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ORIGINAL ARTICLE

Efficacy of QR678 Neo® hair growth factor formulation for the treatment of hair loss in Covid-19-induced persistent Telogen Effluvium—A prospective, clinical, single-blind study

Debraj Shome MD, FRCS (Glasgow), FACS, MBA[1] | Rinky Kapoor MD[2] | Monika Surana MDS[1] | Sapna Vadera MDS[1] | Ronak Shah MSc[3]

[1]Department of Facial Plastic Surgery & Facial Cosmetic Surgery, The Esthetic Clinics, Mumbai, India

[2]Department of Dermatology, Cosmetic Dermatology & Dermato-Surgery, The Esthetic Clinics, Mumbai, India

[3]Clinfotics LLP, Vadodara, India

Correspondence
Debraj Shome, Facial Plastic Surgeon, Department of Facial Plastic Surgery & Facial Cosmetic Surgery, The Esthetic Clinics, Mumbai, India.
Email: debraj.shome@theestheticclinic.com

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Abstract

Background: Telogen Effluvium (TE) in a post-Covid-19 patient causes excessive shedding of hair. No definite treatment is available till now. Past studies demonstrates that QR678Neo® has shown promising results in various types of Alopecia.

Aim: In this study, we aim to establish efficacy of QR678 Neo® hair growth factor formulation administration in Covid-19-induced persistent TE for treatment of hair loss and for hair regrowth.

Material & Method: Twenty adult patients (all females) presenting with persistent TE starting few weeks after recovery from Covid-19 infection, and continuing beyond 6 months were included for the study. A 1.5 mL solution of QR678 Neo® hair growth factor formulation was administered in the scalp per session. A total of 8 sessions (one session every 4 weeks) were done. The results were assessed at the baseline, after 4thsession, and 1 month after 8th session.

Results: Most of the patients showed significant reduction in hair fall; 89% patients showed excellent hair growth. Global photographic assessment score showed marked improvement, which maintained even post therapy. Videomicroscopic assessment showed increase in the hair count (mean =29.32) after 8th session, that further improved even post therapy. The subjective assessment scores for overall hair growth, appearance of hair, reduction in visibility of the scalp, and hair loss were 4, 4.5, 4.25, and 5, respectively.

Conclusion: Management of Covid-19-induced persistent Telogen Effluvium has been unclear and futile so far. Intra-dermal administration of QR678 Neo® hair growth factor formulation in the scalp, reduces hair fall, improves hair regrowth, and increases the hair density.

KEYWORDS
Covid-19, hair growth therapy, QR678 Neo®, Telogen effluvium

1 | INTRODUCTION

Alopecia is a very common issue and can be of different types; the most common being Androgenetic alopecia in males and females, alopecia areata, anagen effluvium, and telogen effluvium (TE) among others.[1]

The concept "diffuse cyclical hair loss" (DCHL) was first used to describe isolated, transitory episodes of diffuse hair shedding that improved with corticosteroids.[2] Kligman coined the word Telogen Effluvium to characterize accelerated shedding of normal club hair. It is an abnormality of hair cycling occurring as a reaction pattern to various physical or mental stressors.[3,4] He described it as "Nonspecific reaction pattern of hair loss with increased shedding of telogen hair that developed after 3–4 months of the causing event. Alopecia would occur only when about 40% of hair has been shed."[5]

It also depends on the severity and length of exposure. Any interruption of the hair cycle that results in accelerated, coordinated telogen shedding causes TE.[1]

Its true incidence or prevalence is largely unknown. Women are overrepresented most likely due to males' unawareness or underreporting. Also, postpartum women may be more susceptible to increased amount of hair fall owing to the hormonal imbalance. Hence, they present to the clinics seeking treatments for hair fall more than their male counterparts.[6,7]

Various factors have been implicated for causing TE such as nutritional deficiency, vitamin and mineral deficiency, especially vitamin D level, thyroid profile, hormonal imbalance, stress due to work, emotional stress among others, environmental change, major illness or surgery or history of hospitalization, or recent chemical hair treatment or sudden stoppage of minoxidil have been found to be important while examining for TE-related hair loss.[8,9]

