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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *GUNJA* SEEDS AS A LOCAL APPLICATION IN THE MANAGEMENT OF *INDRALUPTA*

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ABSTRACT

'Indralupta' or 'Alopecia areata' is mainly a cosmetic condition where we find a patchy loss of previously existing body hairs. When we go through different Ayurvedic texts lot of references are found indicating the use of poisonous drugs as an external application for various types of diseases & alopecia areata is a disease which requires a topical type of treatment. It is one of the common therapeutic problems which challenge the skill of the people working in the field of dermatology.

Ayurveda accepts the utility of toxic substances in treating the diseases keeping in mind some medicinal properties hidden inside. A thorough literature research gave us the scope to expect some good results from a herbal irritant drug - *'Gunja'.*

The present study was carried out on 20 patients diagnosed with *Indralupta*. *Lepa* of fine powder of the seeds of *Gunja* was used for topical application two times per day for 56 days.

The study shown that in 40% of cases complete reoccurrence of hair growth was noted where as 50% showed partial growth and 10% showed no change at all. According to the modern science the need of activation of the hair follicles through induction of mild irritant contact dermatitis is necessary in this disease for regeneration and growth of hair with its inherent properties, *Gunjabeejalepa* irritates the lesions with *Tikshnaguna* and *Ushna Veerya* and *Tikta* rasa. Combine these virtues act to irritate and activate the hair follicles thereby promoting hair growth of the affected part.

KEYWORDS: *Indralupta, Gunja*, Alopecia areata.

INTRODUCTION

Seeds of *Abrus precatorius* are well known for their toxic effects[1,2]; abrin an albuminoid substance, being a chief poisonous ingredient.[8] As described earlier Ayurveda clearly mentions the signs and symptoms of abrus toxicity. In spite of these hazardous effects our ancient healers have successfully tried to utilize them to treat various disease conditions.[3,4,5]

Ayurveda explains different pharmaceutical processes on a crude drug to make it acceptable for human race. One of them is a process of *Shodhana*. This particular process changes the drug as follows:

1. Enhances the ease of administration.
2. Ensures easy digestion and assimilation.
3. Makes it less toxic and more tolerable
4. Increases therapeutic efficacy.

These points indicate that this procedure affects the morphological, microscopic, physical, chemical and biological properties of the natural drug. As this process affects the pharmacognostic aspects of the crude drug, it becomes necessary to try to design a study to observe these changes systematically and to expose all truths scientifically with the help of modern methods.

When this herb was studied extensively through ayurvedic as well as modern texts, lot of reference was found regarding its medicinal properties.[6,7] Maximum texts have focused the *'Keshya'* property of the seeds.[1,2] So we decided to carry out a parallel study regarding this particular property of the seeds. Also, hairs contribute one's personality & have always remained the centre of attraction. So everybody is extra conscious about it now-a-days and is in search of better remedy for their growth.

The treatment known so far to the medical world is still not that much satisfactory.[9] Hence we should keep our options open to find out an ideal answer to come out of this helplessness & frustration.

Aims and Objectives

1. To assess the validity and potentialities of *Gunja* seeds as a local application (in the form of' *Lepa*[1]) in "*Indralupta*".
2. To put forth the adverse reactions (if any) during the therapeutic trial of this drug.
3. To provide cheap and easily available single drug therapy for *Indralupta*.

Material and Methods

1. *Raktagunja* with black spots was used for the complete course of the study.[3]

2. 500gm. of Abrus seeds were purchased from the market. Out of them about 100 gm. were found to be detonated; hence discarded.
3. Seeds were subjected to coarse powder for *Shodhana* and analytical study where as during the whole period of therapeutic study, fine powder of the seeds was utilized.
4. 200gm. of the coarse powder was used for the process of *Shodhana* and the remaining 200 gm. was utilized for extraction and chemical analysis.
5. The process of *Shodhana* was carried out as mentioned in Rasatarangini at Dept. of Rasashastra, Govt. Ayurved College, Nagpur.
6. Extractions, thin layer chromatography and other chemical tests were done in Laboratories.
7. As far as the therapeutic trial is concerned, all the subjects included were selected from the outpatient Department of Kayachikitsa, Govt. Ayurveda College and Hospital, Nagpur. All the patients who were diagnosed as a case of "alopecia areata" were subjected to this therapeutic study .

