

SINGLE ARM, OPEN LABEL EFFICACY STUDY OF TOPICAL CHAKRAMARDA BIJA TAILA IN SUBJECTS WITH DADRU - TINEACORPORIS / CRURIS

¹Dr.Shrividya, ²Dr.G. Shrinivasa Acharya, ³Dr.Aniruddha Saralaya

¹3rd P.G Scholar, ²Professor, Guide and Principal, ³ Associate Professor

^{1,2,3}Department of Kayachikitsa And Manasaroga, Sri Dharmasthala Manjunatheshwara College Of Ayurveda and Hospital, Kuthpady, Udupi, Karnataka, India.

ABSTRACT

One of the most often dermatological conditions is Dadu kushta. In classical the skin ailments are listed under the heading of Kushta roga. Dadru kushta is corelated to the fungal infection of the skin. Most often seen in the clinical practice. In the present study the tinea corporis and tinea cruris patients were included in the study which constitutes upto 8-10% of prevalence rate. Dadru kusta is one of the variety of kusta which involves rasa,rakta, mamsadhatu and with presenting features of kandu,raga,mandala, udgata, Shakala and pidaka.Chakramarda possess katu tikta rasa ushna veerya , ruksha guna and kapha vata hara , vishagna ,krimighna and kushtahara karma. Further, In regards to the treatment the topical medication has edge over any internal medication in all dermatological conditions including Dadru.

Study included 30 patients from OPD and IPD of Sri Dharmasthala College of Ayurveda and Hospital kuthpady ,Udupi who were diagnosed based of the signs and symptoms of dadrukushta and positive for KOH test.

Key words: Chakramarda bija taila, Tinea corporis, Tinea cruris, Dadru, Potassium hydroxide test.

INTRODUCTION

Healthy skin is the result of overall health condition of the individuals. Being the protective organ, it is also the target organ for many of the infectious disorders. skin diseases are manifested due to the many of the etiological factors such as altered lifestyle, mental stress, unhygienic condition and exposure to chemical, pollution etc. In Ayurveda skin diseases are considered as the twak vikara and kushta roga. Eighteen maha kushtas and 11 kshudra kushtas based on the etiopathogenesis it is subdivided into major and minor forms.¹

Skin and the manas is considered as the reflection of each other. Among which dadru is one of the commonest twak vikara which can affect individual of any age. This contagious minor form is characterised by circular, elevated, erythematous with profound itching². Also, an aupasargika vyadhi³ the one which spread. Tinea analogues to Dadru in contemporary science. This illness exhibits a prompt response if treated carefully, if not it may enter deeper tissues and attain chronic course extending into larger area of the body. Incidence of dadru is increasing due to contagious nature of the dadru by sharing cloths, unclean habits, high moist environmental temperature and overweight and obesity, increased rate of perspiration a major cause in the general population. Further Chakramarda seeds are specially used in treating Kandu and Dadru⁴ more to this chakramarda is claimed to be kushtagna, krimighna and vishagna and alleviates the excessive kapha dosha. Hence the oil prepared out of chakramarda seeds was taken for the study.

Objectives of the study

- To assess the efficacy of topical application of chakramarda bija taila for the treatment of Dadru/ Tinea corporis/cruris.
- To assess treatment satisfaction as rated by patient.

Source of data

30 patients fulfilling diagnostic criteria of Dadru - tinea corporis / cruris were taken for study from OPD and IPD of Sri Dharmasthala Manjunatheshwara Ayurveda Hospital, Kuthpady, Udupi. The selection of patient was irrespective of their gender and caste.

Method of collection of data

A special proforma was prepared with all points of history taking, physical signs, symptoms and laboratory investigations as mentioned in Ayurveda as well as conventional medicine if any.