With the emergence of the novel corona virus SARS-CoV-2, which is the cause of COVID-19, the virus's life-threatening pulmonary and cardiovascular manifestations have gotten a lot of attention. However, cutaneous disease signs and symptoms associated with skin such as urticarial rash, vesicular eruptions, petechiae, and hair loss or alopecia, have also been identified and can have a considerable effect on patients psychologically leading to stress in them.[8,9]

Covid-19 is known to cause physiological and psychological stress in those afflicted by the virus which in turn causes tissue damage and other complications. This leads to TE via the systemic inflammatory response and/or micro thrombi in hair follicles.[8]

If the hair loss continues for more than 6 months, it can turn chronic. Various treatment modalities such as oral and topical minoxidil, finasteride, DHT blockers, multivitamins, natural hair growth serums, and surgical hair transplant have been used for hair growth in TE patients. But none of these have a standard protocol for hair regrowth in chronic TE patients post-Covid-19 recovery.[10,11]

In 2010, Kapoor and Shome invented a recombinant; bioengineered hair growth formulation called QR678 Neo® containing plant-based growth factors. Since then it has been used for hair growth in the treatment of alopecia areata, post chemotherapy hair loss, females suffering hair loss due to PCOS, and post hair transplant patients. It has also been compared with Platelet rich plasma (PRP) therapy and has proven to be more effective than PRP. It has been found to be even more efficacious when given in combination with topical minoxidil and oral finasteride in advanced androgenetic alopecia.[12–17]

Keeping in mind the lack of definitive treatment for continued TE post-Covid-19 recovery, this study aims to evaluate the efficacy of QR678 Neo® therapy for the treatment of Covid-19-induced TE-related hair loss.

2 | MATERIAL & METHOD

2.1 | Study design

The prospective clinical, single-blind study was conducted from September 2020 to May 2021 after seeking approval from the Institutional Ethics Committee. Informed, written, and signed consent was obtained from all the participants. The sampling method was random sampling.

2.2 | Inclusion criteria

- Patient presenting between the ages of 20 and 50 years after recovery from RT-PCR proven Covid-19 infection with sustained hair fall even after 6 months.
- Patients having noticeable increased hair loss, and losing hair in bulk.

2.3 | Exclusion criteria

- Patient complaints of significant hair loss after suffering from Covid-19 infection.
- Patients diagnosed with any other type of alopecia other than TE.
- Female patients who were pregnant or lactating.
- Patients who had recently started or stopped the consumption of oral Finasteride/spironolactone
- Those on Minoxidil and/or oral contraceptives (to alleviate the bias due to confounding factors)
- Patients who had any other medical disease or on drugs which affect hair loss.

2.4 | Injection technique

At baseline, each patient was evaluated using standard digital imaging as well as a video microscopic examination was performed to determine hair condition. At each visit, 1.5 mL of QR678Neo® solution was administered into the scalp skin of all the patients.

Using a 31-G needle and the nappage technique, a good number of painless administration (on average 60–70) were delivered into the scalp. Administration was done in areas where hair thinning was

visible. The administration sites were spaced 1cm apart. A total of 8 sessions were conducted; each session 4 weeks apart. The patients were evaluated before starting the session, after 4th session and 1 month after completion of the 8th session.

2.5 | Establishment of diagnosis of persistent Telogen Effluvium

Before onset of the treatment, patients were evaluated to establish the diagnosis of persistent TE secondary to Covid-19 infection and to rule out other causes of alopecia.

Diagnosis was established on the basis of:

1. History of significant hair loss beginning after few weeks of Covid-19 infection
2. No history of significant hair loss prior to the infection
3. Examination of scalp to assess if hair loss is diffused throughout the scalp, or majorly from the fronto-parietal areas.
4. Evaluation of the hair strands that were lost, under microscope to find majority club hair.
5. Strongly positive pull test and modified wash test.
6. Dermoscopic criteria for chronic TE (decreased hair density, few empty hair follicles, predominance of hair follicle openings seen with only the emerging hair shaft within it, minimal variation in thickness of hair, and lack of any inflammatory changes in scalp skin)
7. Blood evaluation for: Hemoglobin and complete blood count, thyroid profile and iron profile, blood sugar levels, serum zinc, serum copper, vitamin D3 and vitamin B12 levels for all patients before the onset of the study.

