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Research Article

A COMPARATIVE STUDY OF EFFICACY OF MINOXIDIL 2% AND HAIR SERUM IN ALOPECIA AREATA IN A TERTIARY CARE CENTER AT KARAIKAL, PUDUCHERRY

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A B S T R A C T

Background: Alopecia areata is a unique, idiopathic disease in which there is patchy hair loss. The variable and uncertain natural history of alopecia areata is accounting for the multiplicity of uncritical claims for a large variety of therapeutic procedures.
Aim: To find the therapeutic comparison between hair serum and Minoxidil 2% solution.
Material and Methods: Patients attending skin out patient department in Vinayaka Mission's medical college & hospital, Karaikal were screened and the consenting cases of Alopecia Areata (AA) from July 2019 to June 2020 were chosen for study. There were 50 patients in the study. It is a randomized, single blind study. The eligible patients for the study were randomly allocated into two groups-Group A and Group B (25 in Group A and 25 in Group B). Patients in Group A were treated with 2% Minoxidil solution to be applied twice daily over the alopecia patch, where as Patients in Group B were treated with hair serum applied twice daily. Patients were followed up at 2, 4, 6, 8, 10 and 12 weeks. Alopecia Grading Score (AGS) was calculated at baseline and 12 weeks. Regrowth Score (RGS) was calculated at 12 weeks.
Observations: Total 46 patients completed the study (24 in Group A and 22 in Group B). In our study RGS ≥ 3 was observed in 62.7% of patients treated with Minoxidil 2% solution and 42.47% of patients treated with hair serum.
Conclusion: In our study Minoxidil 2% solution had better stimulatory effect on hair growth compared to hair serum in the treatment of mild to moderate patchy alopecia areata. The combination treatment may yield a better clinical response than either of the agents used singly.

INTRODUCTION

Alopecia areata is a unique, idiopathic disease in which there is a patchy hair loss that is usually confined on the scalp but may occur on beard region, moustache, eyelashes, eyebrows, axilla, genitalia & general body surface. Alopecia totalis is a condition if all the hair on the scalp is lost and Alopecia universalis is a condition if in addition to scalp, there is complete loss of body hair [1].

It occurs equally in both males and females and onset can be at any age, but most often in children and young adults [2].

The etiology of alopecia areata is not known with certainty. Factors implicated are-autoimmune theory, genetic factors, atopic state, infectious agents and emotional stress.

Alopecia areata progresses as a wave of follicles enter telogen phase prematurely.

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It is characterized by non-scarring round and/or oval patches of hair loss. The diagnostic hallmark of alopecia areata is an exclamation mark hair at the active hair margin. The lesions are largely asymptomatic, which may manifest either as alopecia areata classic, reticulate alopecia areata, alopecia totalis/universalis, or ophiasis and ophiasis inversa [3].

Associated clinical changes include nail involvement, cataract, vitiligo etc.

Diagnosis is based mainly on the clinical presentation and is corroborated by histology [4]. The variable and uncertain natural history of alopecia areata is accounting for the multiplicity of uncritical claims for a large variety of therapeutic procedures.[5] In the present study, a therapeutic comparison between hair serum and minoxidil 2% solution in the treatment of alopecia areata is undertaken.

Minoxidil

Minoxidil (2,4-diamino-6-piperidinopyrimidine-3-oxide) was initially developed as a drug for antihypertensive therapy.

Although minoxidil has been used as a hair regrowing agent for more than 20 years, its mode of action is not fully understood. Minoxidil does not appear to have either a hormonal or an immunosuppressant effect. Minoxidil most likely has a direct mitogenic effect on epidermal cells, both in vitro and in vivo. Anagen-phase hair bulbs plucked from men applying minoxidil showed a significant increase in proliferation index as measured by DNA flow cytometry. Minoxidil also has been shown to prolong the survival time of keratinocytes in vitro. Finally, minoxidil may oppose intracellular calcium entry. Calcium influx normally enhances epidermal growth factors to inhibit hair growth. Minoxidil is converted to minoxidil sulfate, which is a potassium channel agonist and enhances potassium ion permeability, thus opposing the entry of calcium into cells. Local vasodilatation does not appear to play a primary role in hair growth associated with minoxidil. There are some reports indicating that minoxidil also has some immunosuppressive effects [6,7].

Adverse effects- contact dermatitis, hypertrichosis (facial hair growth)[8].

How to apply

Scalp should be dried before applying. The dropper is filled upto 1ml mark.

It is then applied to the bald areas. Once applied, rub it in & avoid wetting hair for at least 4 hrs

Hair Serum

Hair serum helps in stimulating hair roots, improving hair length and promoting healthy hair growth.