Design: Open non comparative trial.

Number of Patients - Twenty.

Criteria for Selection of Patients

- The present study was confined to the outdoor patients irrespective of age and sex.
- The diagnosis in every patient included in this study was made strictly on clinical grounds.
- The help of magnifying lens was taken to differentiate between scaring & non scaring lesions.

Criteria for Refusal of Patients

- Patient having associated major illness like Tuberculosis, Diabetes Mellitus, AIDS, Leprosy or any endocrine disorder, were rejected.
- Patients of diffuse alopecia as well as of male pattern baldness were rejected.

Selection of Drug

Red seeded variety with black spots was used for complete course of the study. Seeds were subjected to fine powder.

Administration

Lepa of fine powder of the seeds was made (freshly prepared each time) with water as a medium. The route of administration was topical. *Lepa* of about 120 to 240 mg of powder (1-2 seed) per square cm. area was applied. Application had a thickness of about one fourth *Anguli*. It was applied to the affected part in the morning and evening two times per day. It was kept there till it dries off & was subsequently wiped out with the help of wet cotton.

PROCEDURE FOLLOWED

1. ***Shodhana* (Purification)**
   Coarse powder of abrus seeds weighing 200 gm. was tied in a cotton cloth in the form of *Pottali*. One litre of cow milk was taken in a stainless steel container and the *Pottali* was hang in such a way that it didn't touch the base of the container. This unit named *Dolayantra* was kept on low fire for 6 hours. Cow milk was added further as and when required. These seeds were subsequently washed with warm water and dried.
2. From the proteinous nature of ABRIN it was decided to carry out extraction of the seeds of *Abrus precatorius* using a non-polar solvent i.e. Petroleum Ether (60-80°c).
   For extraction S*oxhlet* extraction assembly was used and the seeds were extracted for 20 hours. The extract thus obtained was concentrated and used for determining its components using Thin Layer Chromatography (TLC).
   For TLC, sample was prepared by dissolving the extract in Petroleum Ether. Small amount of sample was loaded on the TLC plate. The solvent system selected was PE: Benzene 60:40. Plates were run in the saturated TLC chamber.
3. Results of various chemical tests namely moisture content, acid insoluble ash, Total ash, Fat content, Total nitrogen (i.e. total protein content which is obtained by multiplying with 6.25 to the value of total nitrogen content) and pH were obtained of both treated as well as untreated sample.
4. Regarding the therapeutic trial, a standard clinical proforma with few important Ayurvedic and modern principles were prepared to note down all particulars of the patient and the disease.
5. All patients were analysed according to age, sex, socioeconomic status, site of the disease, previous therapy, nature of work, dietary habits, addictions, pattern of sleep, state of mind, *Prakriti* & periodicity of *Keshabhyanga* & *Keshdhawanam*.
6. The patient was reviewed every 3rd day for first two weeks & then once a week for two months.
7. Changes in the these signs & symptoms were taken into consideration: colour, regrowth of hairs, local temperature, sweating, sensation, itching, dryness, unctuousness, inflammation.
8. The effects & all of the topical responses/reactions (adverse if any) were noted down completely.
9. Laboratory examination Viz. Hb %, TLC, DLC, Urine-routine & microscopic were done to exclude systemic diseases.
10. Instruction to the patient: All patients were instructed to report immediately if any unacceptable symptom is realized.

Assessment of Efficacy

1. An ink outline of the affected area was traced on butter paper on day-0 indicating 0% of regrowth of hairs. Thus total patch was taken equivalent to 100%
2. The average of reproduced hairs was measured in millimeter scale on 0^{th}, 14^{th}, 28^{th}, 42^{nd} & 56^{th} day of treatment for comparison.
3. Each patient was screened for color of local skin, local temperature, sweating, sensation, itching, dryness, unctuousness & inflammation; before & after treatment.
4. The results of the therapeutic study were recorded as follows in terms of improvement (concentrating

predominantly on regrowth of hairs both lengthwise & area wise).

