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#### A Randomized controlled clinical study to evaluate the efficacy of the *Mulakadi malahara* in the treatment of *Dadru* in Children.

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#### Abstract:

Skin diseases are common manifestation seen in younger age group & contributes to 1/3<sup>rd</sup> of pediatric ailments. In *Ayurveda, Kushta* is broadly classified into Mahakushta & Kshudra kushta Dadru is a variety of kshudra kushta with pitta-kapha predominance. The clinical features of Dadru are kandu, raga, pidakas, daha, Rukshata & Udgata mandala etc these features are very similar to that of tinea infection. It is an infection caused by highly contagious keratophilic fungi which consist of multicellular filaments which multiply by spore formation. The *Mulakadi lepa* mentioned in "*Bhaishajya Ratnavali"* is modified to malahara for the easy mode of application in pediatric age group was compaired with Gandhaka malahara a proprietary medicine which is widely used practically for treating Dadru in the study. **Objective** 11 To evaluate the efficacy of Mulakadi malahara in Dadru kushta. 21 To compare the efficacy of Gandhaka malahara & Mulakadi malahara in the management of Dadru kushta. **Methodology:** A Randomised controlled clinical trial was carried out in 60 diagnosed cases of Dadru kushta aged 10-15yrs. They were randomly allocated into 2 groups, Group A & Group B with 30 subjects each. In Group A, the trial drug *Mulakadi malahara* & in Group B control drug *Gandhaka malahara* was given for local application twice daily for 21 days. The assessment was done on 14<sup>th</sup> & 21st day of the treatment & follow up on 28th days **Results & Conclusion:** Hence, by this study it can be concluded that both *Mulakadi malahara* & Gandhaka malahara are effective in treating Dadru kushta.

Key words: Dadru, tinea, Mulakadi malahara & Gandhaka Malahara.

#### **Introduction:**

Skin diseases accounts for nearly 1/3<sup>rd</sup> of ailments in the pediatric population the pre-requisite for dermatological diagnosis is in identification of primary & secondary lesion as well as the various pattern they form<sup>1</sup>. Approximately 30 % of pediatric OPD attendance is accounted by dermatological dis-order as such or as associated with other illness among them 20 % is constituted by fungal infection<sup>2</sup>. Fungal infection are very commonly prevalent in tropical & subtropical countries, approximately 5 out of 100 are suffering from tinea infection <sup>3</sup>

All the skin disease in ayurveda has been classified under the broad heading of Kushta which are further classified into Mahakushta & kshudra kushta. Dadru is one among the kshudra kushta which is of pitta — kaphaja in nature characterised by Raga, Kandu, pidaka, Udgata mandala & Rukshata etc 4. All the clinical features of Dadru can be very well correlated to clinical features of "tinea" through modern perspective. Tinea is a superficial fungal infection of the skin caused by a distinct class of fungi.

In contempory medical science management is carried out with usage of topical or systemic antifungal, corticosteroids 5etc. But there is a palliative treatment explained ayurveda for external application, one such external application is *Mulakadi* lepa explained in the text "Bhaishajya Ratnavali 6" which is not widely practiced is taken for the study, for the easy mode of application & for the convenience of patient Mulakadi lepa is modified to Mulakadi Malahara.

In this study, *Mulakadi Malahara* will be taken for 1<sup>st</sup> group which will be compared against a widely used clinical formulation *Gandhaka Malahara* taken as control in the 2<sup>nd</sup> group for local application.

# MATERIALS AND METHODS FOR THE STUDY:

#### Source of Data:

- A] Literary source: Textbooks of Ayurvedic and Modern medicine, journals, articles and information from reliable internet sources, about the disease and the drugs were reviewed.
- **B] Sample Source**: For the present study patients was selected from
- The OPD & IPD of Alva's Ayurveda Medical College &Hospital.
- Special camps.

• Other referral.

#### C] Drug Source:

All the raw drugs was properly identified purchased from the local market & the preparation of the *Mulakadi Malahara & Gandhaka Malahara* was done in the *Rasashastra* & *Bhaishajya Kalpana* lab of Alva's Ayurveda Medical College & Hospital.