Patients were thoroughly examined and detailed medical history pertaining to nutritional deficiency, hormonal imbalance, and deficiency related to vitamin and minerals, stress factors, environmental factors, thyroid function test, usage of medication causing hair loss etc., was evaluated and no specific abnormality was detected.

2.6 | Scalp assessment and evaluation

2.6.1 | Hair pull test assessment

Hair pull test was performed before every session by an independent observer. It was performed three times by the same clinician, wherein a bunch of approximately 50–60 hair were grasped between the thumb, index finger, and middle finger and pulled from the base just close to the scalp. The hair were firmly tugged away from the scalp, and the pulled out hair were counted in every session.

2.6.2 | Global photographic assessment

Photographs of the frontal, vertex, and temporo-parietal regions of the scalp were taken at baseline, 4th, and 8th sessions, as well as 1 month after completion of the 8th session, using a standardized photographic technique. Two dermatologists rated the photos on a scale of 0 (no change) to 10 (dense hair growth). The average score was determined.

2.6.3 | Videomicroscopic assessment

A videomicroscopic optical hand-held camera was used to take the images. The middle of the scalp, which was 20 cm behind or posterior to the glabella in the midline, was set for each photograph. The number of hair per cm^2 was measured. Advanced software was used to assess hair counts, and hair density (Trilogic Company, Moscow, Russia, Tricho science version 1.5). Unpaired *t*-test was used to assess the level of significance within the group. Graph Pad software was used to calculate the results.

2.7 | Patient self-assessment

All the patients were given a prevalidated hair growth questionnaire of four questions in section one, ranging from extremely dissatisfied to very satisfied with the effectiveness of therapy at the end of therapy (Table 1). In section 2, patients were asked to mark the appropriate response to questions about the therapy's side effects. (Multiple answers were also allowed) (Table 2).

3 | RESULTS

In our study, all the patients (20 patients) who presented with complaints of persistent TE post-Covid-19 were females. This shows the severity of TE and early noticed changes in the hair by females. The mean age was 35 years.

TABLE 1 Patient Self-assessment Questionnaire: Section 1 Factors evaluated regarding hair loss

Que No.	Question	Possible response (On a scale of 0–5)
1	Growth of hair	Very satisfied > Very dissatisfied
2	Amount of noticeable new hair	Very satisfied > Very dissatisfied
3	Visibility of the scalp	Very satisfied > Very dissatisfied
4	Rate of hair loss	Very satisfied > Very dissatisfied

3.1 | Hair pull test assessment

Before treatment, the average number of hair pulled out was 25. After 4th sessions, the average number of hair pulled out were 4 (which is a negative pull test) in almost 87% of patients and the pull test remained negative thereafter, suggesting a reduction in hair fall, which is evident during the 8th session (Figure 1).

TABLE 2 Patient Self-assessment Questionnaire: Section 2 adverse effects

Adverse effect	Tick the appropriate response (if noticed)
Itchy Scalp	
Uncomfortable Pain during injection	
Unsteadiness during injection	
Increase in hair fall	

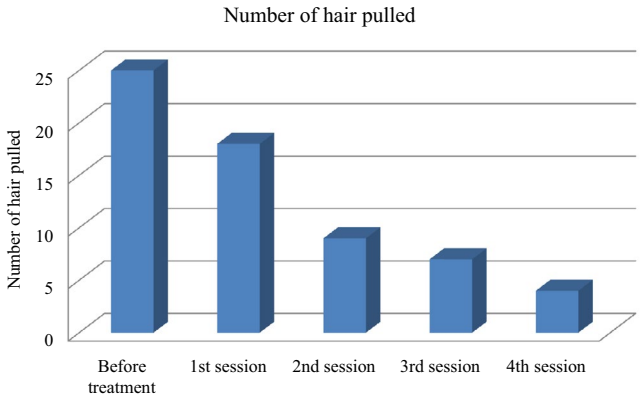

FIGURE 1 Hair pull test showing number of hair pulled before the treatment and at 1st, 2nd, 3rd and 4th session

