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ORIGINAL ARTICLE

Effectiveness of QR678 and QR678 Neo® with intralesional corticosteroid vs. intralesional corticosteroid alone in the treatment of alopecia areata –A randomized, comparative, prospective study

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Abstract

Background: Alopecia areata (AA) is an inflammatory disorder, marked by chronic, persistent, and patchy loss of hair. At present intralesional/topical corticosteroids, Minoxidil solution, and topical immune-therapies are used for treatment. Though all these have side effects and high rate of relapse. As QR678 Neo® is proved to be effective in hair regrowth in male and female pattern hair loss, the aim of the study is to compare the efficacy of QR678 Neo® with intralesional steroid therapy vs. intralesional steroid alone in the treatment of AA of scalp in men and women.

Materials and methods: A total of 20 participants in age group of 20–50 years with nonscarring patchy hair loss were chosen for the study. Patients were arbitrarily divided into two groups (Group A—intralesional steroid with placebo and Group B-intralesional steroid with QR678 Neo®). All the participants were evaluated at baseline, 3 months and 6 months with standard global photography, dermoscopic assessment, and self-evaluation questionnaire at the end of study.

Result: Marked improvement was seen in the global assessment score after 6 months (mean- 6.6 SALT) as compared to baseline (38.5 SALT score) in group B. There was significant reduction of black dots, yellow dots, broken hairs, and tapered hair at 6 months on video dermoscopic examination in group B. Also, higher satisfaction was experienced with the treatment in group B patients.

Conclusion: QR678 Neo® in combination with intralesional steroids therapy proved to be significantly beneficial, efficient, and can be considered as safer treatment option for alopecia areata.

KEYWORDS
alopecia areata, hair regrowth therapy, intralesional corticosteroid, QR678

1 | INTRODUCTION

Hair is a distinctive and valued facial feature, and the way it is presented tends to establish the concept of itself and the person's personality. In hair loss, the ability to control and enhance attractiveness can get ambiguous and out of control.[1] Interestingly, women's self-esteem is much more dependent on physical appearance than men, and hair has a major impact on whether a person is aesthetically attractive or not.[2]

Alopecia areata (AA) is an inflammatory disease, characterized by chronic, recurrent, and deteriorating patchy hair loss.[3] The first diagnostic overview of AA was contributed by Celsus (14 to 37 B.C.) and the term AA is defined by Sauvages.[4,5] The condition may be limited to one or two small, rounded or oval, and bald spots that are well-circumscribed on the scalp or body (alopecia areata focal; AAF) or include the entire scalp (Alopecia areata totalis; AAT) or the whole body (Alopecia areata universalis; AAU).[3,6]

AA comprised between 1% and 2% of the population.[7] AA may occur at any age; however, more than 60% of cases are noticed before the age of 20 years. The incidence increases between the 2nd and 4th decades of life.[8,9] The median age is 33 years.[10] Around 14%–25% of patients are predicted to have ultimate total alopecia on the scalp.[11] It is estimated that patients with AA carry the inheritance of the disease are between 0% and 8.6%.[12,13]

As per the guidelines of the American National Alopecia Areata Foundation, AA is classified according to the Severity of the disease. (Table 1).[14] There is evidence that T cell lymphocytes aggregate around such hair follicle, trigger inflammation, and eventually lead to hair loss.[15] Unfavorable stimulus like immunological and endocrine abnormalities, infections, and neurological/psychological disorders is believed to interfere with genetic cause to induce the disease.[9,16]

The scalp is the most commonly affected area. Particularly, the occipital area with 38.4% of males and 33.4% of females.[17] The classic clinical expression of AA is shedding of telogen hairs asymptomatically with patchy nonscarring hair loss.[9] In addition to these findings, the hair shows accumulation of melanin pigment in the distal area of the body (Widy's sign).[18]

Apart from these findings, patients of AA may have a debilitating effect on quality of life (QoL). A latest systematic study has shown that patients with AA with more scalp intervention are strongly associated with lower QoL.[19] The psychosocial consequences include stress, low self-esteem, a distorted self-image, and less active and satisfying social participation.[20]