#### D] METHOD OF PREPARATION:

#### 1] Mulakadi Malahara

Table No :1 Mulakadi Malahara ingredients & Quantity

	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
In <mark>gredients</mark>	Quantity
Mulaka beeja	100 gm
Sarshapa	100 gm
<u>Laksha</u>	100gm
Haridra Haridra	100 gm
Chakramarda beeja	100 gm
Shunti	100 gm
<i>Trikatu</i>	100 gm
Vidanga	100 gm
Kushta	100 gm
Gomutra	100 ml
Tila taila	1 lt
Siktha	200 gm

#### **Method of Preparation:**

All the ingredients from Mulaka beeja to Kushta has to be made into a fine powder and filtered through a clean &

- dry cloth to separate the coarse particles and 100gms each of filtered ingredients is taken.
- 1 It of *Tila taila* is taken in a dry and clean vessel and heated over low flame.
  - 200 gm of *Siktha* is slowly added to the vessel containing the *Tila taila* and stirred carefully until it dissolves completely.
- After complete dissolution process of Siktha taila, it is filtered through a clean cloth to separate insoluble particles possibly present in Siktha taila.
- The Siktha taila is then poured unto mortor and the fine powder of the above said ingredients are added little by little.
- ❖ The contents were continuously stirred till it attains a homogenous mixture.
- When it is properly cooled 50 gm of mixture shifted to sterile containers & stored.
- The Quantity of *Malahara* obtained is 2054gms.

#### 2] **Gandhaka Malahara**:

Table No 2: Gandhaka Malahara ingredients & Quantity

Ingredients	Quantity
Sudha Gandhaka	300 gms

Siktha	300 gms
Tila Taila	1500 lt

#### **Method of Preparation:**

- ❖ 1.5 It of *Tila taila* is taken in a dry & clean vessel & heated over low flame.
- 300 gm of Siktha taila is slowly added to the vessel containing the tila taila & stirred carefully until it dissolves completely.

After complete dissolution of *Siktha taila*, it is filtered through a clean cloth to separate insoluble particles possibly present in *Siktha taila*.

- ❖ The Siktha taila is then poured unto mortor and the fine powder of the Sudha Gandhaka is added little by little.
- The contents were continuously stirred till it attains a homogenous mixture.
- When it is properly cooled 50 gm of mixture shifted to sterile containers & stored.
- The Quantity of Gandhaka Malahara is 2056 gms.

#### E] 1]Study Design:

A Randomized Controlled Clinical Study

#### 2] Method of Sampling:

**Lottery Method** 

## F] METHOD OF COLLECTION OF DATA:

Minimum of 60 subjects randomly was selected for the study irrespective of sex, Socio-economic status & Religion, divided into 2 equal groups that is Group A & Group B with 30 subjects in each.

#### Diagnostic criteria:

Diagnosis was done on the basis of following *Lakshana* of *Dadru Kushta* 

- Udgata Mandala [ annular lesion ]
- Kandu [ Itching ]
- Raga [ Erythema ]
- Pidaka [ Eruption ]
- Daha [ Burning sensation ]
- Rukshata [ Dryness ]

#### **Inclusion criteria:**

- Subjects who are fulfilling the Diagnostic criteria.
- Subjects irrespective of gender,
   religion & Socio economic status
   having age group of 10 -15yrs will be
   randomly included for the study.

#### **Exclusion criteria:**

- Subject who have lesions with secondary infection.
- Subjects with any other systemic disorders.

#### **G] INTERVENTIONS**

Table No: 3

Group	Medicine	Mode of Usage	Dose	Time	Duration
Group A [ Trial Group ]	Mulakadi Malahara	External Application	QS	BD	21 days
Group B [ Control Group]	Gandhaka Malahara	External Application	QS	BD	21 days

#### **H] PERIOD OF OBSERVATION:**

- Both the group clinical findings were recorded in the case sheet Proforma BT on 14<sup>th</sup> & 21<sup>st</sup> day of treatment to assess the progress.
- Post –Treatment follow up was done 7 days later [on 28<sup>th</sup> day].
- Total Duration of study: 28 days.

#### I] ASSESSMENT CRITERIA:

Assessment was based on the following parameter

#### **Subjective Parameter:**

- Kandu,
- Daha.

#### **Objective Parameter:**

- Udgata Mandala.
- Rukshata.
- Raga.
- Pidaka.

#### **Investigation:**

Investigations was done if necessary so as to rule out any other systemic diseases / disorder accordingly.

