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 1/3rd 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 compared with Gandhaka malahara a proprietary medicine which is widely used practically for treating Dadru in the study. Objective 1] To evaluate the efficacy of Mulakadi malahara in Dadru kushta. 2] 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 14th & 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.
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**Introduction:**
Skin diseases accounts for nearly 1/3rd 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. 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. Fungal infection are very commonly prevalent in tropical & subtropical countries, approximately 5 out of 100 are suffering from tinea infection. 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. 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 contemporary medical science management is carried out with usage of topical or systemic antifungal, corticosteroids etc. But there is a palliative treatment explained in *ayurveda* for external application, one such external application is *Mulakadi lepa* explained in the text “Bhaishajya Ratnavali” 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 1st group which will be compared against a widely used clinical formulation *Gandhaka Malahara* taken as control in the 2nd 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

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mulaka beeja</td>
<td>100 gm</td>
</tr>
<tr>
<td>Sarshapa</td>
<td>100 gm</td>
</tr>
<tr>
<td>Laksha</td>
<td>100 gm</td>
</tr>
<tr>
<td>Haridra</td>
<td>100 gm</td>
</tr>
<tr>
<td>Chakramarda beeja</td>
<td>100 gm</td>
</tr>
<tr>
<td>Shunti</td>
<td>100 gm</td>
</tr>
<tr>
<td>Trikatu</td>
<td>100 gm</td>
</tr>
<tr>
<td>Vidanga</td>
<td>100 gm</td>
</tr>
<tr>
<td>Kushta</td>
<td>100 gm</td>
</tr>
<tr>
<td>Gomutra</td>
<td>100 ml</td>
</tr>
<tr>
<td>Tila taila</td>
<td>1 lt</td>
</tr>
<tr>
<td>Siktha</td>
<td>200 gm</td>
</tr>
</tbody>
</table>

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 lt 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

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sudha Gandhaka</td>
<td>300 gms</td>
</tr>
</tbody>
</table>
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<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Siktha</em></td>
<td>300 gms</td>
</tr>
<tr>
<td><em>Tila Taila</em></td>
<td>1500 lt</td>
</tr>
</tbody>
</table>

**Method of Preparation:**

- 1.5 lt 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 mortar 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.

**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.

**E] 1] Study Design:**

A Randomized Controlled Clinical Study

**2] Method of Sampling:**

Lottery Method
G] INTERVENTIONS
Table No : 3

<table>
<thead>
<tr>
<th>Group</th>
<th>Medicine</th>
<th>Mode of Usage</th>
<th>Dose</th>
<th>Time</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A [ Trial Group ]</td>
<td>Mulakadi Malahara</td>
<td>External Application</td>
<td>QS</td>
<td>BD</td>
<td>21 days</td>
</tr>
<tr>
<td>Group B [ Control Group ]</td>
<td>Gandhaka Malahara</td>
<td>External Application</td>
<td>QS</td>
<td>BD</td>
<td>21 days</td>
</tr>
</tbody>
</table>

H] PERIOD OF OBSERVATION:
- Both the group clinical findings were recorded in the case sheet Proforma BT on 14th & 21st day of treatment to assess the progress.
- Post –Treatment follow up was done 7 days later [on 28th 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

<table>
<thead>
<tr>
<th>Lakshana</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kandu</td>
<td>No itching</td>
<td>Mild itching</td>
<td>Moderate Itching</td>
<td>Severe Itching</td>
</tr>
<tr>
<td>Pidaka</td>
<td>No eruption</td>
<td>Eruption in 0-25% of affected area</td>
<td>Eruption in 25-50% of affected area</td>
<td>Eruption in 50-75% of affected area</td>
</tr>
<tr>
<td>Daha</td>
<td>No Burning sensation</td>
<td>Mild burning sensation</td>
<td>Moderate burning sensation</td>
<td>Severe burning sensation</td>
</tr>
</tbody>
</table>
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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 | Severe 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>
<thead>
<tr>
<th>Table No 5: Overall assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement</td>
</tr>
<tr>
<td>Complete</td>
</tr>
<tr>
<td>Marked</td>
</tr>
<tr>
<td>Moderate</td>
</tr>
<tr>
<td>Mild</td>
</tr>
<tr>
<td>No improvement</td>
</tr>
</tbody>
</table>