Cured: Complete regrowth of the hairs on the lesions.

Improved: Regrowth of hairs on maximum area of the lesions barring some of the total area of lesion.

Stationary: No change at all.

Detonated: Increase in number of lesions & in area of existing lesions or long-standing adverse reactions left behind.

5. The data was tabulated and analysed statistically.

Observations

Table 3: Sex wise Distribution of 20 cases of *Indralupta* (Alopecia Areata)

S.No.	Sex	No. of Cases	Percentage of Cases
1.	Male	15	75%
2.	Female	05	25%

Sex

In the sample of present study among 20 patients 75% patients were male while 25% were female.

Table 4: Incidence of Age in 20 cases of *Indralupta* (Alopecia Areata)

Sr.No.	Age group	No. of Cases	Percentage of Cases
1	0-16 yrs. *Balyawastha*	5	25%
2	16-30 yrs. *Tarunawastha*	9	45%
3	30-55 yrs. *Praudhawastha*	6	30%

Age

20 patients were classified according to their age while doing this experimental study. Percentage of patients from *Balyawastha* was 25; that of *Tarunawastha* was 45 and 30% cases were from *Praudhawastha* age group.

Table 5: Assessment of Marital Status in 20 cases of *Indralupta* (Alopecia Areata)

Sr.No.	Marital Status	No. of Cases	Percentage of Cases
1	Married	10	50%
2	Unmarried	10	50%

Marital Status

Marital Status was assessed in all the cases while conducting this study. The incidence of married as well as unmarried cases was 1 : 1 i.e. 50% each.

Table 6: Distribution of Educational status in 20 cases of *Indralupta*

Sr.No.	Educational Status	No. of Cases	Percentage of Cases
1	Literate	10	50%
2	Illiterate	07	35%
3	Children (below primary level of Education)	03	15%

Educational Status

All the 20 patients were highlighted for their status of education. 50% of the cases were literate, 35% were illiterate and remaining 15% were children below primary level of education.

Table 7: Incidence of Economic Status in 20 cases of *Indralupta*

Sr.No.	Economic Status	No. of Cases	Percentage of Cases
1	Lower	18	40%
2	Middle	12	60%
3	High	00	00%

Economic Status

It is a well known fact that economic status of the family not only affect social life but also gives its impact on the health of family members. To serve the purpose economical status was screened in all the cases. 40% patients were from low economic group and 60% patients from middle class families. Not a single patient was there from rich group.

Table 8: Incidence of Dietary Habits in 20 cases of *Indralupta*

Sr.No.	Type of Diet	No. of Cases	Percentage of Cases
1	Regular	12	60%
2	Irregular	08	40%
3	Spice	07	35%
4	Non Spice	13	65%
5	Veg	10	50%
6	Mix	10	50%

Dietary Habits

All 20 patients were asked for their Dietary habits. The study revealed.

1. 60% of patients taking regular diet while 40% were very much irregular with their timings of taking meals.
2. 35% patients had a habit of taking spicy foods while 65% were taking non-spice type of diet.
3. The incidence of vegetarian and mix type of diet was equal i.e. 50% each.

Table 9: "*Dehaprakriti*" wise Distribution of 20 cases of *Indralupta*

Sr.No.	Type of *Prakriti*	No. of Cases	Percentage of Cases
1	*Vata*	0	0%
2	*Pitta*	0	0%
3	*Kapha*	0	0%
4	*Vatapitta*	7	35%
5	*Vatakapha*	8	40%
6	*Kaphpitta*	5	25%
7	*Tridosha*	0	0%

Prakriti

Prakriti Parikshanam of all patients was carried out briefly which concluded giving 35% of *Vatapittaprakriti*, 40% *Vatakapha* and 25% patients had *Kaphapitta* type of constitution.