#### **Gradation of Clinical Features:**

Table No: 4 Showing Gradation of Clinical Features

Lakshana	0	1	2	3
Kandu	No itching	Mild itching	Moderate	Severe
			Itching	Itching
Raga	Normal skin colour	Mild Redness [pinkish]	Moderate Red	Deep Brown
Pidaka	No eruption	Eruption in 0- 25% of affected area	Eruption in 25-50% of affected area	Eruption in 50-75% of affected area
Daha	No Burning sensation	Mild burning sensation	Moderate burning sensation	Severe burning sensation

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Rookshata	No dryness	Loss in skin's normal unctuousness	Moderate dryness	Excessive dryness
Udgata mandala	No elevation of the skin	Mild elevation of the skin	Moderate elevation of the skin	Sever elevation of the skin

#### J] Statistical analysis:

The obtained data was analysed statistically with paired't' test & unpaired't 'test to test the hypothesis of the study.

- P < 0.05 was considered as statistically significant.
- P value < 0.01 & < 0.001 was considered as highly significant.

The level of significance was noted & interpreted accordingly.

# K] Discussion & Interpretation of findings:

The results & findings from statistical analysis were subjected to scientific discussion.

#### Overall assessment:

The overall assessment was made based on the following criteria

**Table No 5: Overall assessment** 

Improvement	Percentage
Complete	100%
Marked	50-75%
Moderate	25-50%
Mild	0-25%
No improvement	0%

#### **RESULTS AND DISCUSSION:**

Table No: 6 Comparative Effect of Both treatment in Sign & Symptoms on 28<sup>th</sup> day.

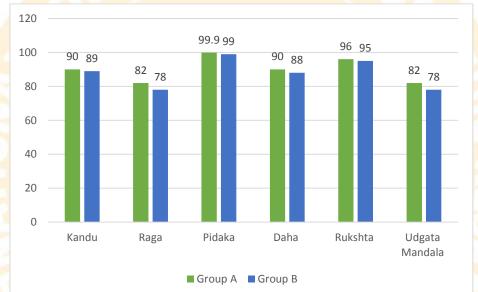
Signs &	Mean difference		Percentage Relief				
Symptoms			%		t-value	p-value	Interpretati
	Group A	Group B	Group A	Group B			on
Kandu	2.1	2.0	90	89	0.812	0.420	NS
Raga	1.8	1.6	82	78	0.288	0.774	NS

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Pidaka	1.2	0.8	99.9	99	0.416	0.679	NS
Daha	1.5	1.2	90	88	0.408	0.684	NS
Rukshata	1.6	1.5	96	95	1.416	0.157	NS
Udgata Mandala	1.5	1.4	82	78	0.167	0.868	NS

The difference in the mean values of the two groups is not great enough to reject the possibility that the difference is due to random sampling variability. There is not a statistically significant difference between the input groups at the level of P > 0.05.

Graph No: 1



#### Assessment of results after treatment.

The selected 60 patients were divided into 2 groups randomly. Each group was given treatment for 21 days and follow up on 28th day of completion of the treatment. Both the groups were assessed before treatment [0th day], During treatment [14th day], After treatment [ 21st day] & After follow up day [ 28th day] .The subjective &

objective parameters were graded for statistical evaluation.

**Kandu**: The test showed highly significant changes in this symptoms after treatment with p-value < 0.001 in both the group.

**Raga:** The analysis of change in Raga showed highly significant after the treatment with p<0.001 in both the group.

Pidaka: The analysis of change in Pidaka showed highly significant after

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the treatment with p<0.001 in both the group.

**Daha**: The comparison of *Daha* showed that, there is highly significant after the treatment with p<0.001 in both the group.

**Rukshata**: The evaluation of change in *Rukshata* showed highly significant

change with p<0.001 in both the group.

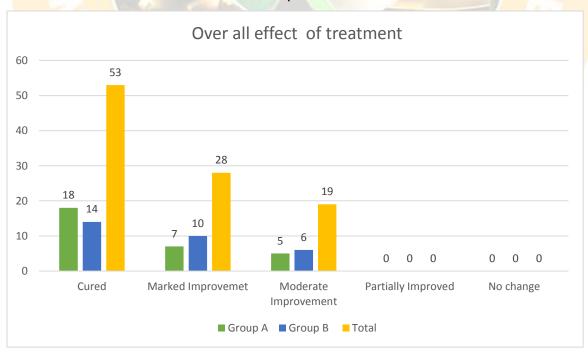
**Udgata Mandala**: The study showed that ,there is statistically highly significant change with p<0.001 in both the group.

