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## CLINICAL STUDY ON HARATALADI LEPA FOR LOMASHATANA IN HIRSUTISM

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### ABSTRACT:

*Poly cystic Ovary Syndrome (PCOS) is a gynecologic metabolic disorder of unknown origin with dermatological manifestations like hirsutism (70%), acne (30%) and acanthosis nigricans (5-10%). The present study was carried out to evaluate the efficacy of HarataladiLepa in the management of facial hirsutism either due to PCOS or idiopathic cause. Assessment was done using Modified Ferrimann-Gallwey scoring pattern and special scoring pattern designed for cardinal features like reduction in hair density, hair re-growth, etc. The herbomineral compound HarataladiLepa was selected from SharngadharaSamhita and beneficial in Lomashatana was utilized for the management of hirsutism characterized by excessive terminal hair growth in women with PCOS. The present clinical study is an effort to evaluate the applicability of HarataladiLepa in facial hirsutism. A total of 15 patients with hirsutism were selected and HarataladiLepa was applied topically over cheeks and chin for 45 days after initial threading. Follow up was done for 45 days. Results obtained were analyzed statistically using paired 't' test. Encouraging outcome obtained in this study show the role of herbo-mineral combination as a cost effective, safe alternative Ayurvedic treatment for depilation in hirsutism.*

**Key Words:** FerrimannGallwey Scoring, HarataladiLepa, Hirsutism, Lomashatana, Poly Cystic Ovary Syndrome, SharngadharaSamhita.

### INTRODUCTION

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#### INTRODUCTION

Poly Cystic Ovary Syndrome (PCOS) is a gynecologic metabolic disorder of unknown origin with dermatological manifestations. Clinical manifestations like hirsutism due to PCOS is 70%<sup>1</sup>, acne

(30%), acanthosis nigricans (5-10%) and androgenic alopecia (8%) due to associated hyperandrogenism and hyperinsulinemia accounts for major cosmetic problems which reveal the presence of PCOS in adolescent female population in India. Worldwide incidence of hirsutism due to PCOS is 5-10% in the child bearing period<sup>2</sup>. Lack of physical exercise with excess use of *Virudhahara*, abnormal sleeping habits, and sedentary life style trigger the manifestation of PCOS with menstrual irregularities and anovulation in addition to hormonal disturbances. *Atilomata* is mentioned as a *Lakshana* of *Astaninditapurusha*<sup>3</sup> in *Ayurveda*. In *PushpaghniJataharini*<sup>4</sup> also excessive hair growth over cheeks may be inferred. *Lomashatana Lepa* are mentioned for depilation and therapeutic cosmetic purposes in *Sushruta Samhita*<sup>5</sup> and later works like *Sharngadhara Samhita*. *Harataladi Lepa*<sup>6</sup> is a time-tested, effective, economical and safe *Lomashatana Lepa* for facial hirsutism and requires scientific validation through clinical trials. So the present study proved the utility of this Ayurvedic formulation in facial hirsutism.

#### **Lepa Kalpana:**

*Lepa* are *Bahiparimarjanachikitsa*<sup>7</sup> applied for *Savarnikarana*, *Krishnikarana*, *Lomasanjanana*, *Lomashatana* etc. and are classified as *Alepa*, *Pradeha* and *Pralepa* depending on the mode of application<sup>8</sup>. Based on the effect of *Lepa*, they can be *Doshaghna Vishaghna*, *Varnya*<sup>9</sup>. Further based on *Guna* and *Karma* they can be classified into 10; *snaihika Nirvapana*, *Prasadana*, *Stambhana*, *Vilayana*, *Pachana*, *Peedana*, *Sodhana*, *Shoshana* and *Savarneekarana*<sup>10</sup>. Thus *Lepa Kalpana* may be used in preoperative, operative and

post traumatic care and wound healing, in toxicology and also for cosmetic purpose.

Common rules for application of *Lepa*<sup>11</sup>:

#### **Mode of Application:**

Uniformly, and in reverse direction of *Lomakupa*.

**Selection of Sneha:** Based on *dosha* dominance.

**Time:** Contraindicated at night time.

**Duration:** Retained till in wet state and on drying should be removed and not to be left as such after drying.

*Lepas* should be prepared and used fresh. *Lepas* should be applied only once and should not be applied over the previous one.

#### **Thickness of Lepa:**

*Sushruta* has compared the thickness of *Lepa* to the "*ArdraMahishaCharmavat*" (thickness of buffalo's skin), *Pralepa* is thinner (*Laghu*, *Sheeta*, *Vishoshi*). *Pradeha* is thicker (*Ushna/Sheeta*, *Ghana*, *Avishoshi*) to buffalo's skin and in between is considered as *Alepa*<sup>12</sup>. *Acharya Sharangadhara* mentioned thickness of *Lepa* for *Doshaghna Lepa*-1/4 *Angula*, *Vishaghna Lepa*-1/3 *Angula* and *Varnya Lepa*- 1/2 *Angula*<sup>13</sup>.

#### **MATERIALS AND METHODS:**

**AIM AND OBJECTIVES:** Aim and Objective of the study was to evaluate the clinical efficacy of *Harataladi Lepa Yoga* applied locally in facial hirsutism due to PCOS.

