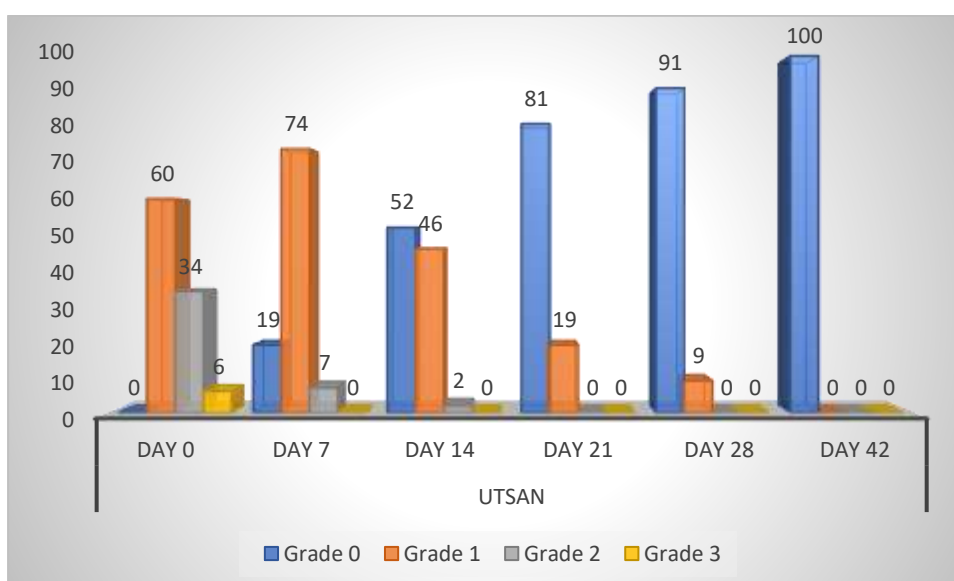


Ruja was present in 65 patients with grade 1 severity on day 0 which reduced to 41 patients by day 7 and 12 patients by day 14 respectively.

<i>Ruja</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	0.65	1.00	0.48	-8.062 ^a	0.000	100.00	Sig
AT	0.00	0.00	0.00				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Ruja* is significant. Effect observed in *Ruja* is about 100%.

2.6 UTSAN MANDAL

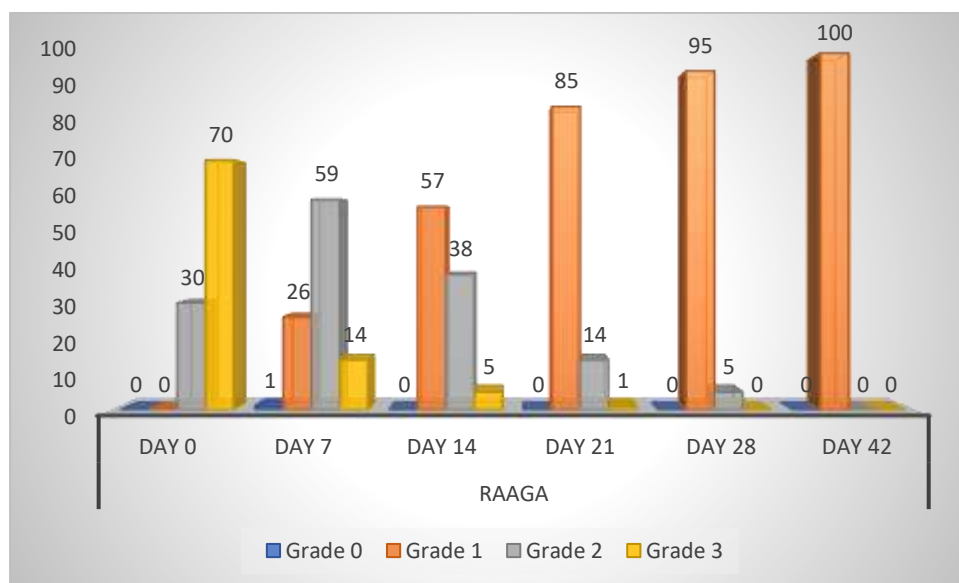


The symptom of *Utsan* mandal was seen in 6 patients with grade 3 severity, 34 patients with grade 2 severity and 60 patients with grade 1 severity on day 0 which reduced to 0 patient, 7 patients, 74 patients respectively by day 7. On day 14, there were 2 patients with grade 2 severity and 46 patients with grade 1 severity which reduced to 0 patient and 19 patients respectively by day 21. Only 9 patients remained with grade 1 severity by day 28.

<i>Utsan</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	1.46	1.00	0.61	-9.027 ^a	0.000	93.84	Sig
AT	0.09	0.00	0.29				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Utsan* is significant. Effect observed in *Utsan* is about 93.84%.