Currently, intralesional injection of triamcinolone, minoxidil 5% solution, topical or systemic corticosteroid, topical immunotherapy, psoralen photochemotherapy, or combination therapy are used to treat AA.[9] However, each of these options may have side effects like skin atrophy, hypopigmentation, dermatitis, and high rate of relapse. Although these treatments are currently available and are widely used, there is still no safe and successful treatment for hair regrowth that will provide long-term results.[21]

In 2010, Kapoor and Shome developed the QR678® hair growth factor regime, a bioengineered, recombinant formulation made up of a combination of growth factors.[22] QR678 Neo® formula is a plant-based polypeptide formulation that biologically reproduces the function of QR678® and they have been proved to be equivalent in the efficacy and safety. QR678 Neo® contains a unique concentration of Sh-Polypeptide-9 (bio-mimicking Vascular endothelial growth factor -VEGF), Sh-Polypeptide-1 (bio-mimicking Fibroblast growth factor-bFGF), Sh- Oligopeptide-2 (bio-mimicking Insulin like growth factor–IGF 1), Sh-Polypeptide-3 (bio-mimicking Keratinocyte growth factor-KGF), copper tripeptide, and Sh-Oligopeptide-4 (bio-mimicking Thymosin β4) dissolved in a sterile solution.[23]

QR678 Neo® has been shown to be successful as a hair regrowth therapy in male and female pattern hair loss, in female patients with alopecia in PCOS, chemotherapy-induced alopecia, and it has also shown remarkable effectiveness in combination with Minoxidil and Finasteride.[24,25] The literature also suggests its beneficial effects and longevity of hair greater than PRP.[26] The aim of this study is to compare the effectiveness of intralesional steroid with placebo (normal saline) and intralesional steroid in combination with QR678 Neo® for the treatment of AA of scalp in men and women.

TABLE 1 Classification of alopecia areata scalp severity in Group A and Group B patients

Classification of alopecia areata according to severity	
Severity	**Scalp involvement**
S1	<25% scalp involvement
S2	26%–50% scalp involvement
S3	51%–75% scalp involvement
S4	76%–99% scalp involvement
S5	100% scalp involvement

2 | MATERIAL AND METHODS

2.1 | Study design

A double blind, comparative, prospective clinical study was conducted following approval from the review board of the Institutional Ethical committee. A total of 20 (10 male and 10 female) patients diagnosed with AA of scalp in the age group of 20–50 years were selected for the study. The participants were arbitrarily divided into two groups (Group A—intralesional steroid with placebo and Group B—combination of QR678 Neo® with intralesional steroid) of 10 patients each. Signed, written, and informed consent was taken from all the participants.

2.1.1 | Inclusion criteria

A total of 20 patients with patchy hair loss on clinical assessment were selected for the study. They had to accomplish the following criteria:

- Patients with complaint of patches of nonscarring hair loss and untreated for minimum of 3 months.
- AA patches with size range from 1 × 1 cm to 3 × 3 cm measured with caliper were-selected for the study.
- Patients with minimum 1 patch to 5 patches of hair loss were included in the study.

2.1.2 | Exclusion criteria

- History of patchy areas of hair loss for less than 3 months.
- Evidence of hair regrowth in the patches in past 3 months.
- Scarring alopecia patches
- Patients who are on steroid injections/have taken steroid injections/other treatments for AA in past 3 months.
- Patients with severe medicine allergy, suspected malignancy, autoimmune/hematologic disease, Seborrheic dermatitis, or other disease of scalp.
- Expecting and lactating female.

Also, patients were instructed not to alter hairstyle or use hair dye during the treatment.

2.2 | Administration technique used for scalp

All of the patients were assessed using standard global photography as well as a dermoscopic examination at the start of the study, to determine the state of their hair. At each visit triamcinolone acetonide (5 mg/ml) was administered to the patients in both groups, at 1 cm interval with 0.1 ml on each site of in the alopecia patch. Highest of 2 ml was administered in every visit using a 31 gauge needle. Sessions were repeated every 3 weeks for 3 such sessions. In Group A patients, additionally 1 ml of placebo (Normal saline) and in Group B patients, 1 ml of QR678 Neo® formulation was administered in the scalp skin of the affected areas of patients. Few, tiny and nearly painless intradermal injections were given in the observable areas of alopecia through nappage system. Each administration was 1cm apart with 0.02 ml of quantity per site. Total of 8 sessions were performed at a period of 3 weeks each, in both the groups.

