

“Randomized open controlled clinical study of therapeutic effect of *Sarivadyataila* external application as *Shiroabhyanga* with comparison to *gunjataila* external application as *Shiroabhyanga* in *Darunaka* patients with special reference to *Pityriasis capitis* (dandruff).”

Jaiswal Shubham Santoshlal*¹, Jaiswal MamtaS.², Jamdhade SubhashB.³

P.G. Scholar¹, Assistant Professor², Professor and HOD³
 Kayachikitsa Department, D.M.M. Ayurved College, Yavatamal, Maharashtra, India

*Corresponding author: shubham.jaiswal.kap77@gmail.com

ABSTRACT

Introduction –*Darunaka* is a *KapalgataRoga* in the opinion of *AcharyaVagbhata* and *Sharangadhara*, although *AcharyaSushruta* and other *Acharya* classified the disease as a *KshudraRoga*. In *Darunakavyadhi*, symptoms like *Kandu* (itching), *Rukshata* (dryness), *twaka-sphutan* (scaling), and *Keshachyuti* (hair fall) emerge as a result of the vitiation of the *Vata* and *KaphaDosh*. *Sarivadyataila* is used in the administration of *Darunaka*, according to *Gadanigraha*. **Aim and objective** –To study the therapeutic effect of external use of *Sarivadyataila* as *Shiroabhyanga* with compare to external application of *GunjaTaila* as *Shiroabhyanga* in the management of *Darunaka*. **Material and methods** – total 76 patients of *Darunaka* were selected randomly, which is then divided into two equal groups i.e. 38 patient in each

group. Giving intervention by *Sarivadyataila Shiroabhyanga* for group A and *GunjaTaila* for Group B for 30 days' treatment and followed up taken for post therapy 30 days. Analysis of all patient were done and after that result and conclusion were drawn. **Result and Conclusion** –*Sarivadyataila* and *GunjaTaila* both are effective in the management of *Darunaka* to reduce the sign, symptoms i.e. *Kandu*, *Keshachyuti*, *Rukshata*, *Twakasphutana*. On the basis of overall percent relief, *Sarivadyataila* external application as *Shiroabhyanga* has found more effective than that of *GunjaTaila* external application as *Shiroabhyanga* in the management of *Darunaka*.

Keyword– *Sarivadyataila*, *Darunaka*, *pityriasis capitis*, dandruff, *GunjaTaila*, *Shiroabhyanga*.

INTRODUCTION- Ayurveda is deep ocean of knowledge in which not only systemic diseases but also local minor diseases are described in detail. Cosmetic diseases are the diseases which affects emotional, psychological and social well-being of affected person. *Darunaka* is harmless causing no pain but lower self-confidence and leads to psychological stress. *Darunaka* is ignored most of the times. Now a day's healthy hair plays a most important role in personality. Everyone is very conscious about hair care and *Darunaka* is one of the major causes of hair loss (according to *Ashtang Hridaya Keshachyuti* i.e. hair loss is one of the symptom). According to *Vagbhata* and *Sharangadhara* *Darunaka* is *KapalgataRoga* but *Sushruta* and other *Acharya* explained *Darunaka* disease under *KshudraRogas*.

Now a day's pollution is increased and due to busy life style people are taking fast food like *Ahar* and improper *Vihar*, many of young peoples are applying chemicals over scalp to styling the hair and these people not applying proper hair oil etc. causing incidence of *Darunaka* with symptoms like *Kandu*, *Rukshata*, *Twaksputan*, *Keshachyuti* etc due to vitiation of *Vata* and *KaphaDosha*.

Due to similarity of sign and symptoms, In Ayurveda the nearest correlation of dandruff (*pityriasis capitis*) and seborrheic dermatitis can be made with *Darunaka*. The scalp forms skin cells on a continuous basis, therefore the shedding of dead skin cells is also a natural process. In case of dandruff, the skin cells shed at a faster rate than usual. The worldwide prevalence of seborrheic dermatitis is around 5% but the prevalence of its non-inflammatory variant, dandruff

(*pityriasis capitis*) is 50% in general population. *Darunaka* affecting the large population. It occurs in both sexes and persons of all races. It is extremely difficult to take adequate care of hair in today's fast life hence the incidence of *Darunaka* is increasing. If it is not treated in time the severity of it may occur and may complication (*Upadrava*) like blepharitis, acne, seborrheic dermatitis etc. may occur. So there is need to find effective and safe treatment of *Darunaka*.

