

CLINICAL STUDY TO EVALUATE THE LOMASHATHANA EFFECT OF HARIDRADI LEPA IN HIRSUTISM

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ABSTRACT

Hirsutism is defined as the presence of male pattern coarse hairs in females. It affects around 5-10% of the women^[1] and for cosmetic reasons, it is a common presenting complaint in the Out Patient Department. Hirsutism is commonly seen in hyperandrogenism associated with conditions like PCOS. It has a huge psychological impact,^[2] especially in young females. Kāśyapa Saṃhitā mentioned Puṣpagni jātahāriṇī^[3] characterized by sthauilya and lomaśa gaṇḍa (Hairy and Corpulent cheeks) which can be clinically correlated with manifestations of hirsutism in PCOS. In contemporary medicine there are several methods available today for hair removal, temporary as well as permanent including procedures like electrolysis. Most of them can cause various medical problems like skin discoloration, dryness of skin and are expensive. In the present study external application of powder of commonly available drugs like haridrā, mudgā, sarśapa, saindhava lavaṇa with tila taila for the hair removal purpose. All the above drugs are easily available and economic. Till now there are no research works with strong evidence to support the effectiveness of herbal formulations in hirsutism and hence the lomashathana effect of these drugs is evaluated in the present study in patients complaining of hirsutism.

KEYWORDS: Hirsutism, Puṣpagni jātahāriṇī, hyperandrogenism.

INTRODUCTION

Hirsutism is a psychosomatic disease which gives inferences of various endocrinological etiologies for hair growth. It is one of the common distressing symptoms, having a huge

psychological impact among the young females. It is the most common presenting complaint in outpatient department for cosmetic reasons. Hirsutism is the presence of excess body or facial terminal hair growth typically of a male –like pattern especially in females, which is an important sign of underlying androgen excess. The underlying pathology is more significant than the manifested hirsutism which represents the hyperandrogenism^[4] associated with Polycystic ovary Syndrome (PCOS). In our classics the main clinical feature, Atilomatā is explained under different contexts. Kāśyapa Saṃhitā mentioned Puṣpagni jātahāriṇi characterized by sthauḷya and lomaśa gaṇḍa (Hairy and Corpulent cheeks), correlated with manifestations of hirsutism in PCOS. Hirsutism can be commonly noticed in cases of PCOS, metabolic syndrome associated with obesity,^[5] insulin resistance or it may be idiopathic,^[6] where normal ovulatory function having normal circulating levels of androgens.

In the management of hirsutism, education of patient regarding the cause of hirsutism and reasonable treatment expectations and emotional support are important. In contemporary medicine there are numerous medicines and procedures to remove the unwanted hairs, which are carried out for depilation action. There are several methods available today for hair removal, temporary as well as permanent.^[7] Most of them can cause various disadvantages like skin discolorations, dryness of skin and are expensive. Electrolysis procedure, which is a permanent method being practiced today is painful as well as time consuming. Cosmetic hair removal cannot give a permanent solution to excess growth and have to be repeated regularly. However, the main advantage of it is that they can be applied at home quickly and easily. In Ayurvedic classics, various references regarding hair removal methods are available in the form of herbo-mineral formulations. Till now there are no research works with strong evidence to support the effectiveness of herbal formulations in hirsutism and hence the lomaśātana effect of these drugs is evaluated in the present study in patients complaining of hirsutism. Only a few research works have been carried out in this regard with sufficient evidence to prove their efficacy. Thus, there is necessity of better and cost effective medicine which removes hair permanently. Hence the main objective of the present study is to assess the lomaśātana effect of this herbal combination of certain drugs in hirsutism.

AIMS AND OBJECTIVE

To evaluate the lomashathana effect of herbal combination of haridradi lepa in hirsutism.

MATERIALS AND METHODS

An open label study with pre and post test clinical evaluation was done on 30 selected patients of age group 15-40years after attaining prior permission from the institution, the hospital authority, and the patients. A special case record form was prepared with detailed history and other signs and symptoms. The pre and post photographs of the selected area (area of abnormal hair growth) were taken during the course of the clinical study. Pre and post evaluation were done and the progress observed were noted in specially prepared case sheet. After the study period, the patients were reassessed using the assessment criteria. Changes in scores were recorded. Results obtained were statistically analyzed using paired t test and Wilcoxon signed rank test using the IBM SPSS Statistics software, Version 20.