Ingredients*:* Biotin, pea sprouts extract and Pro-vitamin B5 Biotin and Pro-vitamin B5 help in nourishing the hair follicles, strengthening their roots and promote thicker and healthier hair growth.

***Adverse effects* –** Itchingand rash.

How to apply

Dispense 2-3 drops of serum directly onto the scalp or into the palm of your hand.

Using fingertips, gently work into the scalp with massaging in a circular motion.

Distribute with fingertips from mid-length to ends, wrapping longer hair into a bun to soak in.

Allow time for hair to fully absorb serum.

MATERIALS AND METHODS

Ethical clearance was obtained from the Institutional Ethical Review Board. A written informed consent was obtained from all the patients enrolled in the study.

Inclusion Criteria

1. All patients with circumscribed, bald patch without any signs of inflammation or scarring.
2. Patients with short, easily extractable broken hair at the margin of a bald patch.
3. Skin within the bald patch being normal.
4. Patients above the age of 12 years.

Exclusion Criteria

1. Patients with re-growing hair.
2. Patients with secondary infection.
3. Patients already on some other medication for AA.
4. Patients having scar over the bald patch.
5. Patients below the age of 12 years.

Study Design

It is a single-center, prospective, randomized, single blind, and comparative study. Patients with clinical evidence of Alopecia Areata attending Outpatient Department of Dermatology, Vinayaka missions medical college, karaikal were taken for study.

Relevant history taken and clinical examination including general, systemic and local examinations were made.

The total number of patches and their measurements were noted in all quadrants of scalp.

Alopecia Grading Scale (AGS) was calculated as follows - The percentage of hair loss in each quadrant was added and divided by four to get the average. Presence of exclamatory hairs was noted.

Patients eligible for the study, were randomly allocated into two groups-Group A and Group B. Patients in Group A were treated with 2% Minoxidil solution applied twice daily over the alopecia patch where as Patients in Group B were treated with hair serum applied twice daily over the alopecia patch.

Both the groups were explained about the nature and course of the disease and were followed up at 2,4,6,8,10 and 12 weeks. In each visit- history of any side effects, any new patches and patient compliance were noted. Alopecia Grading Score (AGS) was calculated at baseline and 12 weeks.

Regrowth Score (RGS) was calculated at 12 weeks as follows – 0 (regrowth < 10%), 1 (regrowth 11– 25%), 2 (regrowth 26–50%), 3 (regrowth 51– 75%) and 4 (regrowth>75%).
Serial photographs were taken in each follow up.

Investigations

Selected investigations were done only in doubtful cases of AA,

- KOH preparation and fungal culture;
- Hair microscopy;
- Skin biopsy;
- Serology for lupus erythematosus;
- Serology for syphilis.

Study Duration

This study was conducted from July 2019 to June 2020.

Statistical Analysis

The primary efficacy measurement was the mean change in the Alopecia Grading Score (AGS) and to compare the hair regrowth rate by using hair regrowth score (RGS).

RESULTS

Out of the 50 patients who were enrolled, 46 patients completed the study (24 in Gr A and 22 in Gr B). (Table 1)

Table 1 Patient Profile

	Group A	Group B
Total number of patients	25	25
Remained in study	24(96%)	22(88%)
Study left out	1	3

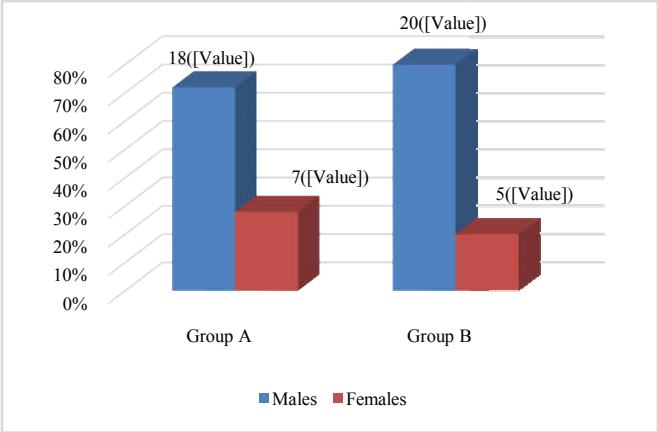

Figure 1 Sex distribution

Table 2 Age distribution

	Group A	Group B
20-30yrs	4(16%)	5(20%)
31-40yrs	8(32%)	8(32%)
41-50yrs	13(52%)	12(48%)