AIM AND OBJECTIVES

Primary objectives

1. To study the therapeutic effect of external use of *SarivadyaTaila* as *Shiroabhyanga* with compare to external application of *GunjaTaila* as *Shiroabhyanga* in the management of *Darunaka*

Secondary objectives

1. To study details about *SarivadyaTaila* and classical view of *Darunaka*.
2. To evaluate the efficacy of *GunjaTailaShiroabhyanga* in the management of *Darunaka*.
3. To compare the effects of *shiroabhyang* with *SarivadyaTaila* and *GunjaTaila* in the management of *Darunaka*

MATERIAL AND METHODS-

Study Design: Prospective, randomized, controlled, open labelled clinical study.

Place— PG Department of *kayachikitsa* *Laxmanrao Kalasapurakar Ayurved College*, *Yavatamal*, affiliated with *D.M.M, Ayurved College, Yavatamal*

Duration: One-month drug intervention and after that one month follow up.

SELECTION OF PATIENT –**INCLUSIVE CRITERIA**

- Ambulatory patients of both sexes with an age group between 14 to 70 yrs.
- Cases with classical sign and symptoms of *Darunaka* were considered i.e. *Kandu* (itching), *TwakaSputana* (scaling of skin), *Rukshata* (dryness of scalp), *Keshchyuti* (hair fall)
- Patients willing for clinical trial.
- Irrespective of gender, occupation, Religion, economical barrier.
- patient who will fulfill criteria and take regular medicines with regular follow up.

EXCLUSION CRITERIA

- Patients with severe dermatitis involving face, neck and extremities.
- Psoriasis, allergic contact dermatitis.
- *Indralupta* (alopecia areata)
- Patient with *DushtaVrana* over scalp
- Age group below 13 years and above 70 years.

WITHDRAWAL FROM THE STUDY

- Patient not following regular follow up.
- Change of patient mind not willing to continue treatment.
- Allergies to trial medicine
- Worsening the disease condition severely while taking the trial medicine drug.



| Group | Group A | Group B |
|------------------------|---|---|
| Number of Patients | 38 | 38 |
| Treatment | <i>SarivadyaTaila</i> | <i>GunjaTaila</i> |
| Dose | 5 ml | 5 ml |
| <i>Kalpna</i> | <i>Taila</i> (oil) | <i>Taila</i> (oil) |
| Duration | 30 days therapy and post therapy 30 days follow up | 30 days therapy and post therapy 30 days follow up |
| Time of Administration | Once in night (before one hour of bed time) | Once in night (before one hour of bed time) |
| Route | Local (<i>Shiroabhyanga</i>) | Local (<i>Shiroabhyanga</i>) |

TREATMENT DETAILA-**Contents of SarivadyaTaila**

Sariva, *Ugra* (*Vacha*), *Amruta* (*Guduchi*),
Yastimadhu, *Triphala*, *Nilautpala*

(*Nilkamal*), *Nili*, *Bhrungaraj*, *Kasis*,
Mahanimb, *Madanphala*, *KatuTaila*, *Yava*.

Contents of Gunja Taila

Gunja, *Bhrungaraj*, *TilaTaila*

ASSESSMENT CRITERIA:

| Grade \ Symptoms | <i>Keshachyuti</i> (Hair Fall) | <i>Rukshata</i> (Dryness Of Scalp) | <i>Kandu</i> (Itching) | <i>TwakSputan</i> (Scaling / Crackling Of Skin) |
|--------------------------------|--|---|---|---|
| GRADE 0 G 0 | Absent (no hair fall i.e. upto 10 hair) | Absent (no dryness) | No itching | No scaling (absent) |
| GRADE 1 G 1 | Hair fall after washing hair (10-20, occasionally) – mild | Negligible (dryness with rough skin) – mild | Itching only once or twice a day (occasionally / tolerable) - mild | Scaling absent during combing of hairs but seen over the scalp only after thorough examination of hairs or scaling <1/4 th part usually on vertex (visible inside the hair) – mild |
| GRADE 2 G 2 | Hair fall during combing or washing of hair (20-30, moderate loss) – moderate | Without discomfort on scalp (dryness with scaling) – moderate | Intermittent itching for more than 10 times a day (frequently / non tolerable but not disturb sleep) - moderate | Scaling seen only at the time of combing or scaling is more than 1/2 part (visible over the hair) – moderate |
| GRADE 3 G 3 | Hair fall at any time and also on touch or simple hand strength (numerous / maximum loss) – severe | With discomfort on scalp dryness with cracking) – severe | Itching continuous during day (constantly / disturb sleep and other activity) - severe | Scaling seen at the time of combing and also at other time or complete scaling (spread over the shoulder) - severe |