2.3 | Scalp assessment and evaluation

2.3.1 | Global photographic assessment

Standard clinical photographs of the vertex, right, and left lateral scalp area and occipital area were taken of all the patients for the clinical assessment at baseline, 3 months and 6 months. Photos were reviewed by 2 blinded dermatologist reviewers. The severity of hair loss was assessed by measuring the percentage of the alopecic area on the scalp using Severity of Alopecia Tool (SALT).[24] (Table 1) The SALT score is assessed by calculating the percentage of hair loss in each of the 4 areas of the scalp (40 per cent vertex, 18 per cent right profile, 18 per cent left profile, 24 per cent posterior) and by adding the sum to the total score.

2.3.2 | Dermoscopic assessment

With the help of dermoscope, evaluation was done at the patchy areas of the lesions of scalp. The images were taken to calculate and analyzed for black dots (cm^2), yellow dots(cm^2), broken hairs(cm^2), and tapered hair (cm^2) at baseline, 3 months and 6 months using specialized software. Chi-square test was used to assess the level of significance. Graphpad software was used to calculate the results. [27]

2.3.3 | Patient self-assessment

Patients accomplished a pre-validated questionnaire at the end of study comprising 5 questions. The questions were associated with the efficiency of the treatment which was to be rate on a scale of 0–5, with 0 being strongly disagree and 5 being strongly agree. Patients were asked to score the suitable answer. (Table 2).

3 | RESULTS

A sum of 20 patients was involved in the study with the age group of 20–50 years. Demographic distribution of patients according to Age, gender, BMI, severity score, and group has been mentioned in Table 3. As per the AA classification of severity, 8 patients were with

TABLE 2 Patient self-assessment questionnaire: patients satisfaction score

Que. No.	Question	Possible responses (On a scale of 0–5)
1	Is the bald spot getting any better?	Strongly disagree >Strongly agree
2	Is there any improvement in appearance?	Strongly disagree >Strongly agree
3	Is there any improvement in growth of hair since start of the therapy?	Strongly disagree >Strongly agree
4	Is the treatment effective?	Strongly disagree >Strongly agree
5	Are you satisfied with the treatment?	Strongly disagree >Strongly agree

grade S1, 8 were with grade S2, and 4 patients were with S3 grade severity score. All the patients were uniformly divided into two groups. (Table 3).

3.1 | Global photographic assessment

Subjective evaluation of the clinical photographs was done by 2 blinded reviewers (Figures 1 and 2) using the SALT score. The mean SALT score at the baseline were same for both the groups (38.4- Group A and 38.5- Group B). Marked improvement was seen in the global assessment score after 3 months in Group B (mean- 18.28 SALT). And further improvement was continued till 6 months (mean-6.6 SALT) which was maintained for longer follow-ups. But, the improvement in Group A (mean-24.2 SALT) at 6 months was not significant. (Table 4, Figure 3) It was also remarkable to notice that in 1 individual (5%) showed increase in the numbers of patches in Group A. (Table 5).

3.2 | Dermoscopic assessment

The baseline and final values for black dots (cm^2), yellow dots (cm^2), broken hairs (cm^2), and tapered hair (cm^2), at the beginning of the study, 3 months and 6 months values have been mentioned in Table 6. Chi square test was applied to find out the level of significance within the group. It was found that there was a significant enhancement in all the parameters in Group B as $p < 0.005$ from the

TABLE 3 Demographic distribution of patients of both the groups as per grading of severity, age, gender, and BMI

Group (*N*)	Gender (*N*)	Age range (years)	Alopecia areata severity Score	*N* (%)	Age (mean years ± SD)	BMI (mean ± SD)
Group A (10)	Male-5 Female–5	20–50	S1	4(20.0%)	33.0 ± 1.08	23.70 ± 1.1
			S2	4(20.0%)	32.7 ± 1.54	24.43 ± 2.3
			S3	2(10.0%)	34.2 ± 1.5	25.50 ± 2.7
Group B (10)	Male–5 Female–5		S1	4(20.0%)	33.7 ± 2.6	23.21 ± 1.5
			S2	4(20.0%)	34.8 ± 1.30	23.2 ± 2.55
			S3	2(10.0%)	32.0 ± 1.6	24.0 ± 1.3