Diagnostics Criteria

- Clinical diagnosis of dadru based on the symptoms of erythematous circumscribed circular elevated lesions with eruptions and itching on body parts or groin
- Clinical evidence of tinea corporis / cruris infection on the basis of moderate erythema moderate induration, mild scaling and itching
- KOH positive skin scrapings obtained from most seriously affected lesion

Inclusion criteria

- Diagnosed cases of dadru / tinea corporis, cruris as per the diagnostic criteria
- Lesions at multiple sites covering a total of at least 1% body surface area.
- No previous treatment with antimycotic medication for the current dermatologic lesion.
- Subject of either gender
- Non-pregnant females
- Age of subjects > 16 years and < 70 years (16 to 70 years, inclusive)
- Subjects having ability and willingness to sign a written informed consent
- Subjects having adequate ability of communication, willingness and ability to comply with study requirements

Exclusion criteria

- Tinea infection of the face, scalp, and/or feet
- Uncontrolled diabetes mellitus
- Current diagnosis of immune compromising conditions (due to disease, e.g., HIV or medications, cancer)
- Pregnant or lactating women
- Subjects with evidence of contact dermatitis in the area to be treated
- Subjects who are unable to properly communicate or cooperate during the study

Outcome measures

Primary Outcome Measures

Clinical cure at Days 15 and 30 [Time Frame: Days 15 and 30] (Clinical cure is defined as total absence of erythema / erythema score 0; absence of induration / induration score 0; absence of desquamation / scaling score is 0; absence of itching / itching score 0.)

Mycological cure at days 15 and 30 defined by negative KOH result

[Time Frame: Days 15 and 30] (Mycological cure is defined as negative result for the direct mycological examination (potassium hydroxide [KOH] test).

Secondary Outcome Measures:

Change in the symptom score of raga / erythema from the base line

[Time Frame: Days 15 and 30] (erythema evaluation by four-point categorical scale - 0=absent, 1=mild, 2=moderate, 3=severe)

Change in the symptom score of kandu / itching, stinging, burning from the base line [Time Frame: Days 15 and 30] (itching evaluation by four-point categorical scale - 0=absent, 1=mild, 2=moderate, 3=severe)

Change in the symptom score of pidaka / blistering, papules, pustules from the base line [Time Frame: Days 15 and 30] (eruption evaluation by four-point categorical scale - 0=absent, 1=mild, 2=moderate, 3=severe)

Change in the symptom score of udgata / induration from the base line [Time Frame: Days 15 and 30] (induration evaluation by four-point categorical scale - 0=absent, 1=mild, 2=moderate, 3=severe)

Change in the symptom score of shakala / desquamation from the base line

[Time Frame: Days 15 and 30] (desquamation evaluation by four-point categorical scale - 0=absent, 1=mild, 2=moderate, 3=severe)

Mean subject satisfaction score on completion of the treatment [Time Frame: Days 15 and 30] (subject satisfaction score was obtained by using 10-point visual analogue scale. the score ranges from 0 to 10 where 0 means no satisfaction, 10 means complete satisfaction. higher values represent better subject satisfaction)

Assesment Criteria

Assessment was done before intervention, on 15th day on 30th day followup was done based on the gradings mentioned above for each signs and symptoms.

Method of Clinical Study

Patients fulfilling the diagnostic criteria, inclusion exclusion criteria were included in the study. The selected patients were undertaken with potassium hydroxide test. The subjects with the positives for this the detailed history was filled in the proforma and were given with the application of chakramarda taila twice a day morning and evening after cleaning the surface area of dadru and kept untouched. the assessment was repeated on day 15 and day 30 and followup was done.

Method of preparation of taila

Chakramarda seeds are collected and later its it dried under the shades, its put in a gaana (oil milling) and the oil is extracted directly⁵. This oil is stored in a clean container and packed in a bottle of 30 ml each.

Matra : Sufficient for external application.

RESULTS

In the present study 30 patients of Dadru kushta were registered and treated successfully with external application of Chakramarda bija tala for one month. The effect of treatment was assed clinically with regards to primary and secondary outcome measures.

EFFECT OF CHAKRAMARDA TAILA ON PRIMARY OUTCOME MEASURES**EFFECT ON CLINICAL CURE:**

Effect of external application of Chakramarda taila was assessed by remission of symptoms such as Erythema / Raga , Induration / Udgatha, Desquamation / scaling /Shakala,Itching / Kandu.AT the base line the mean score was 9.800(0.334), on 15th day it was 5.533(0.342) and after intervention reduced to 1.500(0.295).Significant improvement on statistical analysis i.e.; test of significance is P value <0.001 and Z value -4.823. In detail represented below in table and charts.

