Rasamruta
ISSN 0976-0075 Ayurveda e-Journal Rasamruta
World's First e - journal of Ayurveda
Scientific Revolution in Ayurveda!

Clinical Study of Romashatana Lepa W.S.R. to its Depilation Activity

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Abstract

Unwanted hairs which are present in the body causes cosmetological as well as psychological problems for an individual .To remove the unwanted hairs there are numerous medicines and procedures, which are carried out for depilation action. These medicines are mainly chemicals 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.

Ayurveda claims number of medicines for the permanent depilation. In Sharangdhara, for permanent depilation Romashatana Lepa has been mentioned.

In present study an attempt is made to evaluate the efficacy Romashatana Lepa in Foot Hairs.

KEYWORDS: Romashatana Lepa, unwanted hair, depilation

Introduction

Unwanted hairs which are present in the body causes cosmetological as well as psychological problems for an individual .To remove the unwanted hairs there are numerous medicines and procedures, which are carried out for depilation action.[1]

Ayurveda claims number of medicines for the permanent depilation. Local applications are beneficial because they are quickly absorbable and they protect the skin from external irritants and from sunlight, promote percutaneous absorption of the incorporated drug, thus allowing an active pharmacological effect on the skin[2]

As there are so many medicines which are available in the market for the other diseases like jwara, sandhgataivata, amavata, amalpitta, shwasa, kasa etc. but for the romashatana there are no such frequently available medicine. The hair removal products which are available in the market are not herbal or herbomineral. They are chemicals and have their side effects also.

In Sharangdhara, for permanent depilation Romashatana Lepa has been mentioned[3]. (*,hartrala*[4,5]*, Shankha*[6]*, palasha kshara*[7,8]) as main ingredients He stated that by using these lepas depilatory effect is seen. So Romashatana Lepa is taken with a view to find out efficacious safer, cost effective and easily available drug

AIM &OBJECTIVE:

The study has been undertaken with the following aims and objectives

- To observe the depilation activity of romashatana lepa after standardization

MATERIALS AND METHODS

Table no 1 Standarsiation of romashatana lepa [9,10] from BANGLORE TEST HOUSE

S.No	Test	Results
1	Determination of pH	8.78
2	Loss on drying at 110^0c	1.25%w/w
3	Loss on ignition	18.85%w/w
4	Determination of total ash	81.15%w/w
5	Acid insoluble ash	8.89%
6	Determination of particle size	84.43% pases through sieve no 120
7	Water Solubility	5.52%
8	Alcohol solubility	16.72%
9	Estimation of arsenic	2.31% w/w
10	Estimation of calcium	22.0%w/w

Design of clinical study

I. Selection of patients.
II. Research Design.
III. Duration and Method of administration of drug.
IV. Parameters of Assessment.
V. Criteria for Assessment of Results

I. SELECTION OF PATIENTS :

The 30 volunteers who had hair in the foot region were selected after critical adaptation of inclusion and exclusion criteria. 30 volunteers were taken from OPD of DGM Ayurvedic Medical College Hospital, Gadag. The Samples were selected by simple sampling technique.

Inclusion criteria :

- Age- Volunteers having hair over foot region from 15-45 age groups are taken for study.

- Apparently healthy volunteers are taken
- Sex- Volunteers of either sex are included.

Exclusion criteria:

- Volunteers suffered with fever for more than 15 days, past two months will be excluded.
- Volunteers taking medicine like Allopurinol, choloroquinine will be excluded.
- Volunteers who are suffering from allergic skin manifestations like dermatitis, eczema, and other skin diseases will be excluded.
- Volunteers who are taking one of the ingredients as Haratala, Shankha, Palasha kshara in medicine formulations for any diseases will be excluded.

Intervention:

- The volunteers are assessed before treatment and on follow up as per assessment criteria.
- The 13 volunteers are male and 17 volunteers are female.
- Preparation of the part.

  The 3 sq.cm area on the dorasal surface is shaved in the foot region in males.