#### **STUDY DESIGN:**

The present study was designed as an observational open labeled clinical trial among 15 clinically diagnosed patients of PCOS with facial hirsutism or idiopathic hirsutism, fulfilling the criteria of inclusion, selected from the Out-patient and In-patient department of SDMCAH, Udupi.

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.

**Protocol:** The details of the data collected from the enrolled subjects were as per the Case Record Forms for the clinical study. Special assessment criteria were designed for the cardinal features like reduction in hair density, redness, swelling, itching, re-growth of facial hairs; Modified Ferrimann- Gallwey Scoring (FG score) <sup>14</sup> pattern for hirsutism; scoring pattern to assess the effect of therapy.

**Duration :** Total duration of treatment was for 45 days.

**Follow up:** Total duration of follow up was for 45 days.

**INCLUSION CRITERIA:**

1. Females with idiopathic hirsutism.
2. Diagnosed patients of PCOS presenting with features of hirsutism.

3. Women aged between 16 to 40 years.

**CRITERIA FOR EXCLUSION**

Diagnosed cases of congenital adrenal hyperplasia, endocrine disorders, androgen secreting tumor of ovary; and patients with history of skin allergy, any skin related disorder were excluded from the study.

**Diagnostic criteria:**

Patients with minimum hirsutism score of 8 and a maximum score of 36 and with facial hirsutism with scores between 2 and 8 (2 areas of chin and cheeks; upper lip) as per Modified Ferrimann--Gallwey scoring pattern were diagnosed as hirsute. Scores of Mild coverage-1, Moderate coverage-2, Complete light coverage-3 and Heavy coverage -4 was attributed for assessment of improvement of treatment for 2 areas of face i.e; chin and cheeks; upper lip.

**Laboratory Investigations:**

Essential haematological investigations like Hb%, TLC, DC, ESR; and hormonal assay for T<sub>3</sub>, T<sub>4</sub>, S.TSH (B.T), S.FSH, S.L.H were carried out. LH: FSH ratio >2 was diagnosed as PCOS.

**Drug and dosage:**

**Table1. Drug, Form, Dosage, Duration, Mode of administration and follow up**

Drug	Form	Dose	Duration	Mode of Administration	Follow up
HarataladiLepa (Sar.Sam.Utt.11/35-37)	Paste	5-10 gms.OD.	1½Month	Topical application	1½Month

**Table 2. Ingredients, chemical composition and proportion of HarataladiLepa**

Sr. No	Drug	Varga	Chemical composition	Kalpana	Quantity
1.	Haratala	Uparasa	Arsenic TrisulphideAs <sub>2</sub> S <sub>3</sub>	Churna	1 part
2.	Manashila	Uparasa	Arsenic sulphideAs <sub>2</sub> S <sub>2</sub>	Churna	½ part
3.	Sarjakshara	Kshara	Sodium Bicarbonate (Na <sub>2</sub> (CO <sub>3</sub> , 10 H <sub>2</sub> O))	Churna	1 part
4.	Shankha	Sudha	Calcium sulphate Ca <sub>2</sub> So <sub>4</sub>	Churna	2 part

Observation and Results: Facial hirsutism as assessed by considering only two

regions of FG score of face i.e.; chin and cheeks; and upper lips revealed that

12.50% , 62.50% and 25% patients had mild, moderate and severe facial hirsutism before trial.

The use of *Harataladi Lepa* in hirsutism due to PCOS has helped to eradicate the complaints of excessive facial hairs. Moderate improvement of 6.67%, marked improvement of 60%, complete cure of 13.33% and unchanged hirsutism in 20% patients respectively was noticed regarding reduction in hair density. Reduction in hair re-growth was observed as moderate improvement in 13.33%, marked improvement of 16.67%, complete cure of 46.67% and unchanged in 6.67% patients respectively. 25% patients reported with

warmth and itching for 1 week after the application of *Lepa*. No other adverse reactions were reported during the trial period.

Result on hair density based on FG score by paired ‘t’ test:

The statistical analysis revealed that the mean hair density based on FG Score was 5.867 before the treatment which got reduced to 2.600 after the treatment with mean difference of 3.267. The analysis by applying paired ‘t’ test proved that the changes are highly significant with  $P < 0.001$ . Table No.3: Results on hair density and hair re-growth by paired’ test

**Table No.3: Results on hair density and hair re-growth by paired ‘t’ test**

Assessment Criteria	Mean		Mean Difference	Paired ‘t’ test			
	BT	AT		S.D	S.E.M	‘t’	P
Hair density	5.867	2.600	3.267	2.017	0.521	6.274	(P = <0.001)
Hair Re-growth	2.600	1.067	1.533	0.834	0.215	7.122	(P = <0.001)

**Results on re-growth in hair based on paired ‘t’ test:**

The statistical analysis revealed that the mean hair re-growth in Group H was 2.600 before treatment which got reduced to 1.067, after the treatment with mean

difference of 1.533. The analysis by applying the paired ‘t’ test proved highly significant results on reduction of the hair re-growth with  $P < 0.001$ . (Table no.3)