Table 1: Effect on Clinical cure

Outcome	MEAN			Comparison between BT and AT(30)			
	BT (±SE)	AT15 (±SE)	AT30 (±SE)	BT-AT	%	Z	P
(0-3)	9.800 (0.334)	5.533 (0.342)	1.500 (0.295)	8.3	84.69	-4.823	<0.001

Effect on mycological cure

Potassium Hydroxide Test (KOH) test, was used to confirm the presence of tinea.AT the base line the mean score was 1.000(0.000) ,on 15th day it was 0.200(0.0743) and after intervention reduced to 0.0667(0.0463).Significant improvement on statistical analysis i.e.; test of significance is P value <0.001 and Z value-5.292.In detail represented below in table and charts.

Table 2: Effect on Mycological cure

Outcome	MEAN			Comparison between BT and AT(30)			
	BT (±SE)	AT15 (±SE)	AT30 (±SE)	BT-AT	%	Z	P
Present/ Absent	1.000 (0.000)	0.200 (0.0743)	0.0667 (0.0463)	0.9333	93.33	-5.292	<0.001

EFFECT OF CHAKRAMARDA TAILA ON SECONDARY OUTCOME MEASURES**Effect on Raga:**

Effect of external application of Chakramarda taila was assessed using the four point categorical scale.AT the base line the mean score was2.767(0.0785), on 15th day it was1.733(0.0821) and after intervention reduced to 0.500(0.0928) .Significant improvement on statistical analysis ie; test of significance is P value <0.001 and Z value-4.977. Details given below in table and charts.

Table 3: Effect on Raga

Outcome	MEAN			Comparison between BT and AT(30)			
	BT (±SE)	AT15 (±SE)	AT30 (±SE)	BT-AT	%	Z	P
Raga (0-3)	2.767 (0.0785)	1.733 (0.0821)	0.500 (0.0928)	2.267	81.92	-4.977	<0.001

Effect on Kandu:

Effect of external application of Chakramarda taila was assessed using the four-point categorical scale.AT the base line the mean score was 2.867(0.0631), on 15th day it was 1.8393(0.0692) and after intervention reduced to 0.443(0.0920). Significant improvement on statistical analysis ie; test significance is P value <0.001 and Z value -4.939. Table and charts below represent in detail.

Table 4: Effect on Kandu

Outcome	MEAN			Comparison between BT and AT(30)			
	BT (±SE)	AT15 (±SE)	AT30 (±SE)	BT-AT	%	Z	P
Kandu (0-3)	2.867 (0.0631)	1.8393 (0.0692)	0.433 (0.0920)	2.434	84.89	-4.939	<0.001

Effect on Pidaka:

Effect of external application of Chakramarda taila was assessed using the four-point categorical scale. AT the base line the mean score was 2.433 (0.104), on 15th day it was 1.467 (0.115) and after intervention reduced to 0.367 (0.0895). Significant improvement on statistical analysis i.e.; test of significance is P value <0.001 and Z value -5.027. In detail represented below in table and charts.

Table 5: Effect on Pidaka

Outcome	MEAN			Comparison between BT and AT(30)			
	BT (±SE)	AT15 (±SE)	AT30 (±SE)	BT-AT	%	Z	P
Pidaka (0-3)	2.433 (0.104)	1.467 (0.115)	0.367 (0.0895)	2.066	84.91	-5.027	<0.001

Effect on Udgatha

Effect of external application of Chakramarda taila was assessed using the four-point categorical scale. AT the base line the mean score was 2.267 (0.126), on 15th day it was 1.167 (0.128) and after intervention reduced to 0.300 (0.0851). Significant improvement on statistical analysis i.e.; test of significance is P value <0.001 and Z value -4.994. Table and charts below represent in detail.

Table 6: Effect on Udgatha

Outcome	MEAN			Comparison between BT and AT(30)			
	BT (±SE)	AT15 (±SE)	AT30 (±SE)	BT-AT	%	Z	P
Udgatha (0-3)	2.267 (0.126)	1.167 (0.128)	0.300 (0.0851)	1.967	86.76	-4.994	<0.001

Effect on Shakala

Effect of external application of Chakramarda taila was assessed using the four-point categorical scale. AT the base line the mean score was 1.933 (0.1430), on 15th day it was 0.833 (0.136) and after intervention reduced to 0.200 (0.0743). Significant improvement on statistical analysis i.e.; test of significance is P value <0.001 and Z value -4.869. In detail represented below in table and charts.

