

## Usefulness of Individualised Homoeopathic Medicines in the Treatment of Alopecia Areata- Single-Arm Clinical Study

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### ABSTRACT:

Alopecia areata (A.A) is an autoimmune disease affecting genetically susceptible people, characterised by hair loss in sharply defined skin areas. It is the most prevalent autoimmune disorder and the second most common hair loss disorder after androgenetic Alopecia. The lifetime incidence of A.A. is approximately 2% worldwide. Alopecia areata is still a puzzle to dermatologists due to its unpredictable response to medications. The recurrence of complaints and variation in clinical presentations like alopecia totalis, alopecia universalis, and ophiasis are potentially can cause significant cosmetological damage in adolescents and young individuals. In conventional medicine, there is no preventative therapy or cure, and it increased the global burden of disease. In contrast, the homoeopathy system of medicine offers promising results in treating alopecia areata with individualised homoeopathic medicines. The main objective of this study was to evaluate the usefulness of Individualized Homoeopathic medicines in the treatment of Alopecia areata. A prospective, non-randomised, single-arm clinical study on alopecia areata was conducted on participants recruited from the OPD of the Department of Materia Medica, Govt. Homoeopathic Medical College, Calicut, Kerala, India. The participants who fulfilled various inclusion and exclusion criteria were recruited for the study. The usefulness of individualized homoeopathic medicines was evaluated by reduction in the bald patch size after the treatment using appropriate statistical tests. Among 30 participants, twenty-five completed the study and five participants dropped out and sample of n=25 was analysed. Among the analysed participants, most of the cases were cured with individualised homoeopathic remedies by reduction in the sizes of bald patches after treatment. There was a statistically significant reduction in the median size of the bald patches (6.00(3.50,17.65) vs 0.00(0.00,4.25),  $Z=-4.108$ ,  $P< 0.001$ ) after treatment in comparison to the size of the bald patches at baseline when analysed by using Wilcoxon Signed Rank test. The results showed the positive role and usefulness of individualised homoeopathic medicines in the treatment of alopecia areata. Randomised controlled trials are further warranted.

**KEYWORDS:** Alopecia, Autoimmune, Homoeopathy, Individualisation, Single-arm.

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**INTRODUCTION:**

Alopecia areata (A.A.) is an autoimmune disorder characterised by patches of non-scarring hair loss affecting scalp and body hair. A.A is classified under L63.0 as per the ICD-10. This condition may affect the eyebrows, eyelashes, and beard.<sup>[1]</sup> It is the most prevalent autoimmune disorder and the second most common hair loss disorder after androgenetic Alopecia.<sup>[2]</sup> The disease may be limited to one or more discrete, well-circumscribed, round, or oval patches of hair loss on the scalp or body. But in some cases, it may affect the entire scalp, known as alopecia totalis or the whole body, known as Alopecia Universalis.<sup>[3]</sup> Various triggers such as infections, trauma, hormones, and stress worsen the disease.<sup>[4]</sup> In diffuse alopecia areata cases, the prognosis may be worse.<sup>[5]</sup> The lifetime incidence of A.A. is approximately 2% worldwide.<sup>[2]</sup> In most patients, the onset is within the first three decades of life, although alopecia areata can start at any age. The sex incidence is probably equal.<sup>[6]</sup> Psychosocial stress has been reported to play a role in the onset and exacerbation of alopecia areata.<sup>[7]</sup> A.A. is associated with psychiatric and medical comorbidities, including depression, anxiety, and autoimmune disorders.<sup>[2]</sup> Diagnosis is made by clinical history, the pattern of Alopecia, and clinical examination. In diffuse cases, trichogram and biopsy are advised.<sup>[8]</sup> Loss of hair is considered an autoimmune process is leading to chronic inflammation due to organ-specific CD8+ T-cell-dependent response mainly affecting hair follicles.<sup>[4]</sup> In conventional medicine, there is no preventative therapy or cure, and it is increased the global burden of disease, a systematic review on the epidemiology and the burden of alopecia areata concluded.<sup>[2]</sup> Whereas the homoeopathy system of medicine offers promising results in treating alopecia areata with individualised

homoeopathic medicine, it can also treat root causes to prevent recurrence and ensure healthy hair growth.<sup>[5]</sup> Although some previous case studies showed evidence of the effectiveness of homoeopathic remedies in managing alopecia areata, there is still a lack of commendable clinical studies to support homoeopathy in treating alopecia areata. A case study reported a positive role of Homoeopathy in treating A.A.<sup>[4]</sup> In homoeopathic literature, various medicines are mentioned with indications for treating alopecia areata in detail.<sup>[10]</sup> So, this clinical study was conducted to develop an evidence-based record to support the positive role of individualized homoeopathic medicines in the management of alopecia areata and to find a group of homoeopathic remedies that can be frequently useful in alopecia areata.

