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# "A RANDOMISED CONTROLLED CLINICAL STUDY TO EVALUATE THE EFFICACY OF SHIRISHA TWAK MALAHARA IN THE MANAGEMENT OF DADRU KUSHTA IN CHILDREN"

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## ABSTRACT

**HISTORY**: The skin is said to be the biggest organ in the human body. Skin is vulnerable to a range of conditions depending on its size and exterior locations. The most frequent causes of skin disorders are fungi, germs, etc. In Ayurveda, all skin symptoms are grouped together under the general name Kushta. It is subdivided into Kshudra Kushta and Maha Kushta. Dadru is one of those. The present study is a clinical study to evaluate the efficacy of *SHIRISHA MALAHARA* and *GANDHAK MALAHARA in* the management of *Dadru kustha* in children. **METHODOLOGY:** A randomised Clinical Trial was carried out in 60 subjects with the age group of 10-15 yrs, presenting with classical signs and symptoms of *Dadru Kushta*. They were randomly allocated in to 2 groups, Group A and Group B with 30 subjects each. In Group A, *Shirisha twak malahara* and in Group B gandhak malhara was given for local application twice daily for 21 days. The observation was done on 15$^{th}$ and 22$^{st}$ day of treatment and follow up was on 29$^{th}$ day. **RESULTS:** The statistical analysis for analyzing the significant effect of each parameter before and after the treatment with in the group was done statistically using the ANOVA test with the statistical software package. The post hoc test used by the software was Tukey test. Comparative analysis between the groups was done by using t- test for objective criteria's and Mann- Whitney Rank Sum test for Subjective criteria's. **CONCLUSION:** Hence by this study, it can be concluded that, both Shirisha Twak Malahara amd Gandhak malhara are effective in treating *Dadru Kushta.*

**KEY WORDS:** *Dadru,* Tinea, shirisha twak malahara, gandhak malhara

## INTRODUCTION

The body's defence organ is the skin. It is a target organ for numerous infections and is a reflection of the person's health. After a skin condition develops, it is difficult to treat, which can be embarrassing on a social, psychological, and physical level. Approximately one-third of paediatric disorders are related to skin conditions. Dermatological diagnosis requires the identification of primary and secondary skin lesions as well as the patterns that these lesions form[1].

A World Health Organisation (WHO) review of prevalence studies done on skin disease reported an overall prevalence ranging from 21% to 87% . Around 30% of paediatric outpatient visits are due to skin disorders, either on their own or linked to other illnesses[2].Of these, about 20% are caused by fungal infections, which are most common in tropical and subtropical regions.[3]

In Ayurveda, all skin diseases are referred to as "*Kushta*" by various *Acharyas*. These are further divided into two types: *Maha Kushta* (major skin diseases) and *Kshudra Kushta* (minor skin diseases). *Dadru* is a type of *Kshudra Kushta* and is primarily caused by an imbalance of Pitta and *Kapha Doshas*. The symptoms of *Dadru Kushta* include redness (*Raga*), itching (*Kandu*), small eruptions (*Pidaka*), raised patches (*Udgata Mandala*), and dryness (*Rookshata*).[4]

In modern medicine, Tinea is treated with topical or oral antifungal medications[5], corticosteroids, and other drugs. Ayurveda, however, mentions external treatments for relief. One such remedy is *Shirisha Twak Malahara*, found in Charaka Samhita[6], and another is *Gandhak Malahara*, mentioned in the book *Yogaratnakara*[7]. These treatments are not widely used but were selected for study.

## OBJECTIVES

1. To evaluate the efficacy of Shirisha Twak Malahara in Dadru Kushta.
2. To compare the efficacy of Shirisha Twak Malahara with Gandhaka Malahara in Dadru Kushta.

## MATERIALS AND METHOD

Sample size: A minimum of 60 subjects fulfilling the diagnostic and the inclusion criteria were selected and allotted in Group A and B with 30 subjects each.

Design of study: Randomized controlled clinical study

**Preparation of Medicine**

- Collection of raw drugs.
- Preparation of *Shirisha Malahara*
- Preparation of *Gandhak Malahara*

**a) Collection of Raw Material:**

All the raw materials which was required for the preparation of both the *Malahara* was properly identified by the experts. Later it was purchased from the local market & the preparation was carried in *Rasashastra Bhaishajya Kalpana* lab of Alva's *Ayurveda* college & Hospital.

**b) Preparation of the Drug used for the study:**

***1. Shirisha Twak Malahara***

**Table No 1 *Shirisha Twak Malahara* ingredients & Quantity**

| Ingredients | Quantity |
|---|---|
| **Shirisha twak** | **400g** |
| **Siktha** | **400g** |
| **Tila taila** | **2lt.** |

**Method of Preparation:**

- 400g of *Shirisha Twak* is made into a fine powder and filtered through a clean & dry cloth to separate the coarse particles.
- 2 lt of *Tila Taila* is taken in a dry and clean vessel and heated over low flame.
- 400 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 mortar 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 2060gms.