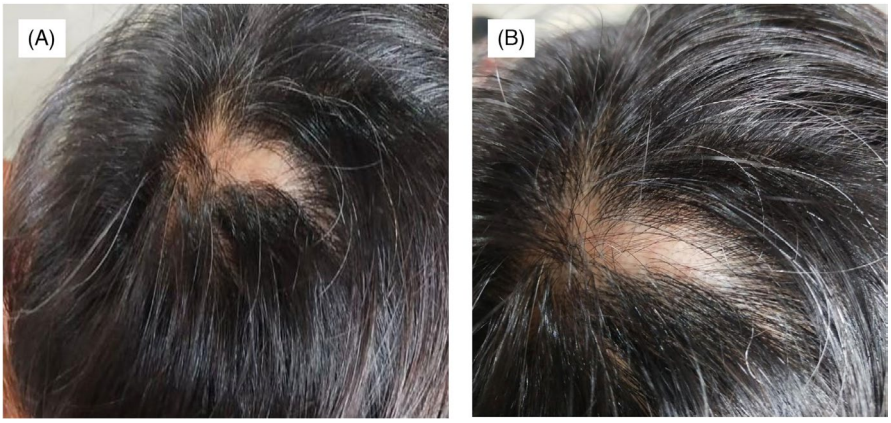

FIGURE 1 Group A clinical photographs. (A) Pretreatment. (B) After 6 months

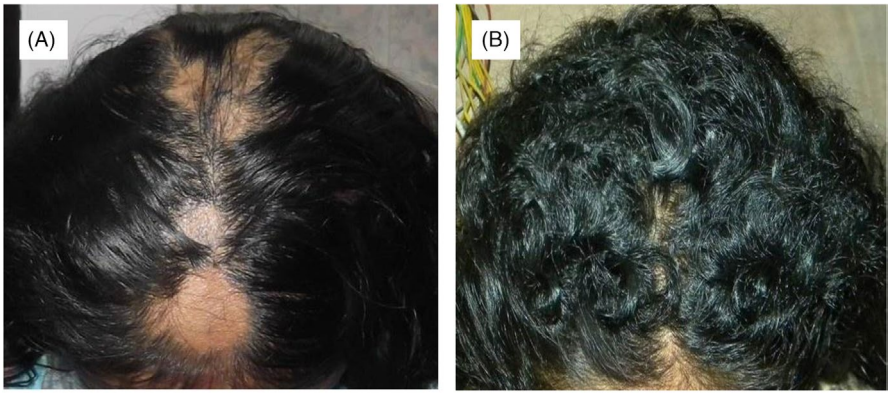

FIGURE 2 Group B clinical photographs. (A) Pretreatment. (B) After 6 months

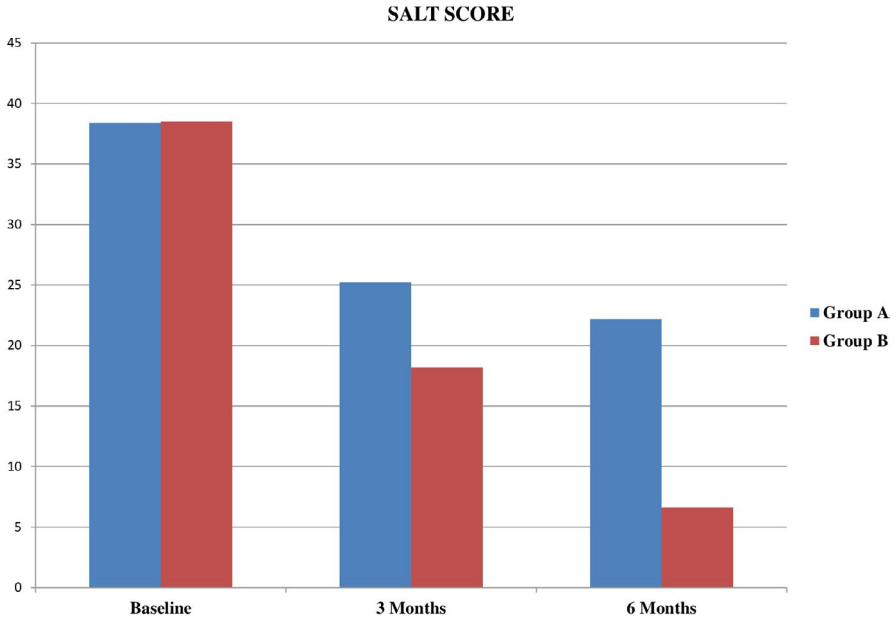

FIGURE 3 Subjective evaluation by SALT score by Reviewers 1 and 2

Group	Average mean salt score				
	Baseline	3 Months	6 Months	δ	*p* value
Group A	38.4	25.2	24.2	14.2	0.065
Group B	38.5	18.28	6.6	31.9	0.0000

TABLE 4 Subjective evaluation by Severity of Alopecia Tool (SALT) score by Reviewers 1 and 2

Note: p value <0.05 indicates statistical significant value.

TABLE 5 Subjective evaluation by Severity of Alopecia Tool (SALT) score by Reviewers 1 and 2, where patients showing no improvement and worsening

	No. of Patients showing no Improvement	No. of Patients showing worsening
Group A	0	1
Group B	0	0

baseline to the last value, but in Group A there was no significant alteration after 3 months and 6 months (Figure 4).

3.3 | Patient self-assessment

Patient self-assessment score proved significant difference between Groups A and B. (Figure 5) Mean score was highest in group B for the improvement in growth of hair (mean = 5), also score for the appearance (mean = 4.5), and satisfaction with the treatment (mean = 4.5) was better. In comparison to group B, group A patients were less satisfied with the treatment (mean = 2.5); also, their response to appearance was low after treatment (mean = 2.5).

4 | DISCUSSION