**Methododology:**

**Setting and Design:** A prospective, non-randomised single-arm clinical study was conducted on the participants suffering from alopecia areata at the OPD of Material Medica, Govt. Homoeopathic Medical College, Calicut. Kerala, India. The ethical committee approved the study protocol at the institution level under the university of Calicut, India. The proposed plan of work adhered to the Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects adopted by the 18<sup>th</sup> WMA general assembly, Helsinki, Finland, June 196.<sup>[17]</sup> Written informed consent was obtained from each participant before the study started. In the case of children, assent was obtained from parents by providing all the information related to the study. Participants are well informed that they are free to exit from the study at any point before the completion of the study.

**Study Period:** The study was undertaken for 12 months, out of which cases were enrolled in the first three months, so the first prescription and follow-up of 8 months were completed in all cases.

**Selection of Samples:** The participants who have fulfilled various inclusion and exclusion criteria have been selected for the study. Alopecia areata was diagnosed by clinical history, the pattern of hair loss, and clinical examination (by identifying 'exclamation marks' in hair loss patches known as a pathognomonic feature of Alopecia Areata)<sup>[1]</sup>. Diagnosed cases of Alopecia areata, participants under all age groups, both sex, and participants who have provided informed consent (in children assent from parents) were included in the study. Participants suffering from alopecia totalis, universalis, scarring alopecia, telogen effluvium, androgenetic alopecia, tinea capitis, traction alopecia, and other systemic illness were excluded. Considering a chance of dropping out of 20%, the sample size was fixed at 30. Therefore, a sample size of 30 participants has been recruited for the study. Since it was a single-arm study, the statistical analysis was performed by using Wilcoxon Signed Rank test.

#### STUDY PROCEDURE AND INTERVENTION:

As per the specified eligibility criteria, participants underwent preliminary screening. After enrolment, a complete case-taking was undertaken on a pre-designed case recording format. Individualised homoeopathic medicine

selection based on the totality of symptoms, repertorization, and consultation with materia medica.<sup>[10,12,16]</sup> The selected medicine administration and the follow-up prescriptions were based on homoeopathic principles.<sup>14</sup> Homoeopathic medicines, dilution methods, potency, pharmaceutical form, and dose were recorded. All medicines were procured from a GMP-certified firm, The Kerala State Homoeopathic Co-operative Pharmacy Ltd, sponsored by Govt. of Kerala, India. Each dose was directed to be taken orally on a clean tongue, and it consisted of four medicated sugar globules (Two globules for children) of size 30. Each participant enrolled was treated for eight months, and follow-up was done every two weeks or when required by the participant. All the participants were advised to avoid certain things which can disturb the action of prescribed medicine like coffee, camphor, etc.

**Outcome Assessment:** The usefulness of individualized homoeopathic medicines was assessed by the reduction in the size of the bald patches after treatment compared to baseline sizes. Pre and Post-treatment photographs were taken for all cases. The sizes of bald patches at baseline and after eight months of treatment were calculated for Statistical analysis.

**Statistical Analysis:** Statistical analysis was performed with using SPSS Version 16.0. Wilcoxon Signed Rank test was used. P value <.05 considered as statistically significant.

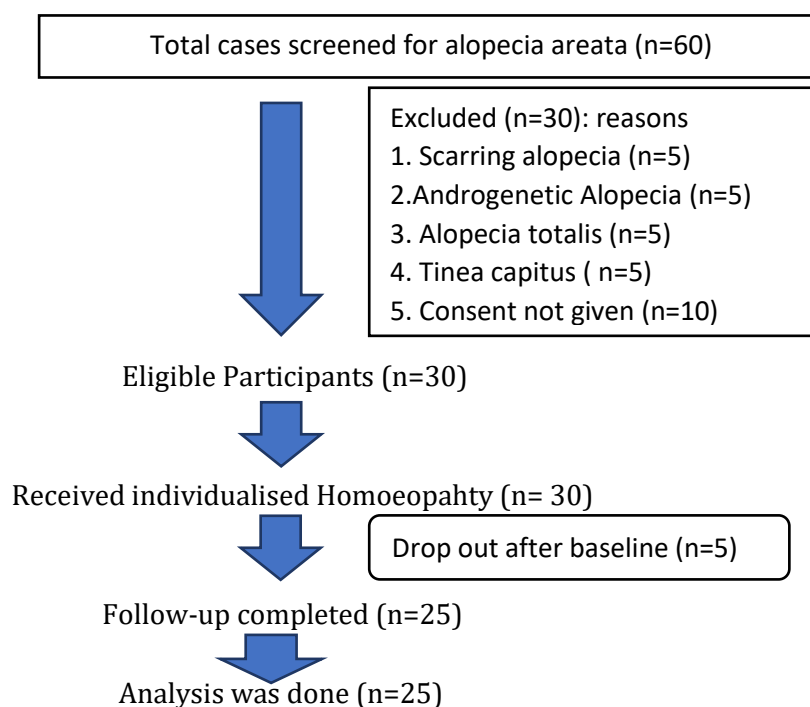
**Table 1: Sociodemographic information (n=25)**