**2. *Gandhaka Malahara*:**

**Table No 2 *Gandhaka Malahara* ingredients & Quantity**

| Ingredients | Quantity |
|---|---|
| *Sudha Gandhaka* | 400g |
| *Siktha* | 400g |
| *Tila Taila* | 2lt. |

**Method of Preparation:**

- *Taila* is taken in a a dry & clean vessel & heated over low flame 2 It of *Tila*
- 400 gm of *Siktha Taila* is slowly added to the vessel containing the fills tails & stirred carefully until it dissolves completely.
- After complete dissolution of *Siktha Taila*, it is filtered through a clears 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.

**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.

**Table No 3** INTERVENTIONS

| GROUP | MEDICINE | MODE OF USAGE | DOSE | TIME | DURATION |
|---|---|---|---|---|---|
| **Group A [Trial Group ]** | ***Shirisha Malahara*** | **External Application** | **QS** | **BD** | **21 DAYS** |
| **Group B Control Group]** | ***Gandhaka Malahara*** | **External Application** | **QS** | **BD** | **21 DAYS** |

**PERIOD OF OBSERVATION:**

- Both the group clinical findings were recorded in the case sheet proforma on BT 8$^{th}$,15th & 22 day of treatment to assess the progress.
- Post-Treatment follow up was done 7 days later [on 29th day].
- Total Duration of study: 29 days.

**ASSESSMENT CRITERIA:**

Assessment was based on the following parameter with **KASI** method of grading.

**Subjective Parameter:**

- *Kandu*
- *Rukshata*
- *Raga*
- *Daha*

**Objective Parameter:**

- *Udgata Mandala*
- *Pidika*

**Table No 4 Assessment criteria Grading's**

| Lakshana | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| **Kandu** | **No itching** | **Mild Itching** | **Moderate Itching** | **Severe 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% affected area** | **Eruption in 50-75% of affected area** |
| **Daha** | **No sensation Burning** | **Mild burning sensation** | **Moderate burning sensation** | **Severe burning sensation** |

| | | | | |
|---|---|---|---|---|
| **Rookshata** | **No dryness** | **Loss in skin's normal unctuousness** | **Moderate dryness** | **Excessive dryness** |
| **Udgata** | **No elevation of the skin** | **Mild elevation of the skin (<2mm)** | **Moderate elevation of the skin (<2-6mm)** | **severe elevation of the skin (<6mm)** |

**Statistical analysis**: Obtained data were analysed statistically with RM ANOVA on rank Test and Mann-Whitney Test to test the hypothesis of the study. $P < 0.05$ was considered statistically significant.

## Observation

**Table 05**

| OBSERVATION | PREDOMINANCE | % | INTERPRETATION |
|---|---|---|---|
| **AGE** | **13-15 YRS** | **55%** | **This is may be because of increased sebaceous gland activity in adolescent age group which favours the growth of fungal infection and other contributing factor is lack of hygiene.** |
| **GENDER** | **MALE** | **91%** | **This is more common in boys than in girls during adolescence, because boys will have more sebaceous secretion and excessive sweating.** |
| **RELIGION** | **HINDU** | **100%** | **The fact may be the area where the study conducted was having predominance of Hindu religion.** |
| **DIET** | **MIXED** | **66.6%** | **So *Dadru* was more common in Non-vegetarian because of the fact that they intake more oily, fried and spicy food stuffs which are unwholesome for the body** |
| **SLEEP** | **DISTURBED** | **53%** | **The disturbed sleep that may be due to excess *Kandu* which might have persisted in night also.** |
| **PRAKRUTHI** | **PITA KAPHA** | **50.5%** | ***Dadru* is *Pitta Kaphaja kushta*, so the same was found more in *Pitta-Kaphaja Prakruti* persons.** |
| **MODE OF ONSET** | **GRADUAL** | **81.5%** | **This explains the *chirottana* of the disease which explains that, this disease is gradual in onset and it stays for a long time in the body.** |
| **AGGREVATING FACTORS** | **EXCESS SWEATING** | **51.6%** | **. This may be because the excess heat of the sun results in the excess production of sweat and the moisture give shelter for the fungi to develop.** |

| | | | |
|---|---|---|---|
| **AFFECTED AREA** | **INGUINAL REGION** | **41.6%** | ***Dadru* can occur anywhere in the body and can be spread from place to place.** |