Hair loss can be expressed in terms of deformity and inability to meet standards of physical appearance in the community, and has the ability to distinguish individuals in their own perception and in the opinion of others. Therefore, patches of hair loss as in AA greatly impact a person's self-image, psychological influences, and also adversely affect their quality of life.[28,29]

A lifelong incidence of mental illness has been recorded in approximately 66%–74% of AA patients.[30,31] In addition, traumatic experiences related to hair loss have been documented in 9.8% of adults and 9.5%–80% of adolescents.[32] AA tends to reduce quality of life (QOL) in most of the patients and is correlated with nearly 70% of the lifelong incidence of emotional connection issues.[33]

Also, atopy has been documented between 11%–38.2% in individuals with AA.[34] Vivien et al. investigated AA and found a 65% probability of its advancement to chronic condition.[35]

Treatment targets prevention of disease development and to ensure sufficient hair growth.[35] There are a variety of therapeutic methods for regrowth of hair in AA but neither of it has been seen to be completely beneficial or to absolutely help the participants to get rid of the disease.[3]

TABLE 6 Videomicroscopic assessment

Variables	Outcome	Group A	δ	*p* value	Group B	δ	*p* value	Df	Chi Square Value
Black dots (cm^2)	Baseline	48	20	0.06	50	46	<0.001	2	15.7
	3 Months	36			16				
	6 Months	28			4				
Yellow dots (cm^2)	Baseline	60	23	0.06	62	57	<0.001		26.5
	3 Months	48			14				
	6 Months	37			5				
Broken hair (cm^2)	Baseline	58	20	0.08	56	48	<0.001		11.4
	3 Months	42			22				
	6 Months	38			8				
Tapered Hair (cm^2)	Baseline	16	8	0.2	14	12	0.0111		2.3
	3 Months	10			8				
	6 Months	8			2				

Note: p value <0.05 indicates statistical significant value.