Among 50 cases, 8 patients are farmers (16%) that include 6 males and 2 females, 11 patients are fisherman (22%) that include 8 males and 3 females 11 patients are unemployed (22%) that include 8 males and 3 females, 11 patients are unskilled working in outdoor environment (22%) that includes 9 males and 2 females, 9 patients are skilled (18%) that includes 7 males and 2 females.(Table 3)

Table 3 Occupation

	Males	Females
Farmer (16%)	6(12%)	2(4%)
Fisherman(22%)	8(16%)	3(6%)
Unemployed(22%)	8(16%)	3(6%)
Unskilled workers(22%)	9(18%)	2(4%)
Skilled workers(18%)	7(14%)	2(4%)

Among 50 cases, 4% patients belonged to an upper high class, 8 % patients belonged to a high class, 24% patients belonged to an upper middle class, 26% patients belonged to a lower middle class, 30% patients were poor, and 8% were very poor.(Figure 2)

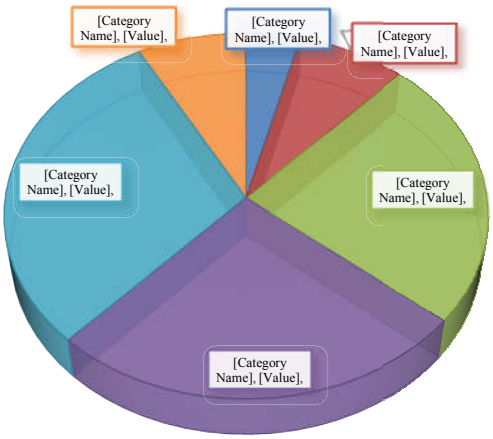

Figure 2 -Socio Economic Status

Distribution according to literacy among 50 patients, in the present study, illiterate people comprises of (24%), primary (16%), Secondary (22%), intermediate (22%) and graduates are (16%). (Figure 3)

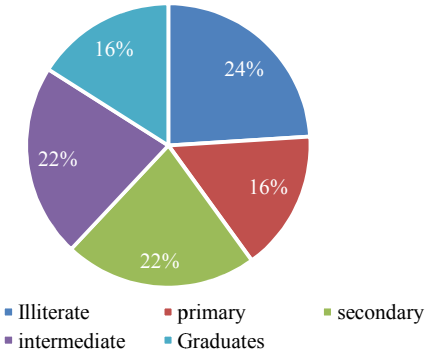

Figure 3 Literacy

Table 4 Mean Alopecia Grading Score (AGS)

	Group A	Group B
Baseline	9.66	9.98
12 weeks	4.02	4.93

A RGS of 0 and 1 are taken as Poor, 2 is taken as Moderate improvement, 3 is taken as Good and RGS of 4 as Excellent.

From the below graph(figure 4), it is apparent that the number of patients achieving –

Excellent regrowth was higher in Gr A (20 patients) compared to Gr B (16 patients).

Total 46 patients completed the study (24 in Gr A and 22 in Gr B). Regrowth Score (RGS) more than or equal to 3 at the end of 12 weeks were considered as improved and RGS less than or equal to 2 were considered not improved.

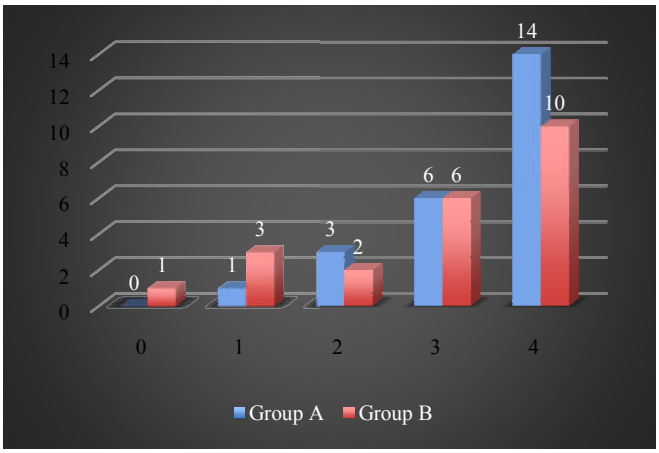

Figure 4 Regrowth Score

Image a A patient on Minoxidil – at the end of 6 months

Image b A patient on hair serum – at the end of 6 months

Safety Parameters

Both the study drugs were well tolerated. Only one patient in minoxidil group withdrew from the study due to suspected contact dermatitis.

DISCUSSION

The earlier trials carried out in alopecia areata, compared single agent such as minoxidil and minoxidil with placebo. [9]

Grading of the Response

The response was graded by assessment of Alopecia Grading Score (AGS) at baseline and after 12 weeks. Only terminal hair growth was taken into account.