  Threading was done in 3 sq.cm area on the dorasal surface in the foot region in females.

- Application of the lepa.

  30 gram of powder (ingredient of romashatana lepa) is taken and mixed with 10 ml of arka patra swarasa to have a uniform paste. This uniform paste is applied on the 3 sq. cm area as per the requirement so as to get the uniform thickness.

It is applied opposite to the direction of the roma.

- Removal of the lepa

Just before complete drying it is removed

II RESEARCH DESIGN:

The study was conducted on total 30 volunteers who could continue the treatment for full duration and come for follow up till to the last, the patient was selected from the OPD, DGM Ayurvedic Medical College & Hospital for prospective clinical trial.

III DURATION AND METHOD OF ADMINISTRATION OF DRUG :

Treatment duration - 7days. Follow up - 7 days.

Method of Administration**:** Local application of romashatana lepa

Dosage – As required Total study duration- 14 days

IV PARAMETERS FOR ASSESSMENT:

Assessment of Result:

Assessment of results will be done based on the gradings and before treatment & on follow up by carrying paired 't' test .

1) Number of hair in 3 sq. cm area
2) Growth of hair in 3 sq. cm area

Observations related to the effect of the treatment

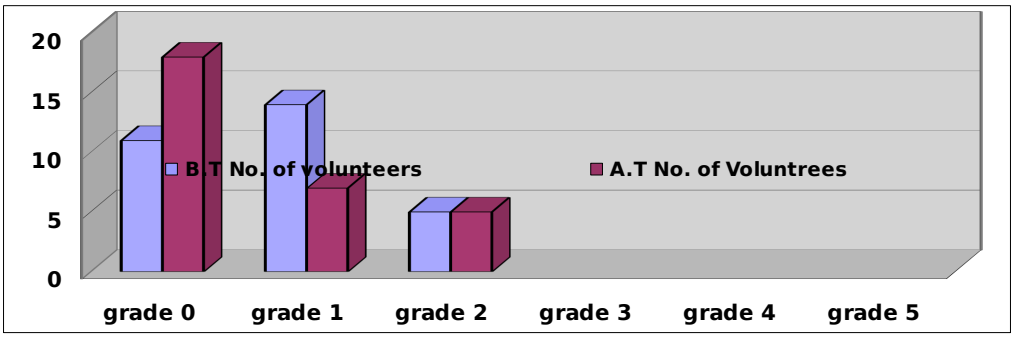
Number of Hair in 3 sq. cm area

Table No.2. Showing the response of the therapy before and after the treatment.

Sl.	Grading	B.T.	%	A.T.	%
		No. of volunteers.		No. of volunteers.	
01.	0	0	0	18	60.00

02.	1	11	36.66	7	23.33
03.	2	14	46.67	5	16.67
04.	3	5	16.67	0	0
05.	4	0	0	0	0
06.	5	0	0	0	0

Graph No.01- Showing response before and after the treatment.(for no.of hair)

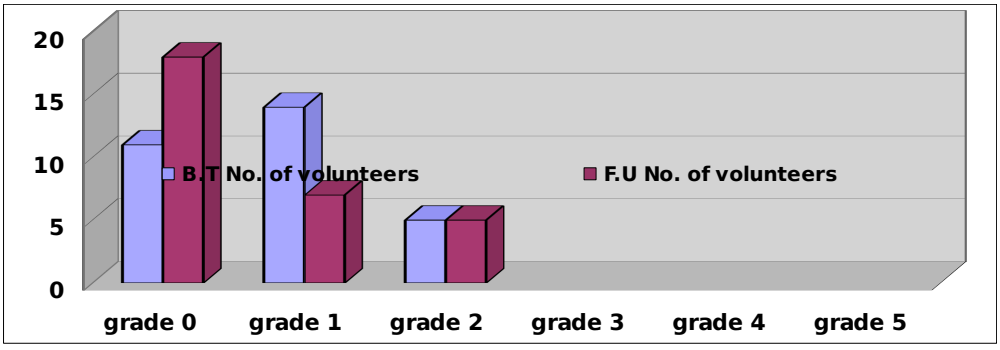


Number of Hair in 3 sq. cm area

Table No.3 . Showing the response of the therapy before and on follow up.