Table 10: Incidence of "Previous Therapy" taken so far in 20 cases of *Indralupta*

Sr.No.	Mode of Treatment	No. of Cases	Percentage of Cases
1	Local Oint/Intralesional Injectable	4	20%
2	Raw Drug application	1	5%
3	Oral	2	10%
4	Nil	13	65%

Previous Therapy

All patients were screened for history of any previous therapy received. 20% patients had used intralesional injectable or local ointments from allopathic system of medicine 5% cases had a history of application of some unknown raw drug. 10% patients had taken per oral treatment from homeopathy system of medicine.

Table 11: Incidence of "Onset of Disease" in 20 cases of *Indralupta*

Sr.No.	Onset of Disease	No. of Cases	Percentage of Cases
1	Sudden	10	50%
2	Gradual	10	50%

Onset of Disease

In the sample of present study among 20 patients; Sudden as well as gradual onset was found to be equal.

Table 12: Incidence of Addictions in 20 cases of *Indralupta*

Sr.No.	Habit	No. of Cases	Percentage of Cases
1	Tea	14	70%
2	Coffee	00	0%
3	Alcohol	07	35%
4	Tobacco Chewing	04	20%
5	Smoking	07	35%

Addictions

While conducting this experimental study all patients were asked for addiction if they had any; 70% patients were habitual of taking tea; 35% used to take alcohol; 20% patients had a habit of tobacco chewing and 35% cases were regular smokers.

Table 13: Assessment pattern of Sleep in 20 cases of *Indralupta* (Alopecia Areata)

Sr.No.	Patterns of sleep	No. of Cases	Percentage of Cases
1	Sound	14	70%

Pattern of sleep

All twenty patients were assessed for their pattern of sleep. It was found later on that 70% of them had sound sleep regularly while remaining 30% patients had some problems related to their sleep.

Table 14: Assessment of *Keshabhyanga* in 20 cases

Sr.No.	*Keshabhyanga*	No. of Cases	Percentage of Cases
1	Regular	15	75%
2	Irregular	5	25%

Keshabhyanga

All patients were asked for their habit of massaging oil on the scalp. 75% used to do it regularly but 25% patients were not habitual of this thing.

Table 15: Assessment of *Keshadhawanam* in 20 cases

Sr.No.	*Keshadhawanam*	No. of Cases	Percentage of Cases
1	Daily	07	35%
2	Periodical	13	65%

Keshadhawanam

All patients were asked for their periodicity of *Keshadhawanam* 35% patients had a habit of daily *Keshdhawanam* while 65% did not have it.

Table 16: Assessment of "State of Mind" in 20 cases of *Indralupta*

Sr.No.	State of Mind	No. of Cases	Percentage of Cases
1	Anxious	05	25%
2	Tense	02	10%
3	Irritable	02	10%
4	Relaxed	11	55%

State of Mind

It is assumed that state of your mind reflects on your face. It plays a vital role in keeping one always in morbid condition. This analytical study came out with 25% of total patients to be anxious and 55% patients were relaxed in their daily routine, while survey revealed some tense and some irritable people having their contribution of 10% each.

Table 17: Assessment of Dryness in 20 cases

Dryness	Day 0	Day 14	Day 28	Day 42	Day 56
Grade 0	6	17	13	15	17
Grade I	12	3	03	04	03
Grade II	02	00	04	01	00
Grade III	00	00	00	00	00

Table 18: Assessment of % of Dryness in 20 cases

% of Dryness	Day 0	Day 14	Day 28	Day 42	Day 56
Grade 0	30	85	65	75	85
Grade I	60	15	15	20	15
Grade II	10	00	20	05	00
Grade III	00	00	00	00	00

Table 19: Assessment of Itching in 20 cases

Itching	Day 0	Day 14	Day 28	Day 42	Day 56
Grade 0	9	19	18	14	18
Grade I	11	1	02	06	02
Grade II	00	00	00	00	00
Grade III	00	00	00	00	00