Mean AGS for Goupr A at baseline was 9.66 and at 12 weeks was 4.02

Mean AGS for Goupr B at baseline was 9.98 and at 12 weeks was 4.93.

Total 46 patients completed the study (24 in Group A and 22 in Group B). Regrowth Score (RGS) more than or equal to 3 at the end of 12 weeks were considered as "Improved" and RGS less than or equal to 2 were considered "Not improved". The data were analyzed using Chi-square test. Group A showed better response then Group B which was found to be of suggestive significance ($0.05<P<0.10$)

Minoxidil 2% showed significantly better response compared to hair serum in the treatment of patchy AA. Among the 50 patients, in the present study majority belonged to age groupsof 20 - 50 years of age which was comparable to study done by Rivitti et al;[10] who quoted that alopecia areata has a peak incidence between 20 and 50 years of age.

Among 50 cases, 8 patients are farmers (16%) that include 6 males and 2 females, 11 patients are fisherman (22%) that include 8 males and 3 females 11 patients are unemployed (22%) that include 8 males and 3 females, 11 patients are unskilled working in outdoor environment (22%) that includes 9 males and 2 females, 9 patients are skilled (18%) that includes 7 males and 2 females. Roselino AM et al;[11] in his study stated that the survey of the literature did not show reports of alopecia areata as an occupational dermatosis. So we did not find any relationship of occupation to alopecia areata.

Distribution according to literacy among 50 patients, in the present study, illiterate people comprises of (24%), primary (16%), Secondary (22%), intermediate (22%) and graduates are (16%). No studies were found regarding relationship of literacy to alopecia areata.

CONCLUSION

Total 46 patients completed the study (24 in Gr A and 22 in Gr B). In our study RGS ≥ 3 was observed in 62.7% of patients treated with minoxidil 2% and 42.47% of patients treated with hair serum. Minoxidil 2% showed better response compared to hair serum in the treatment of patchy AA.

Minoxidil 2% has a significant stimulatory effect on hair growth in AA and can be used as in the treatment of AA. Hair serum is safe and well tolerated, but is less efficacious when compared to topical minoxidil. It can be used as an adjuvant therapy. Studies using the combination of topical minoxidil are required to prove if combination is more effective than either alone.

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References

1. Bergfled WF: Hair Disorders. In: Moschella S, Hurley H.editors. Dermatology. 3rd ed.Philadelphia: W.B. Saunders; 1992; p1545-46.
2. Schwartz RA, Janniger CK: Alopecia Areata. Cutis. 1997; 59:238- 41.
3. Shegal VN, Shrivastava G, Aggarwal AK, Sheti G, Adhikari T: Alopecia areata in Indian subcontinent. Skinmed. 2007; 6:639.
4. Wadhwa S, Khopkar Uday, Nischal KC: Hair and scalp disorders. In: Valia RG, Valia Amit R:Textbook of Dermatology, IADVL, 3rd ed, Mumbai: Bhalani Publishing House; 2008. p.905.
5. de Berker DAR, Messenger AG, Sinclair RD: Disorders of Hair. In: Burns Tony, Breathnach Stephen, Neil Cox, Griffiths Christopher. editors. Text book of Dermatology.7th edition. Oxford: Blackwell Scientific. 2004.p.63.43-45.
6. Tobin DJ, Fenton DA, Kendall MD: Ultrastructural study of exclamation mark hair shafts in alopecia areata. *J Cutan Pathol*. 1990;17:348-54.
7. Fiedler-Weiss VC: Potential mechanisms of minoxidil-induced hair growth in alopecia areata. *J Am Acad Dermatol*. 1987;16:653-6.
8. Lucky AW, Piacquadio DJ, Ditre CM, Dunlap F, Kantor I, Pandya AG, *et al*: A randomized, placebo-controlled trial of 5% and 2% topical minoxidil solutions in the treatment of female pattern hair loss. *J Am Acad Dermatol*. 2004;50:541-53.
9. Olsen EA, DunlapFE, FunicellaT, KoperskiJA, Swinehart JM, TschenEH, Trancik RJ.A randomized clinical trial of 5% topical minoxidil versus 2% topical minoxidil and placebo in the treatment of androgenetic alopecia in men. *J Am Acad Dermatol*. 2002 Sep;47(3):377-85.
10. Moreno GA, Ferrando J. Alopecia areata. Med CutanIbero Latina Americana. 2000; 28:294-312.
11. Roselino AM, Almeida AM, HippolitoMA, Cerqueira BC, Maffei CM, MenezesJB, Vieira RE, Assis SL, Ali SA. Clinicalepidemiologicstudy of alopecia areataInt J Dermatol. 1996;35(3):181-4.