#### **OVER ALL EFFECT OF TREATMENT:**

Table No :7 Overall Effect of the Treatment

Effect of Therapy	Group A	Group B	Total	%
Cured 100 % Relief	18	14	32	53
Markedly Improved >75% Relief	7	10	17	28
Moderately Improved 50-75 % Relief	5	6	11	19
Partially Improved 25-50 % Relief	0	0	0	0
No Change < 25 % Relief	0	0	0	0

Graph No: 2



**Discussion on Overall effect of Therapies:** 

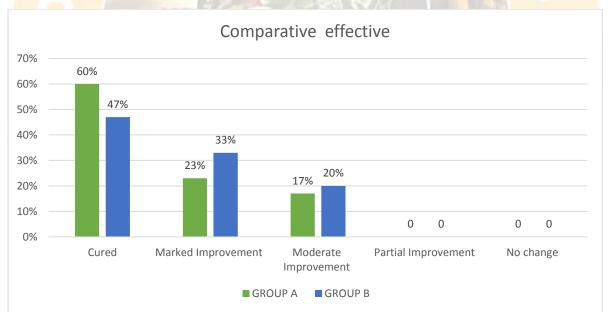
From Group A out of 30 patients, 18[60%] patients got complete cure, 7 [23%] patients got Marked improvement, 5[ 17%] patient got Moderate improvement. Whereas in Group B 14[47%] patients got complete cure, 10[33%] patients got Marked improvement, 6[10%] have got Moderate improvement, Hence overall effect of treatment is significant.

#### **COMPARATIVE EFFECT OF THE TREATMENT**

Table No: 8 Comparative effect of the treatment

Effect of Therapy	Group A	%	Group B	%
Cured 100 % Relief	18	60	14	47
Markedly Improved > 75% Relief	7	23	10	33
Moderately Improved 50-75 % Relief	5	17	6	20
Partially Improved 25-50 % Relief	0	0	0	0
No Change < 25 % Relief	0	0	0	0

Graph No: 3



## Discussion on Comparative effect over criteria of assessment:

**Kandu:** There was 90%[ Group A] & 89% [Group B] relief from *Kandu*, on comparison between the group there was no much difference with p >0.05 [0.420] this shows that both

groups are effective in treating *Kandu* but Group A [ *Mulakadi Malahara*] was more effective than Group B[ *Gandhaka Malahara*] ,This might be due to *Kandughna ,Krimighna* & *Kapha-pittahara* properties of drugs in the *Mulakadi Malahara*.

Raga: In the present study , it was observed that 82% from Group A & 78% from Group B got relief from Raga . On comparison between group there was no much difference with P> 0.05[0.774] this shows that both groups are effective in treating Raga but Group A [Mulakadi Malahara] was more effective than Group B [Gandhaka Malahara] , This might be due to pitta -hara property of Siktha & Laksha Varnya property of Sarshapa , Haridra & Laksha , Sheeta Virya of Laksha ,& Siktha

**Pidaka**: It was observed that 99.9 % from Group A & 99% from Group B got relief from *Pidaka*. On comparison between the group there was no much difference with p> 0.05 [0.679] this shows that both the groups are effective in treating *Pidaka* but Group A [ *Mulakadi Malahara* ] was more effective than Group B [ *Gandhaka Malahara* ] . This might be because of *Rakta shodhaka ,Vranaroopana , lekhaniya & Bedhana* property of the drugs in the preparation which expels the *badha malas*.

**Daha**: In the present study it was observed that 90 % from Group A & 88% from Group B got relief from Daha. On comparison between the

group there was no much difference with p > [0.684] this shows that both the groups are effective in treating Daha but Group A [ Mulakadi Malahara] was more effective than Group B [ Gandhaka Malahara] . This might be because of pitta-hara & sheeta virya of Laksha , siktha etc drugs pacify the ushna & tikshna guna of Dadru.