2.7 RAAGA

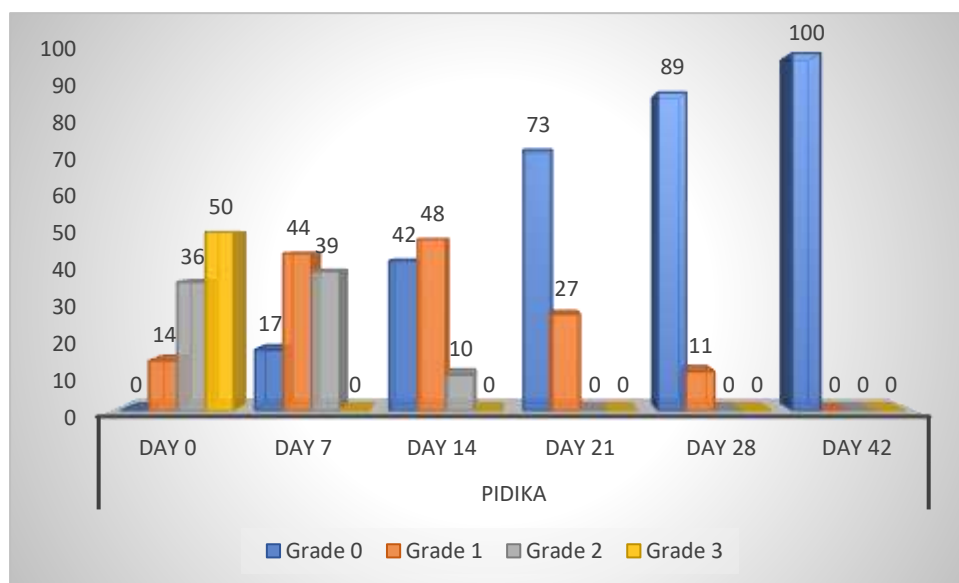


Raaga was reported by 70 patients with grade 3 severity and 30 with grade 2 severity on day 0 which reduced to 14 patients and 59 patients by day 7 and 5 patients and 38 patients respectively by day 14. There were 26 patients with grade 1 severity on day 7 which increased to 57, 85 and 95 by day 14, 21 and 28 respectively.

<i>Raaga</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	2.77	3.00	0.57	-9.042 ^a	0.000	62.09	Sig
AT	1.05	1.00	0.22				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Raaga* is significant. Effect observed in *Raaga* is about 62.09%.

2.8 PIDIKA

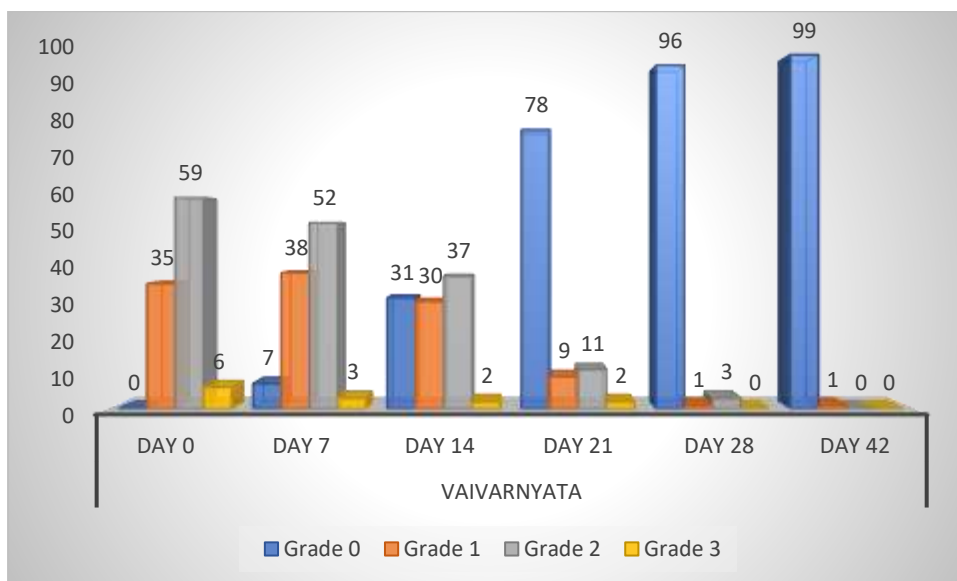


Grade 3 *Pidika* was seen in 50 patients, grade 2 in 36 patients and grade 1 in 14 patients on day 0 which reduced to 0 patient, 39 patients and 44 patients respectively by day 7. On day 14 there were 10 patients with grade 2 severity, 48 with grade 1 severity which further reduced to 0 patient and 27 patients respectively on day 21. On day 28, only 11 patients reported with *Pidika* of grade 1 severity.

