

COMPARATIVE CLINICAL STUDY ON EFFICACY OF LOMASHATANA LEPA IN FACIAL HIRSUTISM

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ABSTRACT

Hirsutism is a common dermatological feature in women with PCOS. An emergence of PCOS in adolescents and reproductive aged women and lacuna in contemporary medical system to successfully address this problem with OC pills or even Laser therapy has necessitated search for an effective, safe and economical treatment in alternative medical field. Study aimed to evaluate and compare the therapeutic efficacy of *HarataladiLepa* and *ShamibeejadiLepa* on the hirsutism in diagnosed patients with PCOS, or with idiopathic hirsutism and to find a safe, effective, economical topical application for facial hirsutism. Randomized open labeled clinical trial on 32 women patients diagnosed with PCOS or idiopathic hirsutism visiting the OPD of Dept. Of Samhita, SDM College of Ayurveda, Udupi. Methods and Material: Total of 32 patients, 16 in each group fulfilling the inclusion criteria were registered and allocated randomly in two groups as Group H-*HarataladiLepa*, and Group S-*ShamibeejadiLepa*. *Lepa* was applied topically for 45 days and followed up for 45 days. Total of 30 patients completed the course of treatment, 15 each in Group H and Group S. Two patients were drop outs one from each group. The assessment was done by specially developed scoring pattern for cardinal features and Modified FG score for facial hirsutism. Statistical analysis used: Paired and unpaired t test using Sigma stat 3.5. The outcome was assessed by the reduction in hair density [marked relief (50%), moderate relief (16.67%) and complete cure (10%)] and the reduction in hair re-growth [marked relief (46.67%), moderate relief (13.33%) and completely cured (33.33%)]. Based on symptomatic relief, the overall effect of therapy on facial hirsutism was observed as (10)33.33% patients got marked relief, (16)53.33% patients got moderate relief, (3) 10% had mild relief. The remaining (1) 3.33% patient remained unchanged. Both *Harataladi* and *ShamibeejadiLepa* are effective in the management of facial hirsutism due to either PCOS or idiopathic origin.

Keywords: Hirsutism, *HarataladiLepa*, *ShamibeejadiLepa*

INTRODUCTION

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Skin represents the outward appearance to the world, unsightly blemishes or lesions can have a significant impact on an individual's self-esteem irrespective of the extent of lesion.

Diseases related to this largest organ account for a great deal of misery, suffering, isolation, inferiority complex and economic loss. Social stigma associated with hirsutism results in morbid-

ity due to psychological stress especially in adult female population. Incidence of hirsutism in Indian women with PCOS is 44.16% and among them 83% had hyperandrogenism¹.

Hyperandrogenism² associated with Poly Cystic Ovary Syndrome (PCOS) accounts for conversion of vellus hairs to terminal hairs in anagen phase (<0.5mm length) under the influence of free testosterone and Insulin like Growth Factors (IGF). *KashyapaSamhita* mentioned *Pushpaghni-Jataharini*³ characterized by *Sthoulya* and *Lomashaganda* (hairy and corpulent cheeks) which can be clinically correlated with manifestations of hirsutism in PCOS. *Atilomata* in *Ashtaninditiya Adhyaya* of *CharakaSamhita*⁴ is another context where in the inference of endocrinal etiology for excessive hair growth may be found. Though the *LepaKalpana* doesn't address the basic pathophysiology, it alleviated the stress of the patients i.e. *DukhaHetu* in its cosmetological view point. So, the present study was carried out to evaluate the clinical efficacy of *LomashatanaLepa*⁵ in facial hirsutism. Thus, it was a preliminary effort to manage the psychological impact of this somatic condition through the principles of Ayurveda and to develop more effective, safe, conservative and noninvasive standard drug and establish it.

Aim and Objectives:

- To evaluate and compare the therapeutic efficacy of *HarataladiLepa*⁶ and *ShamibeejadiLepa*⁷ on facial hirsutism in diagnosed patients with PCOS or with idiopathic hirsutism.
- To find a safe, effective, economical; topical application for facial hirsutism.

Materials and Methods:

Design of the study: An open labeled randomized clinical trial (Allocation-coin toss method).

Sample size and Settings:

A total of 32 diagnosed patients of PCOS with hirsutism and or Idiopathic hirsutism fulfilling the inclusion criteria were registered from the O.P.D. and I.P.D. of SDM College of Ayurveda, Udupi.