## RESULTS

**1. KANDU:**

Table no.6 Effect of treatment on Kandu with in Group A and Group B

| Comparison | q | P<0.050 | q | P<0.050 |
|---|---|---|---|---|
| **BT vs DT1** | 11.595 | YES | 5.223 | YES |
| **BT vs DT2** | 16.865 | YES | 10.466 | YES |
| **BT vs AT** | 18.447 | YES | 13.518 | YES |
| **BT vs FU** | 16.338 | YES | 13.300 | YES |
| **DT1 vs DT2** | 5.270 | YES | 5.233 | YES |
| **DT1 vs AT** | 6.852 | YES | 8.285 | YES |
| **DT1 vs FU** | 4.743 | YES | 8.067 | YES |
| **DT2 vs AT** | 1.581 | NO | 3.053 | YES |
| **DT2 vs FU** | 0.527 | NO | 2.835 | YES |
| **AT vs FU** | 2.108 | NO | 0.218 | NO |

There is statistical significant difference within group analysis of Group A and B on Kandu P <0.05

| GROUP | MEDIAN | | MEAN A | MEAN B | MWUT | P-VALUE | REMARKS |
|---|---|---|---|---|---|---|---|
| | GR A | GR B | | | | | |
| **BT-DT1** | 1.000 | 1.000 | 1.467 | 0.800 | 206.000 | P =<0.001 | YES |
| **BT-DT2** | 2.000 | 2.000 | 2.133 | 1.600 | 268.000 | P = 0.003 | YES |
| **BT-AT** | 2.000 | 2.000 | 2.333 | 2.067 | 358.000 | P = 0.133 | NO |
| **BT-FU** | 2.000 | 2.000 | 2.067 | 2.033 | 439.000 | P = 0.865 | NO |
| **DT1-DT2** | 1.000 | 1.000 | 0.667 | 0.800 | 389.000 | P = 0.290 | NO |
| **DT1-AT** | 1.000 | 1.000 | 0.867 | 1.267 | 312.000 | P = 0.025 | YES |
| **DT1-FU** | 1.000 | 2.000 | 1.233 | 1.533 | 367.000 | P = 0.199 | NO |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **DT2-AT** | 0.000 | 0.000 | 0.200 | 0.467 | 330.000 | P = 0.031 | YES |
| **DT2-FU** | 0.000 | 0.000 | -0.0667 | 0.433 | 280.500 | P = 0.005 | YES |
| **AT-FU** | 0.000 | 0.000 | -0.267 | -0.0333 | 349.000 | P = 0.027 | YES |

Table no. 7 Effect of treatment on kandu in between the groups

There is stastistical significant difference between group A and group B analysis on Kandu by comparing mean value of group A and group B at different time points with BT with DT1, BT with DT2, DT1 with AT, DT2 with AT, DT2 with FU and AT with FU Group A and Group B has equal effect.

No difference noted on comparing with BT with AT, BT with FU, DT1 with DT2 and DT1 with FU suggests both drugs take similar time for significant action

## 2. DAHA

Table no. 8 Effect of treatment on daha Group A and B

| Comparison | q | P<0.050 | q | P<0.050 |
|---|---|---|---|---|
| **BT vs DT1** | 8.541 | YES | 2.98 | YES |
| **BT vs DT2** | 9.965 | YES | 5.573 | YES |
| **BT vs AT** | 10.439 | YES | 7.564 | YES |
| **BT vs FU** | 9.965 | YES | 7.365 | YES |
| **DT1 vs DT2** | 1.424 | NO | 2.588 | YES |
| **DT1 vs AT** | 1.898 | NO | 4.578 | YES |
| **DT1 vs FU** | 1.424 | NO | 4.379 | YES |
| **DT2 vs AT** | 0.475 | NO | 1.990 | NO |
| **DT2 vs FU** | 0.000 | NO | 1.791 | NO |
| **AT vs FU** | 0.475 | NO | 0.199 | NO |

There is statistical significant difference within group analysis of Group A and B on *Daha* P <0.05

| GROUP | MEDIAN | | MEAN A | MEAN B | MWUT | P-VALUE | REMARKS |
|---|---|---|---|---|---|---|---|
| | GR A | GR B | | | | | |
| **BT-DT1** | 1.000 | 0.500 | 1.200 | 0.500 | 225.000 | P = <0.001 | YES |
| **BT-DT2** | 2.000 | 1.000 | 1.400 | 0.933 | 286.000 | P = 0.008 | YES |
| **BT-AT** | 2.000 | 1.000 | 1.467 | 1.267 | 384.000 | P = 0.300 | NO |
| **BT-FU** | 2.000 | 1.000 | 1.400 | 1.233 | 384.500 | P = 0.306 | NO |
| **DT1-DT2** | 0.000 | 0.000 | 0.200 | 0.433 | 351.500 | P = 0.081 | NO |
| **DT1-AT** | 0.000 | 1.000 | 0.267 | 0.767 | 283.000 | P = 0.006 | YES |
| **DT1-FU** | 1.000 | 1.000 | 0.900 | 0.933 | 434.500 | P = 0.814 | NO |
| **DT2-AT** | 0.000 | 0.000 | 0.0667 | 0.333 | 329.000 | P = 0.015 | YES |
| **DT2-FU** | 0.000 | 0.000 | 0.000 | 0.300 | 333.500 | P = 0.014 | YES |
| **AT-FU** | 0.000 | 0.000 | -0.0667 | - | 436.000 | P = 0.677 | No |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | 0.0333 | | | |

Table no. 9 Effects of treatment on daha in between the groups

There is stastistical significant difference between group A and group B analysis on Daha by comparing mean value of group A and group B at different time points with BT with DT1, BT with DT2, DT1 with AT, DT2 with AT and DT2 with FU Group B is better than Group A.