Table 20: Assessment of % of Itching in 20 cases

% of Itching	Day 0	Day 14	Day 28	Day 42	Day 56
Grade 0	45	95	90	70	90
Grade I	55	05	10	30	10
Grade II	00	00	00	00	00
Grade III	00	00	00	00	00

Table 21: Assessment of Inflammation in 20 cases

Inflammation	Day 0	Day 14	Day 28	Day 42	Day 56
Grade 0	20	00	20	20	20
Grade I	00	13	00	00	00
Grade II	00	06	00	00	00
Grade III	00	01	00	00	00

Table 22: Assessment of %of inflammation 20 cases

% of Inflammation	Day 0	Day 14	Day 28	Day 42	Day 56
Grade 0	100	00	100	100	100
Grade I	00	65	00	00	00
Grade II	00	30	00	00	00
Grade III	00	05	00	00	00

Table 23: Assessment of Discoloration in 20 cases

Discoloration	Day 0	Day 14	Day 28	Day 42	Day 56
Grade 0	13	18	17	16	17
Grade I	02	00	00	01	00
Grade II	05	02	03	03	03
Grade III	00	00	00	00	00

Table 24: Assessment of %of Discoloration in 20 cases

% of Discoloration	Day 0	Day 14	Day 28	Day 42	Day 56
Grade 0	65	90	85	80	85
Grade I	10	00	00	05	00
Grade II	25	10	15	15	15
Grade III	00	00	00	00	00

Table 25: Table Showing Ultimate Effect on the Length of Hair

Length of Hair (in mm.)		Difference	SE of Difference	't'	'P'
B.T	A.T.				
X1±SD1	X2±SD2	x ± SDX			
1.2 ±1.32	19.5 ± 6.00	18.3 ±6.03	1.3483	13.57	<0.001

Before starting the treatment the average length of hair was 1.2 ± 1.32 mm which after treatment increased upto 19.5 + 6 mm. The increase in length by 18.3 + 6.03 was analysed statistically with the help of paired 't[1] test, 't' was 13.57; $p < 0.001$ which suggested that increase in length was very highly significant.

Table 26: Table Showing Ultimate Effect on the Area of Alopecia Areata Having Regrowth of Hair

Area of Regrowth (grade)		Difference	SE of Difference	't'	'P'
B.T	A.T.				
X1±SD1	X2±SD2	x ± SDX			
0.6 ± 0598	31 ± 1.07	2.5 ± 1.19	0.2660	9.39	<0.001

Before starting the treatment the grade of area of regrowth was 0.6 + 0.598 which after treatment increased upto3.1 + 1.07. This increment was analysed statistically with the help of paired 't[1] test, 't' was 9.39 $p < 0.001$ which suggested that increase in area having regrowth of hair was very highly significant.

A Parallel Therapeutic Study of *Gunja Beej Lepa* On *Indralupta* (Alopecia areata). In the initial period of this therapeutic trial, *Lepa* of purified *Gunja* seeds was used for local application. But it exhibited no clinical efficacy. Hence it was decided to carry out the trial using *Lepa* of crude drug (untreated seeds).

Plan of Study

All patients included in this therapeutic study were selected from the outpatient department of skin, Govt. Aayurveda Hospital, Nagpur. Twenty patients who were diagnosed as "Alopecia areata" were only subjected to this clinical trial. All patients received fine powder of abrus seeds for application of *Lepa* twice daily after history taking and examination, as mentioned in study proforma. Routine laboratory tests were done to exclude systemic diseases.

The specific parameters evaluating clinical assessment were fixed before treatment and they were traced biweekly for two months.

DISCUSSION

The results obtained have been discussed here in brief:

Distribution of Age, Sex, Marital Status, Economical Status and Educational Status

Incidence of the disease in *Balyawastha* is very less whilst majority of the patients in this series was found to be from *Tarunawastha* and *Praudhawastha*.

There were almost triple number of males. In this course of study, incidence of married as well as unmarried case was 50 : 50. Sixty percent patients were from middle class families and remaining were from low socio economic group. Maximum patients in this study were literate.