Intervention: In Group H –*HarataladiLepa* and in Group S-*ShamibeejadiLepa*- topical application over chin and cheeks, to thickness of <1 cm. for 45 days and followed up for 45 days after comment

P3 Ethical clearance was obtained from the Institutional Ethical Clearance Committee-Human; Ref. No. SDMCAU/ACA-49/EC12/11-12 dated 15/05/2013 and an informed written consent was obtained from all the subjects prior to the clinical trial.

Drugs & Method of preparation:

1. The raw drugs were procured, identified and authenticated from the Pharmacy, of the College of Ayurveda.
2. The *Shamibeeja* was collected personally from its natural habitat.

Method of preparation of *Harataladi Lepa*:

Shankha was powdered finely filtered through cloth; *Sarjikhshara* was prepared and preserved in air tight containers. *Haratala* and *Manashila* were finely powdered and all the drugs were mixed proportionately and the mixture was preserved in air tight containers.

Shamibeejadi Lepa- *Kadali Kanda*, *Shyonaka Mulatvak* were dried and burnt into ashes. *Shamibeeja*, *Haratala*, *SaindhavaLavana* were powdered separately. All of them were taken in equal quantity and mixed properly. Then the products are sieved and stored in air tight containers.

• Primary Outcome Parameters

- A) Subjective parameters: Percentage improvement in hirsutism and gradation of other symptoms.
- B) Objective parameter: Percentage improvement in Ferrimann Gallwey Scoring⁸

- **Secondary Outcome Parameter:** Subjective: Symptomatic relief in patients.

Inclusion Criteria:

1. Females with idiopathic hirsutism.
2. Diagnosed patients of PCOS presenting with features of facial hirsutism.
3. Women aged between 16 to 40 years.
4. Women willing to sign the informed written consent.

Criteria for Exclusion:

1. The patients with history of skin allergy and any skin related disorder.

2. Diagnosed cases of Congenital Adrenal Hyperplasia and other endocrine disorders.
3. Androgen secreting tumors of ovary.

Laboratory Investigations:

Routine haematological and biochemical investigations were carried out wherever found necessary or the available reports from the patients were evaluated.

Haematology: Haemoglobin, T.L.C., D.L.C., E.S.R.

Bio-chemistry: S.TSH (B. T), S.FSH, S. LH

Ethical clearance was obtained from the Institutional Ethical Clearance Committee- Human. Bilingual (Kannada, English) informed written consent was obtained from all the subjects prior to the clinical trial.

The clinical trial protocol and the Case Record Forms for clinical trial were designed basing on available standard protocols for assessment of hirsutism.

Scoring Pattern used to assess various parameters: Hirsutism was assessed using **Modified Ferriman- Gallwey (MFG) scoring pattern**. The minimum score was eight and the maximum score was recorded as 36. The same was modified for evaluation of facial hirsutism with minimum score as two and maximum as eight.

Therapeutic outcome was assessed by adopting standard protocol for scoring of cardinal features like reduction in hair density, changes in pigmentation of skin, redness, itching, burning sensation, swelling and delay in hair re-growth as mentioned below.

Assessment of reduction in hair density

- 0- No reduction in hair density
- 1- Mild reduction 0-25%
- 2- Moderate reduction 26-75%
- 3- Marked reduction 76-100%

Assessment of Burning Sensation

- 0- No Burning sensation
- 1- Mild Burning sensation - 0-25%
- 2- Moderate Burning sensation - 26-75%
- 3- Marked Burning sensation - 76-100%

Assessment of re-growth of hairs

- 0- No re-growth of facial hairs
- 1- Mild re-growth after threading (if any done) 0-25%

- 2- Moderate re-growth after threading (if any done) 26-75%
- 3- Marked re-growth after threading (if any done) 76-100%

Modified Ferriman Gallwey score: (Face, Chin, Chest, Abdomen, Buttocks)

Mild coverage

- 1- Moderate coverage
- 2- Complete light coverage
- 3- Heavy coverage

Total Score: B.T. - Day 0D.T. - 15th Day, 30th Day
A.T. - 45th Day.

After Follow up period of 45 days.