Sl.	Grading	B.T.	%	F.U	%
		No. of volunteers.		No. of volunteers.	
01.	0	0	0	18	60.00
02.	1	11	36.66	7	23.33
03.	2	14	46.67	5	16.67
04.	3	5	16.67	0	0
05.	4	0	0	0	0
06.	5	0	0	0	0

Graph no.02 - Showing response before the treatment and on follow up .(for no.of hair).

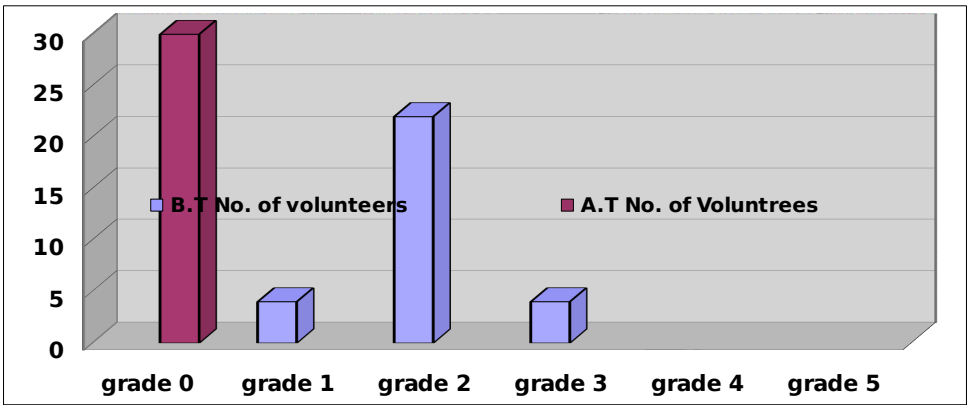


. **Growth of Hair in 3 sq. cm area in mm**

Table No.4. Showing the response of the therapy before and after the treatment.

Sl.	Grading	B.T.	%	A.T.	%
		No. of volunteers.		No. of volunteers.	
01.	0	0	0	30	100
02.	1	4	13.33	0	0
03.	2	22	73.33	0	0
04.	3	4	13.33	0	0
05.	4	0	0	0	0
06.	5	0	0	0	0

Graph No.3 Showing response before and after the treatment (for growth of hair)

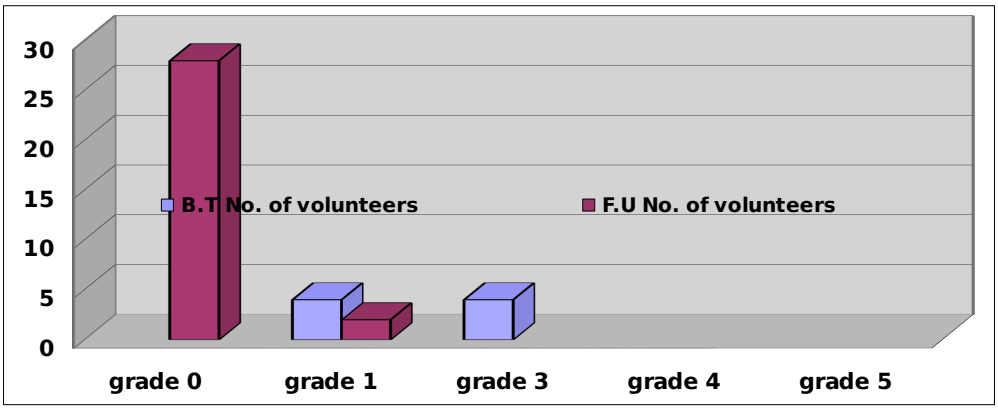


Growth of Hair in 3 sq. cm area in mm

Table No.5. Showing the response of the therapy before and on follow up.