Variable	Value n(%)
Age	19.95 ±10.60
Age Groups (in Years)	
0-10	5 (20)
11-20	7 (28)
21-30	7 (28)
31-40	6 (24)

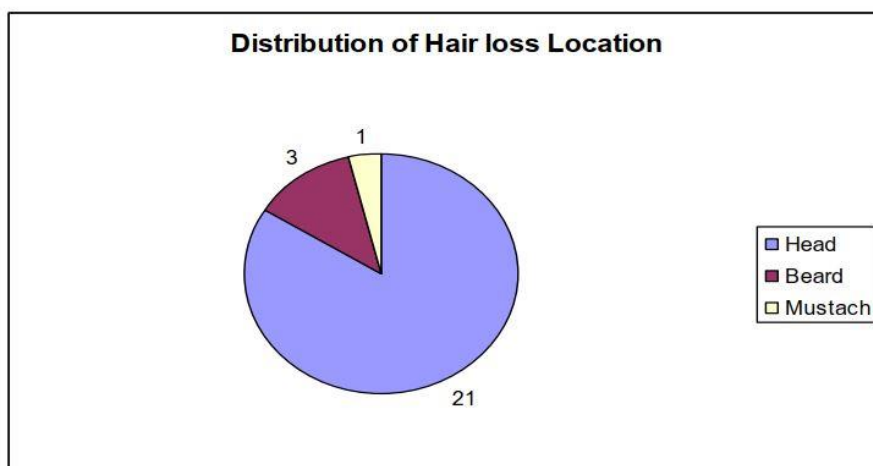
<b>Gender</b>	
Male	15 (60)
Female	10 (40)
<b>Occupation</b>	
Students	15(60)
House Hold work	3(12)
Govt. Employee	4 (16)
Self-employee	3 (12)
<b>Duration of Illness categorised</b>	
Upto 1 month	15 (60)
2 months	07 (28)
6 months	02 (08)
1 year	01 (04)
<b>Family History of Alopecia Areata</b>	
+Ve	08 (32)
-Ve	12 (68)
<b>Residence</b>	
Urban	15 (60)
Rural	10 (40)

**Table 2: Wilcoxon Signed Rank test result.**

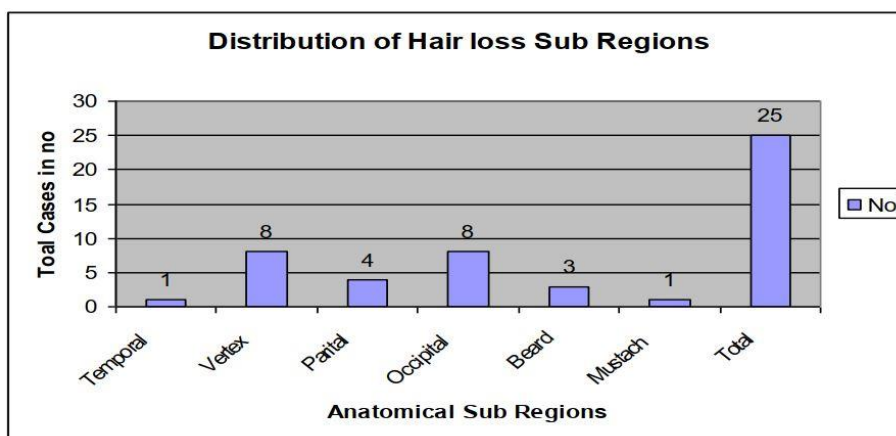
Size of patch	Median (IQR)	Z value	P value
Before	6.00(3.50,17.65)	-4.108	<.001
After	0.00(0.00,4.25)		