OBSERVATION AND RESULT

1. KeshabhumiKandu

Using one tailed Wilcoxon signed rank test

| Group | Mean score | | | Median diff. | IQR of diff. $Q_3 - Q_1$ | Sample size | Wilcoxon signed rank test (T+) | P Value |
|---------|------------|------|------|--------------|--------------------------|-------------|--------------------------------|---------|
| | B.T | A.T | Diff | | | | | |
| Group A | 2.47 | 0.31 | 2.16 | 2.5 | 1.0(3.0 - 2.0) | 38 | 703.00 | < 0.05 |
| Group B | 2.21 | 0.31 | 1.90 | 2.0 | 0.75 (2.0 - 1.25) | 38 | 741.00 | < 0.05 |

For group A and group B, the median reduction in *Keshabhumi Kandu* score after treatment is significant (P-value < 0.05) at 5% level of significance. i.e. it

can be said that there is significant reduction in *Keshabhumi Kandu* for group A and group B.

Comparative Analysis of Groups:

Using Mann-Whitney U test,

| Group | Median difference (bef-aft) | Mean of difference (bef-aft) | S.D. of difference (bef-aft) | Mann-Whitney U statistic | P- Value |
|---------|-----------------------------|------------------------------|------------------------------|--------------------------|----------|
| Group A | 2.5 | 2.1578 | 0.6788 | 883.00 | 0.02922 |
| Group B | 2.00 | 1.8947 | 0.6488 | | |

Reductions in *KeshabhumiKandu* score for group A were significantly higher (p-value = 0.0292) at 5% level of significance than group B.

Thus, treatment A can be considered as more efficacious in reducing *Keshabhumi Kandu* than treatment B.

2. Keshchyuti

Using one Tailed Wilcoxon signed rank test

| Group | Mean score | | | Median diff. | IQR of diff. $Q_3 - Q_1$ | Sample size | Wilcoxon signed rank test (T+) | P Value |
|---------|------------|------|------|--------------|--------------------------|-------------|--------------------------------|---------|
| | B.T | A.T | Diff | | | | | |
| Group A | 2.39 | 0.39 | 2.00 | 2.00 | 0.0(2.0 - 2.0) | 38 | 738.5 | < 0.05 |
| Group B | 1.94 | 0.42 | 1.52 | 2.00 | 1.0 (2.0 - 1.0) | 38 | 666.00 | <0.05 |

For group A and group B., the median reduction in *Keshchyuti* score after treatment is significant (P-value < 0.05)

at 5% level of significance. i.e. it can be said that there is significant reduction in *Keshchyuti* for group A and group B.

Comparative Analysis of Groups:

Using Mann-Whitney U test,

| Group | Median difference (bef-aft) | Mean of difference (bef-aft) | S.D. of difference (bef-aft) | Mann-Whitney U statistic | P-Value |
|---------|-----------------------------|------------------------------|------------------------------|--------------------------|---------|
| Group A | 2.00 | 2.00 | 0.6974 | 1006.00 | <0.05 |
| Group B | 1.5 | 1.5263 | 0.7254 | | |

Reductions in *Keshchyuti* score group A were significantly higher (p -value <0.05) at 5% level of significance than group B.

Thus, treatment A can be considered as more efficacious in reducing *Keshchyuti* than treatment B.

3. KeshabhumiRukshata

Using one Tailed Wilcoxon signed rank test,

| Group | Mean score | | | Median diff. | IQR of diff. Q ₃ - Q ₁ | Sample size | Wilcoxon signed rank test (T+) | P Value |
|---------|------------|------|------|--------------|--|-------------|--------------------------------|---------|
| | B.T | A.T | Diff | | | | | |
| Group A | 2.28 | 0.31 | 1.97 | 2.00 | 0.0 (2.0 - 2.0) | 38 | 741.00 | <0.05 |
| Group B | 1.63 | 0.34 | 1.28 | 2.00 | 1.0(2.0 -1.0) | 38 | 666.00 | <0.05 |

For group A and group B, the median reduction in *KeshabhumiRukshata* score after treatment is significant (P-value <0.05) at 5% level of significance. i.e. it

can be said that there is significant reduction in *KeshabhumiRukshata* for group A and group B.

Comparative Analysis of Groups:

Using Mann-Whitney U test,

| Group | Median difference (bef-aft) | Mean of difference (bef-aft) | S.D. of difference (bef-aft) | Mann-Whitney U statistic | P- Value |
|---------|-----------------------------|------------------------------|------------------------------|--------------------------|----------|
| Group A | 2.00 | 1.9736 | 0.5921 | 1111.00 | <0.05 |

| | | | | | |
|----------------|------|--------|--------|--|--|
| Group B | 1.00 | 1.2894 | 0.6537 | | |
|----------------|------|--------|--------|--|--|

Reductions in *KeshabhumiRukshata* score for group A were significantly higher (p –value <0.05) at 5% level of significance than group B.