No difference noted on comparing with BT with AT, BT with FU, DT1 with DT2 and DT1 with FU and AT with FU suggests both drugs take similar time for significant action.

## RAGA

Table no.10 Effect of treatment on raga within group Aand B

| Comparison | q | P<0.050 | q | P<0.050 |
|---|---|---|---|---|
| **BT vs DT1** | 5.968 | YES | 3.727 | YES |
| **BT vs DT2** | 8.620 | YES | 6.670 | YES |
| **BT vs AT** | 11.273 | YES | 10.593 | YES |
| **BT vs FU** | 13.041 | YES | 9.808 | YES |
| **DT1 vs DT2** | 2.652 | YES | 2.943 | YES |
| **DT1 vs AT** | 5.305 | YES | 6.866 | YES |
| **DT1 vs FU** | 7.073 | YES | 6.081 | YES |
| **DT2 vs AT** | 2.652 | YES | 3.923 | YES |
| **DT2 vs FU** | 4.421 | YES | 3.139 | YES |
| **AT vs FU** | 1.768 | NO | 0.785 | NO |

There is statistical significant difference within group analysis of Group A and B on Raga P <0.05

Table no11 .Effect of treatment on raga in between the groups

| GROUP | MEDIAN | | MEAN A | MEAN B | MWUT | P-VALUE | REMARKS |
|---|---|---|---|---|---|---|---|
| | GR A | GR B | | | | | |
| **BT-DT1** | 1.000 | 1.000 | 0.900 | 0.633 | 350.500 | P = 0.091 | NO |
| **BT-DT2** | 1.000 | 1.000 | 1.300 | 1.133 | 385.500 | P = 0.254 | NO |
| **BT-AT** | 2.000 | 2.000 | 1.700 | 1.800 | 408.000 | P = 0.474 | NO |
| **BT-FU** | 2.000 | 2.000 | 1.967 | 1.667 | 356.500 | P = 0.128 | NO |
| **DT1DT2** | 0.000 | 0.500 | 0.400 | 0.500 | 405.000 | P = 0.445 | NO |
| **DT1-AT** | 1.000 | 1.000 | 0.800 | 1.167 | 311.500 | P = 0.013 | YES |
| **DT1-FU** | 1.000 | 1.000 | 1.400 | 1.300 | 425.500 | P = 0.703 | NO |
| **DT2-AT** | 0.000 | 1.000 | 0.400 | 0.667 | 339.000 | P = 0.061 | NO |
| **DT2-FU** | 1.000 | 1.000 | 0.667 | 0.533 | 450.000 | P = 1.000 | NO |
| **AT-FU** | 0.000 | 0.000 | 0.267 | -0.133 | 286.000 | P = <0.001 | YES |

There is stastistical significant difference between group A and group B analysis on Raga by comparing mean value of group A and group B at different time points with DT1 with AT and AT with FU Group A and Group B has equal effect.

No difference noted on comparing with BT with DT1, BT with DT2, BT with AT, BT with FU, DT1 with DT2, DT1 with FU, DT2 with AT and DT2 with FU suggests both drugs take similar time for significant action.

4. ***RUKSHATA***

Table no. 12 Effect of treatment on rukshta Group A and B

| Comparison | q | P<0.050 | q | P<0.050 |
|---|---|---|---|---|
| **BT vs DT1** | 4.747 | YES | 5.488 | YES |
| **BT vs DT2** | 7.595 | YES | 9.480 | YES |
| **BT vs AT** | 12.105 | YES | 12.972 | YES |
| **BT vs FU** | 13.054 | YES | 13.720 | YES |
| **DT1 vs DT2** | 2.848 | YES | 3.991 | YES |
| **DT1 vs AT** | 7.338 | YES | 7.784 | YES |
| **DT1 vs FU** | 8.307 | YES | 8.232 | YES |
| **DT2 vs AT** | 4.510 | YES | 3.492 | YES |
| **DT2 vs FU** | 5.459 | YES | 4.341 | YES |
| **AT vs FU** | 0.949 | NO | 3.492 | NO |

There is statistical significant difference within group analysis of Group A and B on *Rukshata* P <0.05