FIGURE 4 Dermoscopic evaluation showing Black dots, Yellow dots, Tapered, and Broken hair

4.1 | Steroids

Topical steroids can be the first choice of management and efficient but, for moderate condition and also restricted to aesthetically prone regions. Skin atrophy is a common side effect in the areas that have been exposed to high doses several times. Up until now, oral corticosteroids have been used to control AA and some people have seen regrowth. However, long-term care is required to get the results, which does not justify the risk.[36]

Charuwichitratana S et al. conducted a randomized double-blind placebo-controlled study for the management of AA with cream 0.25% desoximetasone. Fifty-seven percent of patients demonstrated complete regrowth of hair all throughout the treatment.[37] A study by Kubeyinje EP et al. showed somewhat better results with intralesional corticosteroids- triamcinolone acetonide in 63% of patients. They demonstrated complete hair regrowth within 4 months.[38] But, the major adverse effect was cutaneous atrophy.[39] Also, recurrence rates with corticosteroids ranges from 33% to 75%.[40]

In our study, we used triamcinolone acetonide (5 mg/ml), maximum of 2 ml per session and each session was repeated after 3 weeks for 3 such sessions. When we combine triamcinolone acetonide with placebo, improvement was not significant. Also in 5% of patients, we have seen increase in alopecia patches. But, when we combined triamcinolone acetonide with QR678 Neo®, the results were significantly better in comparison to Group A, with no side effects. Also, SALT score and self-assessment score were significantly high in Group B patients.

4.2 | Microneedling

Microneedling is a technique that involves rolling miniature needles through the skin to puncture it superficially. It is traditionally used for a scar and skin rejuvenation, collagen infusion therapy, as well as a trans-dermal delivery tool for therapeutic medicines and vaccine.[41]

Ito et al. in 2017 used a three micro-needle devices for intralesional corticosteroid delivery in the cure of AA with favorable outcome, but it was not clear that a single therapy improved the hair growth or a combination therapy.[42] Deepak et al. in 2014 also showed positive results with 50%–80% of improvement in three cases of resistant AA treated with scalp roller with 5% Minoxidil or triamcinolone acetonide solution. Mild to moderate pain and erythema were reported.[43]

A comparative study by Shome et al. was carried out comparing intradermal injection vs. derma roller technique for administration of QR678 Neo® hair regrowth therapy. We used the intralesional technique for administration of corticosteroid and QR678 Neo® for the management of AA in this study, for convenience. However, using the DermaRoller technique would have worked equally well.[44]

4.3 | Minoxidil

Minoxidil is known to promote follicular synthesis and controls hair physiology independently of the effects of regional blood flow.[45]

A randomized controlled trial by Fenton DA et al. for AA demonstrated that topical Minoxidil as an individual therapy induced hair

growth above placebo in patients with low severity disease but no further studies have shown significant superior outcome and no advantage is seen after discontinuation of treatment.[46] Nonetheless, this may be an option for patients due to the safety of the treatment with very restricted period of result.[47] Topical minoxidil did not show a statistically significant difference when used alone. As a result, it's been suggested as an adjuvant treatment for AA.[48]

A study by Shome et al. also proved effectiveness of the combination therapy of the QR678 Neo® hair growth formulation with Minoxidil solution and oral Finasteride. The study proved the effectiveness of the combination treatment in terms of hair regrowth, hair loss, and hair density. This was especially in advanced cases of hair loss, such as Hamilton Norwood grade III to V alopecia.[49]

4.4 | Fractional laser

Laser light can stimulate apoptosis of lymphocytic cells; alleviate the immune-mediated destruction of the follicles. It's also thought that stimulating and partially destroying the hair follicle (HF) will cause a regenerative reaction, causing the HF to trigger anagen.[4]

Yalici Armagan et al. in 2016 conducted prospective, split lesion study with CO2 laser (10 600 nm) and Nd:YAG* laser (1064 nm) with laser settings at 10–45 mJ/cm^2, 75 100 spots/cm^2, 10 J/cm^2, 30 ms pulse with 3–6 sessions at interval of 2–4 weeks for 2–8 weeks including 32 patients(19 male, 13 female) of AA. But No improvement was seen at the end of treatment in any patients and also had adverse effect like Pain.[50]

However, Issa et al. in 2016 conducted a prospective study including 5 (1 male, 4 female) patients of AA with CO2 laser (10600 nm) and additional topical corticosteroid treatment at energy level of 60 mJ/spot, 100 spots/cm^2, 2 passes with 1–6 Sessions. At 3 weeks interval, they found improvement in all patients with adverse effects of mild burning pain.[51]