<i>Pidika</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	2.36	2.50	0.72	-8.849 ^a	0.000	95.34	Sig
AT	0.11	0.00	0.31				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Pidika* is significant. Effect observed in *Pidika* is about 95.34%.

2.9 VAIVARNYATA



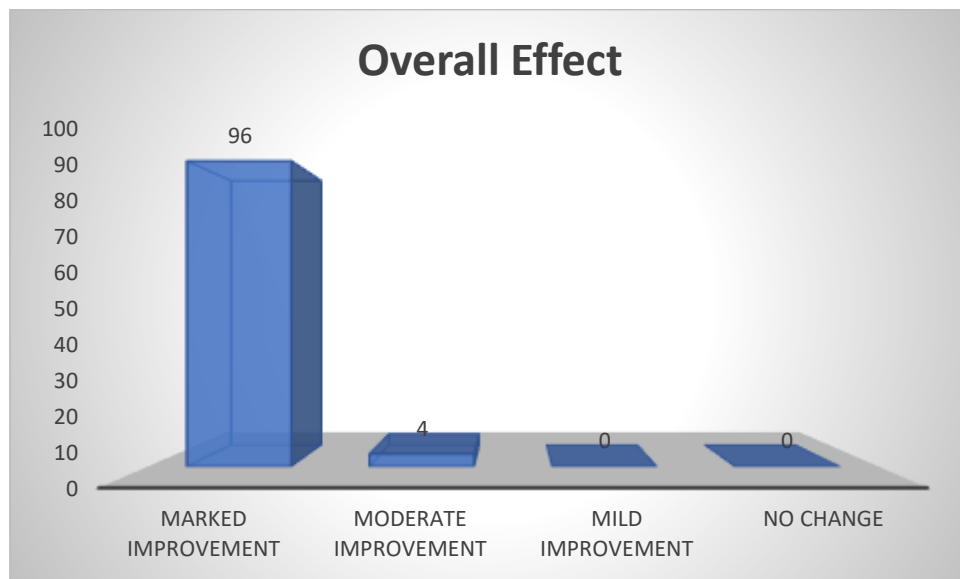
The symptom of *Vaivarnyata* was seen in 6 patients with grade3 severity,59 patients with grade 2 severity and 35 patients with grade 1 severity on day 0 which reduced to 3 patients ,52 patients and 38 patients respectively by day 7.On day 14,2 patients with grade 3 severity,37 with grade 2 severity and 30 patients with grade 1 severity reported .There was no change in no of patients with grade 3 severity on day 21 in comparison to day 14.However there was reduction in no of patients of grade 2 and grade 1 severity i.e 11patients and 9 patients were seen on day 21 which further reduced to 3 patients of grade 2 severity and 1 patient of grade 1 severity by day 28

<i>Vaivarnyata</i>	Mean	Median	SD	Wilcoxon W	P-Value	% Effect	Result
BT	1.71	2.00	0.57	-8.774 ^a	0.000	95.91	Sig
AT	0.07	0.00	0.36				

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table we can observe that, P-Value is less than 0.05. Hence we conclude that, effect observed in *Vaivarnyata* is significant. Effect observed in *Vaivarnyata* is about 95.91%.

Overall Effect

Overall Effect	Frequency	Percentage
Marked Improvement	96	96
Moderate Improvement	4	4
Mild Improvement	0	0
No Change	0	0
TOTAL	100	100



Hence the overall effect can be summarized as 96%patients showed marked improvement whereas 4%patients showed moderate improvement.

DISCUSSION

Fungal diseases are known to affect millions of lives worldwide. However, the epidemiology of fungal infections varies in different geographical regions. In India 57,251,328 (4.1%) people suffer from fungal diseases [13].

Neelitulasydi Kashayam [14,15] pacify the condition by its *Tikta Rasa*, *Vishaghna* and *Sroto-shodhana* properties. The contents of this Kashayam are having *Kaphavatahara* (reduce *Kapha* and *Vata*), *Vishagna* (anti-toxic), *Kushtagna* (pacifies skin diseases), *Vedanasthapana* (reduce pain and *Rakthaprasadana* (Purifies blood) properties. *Neelitulasyadi Kashayam* with local application of *Chakramarda* Gel shows significant effect in various subjective parameters which are as follows:

Srava [16]: The symptom of *Srava* in *Dadru* is due to vitiation of *Kapha Pitta* and *Kleda*. *Neelitulasyadi Kashayam* contain *Neelimoola* and *Ishani Moola* like *Dravya* which are *Laghu, Ruksa* in *Gunas* and help in reducing *Srava*. *Chakramarda* also helps in reducing *Srava* as it is *Laghu Ruksha* and *Kleda Shoshak* in properties.