Rukshata: In the present study, it was observed that 96 % in Group A & 95 % in Group B got relief from Rukshata. On comparison between the group there was no much difference with p >0.05 [ 0.157] this shows that both the group are effective in treating Rukshata but Group A was more effective than Group B [Gandhaka Malahara]. This might be because of Vata-hara & snigadha properties of which increases the kledata of the twak.

**Udgata Mandala:** In the present study it was observed that 82% in Group A & 78% in Group B got relief from *Udgata Mandala*. On comparison between the group there was no much difference with p>0.05[0.868] shows that both the group are effective in treating the Udgata Mandala but Group A Mulakadi Malahara ] was more effective than Group B [ Gandhaka Malahara] . This might be because of ushna , tikshna & Kapha —hara property of the drugs subsides the dushta Kapha .

# Discussion on Mode of action of Malahara:

Dadru is a pitta-kapha pradhana twak vikara affecting 4th layer of skin [
Tamra] which can be co-related to Malphigian layer of epidermis. So in epidermal skin diseases local application of medicine works faster than internal medicine.

Bahirparimarjana in the form of Malahara was used because of its Sthanika Chikitsa effect.

In the present study the classical mentioned *Mulakadi lepa* is modified to *Malahara* i.e *Mulakadi Malahara* in the management of *Dadru Kushta* for the easy mode of application in children.

## Discussion on Probable mode of action of *Mulakadi Malahara*:

The Mulakadi Malahara contains drugs like Vidanga ,Mulaka beeja , Chakramarda, Sarshapa, Kushta , Haridra, Maricha , Pippali ,shunti , Laksha , tila taila , Siktha & Gomutra Guna : Ushna , Tikshna, Laghu , Ruksha etc

Virya: Ushna.

Vipaka : Katu

Doshaghnata: Pitta-Kapha hara

Karma : Kushtaghna , Kandughna , Krimighna ,Varnya & Dadrughna .

- The relief from Kandu is seen in patients due to Kandughna & Krimighna property of Sarshapa , Haridra , Kushta & Chakramarda which is present in the Mulakadi Malahara.
- The relief from Raga is seen in patients due to pitta-hara property of Laksha, Siktha& varnya property of Sarshapa, Haridra, laksha & Siktha.
- The relief from *Pidaka* is seen in patients is due to *Raktha Shodhana* 
   , Varna ropana ,Lekana guna of Kushta , Chakramarda, Sarshapa,
   Shunti .
- The relief from Daha is seen in patient due to pitta-hara & sheeta
   Virya property of Haridra , laksha & Siktha.
- The relief from Rukshata is seen in patients due to vata-hara & snigadha guna of Sarshapa, Chakramarda, Siktha taila.
- The relief from *Udgata mandala* is seen in patients due to *laghu*, tikshna, ushna & Kapha –hara property of Vidanga, sarshapa,

kushta , Haridra ,Chakramarda ,shunti maricha & pippali .

Upon topical application, the active principle in *Malahara* gets readily absorbed to the deeper layers of the skin and stay intact for longer duration & act as Fungicidal.

In terms of ayurveda we can explain Malahara being sukshma, Tikshna & Ushna gets absorbed through the Swedavaha srotas & allows the local toxins [ krimi] to flow out through excessive swedana thus clearing the micro-channels.

## Probable Mode of action of Gandhaka Malahara.

The Gandhaka Malahara contains Shuddha Gandhaka, Siktha [bee wax ] & Tila Taila It is having Ushna Veerya which does the ama pachana locally and removes the toxin through swedana, the tikta, kashaya rasa & lekhaniya guna removes the dushta kapha & pitta.

The Gandhaka Malahara is have the capacity to cure Kandu , Kushta , Dadru, Visarpa, krimi roga & all the twak vikara.

#### **CONCLUSION:**

 Both Mulakadi Malahara & Gandhaka Malahara were effective in the treatment of Dadru with statistically highly significant result with P<0.001. Clinically both the *Malahara* was effective in treated Pidaka, Daha and Kandu very effectively than Udgata Raga.On comparison mandala & between 2 groups there was no statistically significant difference in the effect of treatment with p >0.05. But after follow up it can be concluded that there was more reoccurrence in Gandhaka Malahara group Mulakadi Malahara. So it can be concluded that *Mulakad Malahara* was more effective than Gandhaka *Malahara* in treating *Dadru kushta* in Children.

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