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Pharmaceutico-Analytical And Clinical Study To Evaluate The Depilatory Effect Of Romanashaka Lepa On Healthy Subjects.

Author:

[1.]Dr.Shivanand Koora [2.]Dr. Bandeppa Sangolge[M.D(AYU)]

PG Scholar Dept of Rasashastra & Bhaishajya Kalpana N. K. Jabshetty Ayurvedic Medical College and P.G. Research Center, Bidar, Karnataka.

HOD And Professor Dept of Rasashastra & Bhaishajya Kalpana N.K. Jabshetty Ayurvedic Medical College and P.G. Research Center, Bidar, Karnataka.

ABSTRACT

When viewed in terms of aesthetics unwanted hair present over the body causes cosmetological as well as psychological disturbances in an individual. To remove those unwanted hairs there are numerous medicines and procedures, which are carried out for depilation / epilation action, ranging from shaving to waxing to depilatory creams to laser techniques. Many of these have side effects and irritation to the skin. The techniques which are employed for this purpose are expensive; still the relapse of the hair occurs because these are giving temporary results.

The present study, mentioned in Sharangdhara Samhita is an attempt made to evaluate the depilatory effect *of Romanashaka lepa.*

KEYWORDS: R*omanashaka lepa, Haratala, Palasha kshara, Kadali swarasa, Shanka.*

INTRODUCTION

Beauty enhances the self-confidence of an individual. Unwanted hair which are present on the body causes cosmetologically problems and rejection in the society which leads to psychological distress, especially in women. Around 5 to 10% are more prone to such social difficulty, it is one of the most prevalent health problems and it influences their quality of life.[1]

Unwanted growth of hair can be due to Polycystic Ovarian syndrome(PCOS), drug induced, genetic, unhealthy lifestyle or idiopathic. Hair removal is practiced for the reasons like cultural, sexual, religion and cosmetic purpose. To eliminate unwanted hair there are numerous ways like topical depilatory creams, plucking, threading, shaving, waxing, electrolysis, laser therapy etc. These formulations or methods containing chemicals, herbo -mineral drugs are expensive and cause irritation, minor burns, inflammation, scarring, pain and other side effects with regrowing of hairs. Local application is beneficial because they are quickly absorbable, protect the skin and promotes percutaneous absorption of incorporated drug.

Ayurveda has given importance to both Antahparimarjana and Bahirparimarjana chikitsa, for diseases and cosmetological need. Timely removal of unwanted hair for keeping the skin smooth and clear has been followed since ages. The removal of kesha, shmashru, loma, and nakha three times in a paksha is advised.[2] So there is need of economical formulation for hair removal. In Ayurveda, depilatory action may be correlated with lomanashaka, keshahantri karma, there are many herbal and mineral prepartions mentioned in classics such as Shami, Haratala, Manashila, Ksharadravyas etc.

So for the present study, Romanashaka lepa had been selected for clinical trial since it is easily available, cost effective, non- controversial and no research trials had been conducted by using this lepa either on animals or clinically. Hence, an attempt was made to evaluate the depilatory effect of Romanashaka[3] yoga on healthy individuals by clinical means.

AIMS AND OBJECTIVE

- Physico-chemical analysis of Romanashaka lepa.
- To evaluate the depilatory effect of Romanashaka lepa.

MATERIALS AND METHOD

The ingredients of Romanashaka lepa are

Ingredients:

1. *Shuddha Haratala Choorna* – 1 part
2. *Suddha shankha Choorna* – 3 part
3. *Palasha kshara* – 1 part
4. *Kadali swarasa* – Q.S (while applying lepa)

Method

- The ingredients were taken in the specific quantity in a *Khalwa Yantra.*
- Thorough mixing of all the ingredients was done so that it got mixed homogenously.
- It was later preserved in airtight container.
- During application it was mixed with the quantity sufficient *Kadali Kanda Swarasa* and applied to the part specified.

ANALYTICAL STUDY

- Organoleptic study was carried out in the P.G Department of Rasashastra and Bhaishajya Kalpana, N.K.Jabshetty Ayurvedic Medical College & P.G Centre,Bidar.
- Physico-chemical analysis was done at a certified Drug testing laboratory.
- Instrumental analysis – HPTLC was done at Nishka Research Pvt. Ltd, Hyderabad.

CLINICAL STUDY

The study was conducted on 15 volunteers selected from the OPD of of Sri Siddharoodh Charitable hospital attached to N.K. Jabshetty Ayurvedic Medical College and P.G Centre, Bidar. Volunteers were selected after satisfying all inclusion and exclusion criteria.