For whole Body / For Face and Chin, Cheeks

Score 8-16	-	Mild
Score 2-4	-	Mild
Score 17-24	-	Moderate
Score 5-6	-	Moderate
Score 24-36	-	Severe
Score 7-8	-	Severe

A total Minimum Score ≥ 2 is a sign of facial hirsutism. Maximum score ≤ 8

Statistical Design

The data generated in the clinical study was analyzed by applying paired and unpaired 't' test using Sigma Stat 3.5 and level of significance was calculated as $P > 0.05$ -Statistically non-significant, $P < 0.05$ -Significant and $P < 0.001$ - Highly significant.

Interpretation of Results was done as 25%-Unchanged, 26-50%-Mild relief, 51-75%-Moderate relief, >75%-Marked relief and 100%-Completely cured.

Observations and Results:

Maximum i.e. 75% patients of Group H and 62.50% patients of Group S and a total of 68.75% patients belonged to age group of 21-30 years. Maximum i.e. 43.75% patients in Group H and 31.25% in Group S were housewives; and a total of 43.75% patients belonged to student community which shows the increased incidence of reported cases of hirsutism in this group.

Maximum i.e. 75% in Group H and 81.25% in Group S and a total of 78.13% patients had hirsutism (*Atilomata*) for > 1 year. Maximum i.e. 87.50% patients, each from Group H and

Group S had *Lomashaganda* for > 1 year which shows the chronic nature of complaints.

In Group H, 68.75% and 37.50% patients in Group S and a total of 65.63% patients had *Shoulya* for more than one year. *AlpaPravritti* of *Artava* was observed in 62.50% patients in Group H and 43.75% patients in Group S and a total of 59.38% patients had scanty bleeding during menses for more than 1 year. *AtiPravritti* of *Artava* was observed in 31.25% patients in Group H and 43.75% patients in Group S and a total of 37.50% of patients had *AtiPravritti* of *Artava* (excessive bleeding during menses) for more than one year. Maximum i.e. 68.75% in Group H & 62.50% patients of Group S and a total of 65.63% patients had irregular cycles. *Youvanapidaka* (acne) was seen in 50% patients in Group H and 43.75% of Group S and a total of 46.88% patients had *Youvanapidaka* for more than one year. *Neelika* (*Acanthosis Nigricans*) was observed among 18.75% patients in Group H only and thus total incidence was 9.28% patients for more than one year. Among 32 patients *Swedadhikyata* was reported in 12.50% patients in Group H and 31.25% patients in Group S, with total incidence of excessive sweating in 21.87% patients. These show the prevalence of metabolic and endocrinal disorders in hirsutism due to PCOS.

Family history of hirsutism was observed in 6.25% patients in Group H and 25% patients in Group S with a total incidence of 15.63%.

On analyzing the causative factors for hirsutism; 81.25% and 62.50% patients of Group H and Group S respectively and a total of 71.88% patients had hirsutism due to underlying pathology of PCOS. Idiopathic cause for hirsutism was elicited in 18.75% and 37.50% patients of Group H and Group S respectively and a total of 28.13% patients had unknown causes for hirsutism.

Mild, moderate and severe hirsutism was found (BT) in 56.25% & 43.75%; 31.25% & 50%; 12.50% & 6.25% patients in Group H and Group S respectively. In total mild (50%), moderate (40.63%) and severe hirsutism (9.38%) was observed before trial. Mild, moderate and severe facial hirsutism was observed (BT) in 12.50% & 6.25%; 62.50% patients each in both groups; and 25% & 31.25% patients of Group H and Group S

respectively before trial. A total of 9.38%, 62.50% and 28.13% patients had mild, moderate and severe facial hirsutism respectively before trial.

Effect of therapy:

• Reduction in hair density:

The mean hair density based on FG score in Group H was 5.867 (BT), reduced to 2.600 (AT) with mean difference of 3.267. The mean score in Group S was 6.067 (BT) which got reduced to 2.267 (AT), with mean difference of 3.800. Results were statistically highly significant with $P < 0.001$ and not statistically significant between the groups with $P < 0.05$ though the patients got relief in their complaints (Table No.1,2)

Hair density reduction assessed among 30 patients revealed that 60% & 40% patients had marked improvement; 6.67% & 26.67% patients had moderate improvement; 13.33% & 26.67% patients got completely cured; and 20% & 6.67% patients remained unchanged; in Group H and Group S respectively. While two patients one from each group were drop out, no patient reported with mild improvement in either of the group

Reduction in Hair Re-Growth:

The mean re-growth of hair in Group H was 2.600 (BT) which got reduced to 1.067 (AT) with the mean difference of 1.533. In Group S the mean re-growth of hair was 2.733 (BT) got reduced to 0.533 (AT) with mean difference of 2.200, the changes were statistically highly significant with $p < 0.001$ and not statistically significant between the groups with $P < 0.05$ though the patients got relief in their complaints (Table No.3, 4).