Sl.	Grading	B.T.	%	F.U.	%
		No. of volunteers.		No. of volunteers.	
01.	0	0	0	28	93.33
02.	1	4	13.33	2	6.67
03.	2	22	73.33	0	0
04.	3	4	13.33	0	0
05.	4	0	0	0	0
06.	5	0	0	0	0

Graph no. 4- showing the response before the treatment and on follow up (for growth of hair)



Discussion

Probable mode of action of the drug:

The toxicological mechanism in organic 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 sulfahydril group of dihydrolipoamide preventing regeneration of lipoamide, which is a necessary cofactor in the conversion of pyruvate to acetyl CoA levels, in turn, 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 citric acid cycle activity.

As^{3+} also interferes with Glucose production and uptake, the drop of acetyl CoA levels, discussed above, also inhibits the activity of the pyruvate carboxylase, which catalyzes the conversion of pyruvate to oxaloacetate, the initial step in gluconeogenesis. Animal studies demonstrate that As^{3+} has the greatest effects on gluconeogenesis from pyruvate with lesser effects on gluconeogenesis from other substances such as lactate, amino acids, glycerol. Impaired

gluconeogenesis combined with carbohydrate depletion due to stress of poisoning can result in hypoglycemia. Arsenic also effects other sulfahydral containing enzymes, including membrane transport enzymes involved with insulin dependent cellular glucose uptake. Thus cellular lack of glucose may be a consequential problem in As^{3+} poisoning although it remains unproven in humans.

From the above we can draw an inference that the romashatana lepa works by decreasing the cellular energy level and thereby leading to decreased mitotic activity and cessation of hair follicle formation. As mentioned above the shanka and palasha kshara provides the alkaline medium to facilitate the depilation activity of romashatana lepa

Discussion on clinical study

- Effect on the number of hair in 3 sq. cm area.

60% of the volunteers showed no hair in the 3 sq. cm area after and on follow up reported statistically significant where p value is < 0.001.

- Effect on growth of Hair in 3 sq. cm area.

  100% of the volunteers showed no hair growth in 3 sq. cm area after and on follow up

  reported statistically significant where p value is < 0.001.

- Effect on the number of hair in 3 sq. cm area in males

53.48% of the volunteers showed hair in the 3 sq. cm area in grade 1 after and on follow up reported statistically significant where p value is < 0.001.

This may be due to that males are usually atiloma so the number of hair is reduced to nil was not seen.

- Effect on growth of Hair in 3 sq. cm area in males

100% of the volunteers showed no hair growth in 3 sq. cm area after and 84.61% on follow up reported statistically significant where p value is < 0.001

This may be due to that males are usually atiloma so the number of hair is reduced to nil was not seen in 15.38% of volunteers.

No untoward effect was seen during the treatment.

- Effect on the number of hair in 3 sq. cm area in females

100% of the volunteers showed no hair in 3 sq. cm area after and on follow up

reported statistically significant where p value is < 0.001.

- Effect on growth of Hair in 3 sq. cm area in females.

100% of the volunteers showed no hair growth in 3 sq. cm area after and on follow up

reported statistically significant where p value is < 0.001.

Total effects :

Number of hair in 3 sq. cm area

- 56.66% shows complete relief.
- 43.33% shows marked relief.

Number of hair in 3 sq. cm area in males

- 100% shows marked relief.

Number of hair in 3 sq. cm area in females

- 100% shows complete relief.

Growth of Hair in 3 sq. cm area

- 93.33% shows complete relief
- 6.67% shows marked relief.

Growth of Hair in 3 sq. cm area in males.

- 84.61% shows complete relief.
- 15.38% shows mark relief.

Growth of Hair in 3 sq. cm area in females

- 100% shows complete relief.

CONCLUSION

- The result reveals that romashatna lepa has got good depilation activity.

- There was no untoward effect seen during the study

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Clinical study

Volunteer 1

Fig1 - Before

Volunteer 2

Fig2- Before

Fig3- With Application

Fig4- With Application

Fig 5- Follow Up

Fig 6- Follow Up