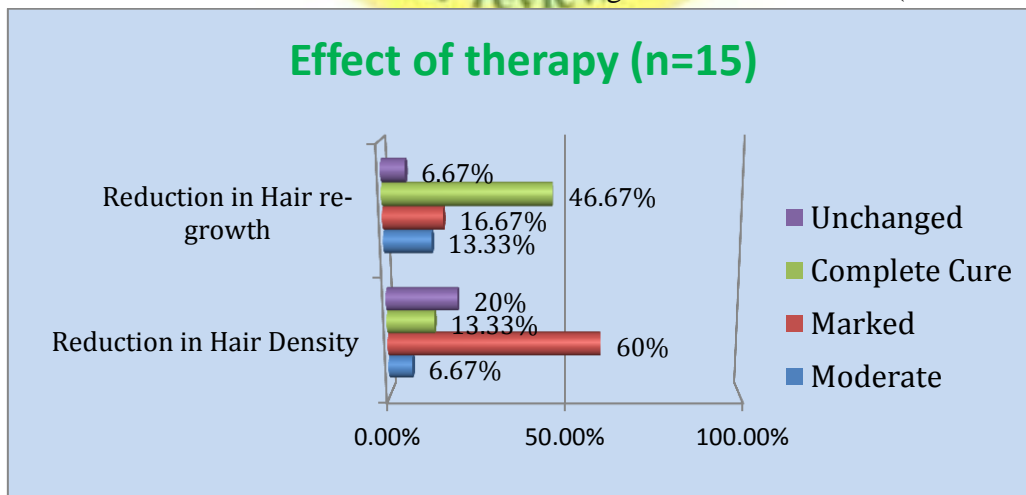


Fig. 1. Results on reduction in Hair density and Hair re-growth

**DISCUSSION**

*Lepa* an important *Bahiparimarjana Chikitsa*, helps in pacifying the vitiated *Doshas* locally situated in the *Bahya Roga Marga*. *Lepa* can be a *Pradhana Chikitsa Karma* in *Alap Dosh Avastha*, or can also be used as a supportive therapy after *Antaparimarjana Chikitsa*<sup>15</sup>. *Alepa*, one among the *Shashti Upakrama* adopted as *Pradhana Upakrama* for *VranaShophaChikitsa*<sup>16</sup>. Among those *Upakrama*'s; *Lomapaharana*<sup>17</sup> was intended for the removal of *Loma* to aid in quick healing of wound, and to serve the cosmetic purpose. *Lepa* used in this study can be considered as the *Varnya*, based on the purpose of use and *Pralepa* type depending on the method of application.

**Possible mode of action of Lepa:**

*Lepa* is usually applied against the direction of hair follicle; topical applications do the *SrotoShodhana*, and *Deepana* of *Agni* which is located in the *Tvacha*<sup>18</sup>. Thus applications on the skin, gets transformed due to the action of *Bhrajaka Pitta* and enters the *Lomakupa*, *Swedavahi Srotas* and *Siramukha*<sup>19</sup>. *Acharya Sushruta* explains *Tiryakgami Siras* are four in number. Their openings are attached to hair follicles and do *Sweda*

and *Rasa Samvahana*. Through these openings the *Veerya* of any *Dravyas* used for *Abhyanga*, *Snana* and *Lepa* enter the body after being transformed in the skin.<sup>20</sup>

The drugs of this herbo-mineral combination were found to be effective in the management of facial hirsutism. The ingredients of the *Yoga* are *Haratala*, *Manashila*, *SarjaKshara*, *ShankhaChurna*; does the *Deepana* of *Bhrajaka Pitta* due to *Katu Rasa*, *Katu Vipaka*, *Ushna Veerya*, *Teekshna Guna*. Because of *Sukshma*, *Teekshna*, *Laghu Guna* it acts as *SrotoShodhaka*, which helps in penetration of the *Veerya* of the *Dravya* through the *Tvacha* to *Lomakupa*, thus leading to *Lomashatana*. Additionally the *Dravyas* possess *Varnya* and *Lekhana Karma* along with the *Keshaghna Karma*. The combined actions of drugs serve the purpose of *Lomashatana* and also reduce the *Neelika* (Blackish discoloration of skin). This may be due to the *Teekshna*, *Kapha*, *Medo Vilayana* action along with *Lomapaharana* (depilatory) action of drugs like *Haratala*, *Shankha* etc. From modern view point also Arsenic lotions are used for depilatory benefits in cosmetic field. Calcium compounds too are proven to be depilatory in nature.<sup>21</sup>

**CONCLUSION**

On judicious use even the toxic drugs may be therapeutically utilized for the cosmetic purposes and the stress of adolescent PCOS women may be substantially reduced by *Harataladi Lepa* which is a safe, economic and effective treatment for facial hirsutism. In contemporary medicines, no single depilatory measure is safe, effective and permanent. Laser

therapy too has chances for recurrence. *Lomashatana Lepa* is less invasive and safe when compared to other contemporary treatments but effective in the management of facial hirsutism.

Source of Support : Nil.

Conflict of Interest : Nil.

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