Hair re-growth assessed among 30 patients revealed that 13.33% patients each in both groups showed moderate improvement; 60% & 16.67% patients had marked improvement; 20% & 46.67% patients got completely cured; and 6.67% patients each remained unchanged in Group H and Group S respectively. Two patients one from each group were drop out. No patients reported with mild improvement in both the groups.

Overall Effect of therapy:

The overall effect of therapy on facial hirsutism assessed based on the symptomatic relief felt by the patients showed that (ten) 33.33% patients got marked relief, (sixteen) 53.33% patients got moderate relief and (three) 10% had got mild re-

lief. The remaining (one) 3.33% patient remained unchanged

DISCUSSION

HarataladiLepa and *ShamibeejadiLepa* are indicated for *Lomashatana* purpose. The ingredients of *HarataladiLepa* and *ShamibeejadiLepa*, possess *UshnaVeerya*, *Laghu*, *Ruksha*, *TeekshnaGuna* and has *Lekhana Karma* and majority of *Dravyas* have *Keshaghna* property also, thus the formulations are apt for this study.

Total of 10% (13.33% in Group H & 6.66% in Group S) patients had complete relief in reduction of hair density and a total of 33.33% patients (20 % in Group H & 46.67 % in Group S) had complete relief in reduction of hair re-growth during treatment, had hirsutism due to PCOS and took internal medication. Possibility of HPO axis regularization by internal medication aided with the use of *Lepa* helped in complete relief of the symptom. The marked improvement in hair density and hair re-growth observed in the patients suffering from idiopathic hirsutism and facial hirsutism due to PCOS without use of internal medication i.e. 50% of patients and 46.67% patients in total; point towards the therapeutic benefits of *LomashatanaLepa*.

Both the *Lepa* were equally effective in reducing the hair density as assessed by modified FG score. Most of the patients showed slight increase in the hair density during the follow up period, which suggests the application in long run may yield better results. Two patients showed mild itching and burning sensation for initial few days (1 week) immediately after applying the *HarataladiLepa* which gradually got self-subsidence.

The medication of 45 days with this topical application though ensures remission in complaints, has not showed complete cure. To get complete cure the topical applications may be continued further until permanent depilation may be achieved.

Possible mode of action of the *Lomashatana Yoga*

Harataladi Lepa

The ingredients *Haratala*, *Manashila*, *Sarja Kshara* and *Shanka Churna*, does the *Deepana*

of *Bhrajaka Pitta* due to *KatuRasa*, *KatuVipaka*, *UshnaVeerya*, *TeekshnaGuna*. Because of *Sookshma*, *Teekshna*, *LaghuGuna* it acts as *Srotoshodhaka*, thus helps in penetration of the *Veerya* of the *Dravya* into the *Tvacha* through *Lomakupa*, leading to *Swedakshaya*. Furthermore, the *Dravyas* possess *Varnya* and *Lekhana Karma* along with the *Keshaghna Karma*. Thus, by synergistic action these drugs serve the purpose of *Lomashatana*.

ShamibeejadiLepa:

The ingredients *Shamibeeja*, *Kadali*, *Shyonaka*, *Haratala* and *SaindhavaLavana* serve the purpose of *Lomashatana* due to the *KatuVipaka*, *UshnaVeerya* thereby leading to the *Deepana* of *Bhrajaka Pitta*. *Laghu*, *Rooksha*, *SookshmaGuna* does *Srotoshodhana*. *Lavana* with its *Sookshma*, *ChedanaGuna* helps in penetration of the *Veerya* of *Lepa*. *Haratala* and *Shamibeeja* have the *Keshaghna Karma*.