3.2 | Global photographic assessment

Two blinded observers (both dermatologists) analyzed the images subjectively (Figures 2, 3, and 4). On a scale of 0 (no change) to 10 (dense hair growth), a rating was given. The assessment was done at the baseline, 4th session, and 1 month after the 8th session. A mean value of 5 was used as a reference point. There was a noticeable improvement in the global assessment score post 8th session with a mean value of 8.8. Only one individual (5%) did not respond to QR678Neo® (Tables 3 and 4).

3.3 | Videomicroscopic assessment

3.3.1 | Hair count and hair density

Each patient's average hair density and increase in hair count was measured 20 cm from the glabella. As compared with baseline, patients had 25.40 and 29.32 after the 4th and 1 month after 8th session, according to Paired *t*-test. The outcome was statistically important ($p = 0.048$). (Table 5, Figure 5).

3.4 | Patient self-assessment

Patients were asked to rate the questions regarding the efficacy of the treatment using a 5-point scale ranging from 0 to 5. A higher

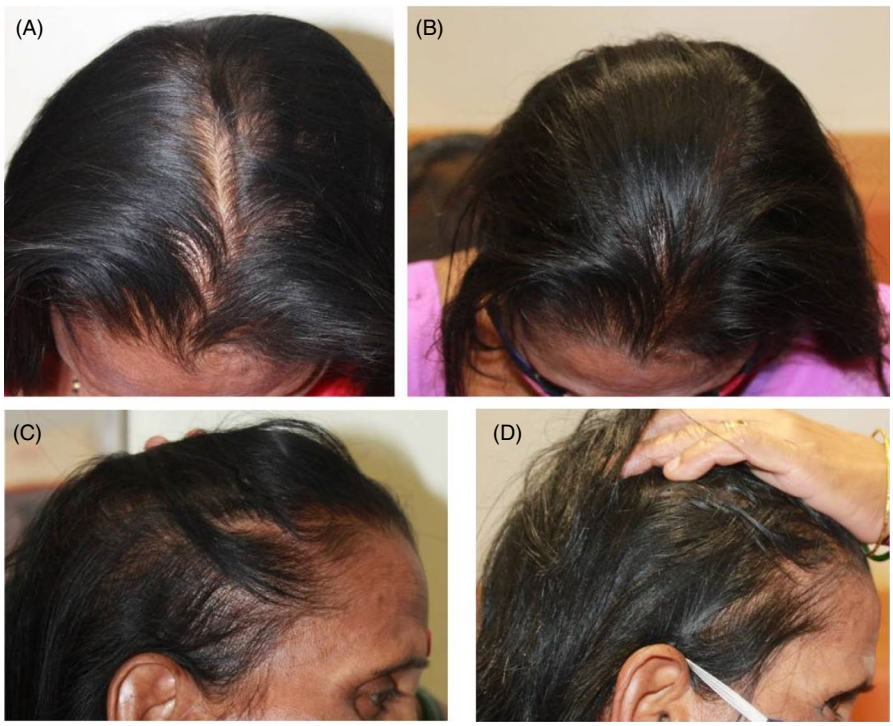

FIGURE 2 Patient 1 clinical photographs: (A and B) Pretreatment and After 4th Session (Frontal View) (C and D) Pretreatment and After 4th Session (Profile View)