Drug and Method of preparation

The drugs were procured, identified and assured that, they are of good quality from the Dept. of Dravyaguna of Amrita School of Ayurveda. The fine powder of these drugs was subjected for analytical study in Dept. of Rasaśāstra and Bhaiṣajya kalpanā. The drugs were properly packed air tightly and stored. The prepared powdered drug (100gm) kept in an airtight packet were dispensed to the patients. They were advised to prepare a paste out of the powdered drugs with tila taila for application over the selected area and are advised to do slight massage for 10 minutes and were kept for 30 minutes and washed off with lukewarm water daily for a period of 90 days. The drugs were dispensed at an interval of 30 days as per need, till the end of the study.

Pre and post evaluation were done and the progress observed were noted in specially prepared case sheet. After the study period, the patients were reassessed using the assessment criteria. Changes in scores were recorded. Results obtained were statistically analysed using graphical methods.

Criteria for selection of patient

Inclusion criteria:-

- ✓ Age group - 15-40 years
- ✓ Patients coming with complaints of hirsutism

Exclusion criteria

- ✓ Patients below 15 years and above 40 years
- ✓ Pregnancy and lactating women

- ✓ Hypersensitive skin
- ✓ Thyrotoxicosis
- ✓ All kinds of benign and malignant tumours.

Outcome measures

Subjective parameters

- ✓ Notable hair loss (Gradation of hair loss by 0-3)
- ✓ Change in hair growth during the treatment (Score ranging from 0-3)
- ✓ Change in hair growth rate (Score ranging from 0-4)

Objective parameters

- ✓ Extent of hair growth in hirsutism patients were assessed with modified Ferriman-Gallwey Scoring (FG Score).
- ✓ Photographs of the selected area were used for assessing density of hair by after analyzing it with imageJ software.
- ✓ Hair count is obtained for the particular selected area using the imageJ software.

Investigations: Blood routine, TFT, USG.

Statistical design: Statistical analysis performed by using Paired Sample t-Test & Wilcoxon signed rank test is with Bonferroni correction using the IBM SPSS Statistics software, Version 20.

RESULT

The effect of treatment on the extent of hair growth assessed by using FG scale (Table no: 1) was found to be significant with p-value 0.0001 which is less than 0.05. On analyzing the effect of treatment in hair density using image J software (Table no:2), there is significant changes occurs in all the stages of treatment with p- values which were less than 0.05, found that the significance of this treatment is more in the time of AT (After treatment). Regarding the effect of treatment on hair count (Table no: 3), the p-value obtained were not significant which is greater than 0.05. Wilcoxon signed rank test is used for the statistical analysis of subjective parameters which showed reduction in hair loss, hair re-growth as well as changes in hair growth rate between BT, 30th day, 60th day, 90th day which is significant in all the stages. The statistical data's were presented in Table no 4, 5 & 6 respectively.

Table no. 1: Effect of treatment on extent of hair growth with FG Scale.

FG Scale	Mean	T	Df	P Value
BT-30 th day	.750	5.665	27	.0001
BT-60 th day	1.500	10.003	27	.0001
BT- 90 th day(AT)	1.821	13.334	27	.0001

Table no. 2: Effect of treatment on hair density.

Hair density	Mean	S. D	t	Df	P-Value
BT-30 th DAY	.0031927	.00752788	2.244	27	.033
BT-60 th DAY	.0158538	.02850778	2.943	27	.007
BT-90 th DAY (AT)	.0247506	.03806404	3.441	27	.002

Table no. 3: Effect of treatment on hair count.

Hair count	Mean	t	Df	P-Value
BT-30THDAY	103.294	1.953	27	.061
BT-60THDAY	-1230.455	-.806	27	.427
BT-90THDAY (AT)	-321.464	-.229	27	.820

Table no. 4: Effect of treatment on hair loss.

Hair loss	Z-value	Asymp sig(2-tailed)
HAIR LOSS -30TH DAY - HAIR LOSS BT	-5.000	0.0001
HAIR LOSS -60TH DAY - HAIR LOSS BT	-5.000	0.0001
HAIR LOSS AT - HAIR LOSS BT	-5.013	0.0001

Table no. 5: Changes in hair regrowth during the stages of treatment.

Hair regrowth	Z-value	Asymp sig (2-tailed)
HAIR REGROWTH- 60TH DAY - HAIR REGROWTH- 30TH DAY	0.00001	1.0000
HAIR REGROWTH- AT - HAIR REGROWTH- 30TH DAY	-4.243	0.0001

Table no 6: Effect of treatment in hair growth rate.