None of the acute or chronic toxic symptoms of arsenic was reported during the study period and follow up. It may be because the formulation contains other *Dravya*, which imparts certain synergistic action, by which the toxic effect of Arsenic may be delimited.

CONCLUSION

In nut shell, 30 female patients with facial hirsutism (idiopathic or due to PCOS) between the age group of 16 to 40 were subjected to randomized comparative clinical trial and treated with topical application of *HarataladiLepa* and *ShamibeejadiLepa*. The study showed that in both the groups there was statistically significant reduction in facial hair density and facial hair re-growth which implies that both *HarataladiLepa* and *ShamibeejadiLepa* are safe and effective in the management of facial hirsutism. Even the toxic drugs when used judiciously for appropriate time duration (minimum six months) may provide complete depilation without significant side effects when compared to hormonal pills, depilatory electrolysis and Laser therapy. Thus, the study suggests that both the trial drugs are effective for facial hirsutism and *HarataladiLepa* has no edge over the *ShamibeejadiLepa* in reducing the facial hirsutism.

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REFERENCES

1. www.ncbi.nlm.nih.gov. Sunita J Ramanand et al. Clinical characteristic of PCOS in Indian women, Indian J of Endocrinol. and Metab. 2013, Jan-Feb;17(1): 138-145.
2. Gita GangulyMukherjee, BNChakravarty, PolyCystic Ovary Syndrome –An Update, First ed., 2007, JaypeeBro.Med.Pub.(P)Ltd, New Delhi, Chapter 7, pg.60.
3. VriddhaJivaka, Kashyapa Samhita, with upodhata of Pandit Hemaraja Sharma, Vidyotinihinditeeka, Chaukhamba Sanskrit Samsthan, Varanasi, 6th edition, 1998, Kalpasthana. Revatikalpaadhyaya sloka-33, pg.192.
4. Agnivesha, CarakaSamhita, Text with Cakra-panteeka, Ed. by Vd.Y.T.Acharya, Chaukhamba Orientalia, Varanasi 2011, Ca.Su.21/3-4, pg.116.
5. Sushruta, SushruthaSamhita, Dalhanateeka, Vd.Y.T. Acharya, Kashi Sanskrit Granthamala-316, Chaukhamba Sanskrit Samsthan, Varanasi, Su.Chi.1/108, pg.405.
6. Sharangdhara, Sharangdhara Samhita, Gudhartha Dipika & Dipikateeka by Kashirama & Adhamalla, Edited by P.S.Vidhyasagar, ChaukhambaSurbhartiPrakashan, Varansi, 1st edition, 2006, Uttara khanda 1/35-37
7. Sushruta, SushruthaSamhita, Dalhanateeka, Vd.Y.T.Acharya, Kashi Sanskrit Granthamala-316, Chaukhamba Sanskrit Samsthan, Varanasi, Su.Chi.1/108pg.405.
8. www.ijtrichology.coms

Table No.1: Results on reduction in hair density in Group H (n=15) and Group S(n=15)

Group	Mean		Mean difference	Paired 't'				Remarks
	B. T	A. T		S. D	S.E.M	't'	P	
Group H	5.867	2.600	3.267	2.017	0.521	6.274	p<0.001	HS
Group S	6.067	2.267	3.800	1.265	0.327	11.635	p<0.001	HS

Table No. 2: Comparative effect on reduction in hair density (n=30)

Group	Mean (BT-AT)	Diff.	Unpaired 't'				Remarks
			S. D	S.E.M	't'	P	
Group H	3.267	0.667	1.944	0.502	1.405	p < 0.05	NS
Group S	3.800		1.387	0.358			

Table No.3: Results on reduction in hair re-growth in Group H (n=15) and Group S (n=15)

Group	Mean		Mean Difference	Paired 't'				Remarks
	BT	AT		S.D	S.E.M	't'	P	
Group H	2.600	1.067	1.533	0.834	0.215	7.122	p < 0.001	HS
Group S	2.733	0.533	2.200	0.676	0.175	12.602	p < 0.001	HS

Table No.4: Comparative effect on reduction in hair re-growth (n=30)

Group	Mean (BT-AT)	Diff.	Unpaired 't'				Remarks
			S.D	S.E.M	't'	P	
Group H	1.533	0.667	0.834	0.215	2.405	p < 0.05	NS
Group S	2.200		0.676	0.175			

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