Assessment of Dietary Habit, *Prakriti* and Onset of Disease

The incidence of vegetarian and mix dietary pattern was found to be equal (50% each). Near about equal incidence of the disease was found in *Vatapitta* and *Vatakaphaprakriti* (35 and 40% respectively) whereas 25% patients had *Kaphapitta* type of constitution. Sudden and gradual onset was found to be equal.

Assessment of Previous Therapy, Pattern of Sleep, State of Mind/ *Keshdhawanam* and *Keshabhynga*

20% patients had used intralesional injectable and local ointments, whereas 10% patients had taken oral treatment from homeopaths, 70% patients had sound sleep regularly; 75% patients used to do *Keshabhyanga* regularly and only 35% patients had a habit of daily *Keshadhawanam*. The study revealed 25% patients to be anxious and 10% to be irritable.

Distribution of Site of Disease And Number of Patches

In this clinical examination occipital as well as temporo-parietal region was found to be commonest site of the disease.

Assessment of Symptomatology

Dryness, itching and local discoloration do not participate actively in the symptomatology of *Indralupta*. It is the indulgence of inflammation which directly affects the progress of therapy. Signs of inflammation were visualised during the second week of application and they subsided subsequently in the next week.

The sign suggesting regeneration of hair and area activation of hair follicles exhibited considerable exaggeration during third week of therapy.

Results

The results of the therapeutic study in 20 patients are recorded here (concentrating predominantly on approximate length of regenerated hair & % of area of regrowth)

Sr.No	Criteria	Explanation	No of patients	Percentage
1.	Cured	Complete regrowth of hair on the lesions	8	40%
2.	Improved	Regrowth of hair on maximum area of the lesions barring some of the total area of lesion	10	50%
3.	Stationary	No Change at all	2	10%
4.	Deteriorated	Increase in number of lesions and in area of existing lesions or longstanding adverse reactions left behind	0	0%

Exclusive Features Within The Course of Therapy

1. In the process of cure of the disease, outgrowth of white coloured hair is noted sometimes in early stage.
2. These white coloured tufts definitely turn darker gradually.
3. The firstly appeared hair are always fine, soft, feathery, which are many-a-times colourless also.
4. Central portion of the patch is the first to exhibit reappearance of hair; peripheries develop later on.

The course of this disease is difficult to predict as the incidence of recurrence is documented. Prospective studies, regarding the long term effectiveness of this therapeutic approach, will unfold the facts.

PROBABLE MECHANISM OF ACTION OF DRUG

Indralupta is a disease of *Pitta dosha sammurchchhit* with *Vata*. Seated with *Kapha* it affects the *Dhatu* "*Rakta*". *Romkupas* are obstructed with vitiated humours. Thus this stage needs *Lekhana* and *Uddipan karma* to combat the local action of *Kaphadosha*.

According to the modern concept of regeneration and growth of hair with reference to this disease, one of the modes of local treatment suggests the need of activation of the hair follicles through induction of mild irritant contact dermatitis.

With its inherent properties, *Gunjabeejalepa* irritates the lesions with *Tikshnaguna* and *Ushna Veerya* and *Tikta rasa*. Combine these virtues act to irritate and activate the hair follicles thereby promoting hair growth of the affected part. This is what "*Sampraptibhanga*" expects.

PRECAUTION

There is always a fear of inducing scarring alopecia by deep ulceration while treating through this

mode of therapy. Hence it should be administered in appropriate quantity and with due caution; best avoided on delicate skin (like over face).

Through this clinical study, preceded by analytical evaluation, multi dimensional aspects of toxicity are considered. An enigma of relationship of micro with the macro power has provided us a solution of every consequence along with the natural treasure. A disease where *Dosha-dushyasammurchana* demands appropriate remedy for health, exclusive properties of herbs reported with due toxicity prove their efficacy through proper administration.

The actual work through this plan genuinely contributes to the conceptual toxicology, pharmacology and medicine in Ayurveda.

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