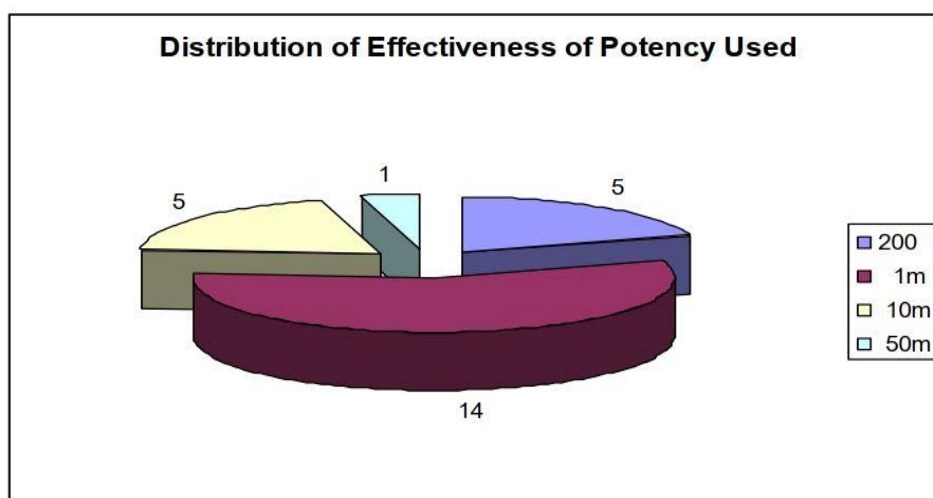
**Fig. 1: The participant flow diagram**