Kandu [17]: *Kandu* is due to vitiation of *Kapha* and excessive *Kleda*. *Neelitulasyadi Kashayam* is *Tridosahara* especially *Kaphavatahara*, *Raktapradoshak* and *Kledahara*. *Chakramarda* is a potent *Dadru* mandal hara *Dravya* when it is applied externally. It is also *Kaphavatahara*, *Kleda Shoshak* *Dadruhara* and *Kandughna*.

Rukshata [18]: *Rukshata* is a secondary symptom in *Tinea corporis* sometime due to *Daha* and vitiated *Vata* it appears. Gel form of *Chakramarda* provides enough *Snigdghata* to the local lesion and as *Neelitulasyadi Kashayam* pacifies *Vata* along with *Kapha*. *Rukshata* is a *lakshan* of *Vata*.

Daha [19]: According to *Ayurved*, every *Kushtha* is *Tridoshak* in nature. *Daha* in *Tinea corporis* is due to vitiation of *Rakta* and *Pitta Dosha*. *Neelitulasyadi Kashayam* is *Tridosahara*. It

contains *Sariva, Yashtimadhu, Tagar* like *Pitta Shamak Dravyas* which are *Madhur, Tikta, Sheeta* in *Gunas* having this *Kashayam* acted as *Dahahara*

Ruja^[20]: It is presented as local tenderness in the lesion which is due to vitiation of *Rakta, Vata* and *Pitta*. *Neelitulasyadi Kashayam* being *Tridosahara* contain *Ashwagandha, Tagar, Nirgundi, Rason, Kushtha* which are potent, *Rujahara* by reducing *Vata, Yashtimadhu* and *Sariva* are potent *Raktaprasadak* help in reducing *Ruja* in *Tinea corporis*.

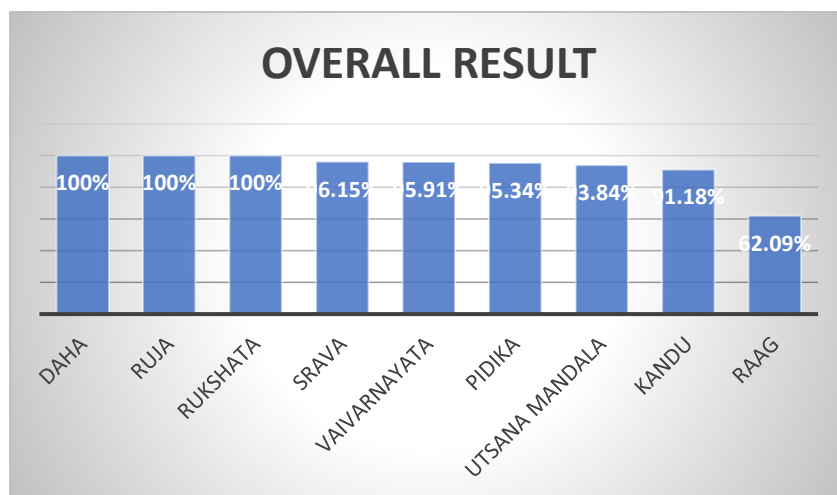
Utsan Mandal^[21]: *Utsan* means elevated lesions, this is due to *Kapha Vata* vitiation. As *Neelitulasyadi* is *Tridosahara* and *Kaphavata Shamak* and *Chakramarda* is *Dadrughna & Kaphavata Shamak*, hence it lead to reduction in the symptom of *Utsan Mandal*

Raag^[22]: *Raag* is redness due to vitiation of *Rakta* and *Pitta*, it's a sign of *Daha*. The herbs like *Sariva, Yashti, Eswarimoola* are *Pitta Shamak* and *Raktaprasadak* helps in reduction of *Raag*.

Pidika^[23]: *Pidika* in *Dadru* is due to *Kapha Vata Dosha*, *Chakramarda* is a potent *Dadrumandalahara Dravya* having *Kapha Vatahar* properties. *Neelitulasyadi Kashyam* is *Shophahara* and *Ropana* in nature, therefore is *Pidikahara*.

Vaivarnyata^[24]: *Vaivarnyata* is a *Lakshana* of *Raktadushti* and *Tridoshaprakopa*. *Neelitulasyadi Kashyam* is *Tridosahara*, contains *Yashti* and *Sariva* like *Dravyas* which are *Varnya*, Thus help in restoring the natural complexion of body.

The overall results can thus be summarised as follows-



Marked improvement was seen in 96% of the cases, whereas it was moderate in remaining 4%.

CONCLUSION

Neelitulasyadi Kashyam and *Chakramarda Gel* showed significant efficacy on *Dadrumandala* as *Neelitulasyadi Kashyam* is *Vishahara, Jantughna, Tridosahara, Raktaprasadak* and *Kushtahara* used in traditional practice in *Kerala* in *Lutavisha* in *Kerala*. After analysis of the

result we can say that this protocol i.e Neelitulasyadi Kashyam along with local application of Chakramarda Gel is quite effective in management of Dadru .

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