Thus, treatment A can be considered as more efficacious in reducing *KeshabhumiRukshata* than treatment B.

4. Twakasphutana

Using one Tailed Wilcoxon signed rank test,

| Group | Mean score | | | Median diff. | IQR of diff. Q ₃ – Q ₁ | Sample size | Wilcoxon signed rank test (T+) | P Value |
|----------------|------------|------|------|--------------|--|-------------|--------------------------------|---------|
| | B.T | A.T | Diff | | | | | |
| Group A | 2.36 | 0.36 | 2.00 | 2.00 | 0.0(2.0 – 2.0) | 38 | 703.00 | <0.05 |
| Group B | 1.97 | 0.5 | 1.47 | 2.00 | 1.0(2.0 – 1.0) | 38 | 703.00 | <0.05 |

For group A and group B, the median reduction in *Twakasphutana* score after treatment is significant (P-value <0.05)

at 5% level of significance. i.e. it can be said that there is significant reduction in *Twakasphutana* for group A and group B.

Comparative Analysis of Groups:

Using Mann-Whitney U test,

| Group | Median difference (bef–aft) | Mean of difference (bef–aft) | S.D. of difference (bef–aft) | Mann-Whitney U statistic | P- Value |
|----------------|-----------------------------|------------------------------|------------------------------|--------------------------|----------|
| Group A | 2.00 | 2.00 | 0.7352 | 1009.00 | 0.0006 |
| Group B | 1.00 | 1.4736 | 0.6466 | | <0.05 |

Reductions in *Twakasphutana* group A were significantly higher (p –value =0.0006) at 5% level of significance than group B.

Thus, treatment A can be considered as more efficacious in *Twakasphutana* than Treatment B.

| Parameter | Group A | | | Group B | | | Comparative Efficacy |
|-------------------------|-------------|---------|--------|-------------|---------|---------|----------------------|
| | Result | Day 30 | Day 60 | Result | Day 30 | Day 60 | |
| <i>Keshabhumi Kandu</i> | Significant | 97.36 % | 87.71% | Significant | 93.42 % | 85.52 % | Treatment A |
| <i>Keshchyuti</i> | Significant | 92.98 % | 82.01% | Significant | 90.35 % | 78.50 % | Treatment A |
| <i>Keshabhumi</i> | Significant | 96.49 | 86.84% | Significant | 90.78 | 80.70 | Treatment |

| | | | | | | | |
|----------------------|-------------|---------|--------|-------------|---------|---------|-------------|
| <i>Rukshata</i> | t | % | | | % | % | A |
| <i>Twakasphutana</i> | Significant | 92.54 % | 82.45% | Significant | 88.15 % | 75.87 % | Treatment A |
| Mean Improvement | % | 94.84 % | 84.75% | | 90.68 % | 80.15 % | |

According to % Relief In Symptoms

Distribution Of Patients According To Relief:

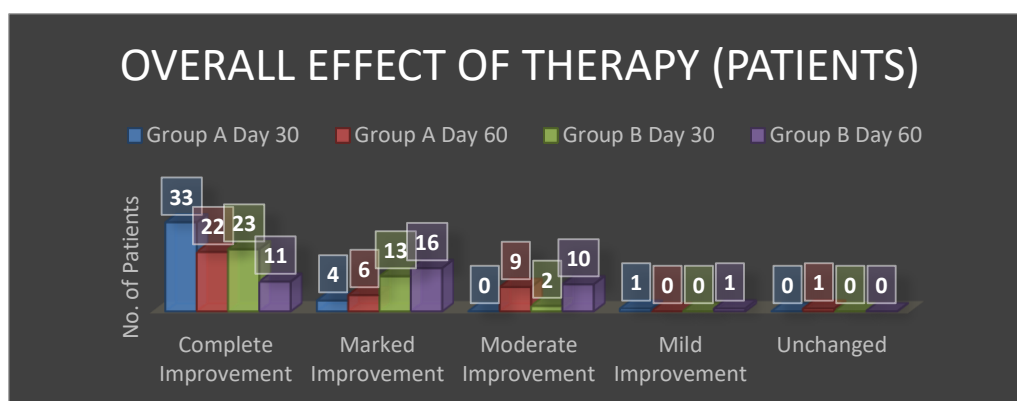
| Overall Effect (patient wise) | Criteria |
|-------------------------------|--|
| Marked improvement | >75 % relief in signs and symptoms |
| Moderate improvement | >50 % to 75 % relief in sings & symptoms |
| Mild improvement | >25% & 50% relief in sings & symptoms |
| Unchanged | Up to 25% relief in sings & symptoms |