Table no. 13 Effect of treatment on *rukshta* in between the groups

| GROUP | MEDIAN | | MEAN A | MEAN B | MWUT | P-VALUE | REMARKS |
|---|---|---|---|---|---|---|---|
| | GR A | GR B | | | | | |
| **BT-DT1** | 1.000 | 1.000 | 0.667 | 0.733 | 421.000 | P = 0.617 | NO |
| **BT-DT2** | 1.000 | 1.000 | 1.067 | 1.267 | 376.000 | P = 0.176 | NO |
| **BT-AT** | 2.000 | 2.000 | 1.700 | 1.733 | 436.000 | P = 0.819 | NO |
| **BT-FU** | 2.000 | 2.000 | 1.833 | 1.833 | 442.500 | P = 0.910 | NO |
| **DT1-DT2** | 0.000 | 1.000 | 0.400 | 0.533 | 390.000 | P = 0.309 | NO |
| **DT1-AT** | 1.000 | 1.000 | 1.033 | 1.000 | 436.000 | P = 0.767 | NO |
| **DT1-FU** | 1.000 | 1.000 | 1.367 | 1.467 | 422.500 | P = 0.662 | NO |
| **DT2-AT** | 1.000 | 0.000 | 0.633 | 0.467 | 375.000 | P = 0.201 | NO |
| **DT2-FU** | 1.000 | 1.000 | 0.767 | 0.567 | 384.500 | P = 0.278 | NO |
| **AT-FU** | 0.000 | 0.000 | 0.133 | 0.1000 | 437.000 | P = 0.765 | NO |

There is no statistical significant difference between group A and group B analysis on Rukshata

## 5. *PIDIKA*:

Table no.14 - Effect of treatment on *pidika*

| Comparison | Q | P<0.050 | q | P<0.050 |
|---|---|---|---|---|
| **BT vs DT1** | 3.534 | YES | 2.765 | YES |
| **BT vs DT2** | 7.540 | YES | 4.424 | YES |
| **BT vs AT** | 11.074 | YES | 6.267 | YES |
| **BT vs FU** | 12.016 | YES | 6.820 | YES |
| **DT1 vs DT2** | 4.005 | YES | 1.659 | YES |
| **DT1 vs AT** | 7.540 | YES | 3.502 | YES |

| | | | | |
|---|---|---|---|---|
| **DT1 vs FU** | 8.482 | YES | 4.055 | NO |
| **DT2 vs AT** | 3.534 | YES | 1.843 | NO |
| **DT2 vs FU** | 4.477 | YES | 2.396 | NO |
| **AT vs FU** | 0.942 | NO | 0.553 | NO |

There is statistical significant difference within group analysis of Group A and B on *Pidika* P <0.05

Table no. 15 Effect of treatment on pidika in between the groups

| GROUP | MEDIAN | | MEAN A | MEAN B | MWUT | P-VALUE | REMARKS |
|---|---|---|---|---|---|---|---|
| | GR A | GR B | | | | | |
| **BT-DT1** | 0.500 | 0.500 | 0.500 | 0.500 | 450.000 | P = 1.000 | NO |
| **BT-DT2** | 1.000 | 1.000 | 1.067 | 0.800 | 350.000 | P = 0.077 | NO |
| **BT-AT** | 2.000 | 1.000 | 1.567 | 1.133 | 339.500 | P = 0.082 | NO |
| **BT-FU** | 2.000 | 1.000 | 1.700 | 1.233 | 335.000 | P = 0.074 | NO |
| **DT1-DT2** | 0.000 | 1.000 | 0.567 | 0.300 | 168.000 | P = <0.001 | YES |
| **DT1-AT** | 1.000 | 1.000 | 1.067 | 0.633 | 288.000 | P = 0.005 | YES |
| **DT1-FU** | 1.000 | 1.000 | 1.433 | 0.900 | 299.000 | P = 0.017 | YES |
| **DT2-AT** | 0.500 | 0.000 | 0.500 | 0.333 | 382.500 | P = 0.253 | NO |
| **DT2-FU** | 1.000 | 0.000 | 0.633 | 0.433 | 377.000 | P = 0.222 | NO |
| **AT-FU** | 0.000 | 0.000 | 0.133 | 0.1000 | 437.000 | P = 0.765 | NO |

There is statistical significant difference between group A and group B analysis on Pidika by comparing mean value of group A and group B at different time points with DT1 with DT2 and DT1 with AT and DT1 with FU Group A is better than Group B. No difference noted on comparing with BT with DT1, BT with DT2, BT with AT, BT with FU, DT2 with AT, DT2 with FU and AT with FU suggests both drugs take similar time for significant action.