A. Study Design: Open labelled Randomized Clinical trial

B. Sample Size: 15 volunteers.

15 subjects were applied with *Romanashaka lepa* for 7 times in a day

C. SELECTION CRITERIA

INCLUSION CRITERIA:

- Healthy individuals between 18 – 40 yrs. of age of both gender.
- Females suffering from PCOD, Hirsutism, excessive hair growth.

EXCLUSION CRITERIA:

- Subjects suffering from dermal allergies.
- Pregnant women, children and old aged people.
- Malignancy conditions like cancer, HIV, HBsAG.
- Wound injury, abscess.

D. ASSESSMENT CRITERIA

1.) Number of hairs was counted before and after application of trial drugs in a patch of 3*3*3cm.

Grade 0(No hair)

Grade 1 (1-25 hairs)

Grade 2 (26-50 hairs)

Grade 3 (51-75 hairs)

Grade 4 (76-100 hairs)

Grade 5 (>100 hairs)

2.) Skin and hair colour changes was observed before and after application of trial drug during and after follow-up.

Skin changes like itching, redness, burning sensation, eruption and discharge was observed during follow up.

E. Intervention

The lepa was applied on both hands in a patch of 3*3*3cm.

15 subjects were applied with *Romanashaka lepa* for 7 times in a day

The lepa was kept for 10 min after application. After 10 min the lepa patch was washed with tap water and again lepa was applied for a total of 7 times in a day.

F. Follow-up of Study

On the 7th, 14th and 21st day after Lepa application.

G. STATISTICAL ANALYSIS

- Statistical evaluation was done by applying Paired Student "t" test.

H. Results:

Results of the study were assessed before and after treatment and the effectiveness of the trial drug was analysed clinically and statistically and compared.

OBSERVATIONS AND RESULTS

Results of present study are described under 3 headings.

A. Results of Pharmaceutical study.

B. Results of Analytical study.

C. Results of Clinical study.

A. RESULTS OF PHARMACEUTICAL STUDY:

Table No.1: Results of Pharmaceutical study

Dravya in Asuddha form	**Quantity taken**	**Loss in gms**	**Gain in gms after shodhana**
Haratala	250 gm	5gm	245gm
Sankha	500 gm	3gm	497gm
Palasha panchanga	12100 gm	3210gm after drying	34gm of Palasha Kshara

B. RESULTS OF ANALTICAL STUDY

1.) ORGANOLEPTIC ANALYSIS

TableNo.2: Showing the Organoleptic character of *Romanashaka Lepa*

Character	**Result**
Varna / colour	Dull white
Roopa/ consistency	Powder form (paste form when mixed with kadali swarasa)
Gandha / odour	Characteristic sulphuric
Sparsha / touch	*shlakshna*/smooth

2.) PHYSICO-CHEMICAL ANALYSIS:

Table No. 3: Showing the result of Physico-Chemical Analysis of *Romanashaka Lepa*

	TEST	VALUES
1	**Total Ash**	54% W/W
2	**Acid Insoluble Ash**	50%W/W
3	**Water Soluble Extract**	25%W/W
4	**Specific gravity**	2.62
5	**Loss On Drying at 110°C**	5.2%W/W
6	**Ph**	12.31
7	**Percentage Of Sulphur**	9.45%
8	**Particle size *>500µm***	38.6% Passed Through Mesh No.100
9	**Arsenic limit test**	Greater than 3PPM

3.) HPTLC DATA ANALYSIS

- The analysis revealed a complex banding pattern with distinct bands observed at both 254 nm and 366 nm. These bands indicate the presence of multiple bioactive compounds, each contributing to the formulation's overall properties.
- Differences in band intensity between the 10 µL and 20 µL applications suggest variability in the concentration of these constituents, highlighting the importance of dosage in the formulation's effectiveness.

3.)Results of Clinical study

1.) Statistical analysis of - ROMANASHAKA LEPA

Table No.4: Statistical analysis of Romanashaka lepa

Lepa	**BT** Mean ± SD	**Follow Up**	**AT** Mean ± SD	df	t-Value	P-Value	Efficacy (%)	Remarks
Romanashaka	4.333±0.617	1st	4.267±0.703	14	1	0.334	0%	NS
		2nd	4.267±0.593		1	0.334	1.53%	NS
		3rd	3.467±0.743		9.539	<0.001	20%	HS
		4th	3±0.534		10.583	<0.001	30.76%	HS
		5th	2.067±0.457		19.179	<0.001	52.30%	HS
		6th	1.2±0.5606		18.963	<0.001	72.30%	HS
		7th Appi	0±0		27.192	<0.001	100%	HS
		7th day	0±0		27.192	<0.001	100%	HS
		14th day	0.466±0.516		23.401	<0.001	89.23%	HS
		21st day	1.267±0.457		20.008	<0.001	70.76%	HS

1.) OVERALL EFFECT OF TREATMENT

Overall effect of the treatment was assessed on basis of percentage of hairs in 3sq.cm area and stated in terms of cured, Marked improvement, Moderate improvement, Mild improvement and No change.