Eckert et al. presented a study of 6 patients with 19 patches of AA and a patient having diffuse universalis AA. Patients were treated with nonablative 1550-nm erbium glass fractional laser. The parameters applied were: fluences 30–45 mJ, 6–10 density, and 8–10 passes. All patients showed notable clinical improvement. No side effects except burning sensation or pain were noted throughout the treatment.[7] Laser therapy has random results and remains unverified although there are a rising number of devices that have been trialed.[52]

4.5 | Cryotherapy

Jun et al. conducted a retrospective study to simplify the therapeutic efficiency and safety of superficial hypothermic cryotherapy for the cure of AA. Out of 353 patients, 61% of patients responded after 3 months of treatment, with improved response rates in patients with shorter gaps in-between sessions. Total of 18 patients had adverse effects including mild pain, pruritus, mild inflammation, and swelling.[53]

4.6 | Platelet Rich Plasma (PRP)

Platelet rich plasma is a type of autologous plasma that contains a variety of growth factors. These growth factors cause the follicular stem cells to switch from dormant to healthy, beginning of the hair development process.[54]

Lee et al. in 2014 documented a comparative study of PRP with Placebo in AA and has showed better results with hair thickness ($p = 0.031$) but not with the hair count ($p > 0.05$) in PRP +Placebo group than the Placebo alone. Although, clinical progress was seen in both mean hair counts (23.2+/− 15.5%) and mean hair thickness (16.8+/− 10.8%) in compare to the baseline value in PRP +Placebo group.[55]

Platelet rich plasma injection really improved hair growth in contrast to triamcinolone injection. In PRP group, 60% of patients showed total setback after 6 months of treatment compared to 27% of patients managed with triamcinolone.[54] Although in a study by Ovidio et al. all the patients vanished their grown hairs at average of 1 year.[56]

Thamer Mubki et al. carried out a case report to evaluate PRP in combination with Triamcinolone acetonide (TrA) Vs. intralesional triamcinolone acetonide alone. At the end of the trial, both the modalities (TrA with PRP and TrA only) have shown increased number of terminal hair (16% and 12%, respectively). But, at side of scalp, only the combination treatment has showed an improvement in the mean hair shaft diameter (+35%) as compared to a reduction by 4% in the TrA only.[57]

4.7 | QR678 Neo®

QR678 Neo® is a bioengineered, recombinant formulation which consists of a combination of growth factors. Various research studies have already proved its efficacy and safety in alopecia in men and women.[23]

In study in androgenetic alopecia with PCOS in female pattern hair loss, QR678 Neo® has showed its effectiveness in terms of lessening hair loss and new hair growth considerably.[24] Also in chemotherapy related alopecia, QR678 Neo® has proved its effectiveness in both men and women with record of lung and breast cancer.[25]

A comparative study by Kapoor et al. proved that hair regrowth formulations QR678 and QR678 Neo® are more beneficial than PRP. QR678 Neo® showed significantly better results in comparison to PRP. Therefore, in this study we have used QR678 Neo® in combination with triamcinolone acetonide for the management of AA.[26]

In our study, we have involved patients with patchy hair loss of scalp and treated with QR678 Neo® for 8 sessions with intralesional corticosteroid for first 3 sessions and compare it with 3 sessions intralesional corticosteroid in combination with placebo for 8 sessions.