## 6. *UDGATA MANDALA*:

Table no. 16 Effect of treatment on udgata mandala with in group A and group B

| Comparison | q | P<0.05 | q | P<0.05 |
|---|---|---|---|---|
| **BT vs DT1** | 5.081 | Yes | 2.483 | No |
| **BT vs DT2** | 6.235 | Yes | 5.774 | Yes |
| **BT vs AT** | 9.757 | Yes | 9.873 | Yes |
| **BT vs FU** | 10.681 | Yes | 9.873 | Yes |
| **DT1 vs DT2** | 1.155 | No | 3.291 | No |
| **DT1 vs AT** | 4.677 | Yes | 7.390 | Yes |
| **DT1 vs FU** | 5.600 | Yes | 7.390 | Yes |

| | | | | |
|---|---|---|---|---|
| **DT2 vs AT** | 3.522 | No | 4.099 | Yes |
| **DT2 vs FU** | 4.446 | Yes | 4.099 | Yes |
| **AT vs FU** | 0.924 | No | 0.000 | No |

**GROUP A:** There is statistical significant difference within group analysis of Group A and B on *Udagata Mandala* P <0.05

Table no. 17 Effect of treatment on *udgata* mandala in between the groups

| GROUP | MEDIAN | | MEAN A | MEAN B | MWUT | P-VALUE | REMARKS |
|---|---|---|---|---|---|---|---|
| | GR A | GR B | | | | | |
| **BT-DT1** | 1.000 | 0.000 | 0.833 | 0.467 | 285.000 | P = 0.003 | YES |
| **BT-DT2** | 1.000 | 1.000 | 1.000 | 0.933 | 423.000 | P = 0.596 | NO |
| **BT-AT** | 1.500 | 1.500 | 1.500 | 1.533 | 442.500 | P = 0.908 | NO |
| **BT-FU** | 2.000 | 1.500 | 1.633 | 1.533 | 403.500 | P = 0.447 | NO |
| **DT1-DT2** | 0.000 | 0.000 | 0.167 | 0.467 | 315.000 | P = 0.014 | YES |
| **DT1-AT** | 1.000 | 1.000 | 0.667 | 1.067 | 296.000 | P = 0.006 | YES |
| **DT1-FU** | 1.000 | 1.000 | 1.200 | 1.300 | 425.000 | P = 0.683 | NO |
| **DT2-AT** | 0.500 | 1.000 | 0.500 | 0.600 | 405.000 | P = 0.445 | NO |
| **DT2-FU** | 1.000 | 1.000 | 0.633 | 0.600 | 435.000 | P = 0.799 | NO |
| **AT-FU** | 0.000 | 0.000 | 0.133 | 0.000 | 390.000 | P = 0.091 | NO |

There is statistical significant difference between group A and group B analysis on Udgata mandal by comparing mean value of group A and group B at different time points BT with DT1, DT1 with DT2 and DT1 with AT Group B is better than Group A.

No difference noted on comparing BT with DT2, BT with AT, BT with FU, DT1 with FU, DT2 with AT, DT2 with FU and AT with FU suggests both drugs take similar time for significant action.

## DISCUSSION

## DISCUSSION ON DISEASE

According to *Acharya Charaka, Dadru kushta* is one among the *Kshudra Kushta* which involves *Prakupitta pitta & Kapha dosha* for its manifestation with *Kandu, Raga, Daha , Rukshata ,Udgata mandala* etc *Lakshanas.*

Specific *Nidanas* for *Dadru Kushta* is not mentioned in Text books. So, *samanya kushta nidanas* which leads to *prakopa* of *pitta* & *kapha* can be considered as *Nidanas.*

Due to various such causes, there will be *Pitta* and *Kapha Prakopa* which in turn aggravates *Vata*. So the vitiated *Tridoshas* will enter in to *Tiryakgata siras* & reaches the *Bahya Roga Marga (Twak*) & produces *Dadru kushta*.

In the present study, two groups are involved where the efficacy of *Shirisha twak malahara* and Gandhak malahara in the management of *Dadru Kushta* are evaluated.

*Acharyas* have given equal importance to systemic and local administration of the drugs indicating that they were well aware of the importance of the topical route as well as systemic route in treating the skin diseases.

## Discussion on results

A result has been drawn after statistical analysis in two sections as within group comparison i.e. effect of drug as before and after treatment. Between group comparison, to compare the efficacy of one drug over other. The effect of the treatment was assessed as follows: • Before and After Treatment was done by RM ANOVA on rank test. • Comparison between the groups was done by the Mann-Whitney test.

**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 29th day of completion of the treatment. Both the groups were assessed before treatment [0th day), During treatment [15th day]. After treatment [22nd day] & After follow up day [29th day] The subjective & objective parameters were graded for statistical evaluation.

1. ***Kandu* (Itching)**: The significant improvement in itching ($p<0.050$) indicates that the treatment effectively reduced inflammation and skin irritation, balancing the aggravated *Kapha* and *Pitta Doshas* responsible for the itching.

2. ***Raga* (Redness)**: Redness decreased significantly ($p<0.050$), likely due to the anti-inflammatory properties of the treatment, which helped soothe the aggravated *Pitta Dosha*, responsible for heat and redness in the skin.