For assessment, all the assessment parameters were used.:

Distribution of patients according to relief:

% Improvement According to Patients

| PATIENTS | Group A | | Group B | |
|-----------------------------|-----------|-----------|-----------|-----------|
| | Day 30 | Day 60 | Day 30 | Day 60 |
| Complete Improvement | 33 (87%) | 22 (58%) | 23 (61%) | 11 (29%) |
| Marked Improvement | 04 (10%) | 06 (15%) | 13 (34%) | 16 (42%) |
| Moderate Improvement | 00 (00%) | 09 (24%) | 02 (05%) | 10 (26%) |
| Mild Improvement | 01 (03%) | 00 (00%) | 00 (00%) | 01 (03%) |
| Unchanged | 00 (00%) | 01 (03%) | 00 (00%) | 00 (00%) |
| total | 38 (100%) | 38 (100%) | 38 (100%) | 38 (100%) |



DISCUSSION

1. Statistical analysis – in trial group (Group A - *SarivadyaTaila*) and in control group (Group B -*GunjaTaila*) (by Wilcoxon Signed Rank test)

From tables we can observed that P values of Group A and Group B are less than 0.05 in *Kandu*, *Keshachyuti*, *keshbhumiRukshata*, *Twakasphutanasymp*ptoms of *Darunaka*. The test has shown significant difference between D0 and D60 symptoms scores. It is hence concluded that *SarivadyaTailaShiroabhyanga* and *GunjaTailaShiroabhyanga* has significantly reduced *Kandu*, *Keshachyuti*, *KeshabhumiRukshata*, *Twakasputana* symptoms of *Darunaka*.

2. Statistical analysis – comparison of Group A and Group B (by Mann Whitney's U test)

By Mann Whitney's U test both the group were statistically analyzed – As per my study hypothesis, the test showed significantly effect between mean difference of Group A and Group B.

It shows that Group A (*SarivadyaTaila*) (trial group) was significantly more effective than Group B (*GunjaTaila*) (control group) in symptoms like *Kandu*, *Keshachyuti*, *KeshabhumiRukshata*, *Twakasphutana*.

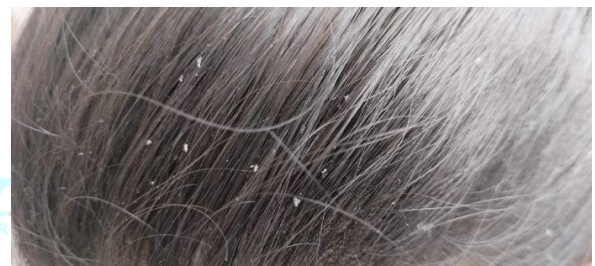
Mean % improvement

Group A (*sarivadyataila*) shows 94.54% improvement on D30 and 84.75% improvement on D60.

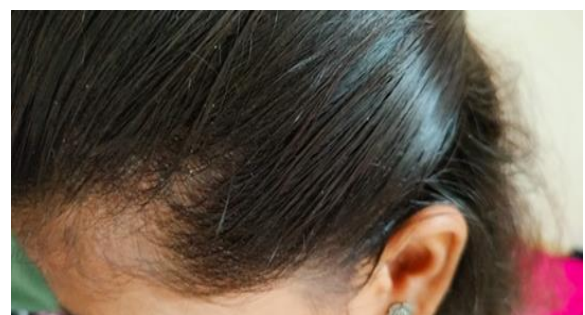
Group B (*gunja taila*) shows 90.68% improvement on D30 and 80.15% improvement on D60.

So it can be stated that *sarivadyataila* is more effective than *gunja taila* in the management of *darunaka* to reduce the symptoms.

BEFORE TREATMENT



AFTER TREATMENT



CONCLUSION-

SarivadyaTaila and *GunjaTaila* both are effective in the management of *Darunaka* to reduce the sign, symptoms i.e. *Kandu*, *Keshachyuti*, *Rukshata*, *Twakasphutana*.

On the basis of overall percent relief and by Mann Whitney's U test, *SarivadyaTaila* external application as *Shiroabhyanga* has found more effective than that of *GunjaTaila* external application as *Shiroabhyanga* in the management of *Darunaka*.

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Jaiswal Shubham Santoshla, Jaiswal Mamta S., Jamdhade Subhash B.

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