Hair growth rate	Z-value	Asymp.sig (2-tailed)
HAIR GROWTH RATE- 30TH DAY - HAIR GROWTH RATE – BT	-5.000	0.0001
HAIR GROWTH RATE -60TH DAY - HAIR GROWTH RATE – BT	-5.000	0.0001
HAIR GROWTH RATE- AT - HAIR GROWTH RATE - BT	-4.963	0.0001

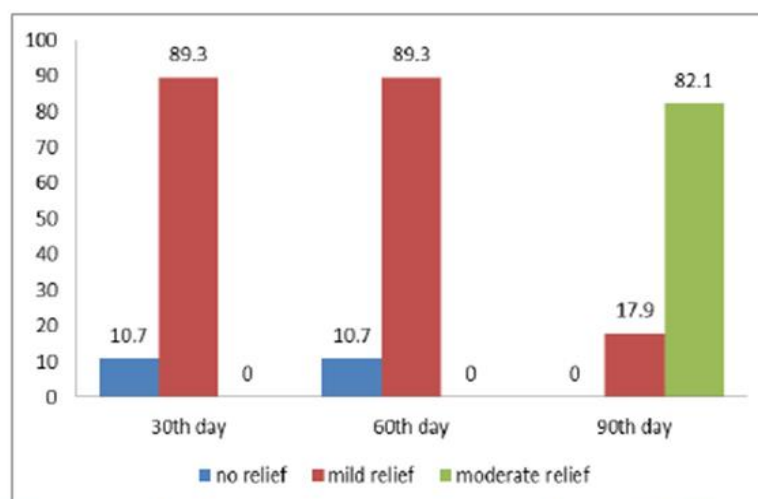


Figure no:1 Graphical representation of overall effect of treatment.

From the statistical analysis it has been found that the overall effect of treatment (Fig no: 1) was improved from mild relief to moderate relief after the completion of treatment after the 90th day.

DISCUSSION

Observations in the study shows the increased reported case among the student community of about 60.7%. It may be due to use concern about the cosmetic outlook sleep disturbances and reduced stress threshold. This distribution may show the sedentary life style as well as the improper indulgence in food habits which may cause the disease. In a previous study conducted also interprets the increase in prevalence of hirsutism among the student community.^[8] In the present study finding coincides with the similar studies that relevant family history^[9] has a role to play in the pathology. About 60.7% of subjects had the family history of hirsutism, either mother or sister having similar complaints. Dietary factors regarding more fatty food intake also contributes to excess androgen leading to the disease pathology. Among the study group, 14.3% of subjects had taken treatment history of electrolysis as well as usage of depilatory creams for a short duration. They discontinued the treatment due to its adverse effects. The observation is similar to the previous studies^[10] which prove the adverse effect of contemporary hair removal therapy.

Facial hirsutism as assessed by considering only three regions of FG score- of face i.e.; chin & cheeks and upper lip revealed that, among 28 patients, maximum patients i.e. 71.4% belonged to moderate grade of hirsutism, 14.3% of patients had severe & mild grade of hirsutism. Computer aided software image J^[11] has been used in this study for assessing the

hair count and hair density which is more powerful and accurate than manual assessment. On statistical analysis regarding the objective parameters, the obtained results in extend of hair growth and hair density were significant which implies the effectiveness of the drug in hirsutism. While analyzing the hair count, the obtained result shows slight increase during the course of treatment. Even though the hair count showed slight increase, the hair pattern has changed from terminal to the vellus and thereby reducing the severity of the problem. The overall effect of the treatment shows that there was mild improvement during the course of treatment and after completing the treatment of three month period there was moderate improvement.

This explains the need of long term application of medicines for a better result.

Probable mode of action of drug: The drugs mentioned in this formulation were indicated in various dermatological conditions. These drugs are having the properties like lekhaṇa, tridoṣa śāṃaka, tvācya and varṇya. Among them, the haridrā possess uṣṇa vīrya, laghu rukṣa guṇa, lekhaṇīya, kapha vātahara, varṇya property. The mudgā and haridrā possess rukṣa guṇa. Haridrā, sarṣapa and tila taila possess uṣṇa vīrya and tikta rasa. Tila taila acts as kapha vātahara. Lavaṇa with its sūkṣma, chedana guṇa enhances penetration of lepa. So in combination due to sūkṣma, tīkṣṇa and laghu guṇa it acts as sroto śodhaka, tvācya and lomaśātana. The tīkṣṇata of the drugs are controlled by tila taila. Additionally the dravyās possess varṇya and lekhaṇa karma along with the keśaghna karma. Thus the combined action of drugs serves the purpose of lomaśātana.

CONCLUSION

Thus from the above observations it has been concluded that the trial drug is effective in some of the characteristics of hirsutism with significant reduction of hair density, hair regrowth pattern and severity of hirsutism. These herbal drugs proved to be safe, effective and economical; without any reported adverse drug reaction during the course of treatment. And hence it is being concluded that combination of these drugs for external application is effective in reducing the severity of the disease and thereby improves the quality of life of patient.

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