Table 7: Effect on Shakala

Outcome	MEAN			Comparison between BT and AT (30)			
	BT(±SE)	AT15(±SE)	AT30(±SE)	BT-AT	%	Z	P
Shakala (0-3)	1.933 (0.1430)	0.833 (0.136)	0.200 (0.0743)	1.733	89.65	-4.869	<0.001

Effect on Visual Analog Scale

Mean subject satisfaction on completion of the treatment of external application of Chakramarda taila was assessed using Visual Analog Scale. AT the base line the mean score was 7.600(0.334), on 15th day it was 4.000(0.220) and after intervention reduced to 0.867(0.157). Significant improvement on statistical analysis i.e; test of significance is P value <0.001 and Z value -4.813. Table and charts below represent in detail.

Table 8: Effect on VAS

Outcome	MEAN			Comparison between BT and AT(30)			
	BT(±SE)	AT15(±SE)	AT30(±SE)	BT-AT	%	Z	P
VAS (0-3)	7.600 (0.334)	4.000 (0.220)	0.867 (0.157)	6.733	88.59	-4.813	<0.001

Effect of treatment on cure rate

Among 30 patients enrolled 30% of the patients got complete cure, 50% of the patients found to be as best remission and 20% of the patient found moderate remission from the disease dadru.

Table 9: Effect of treatment on cure rate

Sl no	Cure rate	No of patients	% of patients
1	Complete cure :100%	9	30
2	Best remission: 75-99%	15	50
3	Moderate remission: 50-74 %	6	20
4	Average remission:25 – 49 %	0	0
5	Minimal remission:1 -24 %	0	0
6	No remission or worsening	0	0

Effect of treatment in relation to duration of medication

After 15 days of course of treatment there was 1 patient observed best remission, 21 patients observed average and 8 patients observed moderate remission and there was no any complete, minimal or cure seen. After the treatment of 30 days 9 patients got complete cure from the signs and symptoms of dadru kushta. 15 patients found best relief and 6 patients observed the moderate remission and there were no any patients left with the signs and symptoms of Dadrukushta.

Table 10: Effect of treatment in relation to duration of medication

Duration	Remission					
	Complete	Best	Moderate	Average	Minimal	No
15 days	0	1	8	21	0	0
30 days	9	15	6	0	0	0

DISCUSSION

Chakramarda bija taila as Bahirparimarjana chikitsa on Dadru kushta. Beeja of chakramarda possess kaphavatahara properties, and as mentioned kandughna, Dhadrughna, kushtagna, krimighna, vishaghna. The rasa panchakas aids in the karma of the drug.

Effect on clinical cure

Among all the 30 patients the result showed the statistical significance with the p value less than 0.001. Effect of external application of Chakramarda taila was assessed by remission of symptoms such as Erythema / Raga, Induration / Udghata, Desquamation / scaling / Shakala, Itching / Kandu. AT the base

line the mean score was 9.800(0.334), on 15th day it was 5.533(0.342) and after intervention reduced to 1.500(0.295). Significant improvement on statistical analysis i.e.; test of significance is P value <0.001 and Z value -4.823.

Effect on mycological cure

Potassium Hydroxide Test (KOH) test, was used to confirm the presence of tinea. AT the base line the mean score was 1.000(0.000), on 15th day it was 0.200(0.0743) and after intervention reduced to 0.0667(0.0463). Significant improvement on statistical analysis i.e.; test of significance is P value <0.001 and Z value -5.292.

Effect on therapy on individual signs and symptoms

Effect of external application of Chakramarda taila was assessed using the four-point categorical scale on all the symptoms.

Kandu

AT the base line the mean score was 2.867(0.0631), on 15th day it was 1.8393(0.0692) and after intervention reduced to 0.443(0.0920). The disease dadru is caused by the vitiation of kapha dosha and is seen in all the registered patients. Most of the cases registered were complaining of grade III kandu. Dadru is mainly of kapha and *pitta* predominant over the superficial skin. It is the local allergic skin reaction caused by the Mycelia. Chakramarda being a potent drug with katu rasa ushna veerya has acted as the krimighna and kandughna and has kaphahara property.

