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RANDOMIZED CONTROLLED CLINICAL STUDY TO EVALUATE ROLE OF *AAMRABEEJA-HARITAKI LEPA* IN *DARUNAK* (DANDRUFF)

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ABSTRACT

Currently available modern treatment for dandruff have various limitations, either due to poor clinical efficacy or due to the compliance issues. Also, these drugs are unable to prevent recurrence. This study evaluates the clinical efficacy and safety of "*Aamrabeeja-Haritaki Lepa*" in the management of dandruff. This study is a prospective, open, comparative, phase II clinical trial. Out of total 60 patients, two groups were made each having 30 patients. Patients from Trial group were given "*Aamrabeeja-Haritaki" lepa* for 7 days and patients of control group were given the "Anti- Dandruff Shampoo with ZPT", twice a week for a period of 3 weeks. The predefined primary efficacy endpoints were reduction in dandruff scaling, itching, reduction in cracking of skin and reduction in hair loss. The predefined secondary safety endpoints measures were incidence of adverse events and overall patient compliance to the drug treatment and recurrence after completion of therapy. Statistical analysis was done by applying t test. This study observed both trail drug and control drug has significant reduction in the mean scores of itching and white scales of dandruff. The control group has better relief in dandruff scaling both area wise and severity wise. Trial group has better relief in itching and cracking of skin than control group. Trail drug is absolutely safe and is economical control drug is known to have hazardous side effects including teratogenic activity, though in the present study only dry, split hairs and hair loss like side effects of control group are observed.

Keywords: *Darunak*, Dandruff, *Aamrabeeja*, *Mangifera indica*, *Haritaki*, *Terminalia chebula*.

INTRODUCTION

Dandruff is the shedding of dead skin cells from the scalp. As skin cells die a small amount of flaking is normal but some people, however, experience an unusually large amount of flaking either chronically or as a result of certain triggers, which can also be accompanied by redness and irritation[3]. Prevalence of Dandruff is high, in India- nearly 18.38%[4]. Having to deal with dandruff is crucial and embarrassing. Recurrence is common. The trial lepa is given in *Laghutrayee*[5]. Contents of trial*lepa*are easily available and are economical.*Lepa* application releases active principles; they enter at proper site in skin and get absorbed. It's*pachana*by*Bhrajakagni* and new metabolites formation occours which causes pacification of *Doshas thus* breaking thepathogenesis.*Content of lepa are Aamrabeeja, Haritaki and Godughda.Haritaki*is an *aushadhi*drug hence it works with its *veerya*[6]and *Aamrabeeja* is an*aahareeyadravya*hence it is assumed to work by its *rasa*[6]. *Haritaki*is

having *ushnaveerya*which pacifies *Vata*and*Kapha Doshas*[7]. *Kashaya rasa* of *Haritaki*acts as *twakaprasadana*(skin nourishing agent) and*vranaropaka*(wound healing agent)[8]. *Haritaki*is said to destroy diseases caused due to *Vata*and *KaphaDoshas*. *Aamrabeeja* is having *Kashaya rasa* – which acts as *twakaprasadana* and *vranaropana*[9].*Godugdha* with its *snigdhaguna* destroys *Rukshata*(dryness) and*Darunata*(harshness)[10].

MATERIALS

A) Sample size: - Total 60 (30 in two groups)

B) Drugs

1) *AamrabeejaMajja*(*Mangiferaindica*kernel) *Choorna*

2) *HaritakiPhala*(*Terminaliachebula*fruit) *Choorna*

3) Fresh unprocessed cow milk

4) Ketoconazole 2% with Zinc Pyrithione (Z.P.T.) 1%

(Readymade market preparation)

Consent

A written informed consent of all patients was taken.

METHODS: - The present study was conducted in two phases

A) Pharmaceutical phase

B) Clinical phase

A) Pharmaceutical phase: – included collection of drugs, authentication of collected drugs and preparation of powders of both the drugs.

B) Clinical phase

Inclusion criteria

1) Patients suffering from dandruff.

2) Age: Between 16-40 years, irrespective of gender, socio-economical and marital status.

Exclusion criteria

1) Psoriasis of scalp

2) Eczema of scalp

3) Immune- compromised conditions and systemic infections

4) Conditions in which head wash is restricted like *Ardita, Pratishyaya*[11],injuries to scalp etc.

Methodology

Selection of samples was done according to inclusion and exclusion criteria. Randomization of samples was done by lottery method. Two groups were allotted, Trial group and control group, each having 30 samples.

Group A- trial drug (*Aamrabeeja-HaritakiLepa*)

Group B- Control group (Ketoconazole Shampoo)

Group A: The *lepa*was prepared by soaking fine drug powders (1:1 proportion) in unprocessed fresh cow milk for 1 hour to obtain a homogeneous mixture. A thick coat of *lepa*(1/4 *angula*thick[12], approximately 3-4 mm) was applied over the scalp. *Lepa*was kept for 20 minutes and then rinsed off with Luke warm water.

Duration – Seven consecutive days.

Group B: For control group, patients were given a market sample of Ketoconazole 2% with ZPT 1%. The shampoo was applied on the affected area, left for 5 minutes and then rinsed off with Luke warm water.

Duration - Weekly twice for three consecutive weeks

Follow ups were taken on 3rd, 7th, 14th, 21st and 30th day.

Withdrawal criteria

1. If patient develops any side effects
2. on aggravation of symptoms
3. Patient not willing to continue the treatment

Assessment criteria

1) Scaling

2) *Kandu* (Pruritus)

3) *KeshbhoomiPrapaatan*(Cracking of skin)

4) *Keshchyuti*(Hair loss)

Gradation index[13]

1) Scaling

a) Area of quadrants affected with grades.