3. **Pidaka** (**Pustules**/**Blisters**): The reduction in pustules ($p<0.050$) reflects the treatment's effectiveness in controlling infection and reducing inflammation, thereby healing the skin lesions.

4. ***Daha* (Burning Sensation):** The significant reduction in burning ($p<0.050$) suggests that the treatment pacified the excess heat caused by aggravated *Pitta Dosha*, alleviating the sensation of heat and discomfort.

5. ***Rukshata* (Dryness):** The marked decrease in dryness ($p<0.050$) indicates that the treatment helped restore moisture and balance, reducing the excess dryness caused by *Vata* and *Pitta Dosha* imbalances.

6. ***Udgata Mandala* (Raised Patches)**: The reduction in raised patches ($p<0.050$) shows that the treatment effectively resolved skin inflammation and swelling, flattening the elevated lesions associated with *Dadru Kushta*.

**Discussion on Comparative effect over criteria of assessment:**

1. ***Kandu* (Itching):**

The results showed that both *Shirisha Twak Malahara* and *Gandhaka Malahara* were highly effective in treating itching, with Group A showing 100% relief and Group B showing 93.99%. The p-value of 0.133 indicates no statistically significant difference between the two groups. Itching in *Dadru Kushta* is primarily caused by the vitiation of *Kapha* and *Pitta doshas*, which block skin channels and lead to the sensation of itching. *Shirisha's Kandughna* (anti-itch) and *Kapha-Pitta hara* properties help in pacifying these *doshas* and clearing the blocked channels, thereby relieving itching. Similarly, *Gandhaka's Kapha-hara* and *Tikshna* properties also help reduce itching by breaking down the *Kapha* accumulations. Although *Shirisha* was

slightly more effective, the overall similarity in outcomes proves that both formulations are comparably effective in treating itching.

2. ***Raga*** **(Redness):**

In the case of redness, Group A (*Shirisha Twak Malahara* ) provided 75% relief, while Group B (*Gandhaka Malahara*) showed 85% relief, with a p-value of 0.474, indicating no significant difference between the two groups. Redness in *Dadru Kushta* is mainly caused by an excess of *Pitta Dosha*, which leads to inflammation and heat in the skin. *Shirisha's Pitta-Hara* and *Sheeta Virya* (cooling potency) properties help in reducing the heat and inflammation, while *Gandhaka's* stronger anti-inflammatory effects also target the redness caused by Pitta. Despite *Gandhaka's* slightly better result, the statistical insignificance of the difference shows that both treatments are equally effective in reducing redness.

3. ***Pidaka*** **(Pustules/Blisters**):

Both groups showed significant improvement in the reduction of pustules, with Group A showing 92.17% relief and Group B showing 80.92% relief. The p-value of 0.082 indicates that the difference is not statistically significant. Pustules are primarily caused by the accumulation of *Kapha* and *Pitta Doshas* in the skin. *Shirisha Twak Malahara* , with its *Tridosha Hara* properties, especially its action on *Kapha* and Pitta, helps clear the blocked skin channels, leading to the resolution of pustules. *Gandhaka Malahara*, through its antimicrobial and *Kapha*-pacifying actions, similarly reduces pustules. The slightly better performance of *Shirisha* in this case does not detract from the overall conclusion that both treatments are equally effective in treating pustules.

4. ***Daha*** **(Burning Sensation):**

In treating the burning sensation, Group A showed 95.64% relief, while Group B showed 90.5%, with a p-value of 0.300, suggesting no significant difference. Burning sensations in *Dadru Kushta* are caused by aggravated *Pitta Dosha*, leading to excessive heat and inflammation in the skin. *Shirisha's* strong *Pitta-Hara* properties and the cooling effects of ingredients like *Siktha* and *Tila Taila* help to pacify the Pitta and reduce the heat, thereby relieving the burning sensation. *Gandhaka* also possesses anti-inflammatory properties that help reduce burning, making it similarly effective. The comparable relief rates between the two groups demonstrate that both formulations are effective in managing the burning sensation in *Dadru Kushta*.

**5. *Rukshata* (Dryness):**

Both *Shirisha Twak Malahara* and *Gandhaka Malahara* were equally effective in reducing skin dryness, with Group A showing 89.47% relief and Group B showing 89.65%. The p-value of 0.819 confirms that there was no statistically significant difference between the two groups. Dryness in *Dadru Kushta* is caused by the imbalance of *Vata Dosha*, which leads to reduced moisture in the skin. *Shirisha's Vata-Hara* properties, along with the moisturizing effect of *Tila Taila*, help to restore skin hydration and balance the dryness. *Gandhaka Malahara* also contains emollient ingredients that nourish the skin and reduce dryness. The nearly identical results in both groups confirm that both formulations are equally effective in treating skin dryness.