Udgatha:

At the base line the mean score was 2.267(0.126), on 15th day it was 1.167(0.128) and after intervention reduced to 0.300(0.0851). It is due to kapha and pitta dosha which leads to vikruta akara of the twak. Chakramarda taila helps in tacking the pitta and kapha dosha. Thus, the significant result is found.

Raga:

At the base line the mean score was 2.767(0.0785), on 15th day it was 1.733(0.0821) and after intervention reduced to 0.500(0.0928). Significant improvement on statistical analysis is found. The chakramarda drug even has the pitta shamana property and which even reduce the kandu hence there is no local irritation there may be reduction in the vaivarnya and raga.

Pidaka:

Effect of external application of Chakramarda taila was assessed using the four-point categorical scale. AT the base line the mean score was 2.433 (0.104), on 15th day it was 1.467(0.115) and after intervention reduced to 0.367(0.0895). Pidaka are caused due to morbid Kapha and pitta dosha afflicting the mamsa dhatu. Chakramarda has pitta kaphahara property hence thereby reducing the inflammation/pidaka.

Shakala:

At the base line the mean score was 1.933(0.1430), on 15th day it was 0.833(0.136) and after intervention reduced to 0.200(0.0743). Chakramarda is been used in the form of taila which mitigates the rukshatha of the surrounding area of dadru, thus the statistical result is acquired.

Effect on Visual Analog Scale:

Mean subject satisfaction on completion of the treatment of external application of Chakramarda taila was assessed using Visual Analog Scale. AT the base line the mean score was 7.600(0.334), on 15th day it was 4.000(0.220) and after intervention reduced to 0.867(0.157) Significant improvement on statistical analysis i.e.; test of significance is P value <0.001 and Z value -4.813.

Overall effect of therapy:

Complete remission and marked improvement: Among 30 patients enrolled 30% of the patients ie, 9 patients got complete cure.

Best improvement: 50% of the patients found to be as best remission i.e., 15 patients out of 30 patients got best improvement.

Moderate improvement:6 patients out of 30 i.e., 20%of the patient found moderate remission from the disease dadru.

Effect of treatment in relation to duration of medication:

After 15 days of course of treatment there was 1 patient observed best remission,21 patients observed average and 8 patients observed moderate remission and there were no any complete, minimal or cure seen. After the completion of the course of the treatment of 30 days 9 patients got complete cure from the signs and symptoms of dadru kushta.15 patients found best relief and 6 patients observed the moderate remission and there were no any patients left with the signs and symptoms of Dadrukushta.

CONCLUSION

Following conclusions are drawn from the study.

- Dadru kushta belonging to the category of kshudra kushta and the clinical features matches with the clinical features of Tinea infection.
- Chakramarda taila proved very effective in reducing the severity of symptoms like kandu,pidaka,udgatha,shakala and raga and also is confirmed by the tests of statistical significance.
- Overall effect was recorded as 30%.50% and 20% as complete cure, best improvement and moderate improvement.
- The single drug therapy in the form of taila used in the form of oil for external treatment showed a highly significant result.
- The medication is effective and equally safe, with no any untoward symptoms.
- Further study with prolonged duration can be done for the Chronic cases with Shodhana therapy.

REFERENCES

1. Agnivesha. Charaka Samhita.Yadavji Trikamji Acharya editor. Varanasi:Choukamba Publications; 2017.Pp.738.p. 451.
2. Agnivesha. Charaka Samhita. Yadavji Trikamji Acharya editor. Varanasi: Chaukhambha Prakashan; 2017. p.451.
3. Agnivesha.Charakasamhitha. Yadvji trikamji acharya, Nidanasthana5th chapter 7th edition2005; Chaukambha surabharathi prakashan Varanasi: pp738; p217.
4. Priyavath sharma, priyanigantu,2nd edition;Chaukambha Surabharati Prakashan;1995;p106;pp275.
5. Kaaledaa krishnagopala .Rasatantra sara / siddha yoga sangrah.a Part 1;19th edition; Rajasthan:Krishnagopala Ayurveda Bhavan; 2010. Pp442. p419.