Table No.5: Overall effect of Treatment

	AFTER 3rd Follow up	
	No. of Pts	**%**
Cured (100%)	1	6.66%
Marked improvement (75-<100%)	13	86.66%
Moderate improvement (50-75%)	1	6.66%
Mild Improvement (25-50%)	0	0%

No Change	0	0%
<25%		

In this present study overall effect of treatment revealed that Out of 15 Volunteers, 1(6.66%) volunteer was Cured, 13(86.66%) volunteers were Marked improved, 1(6.66%) volunteers were Moderately improved.

DISCUSSION

Probable Mode Of Action Of *Romanashaka Lepa*:

1.) The entry of Romanashaka lepa into the Hair follicles might have occurred by the action of Alkenes and Halogens[4a,4b]:

- Alkenes and Halogens have Lipophilic activity, the Chlorine present in the Halogen of *Romanashaka Lepa* might have increased its Lipophilicity further. *Romanashaka Lepa* which is applied over the skin, with the help of Alkenes and Halogen crosses all the layers of the skin including Stratum Corneum which is Lipophilic in nature and reaches the site of action i,e Hair follicle.

2.) Action of Arsenic trisulphide[5] and carbonates of Calcium, Potassium in destroying the Hair follicle:

- The toxicological mechanism in Arsenic differs for the trivalent and pentavalent forms. For trivalent Arsenic, inhibition of the pyruvate dehydrogenase(PDH) complex is the primary biochemical lesion. Dysfunction of this complex, which is comprised of the three enzymes occurs when As^{+3} binds to sulphahydril group of dihydrolipoamide preventing regeneration of lipoamide, which is a necessary cofactor in the conversion of pyruvate to acetyl CoA levels, inturn, reduce citric acid cycle activity with resulting decreased production of ATP. Direct effects As^{+3} on alpha- ketoglutarate dehydrogenase complex, which contain a dihydrolipoyl dehydrogenase identical to that PDH complex, further reduce the citric acid cycle activity.

- As^{+3} also interferes the Glucose production and uptake and there will be drop of acetyl CoA levels, also inhibits the activity of the pyruvate carboxylase, which catalyzes the conversion of pyruvate to oxaloacetate, the initial step in gluconeogenesis. Impaired gluconeogenesis combined with carbohydrate depletion due to stress of poisoning results in hypoglycemia. Arsenic also effect other sulfahydral containing enzymes, including membrane transport enzymes involved with insulin dependent cellular glucose uptake. Thus cellular lack of glucose will take place.

- From the above we can draw an inference that the Romanashaka Lepa works by decreasing the cellular energy level & thereby leading to decreased mitotic activity and cessation of hair follicle formation. The Palasha kshara and Kadali swarasa present in the Lepa provides the alkaline medium to facilitate the activity of Romanashaka Lepa.

3.) Prevention of irritation and Hot sensation by action of Ether 3 ring ether[4c]:

- Ethers have Anaesthetic property; they dissolve in the neurological membranes and exhibit the Anaesthetic action. Ether that is present in the Romanashaka *Lepa* containing this property might have helped in preventing the Irritation and hot sensation.

4.) Providing soothing action to the skin by Phosphorous compounds and hydroxide of Calcium:

- Phoshporous compounds help to maintain the healthy status of the skin.
- Calcium hydroxide is proven to provide soothing effect to the skin by adjusting the pH levels.

CONCLUSION

- *Romanashaka lepa* exhibits a more complex banding pattern with higher intensity at specific wavelengths, suggesting a richer presence of bioactive compounds, particularly those that absorb at 254 nm and fluoresce at 366 nm. This complexity might correlate with a broader spectrum of activity or a stronger effect in its intended application.
- Arsenic trisulphide by its cytotoxic activity and the inorganic components present in the Palasha kshara and Kadali swarasa present in Romanashaka lepa by their caustic action loosen and destroy the hair follicle by which there will be reduction in further development and growth of hairs.

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