6. ***Udgata Mandala*** **(Raised Patches):**

In treating raised patches, Group A showed 75% relief, while Group B showed 83.6%, with a p-value of 0.908, indicating no significant difference between the two groups. Raised patches in *Dadru Kushta* are mainly caused by the accumulation of *Kapha Dosha*, leading to thickening and swelling of the skin. *Shirisha's Kapha-Hara* properties, although effective, act more gently, while *Gandhaka's Ushna* (hot) and *Tikshna* (sharp) properties break down the *Kapha* accumulations more aggressively. Despite *Gandhaka's* slightly better performance, the overall relief rates show that both ointments are comparably effective in reducing raised patches, as they both target *Kapha Dosha*.

## DISCUSSION ON MODE OF ACTION OF MALAHARA:

*Dadru Kushta* is a skin condition primarily influenced by an imbalance of *Pitta* and *Kapha* doshas, affecting the deeper layers of the skin, specifically the fourth layer known as *Tamra*. This layer is akin to the *Malpighian* layer of the epidermis in modern anatomy, which is crucial for skin regeneration and repair. In treating skin disorders like *Dadru Kushta*, topical treatments are often more effective than internal medicines. This is because applying a treatment directly to the affected skin allows the medicinal properties to act locally, addressing the condition at the site where it manifests. This approach, referred to as *Bahirparimarjana* or external treatment in *Ayurveda*, facilitates quicker and more targeted relief by penetrating the skin layers and balancing the *Doshas* directly where they are disrupted.

**Discussion on Probable mode of action of *Shirisha Malaharar*:** *Shiriisha Twak Malahara*, made from *Shirisha Twak Churna* combined with *Tila Taila* and *Siktha*, is effective in treating *Dadru Kushta* due to its unique combination of properties. The *Shirisha Twak Churna* has a *Kashaya, Thikta*, and *Madhura* taste and qualities like *Laghu* (light), *Ruksha* (dry), and *Tikshna* (sharp), which help to clear blockages in the sweat channels and expel toxins through sweat, thus unclogging microchannels[170]. *Siktha* and *Tila Taila* balance the sharpness of the Shirisha, reducing burning sensations and soothing the skin. This formulation effectively addresses symptoms such as itching (*Kandu*) and raised patches (*Utsanna* Mandala) by leveraging its *Kaphaja* (*Kapha*-related) properties, while its *Varnya* (skin-nourishing) and *Kushtagna* (anti-skin disease) qualities significantly reduce redness (Raga), pustules (*Pidaka*), and dryness (*Twakrukshata*)[185-186].

### Probable Mode of action of *Gandhaka Malahara*

Gandhaka Malahara, composed of *Shuddha Gandhaka, Siktha* (beeswax), and *Tila Taila* (sesame oil), acts effectively against skin conditions like *Dadru Kushta*. Its *Ushna Veerya* (hot potency) helps to digest and eliminate toxins locally by promoting sweat (*Swedana*), which aids in removing impurities from the skin. The *Tikta* (bitter) and *Kashaya* (astringent) tastes, along with the *Lekhaniya* (scraping) properties of *Gandhaka*, work to clear out *Dushta Kapha* (vitiated *Kapha*) and Pitta from the skin. This combination not only targets the symptoms of *Dadru Kushta* but also has the capacity to treat other skin conditions such as *Kanchi, Visarpa*, and *Krimi Roga*. Overall, *Gandhaka Malahara* effectively addresses a range of skin disorders by removing toxins, balancing *Doshas*, and promoting skin health[187].

## CONCLUSION

- The study elucidates the effectiveness of *Shirisha Twak Malahara* and *Gandhaka Malahara* in the management of *Dadru Kushta*, a condition characterized by symptoms akin to those observed in Tinea infections.
- Both formulations have demonstrated significant efficacy in alleviating various symptoms associated with this condition, such as itching, redness, pustules, burning sensation, dryness, and raised patches.
- *Shirisha Twak Malahara* and *Gandhaka Malahara* are both valuable in treating *Dadru Kushta*, yet each formulation brings unique therapeutic benefits to the table. The comprehensive evaluation of these treatments highlights their ability to address the multifaceted symptoms of *Dadru Kushta* effectively.
- *So here the null hypothesis is accepeted that there is no statistically significant difference between the effect of Shirisha Twak Malahara and Gandhaka Malahara in the management of dadru kushta in children*

## FUTURE RESEARCH DIRECTIONS

To optimize the management of *Dadru Kushta*, future research should focus on extending treatment durations to evaluate long-term benefits, exploring combination therapies that integrate external and internal

treatments, examining gender-based differences in treatment responses for personalized approaches, and conducting large-scale studies to validate findings and refine protocols. *Shirisha Twak Malahara* and *Gandhaka Malahara* are valuable therapeutic options, each with distinct benefits, and further exploration in these areas could enhance their effectiveness and patient care.

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