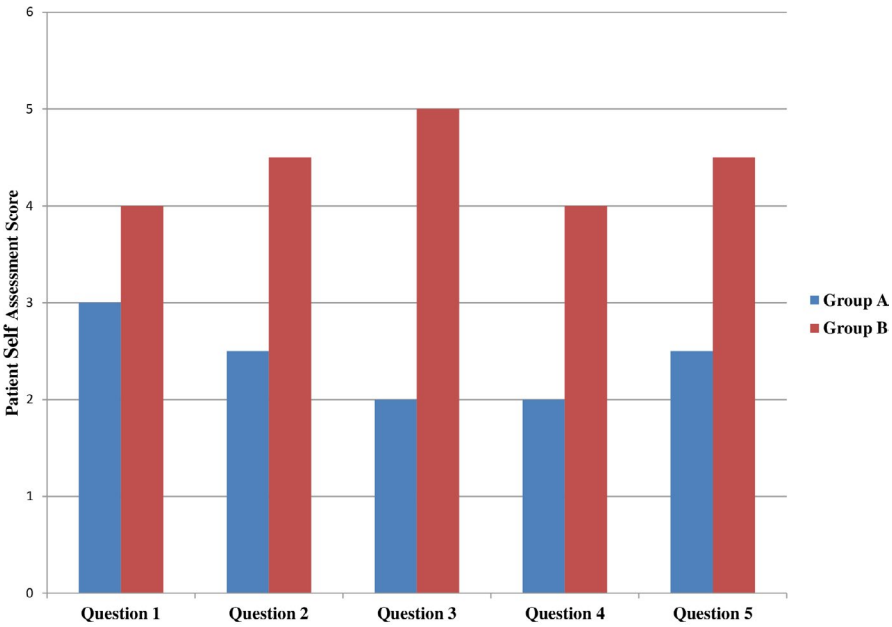

FIGURE 5 Patient Self-assessment questionnaire

The mechanism of topical corticosteroid is chiefly suppression of inflammation and stepping up the healing of damaged hair follicles. Yet, the monotherapy with intralesional corticosteroid has not been proven to be significantly efficient in treatment of AA.[58] QR678 Neo® has proved to have a significant effect on new hair growth as it contains several growth factors that have been shown to have an anti-inflammatory effect with no side effects even over longer period.[59]

Polypeptide growth factors play an imperative role in restoring tissue injury, controlling cell replication, development and differentiation, enhancing wound healing, and tissue regeneration.[60] VEGF induces both vasculogenesis and angiogenesis following cellular damage. It has an immense impact on the permeability of blood vessels and is a potent angiogenic protein in a range of pathological neo-vascularization process. IGF-I and KGF cDNA gene transfer separately helps in the advancement of dermal and epidermal transformation. FGF was also found to be an important factor in healing. Also, vitamins present in QR678 Neo® have been verified to have anti- inflammatory property.[61]

Very similar to the findings of previous QR678 Neo® studies, we found similar results showing efficiency of QR678 Neo® in the treatment of AA also. The photographic evaluation and Dermoscopic evaluation demonstrated that combination therapy of QR678 Neo® and intralesional corticosteroid gives statistically significant improvement in all the parameters. New hair growth was maintained for long-term follow-ups in Group B patients. Also, 1 patient had occurrence of increased patches in Group A. Since all previously mentioned therapies have limited results with adverse effects on long-term follow-up and considerably high relapse rate, QR678 Neo® proved to be the most effective method devoid of any significant adverse effects. Our results with QR678 Neo® in combination with intralesional steroids therapy proved to be significantly beneficial, efficient, and can be considered as safer treatment option for AA.

5 | CONCLUSION

Treatment options like immune-modulators, low-level laser/light, photo chemotherapy (psoralen plus ultraviolet A), sulfasalazine, and other have been evaluated and have been shown varied results for AA. Given the shortcomings of existing methods, it is the need of an hour to research on new treatment modalities with a purpose of enhancing results although reducing side effects. QR678 Neo® is a hair growth factor formulation which has anti-inflammatory effect. This pilot study has proved it to be effective in the treatment of AA with long-term results and relatively free of adverse events. However, more studies with larger sample size are still desirable in order to consider this combination therapy protocol as an important tool for the treatment of AA.

CONFLICT OF INTEREST

The authors have been awarded a patent from the United States Patent & Trademark Office (USPTO) and from the Indian Patent Office administered by the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM) for the invented hair formulation, used in this study.

AUTHOR CONTRIBUTIONS

Dr. Debraj Shome: Research project: Conception, Execution, Manuscript: Review and Critique. Dr. Rinky Kapoor: Manuscript: Review and Critique. Dr. Komal Doshi: Research project: Organization, Manuscript:Writing of the first draft. Dr Ghanshyam Patel: Statistical analysis. Dr. Sapna Vadera: Manuscript: Review and Critique. Dr. Vaibhav Kumar: Manuscript:Writing of the first draft.

ETHICAL APPROVAL

A double-blind, comparative, and prospective clinical study was conducted following approval from the review board of the Institutional Ethical committee.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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