**RESULTS AND DISCUSSION :**
Table No: 6 Comparative Effect of Both treatment in Sign & Symptoms on 28th day.

<table>
<thead>
<tr>
<th>Signs &amp; Symptoms</th>
<th>Mean difference</th>
<th>Percentage Relief</th>
<th>t-value</th>
<th>p-value</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group A</td>
<td>Group B</td>
<td>Group A</td>
<td>Group B</td>
<td></td>
</tr>
<tr>
<td>Kandu</td>
<td>2.1</td>
<td>2.0</td>
<td>90</td>
<td>89</td>
<td>0.812</td>
</tr>
<tr>
<td>Raga</td>
<td>1.8</td>
<td>1.6</td>
<td>82</td>
<td>78</td>
<td>0.288</td>
</tr>
</tbody>
</table>
A Randomized controlled clinical study to evaluate the efficacy of the *Mulakadi malahara* in the treatment of *Dadru* in Children.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pidaka</td>
<td>1.2</td>
<td>0.8</td>
<td>99.9</td>
<td>99</td>
<td>0.416</td>
<td>0.679</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Daha</td>
<td>1.5</td>
<td>1.2</td>
<td>90</td>
<td>88</td>
<td>0.408</td>
<td>0.684</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Rukshata</td>
<td>1.6</td>
<td>1.5</td>
<td>96</td>
<td>95</td>
<td>1.416</td>
<td>0.157</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>Udgata Mandala</td>
<td>1.5</td>
<td>1.4</td>
<td>82</td>
<td>78</td>
<td>0.167</td>
<td>0.868</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

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

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

the treatment with \( p<0.001 \) in both the group.  

**Daha**: The comparison of *Daha* showed that, there is highly significant change 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

<table>
<thead>
<tr>
<th>Effect of Therapy</th>
<th>Group A</th>
<th>Group B</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured 100 % Relief</td>
<td>18</td>
<td>14</td>
<td>32</td>
<td>53</td>
</tr>
<tr>
<td>Markedly Improved &gt;75% Relief</td>
<td>7</td>
<td>10</td>
<td>17</td>
<td>28</td>
</tr>
<tr>
<td>Moderately Improved 50-75 % Relief</td>
<td>5</td>
<td>6</td>
<td>11</td>
<td>19</td>
</tr>
<tr>
<td>Partially Improved 25-50 % Relief</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No Change &lt; 25 % Relief</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Graph No : 2

**Discussion on Overall effect of Therapies:**
A Randomized controlled clinical study to evaluate the efficacy of the *Mulakadi malahara* in the treatment of *Dadru* in Children.

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

<table>
<thead>
<tr>
<th>Effect of Therapy</th>
<th>Group A</th>
<th>%</th>
<th>Group B</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured 100 % Relief</td>
<td>18</td>
<td>60</td>
<td>14</td>
<td>47</td>
</tr>
<tr>
<td>Markedly Improved &gt; 75% Relief</td>
<td>7</td>
<td>23</td>
<td>10</td>
<td>33</td>
</tr>
<tr>
<td>Moderately Improved 50-75 % Relief</td>
<td>5</td>
<td>17</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>Partially Improved 25-50 % Relief</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No Change &lt; 25 % Relief</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

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*. 
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**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 *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]* this 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*].
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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 bejeta, Chakramarda, Sarshapa, Kushta, Haridra, Maricha, Pippali, shunti, Laksha, tila taila, Siktha & Gomutra

Guna: Ushna, Tikshna, Laghu, Ruksha etc
Virya: Ushna.

Vipaka: Katu
Doshagnata: Pitta-Kapha hara
Karma: Kushtaghna, Kandughna, Krimighna, Varnya & Dadrugha.

- 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 & snigadh 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,
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**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 sukhma, 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 mandala & Raga.

On comparison 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 than Mulakadi Malahara. So it can be concluded that Mulakadi Malahara was more effective than Gandhaka Malahara in treating Dadru kushta in Children.

**Reference :**

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

London publication Chapter 17th page 561.

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