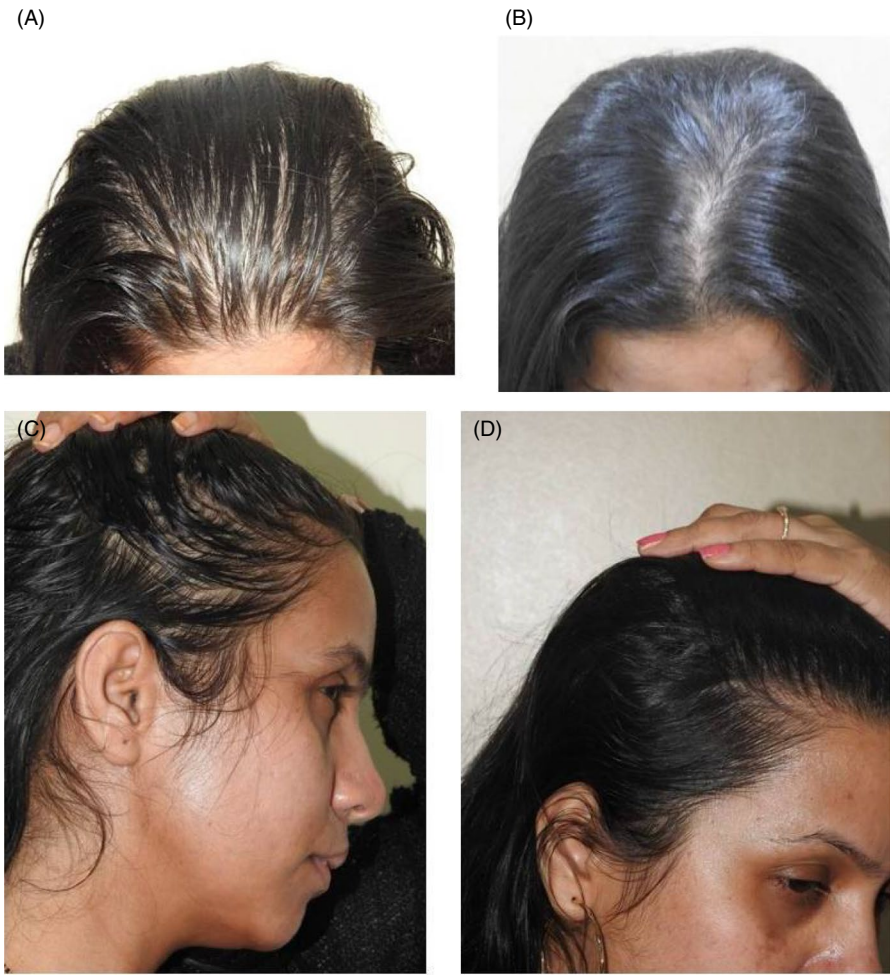

FIGURE 3 Patient 2 clinical photographs: (A and B) Pretreatment and After 4th Session (Frontal View) (C and D) Pretreatment and After 4th Session

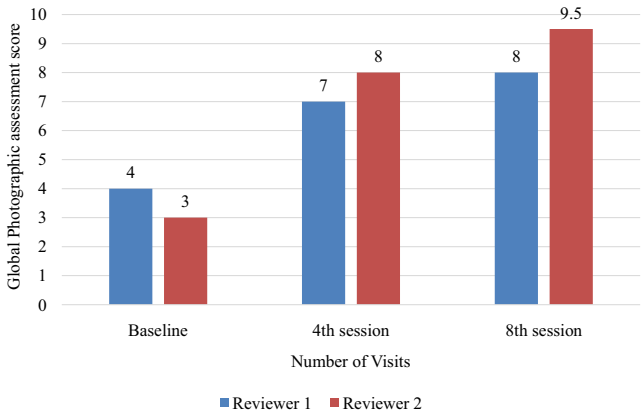

FIGURE 4 Global Photographic Assessment Score by Reviewers 1 and 2

satisfaction score was marked by patients for the rate of hair loss (mean =5). For the growth of new hair, the visibility of scalp, and the amount of noticeable new hair, the mean for the satisfaction score was 4.5, 4.25, and 4, respectively (Figure 6). Five percent ($N = 1$) of patients reported uncomfortable pain during injection, and only 10% ($N = 2$) patients reported itchy scalp after treatment. None of the patients complained worsening of hair fall post-therapy (Figure 7).