**Fig. 2 Distribution of Hair Loss location**



**Fig. 3 Distribution of Hair Loss Sub Regions**



**Fig. 4 Distribution of Effectiveness of Potency Used**



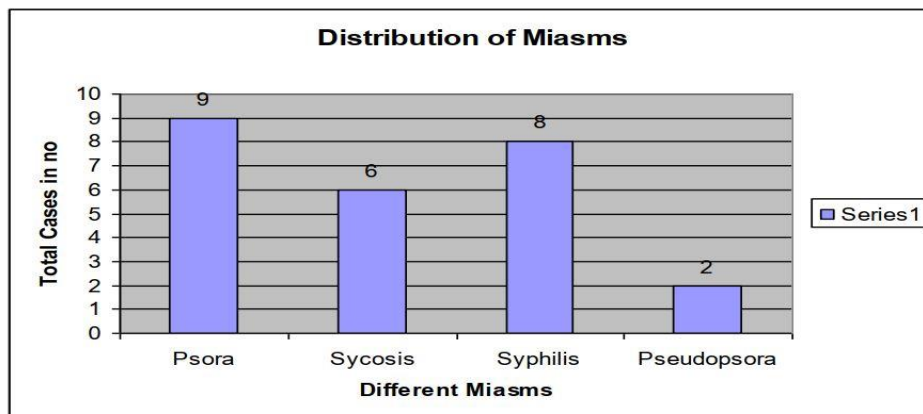


Fig. 5 Distribution of Miasms Dominant

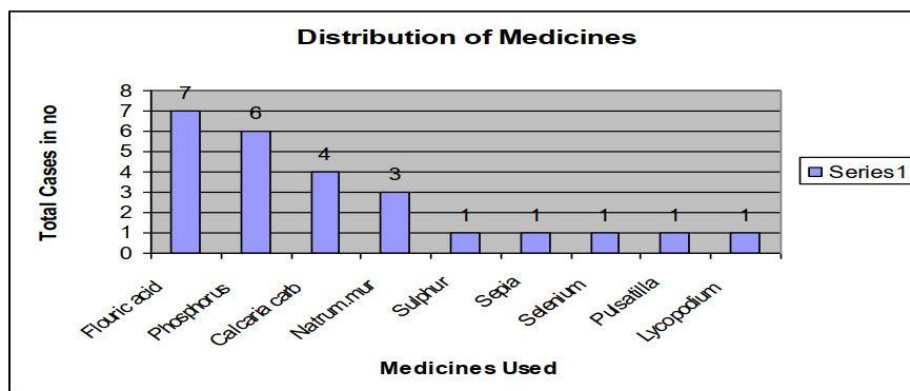


Fig. 6 Distribution of Medicines Used



Fig. No.7 Photographs of the cured cases in this study

**RESULTS:**

60 patients suffering from Alopecia were preliminarily screened, of which 30 (50%) were excluded. Thirty participants met the eligibility criteria and were enrolled on the study. Among those, 5 participants dropped out, and 25 completed the study. The objective was to evaluate usefulness of individualized homoeopathic medicines in the management of alopecia areata by compare the sizes of bald patches at baseline with the sizes of bald patches after eight months of treatment in participants who completed the study as per the protocol. In this study, the usefulness of homoeopathic medicines in the management of Alopecia areata was assessed based on the reduction in the size of the bald patches between baseline and the end of the treatment. There was a statistically significant reduction in the median size of the bald patches (6.00(3.50, 17.65) vs 0.00 (0.00, 4.25),  $Z=-4.108$ ,  $P<0.001$ ) after treatment in comparison to the size of the bald patches at baseline when analysed by using Wilcoxon Signed Rank test. So this study results showed the positive role and usefulness of individualised homoeopathic medicines in treating alopecia areata. And a group of homoeopathic remedies emerged, such as Fluoric acid, Phosphorus, Calcarea carb, Natrum Mur, Sulphur, Sepia, Selenium, Pulsatilla and Lycopodium as frequently useful for the treatment of Alopecia areata. Therefore, individualized homoeopathic remedies were influential and useful in the treatment of alopecia areata. The participants reported no adverse event during study.

**DISCUSSION:**

This study intended to explore the role of individualised homoeopathic medicines in treating alopecia areata. Even though Alopecia areata is an autoimmune disease,

the course and progress can't be predictable. Remissions and relapses often, if not treated carefully, lead to significant cosmological damage in the patients. As there is no effective treatment in modern medicine, the mainline treatment is tropical immunotherapy in diffuse cases and intralesional corticosteroids in localised hair loss patches.<sup>9</sup> Willemsen et al. used hypnosis to treat Alopecia areata.<sup>[11]</sup> A case study reported a positive role of Homoeopathy when individualised medicine is used in treating A.A.<sup>[4]</sup> There is a severe lack of conclusive evidence-based homoeopathic studies on alopecia areata in the mainstream databases. So we designed a study to come up with a clinical single-arm study to find out the positive role of individualised homoeopathic medicines on Alopecia areata. This study reflected a statistically significant result in reducing the bald patches size with increase in the density of hair in bald patches. The usefulness of Individualised homoeopathic medicines was evident by reduction in the size of the bald patches after the treatment, which was the main objective of this study. In this study, 25 cases completed the study, and the maximum no. of patients found in the age groups of 10-20 & 20-30 years equal was 7(28%) each, next in the age group of 30-40 years was 6(24%) and age group of 0-10 years was 5 cases (20%). And gender-wise, males 60% (15) and female 40% (10) of the participants in this study. Predominant Miasm identified was psora 36% (9), Sycosis was 24%(6), Syphilitic was 32%(8), and Pseudo syphilis was 8%(2). Psychological stress has been reported to play a role in the onset and exacerbation of alopecia areata. In this study, all participants were treated with individualised homoeopathic medicine after repertorizing characteristic symptoms and with the consultation of materia medica.<sup>[10,12,14,16]</sup> Along with medicine, diet

and regimen including stress relieving activities are also advised. Frequently given medicines are Fluoric acid, Phosphorus, Calcareo carb, Natrum Mur, Sulphur, Sepia, Selenium, Pulsatilla, and Lycopodium. More frequently indicated potency was 1M for 14, 200C for 5, 10M for 5, and 50M for 1. In total, 25 participants, 17(68%), were completely cured, 6 (24%) were partially improved, and 2 (8%) did not respond to treatment. Since Alopecia areata is an autoimmune disease, external applications are not necessary for the cure, even though it is the mainline treatment in conventional medicine. So this clinical study showed the positive role of individualised homoeopathic medicines in treating Alopecia areata when prescribed based on homoeopathic principles. Since it is a single-arm clinical study without a control group, the sample size was small, and the alopecia areata is associated with a variable and unpredictable remission, well-designed randomised control studies may be taken up to prove the efficacy of Homoeopathic medicines in the management of Alopecia areata.

#### **CONCLUSION:**

This open-label, prospective, single-arm clinical study showed a positive role and usefulness of individualised homoeopathic remedies in the management of alopecia areata. Further studies are merited by adequately powered randomised trials and independent replications with longer follow-ups.

#### **LIMITATION OF THE STUDY:**

However, it is a single-arm clinical study without control in small sample size, and the alopecia areata is associated with a variable and unpredictable remission. Well-designed randomised control studies may be taken up for scientific validation of results.

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