1) Less than 10%-----0

2) 11-30%----------1

3) 31-50%----------2

4) 51-70%----------3

5) More than----------4

70%

b) Severity

1) A small flake resembling a coarse grayish white powder--------1

(Chalk dust size)

2) Intermediate (Refined salt crystal size) ----------2

3) Large flakes very loosely attached to the scalp and----------3

Giving irregular whitish surface (Wooden powder size)

4) Flakes apparently congealed together into yellowish plates-----4

Adhering to scalp, sometimes with evidence of exudates. (larger than grade 3)

2) *Kandu*(Pruritus)

0- Absence of itching

1- Mild itching, ignorable

2- Moderate itching sensation over scalp relieved after itching for a while

3- Severe itching sensation over scalp, interrupting

daily activities

3)*Keshbhoomiprapatan* (cracking of skin)

0– Absent 1 – Present

4) *Keshchyuti*(Hair loss)

It was judged on Visual Analogue scale. Every patient was assigned a score of 10 before starting treatment. Weekly improvement was noted.

0 to 3 ---excellent relief

4 to 6 ---Moderate relief

7 to 9 ---Mild relief

10 ------ No relief.

Diet

Regular diet of all the patients was continued.

Routine

No any daily routine change was suggested during the treatment period.

Total effect of therapy

Total effect of therapy was determined on the basis of relief.

Complete Remission - > 75% relief in symptoms.

Marked Improvement - 51% to 75% relief in symptoms

Moderate Improvement - 25% to 50% relief in symptoms

No effect - below 25% relief in symptoms

OBSERVATION AND RESULTS

The data collected from clinical study was analyzed under two headings

1) Demographic analysis

2) Clinical efficacy of the therapy under study.

Table No.1 Showing Effect on general Score of Patients of *Darunak*

Trail group						
Sr. no	Symptom	BT	AT	Difference	% of relief	
1.	Scaling-Area covered	7 7	1 7	6 0	7 7 . 9 2	
2.	Severity	6 2	3 0	3 2	5 1 . 6 1	
3.	*Kandu*	6 2	0 8	5 4	8 7 . 0 9	
4.	*Keshbhoomiprapatan*	0 4	0 1	0 3	7 5 . 0 0	
5.	Hair loss	3 0 0	1 1 4	1 8 6	6 2 . 0 0	

(BT- Before treatment & AT- After treatment)

Table No.2

Control group						
Sr. no	Symptom	BT	AT	Difference	% of relief	
1.	Scaling-Area covered	76	14	62	81.57	
2.	Severity	69	30	39	56.52	
3.	*Kandu*	61	15	46	75.40	
4.	*Keshbhoomiprapatan*	03	01	02	66.66	
5.	Hair loss	300	129	171	57	

Table No.3 Showing Effect of Therapy on 60 Patients of *Darunak*

Sr. No.	Total effect of Therapy	Relief in percent In symptoms	Trail group		Control group	
			No of Pt.	%	No of Pt.	%
1.	Complete Remission	> 75 %	0	0	1	3.33
2.	Marked Improvement	51% to 75%	27	90	28	93.33
3.	Moderate Improvement	25% to 50%	3	10	1	3.33
4.	No effect	below 25%	0	0	0	0

Table No.4 showing recurrence of dandruff after completion of therapy

Assessment criteria	Recurrence in percent					
	Trial group			Control group		
	1 wk	2 wk	3 wk	1 wk	2 wk	3 wk
Area covered	3.33%	10 %	13.33%	20 %	40 %	50 %
Scaling Severity	3.33%	6.66	16.66%	16.66%	26.66%	33.33%
Kandu	No rec	No rec	3.33 %	6.66 %	13.33%	26.66%
Skin cracking	No rec	No rec	No rec	No rec	No rec	No rec
Hair loss	No rec	No rec	10 %	6.66%	26.66%	40 %

(Rec- Recurrence)

DISCUSSION

Area covered: In trial group only 3.33% patients show recurrence in first week .In control group it is 20%.

In second week after completion of therapy 3.33% patients from trial group and 40% from control group show recurrence

In the third week 16.66% patients from control group show recurrence and from trial group 50% patients show recurrence

Severity: In trial group only 3.33% patients show recurrence in first week while in control group it is 16.66%.

In second week after completion of therapy 6.66% patients from trial group and 26.66% from control group show recurrence

In the third week 16.66% patients from trial group show recurrence and from control group 33.33% patients show recurrence

Kandu: In trial group there is no recurrence of *Kandu* in first two weeks and after third week of completion of therapy only 3.33% patients show recurrence. In control group 6.66 % patients show recurrence in first week, 13.33 % in second week and 26.66% in third week after completion of therapy

Keshbhoomiprapatan: No recurrence is observed in *Keshbhoomiprapatan* in both the groups

Hair loss: In trial group no recurrence was observed in first two weeks. In third week it was observed in 10% patients.

In control group recurrence is 6.66%, 26.66% and 40% in first, second and third week respectively

CONCLUSION

- The control group has better relief in dandruff scaling both area wise and severity wise.
- Trial group has better relief in itching and cracking of skin than control group
- Trail drug is absolutely safe and is economical
- Control drug is known to have hazardous side effects including teratogenic activity, though in the present study only dry, split hairs and hair loss like minimal side effects of control group are observed.Less recurrence is seen in trial group patients.

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