TABLE 3 Global Photographic Assessment by Reviewers 1 and 2: Patient showing improvement

	QR678 Neo® hair re-growth formulation administration			
Reviewer	Baseline	4th session	8th session	
Reviewer 1	4	7	8	$\delta = 5.5$
Reviewer 2	3	8	9.5	p-value: 0.0258
Mean	3.5	7.5	8.8	

TABLE 4 Global Photographic Assessment by Reviewers 1 and 2: Patient shows No improvement or worsening

	No. of patients showing no improvement	No. of patients showing worsening
QR678	1	0

4 | DISCUSSION

The physiological hair follicle activity is cyclical, with anagen (hair growth phase), catagen (involution phase), telogen (dormant phase),

	Mean at baseline	Mean at 4th session	Mean at 8th session	δ	*p*-value
Hair count at 20 cm (μm)	23.68	25.40	29.32	−5.64	0.048

TABLE 5 Mean value of hair count after QR678 hair therapy

FIGURE 5 Videomicroscopic image showing hair count. It shows a photograph of ¼ cm cutout of videomicroscopic images showing hair count. All the measurements shown were multiplied by a factor of 2.77 for conversion to microns

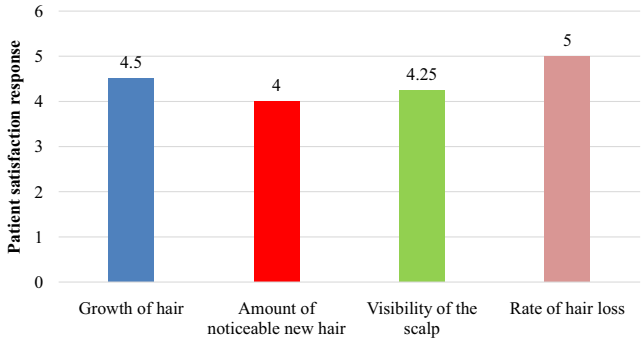

FIGURE 6 Patient Self-assessment Questionnaire

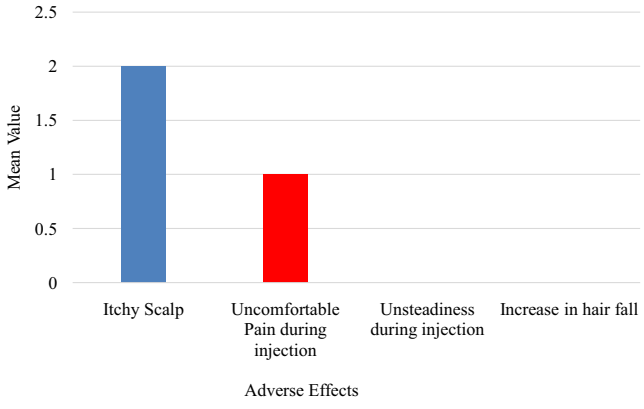

FIGURE 7 Adverse effects as evaluated at the end of the study

and exogen phases (release phase occurring in late telogen or early anagen).[13] After the onset of anagen, a telogen hair will stay in its follicle for up to 4–6 weeks.[6,18] An average normal scalp contains 100 000 hair, with approximately 86% in anagen, 1% in catagen, and 13% in telogen.[19]

One of the most frequent causes of diffuse nonscarring hair loss is TE. TE is often used as a catch-all diagnosis.[1]The ratio changes to 70% anagen and 30% telogen with TE, resulting in regular shedding of up to 300 hair.[20] TE usually appears 2–3 months after a stimulus occurrence, such as a serious infective episode.[16,21-23]

Various causes of emotional and physical stress such as trauma, stressful or major life event, marked weight loss, and extreme dieting, and hospitalization can lead to acute TE.[24]

Covid −19 infection causes emotional and physiological stress on the body including the hair follicles. It also leads to pro-inflammatory phase in the hair follicles causing severe inflammation in the root sheath of hair follicles. This causes immediate anagen release of hair follicle which then enters telogen phase. This is responsible for excessive hair shedding phenomenon called as Telogen Effluvium in Covid-19 patients.[2,12,25–28] The prevalence of generalized hair loss seen in Covid-19 patients is 25% (17–34%).[29]

Acute TE generally improves on its own after a few weeks; however, it may progress and develop a chronic state. Various treatments have been documented in literature such as oral and topical minoxidil solution, finasteride, nutritional supplements like vitamin, minerals, plant-based serums, and Platelet-rich plasma (PRP) therapy for the management of hair loss. Minoxidil is a vasodilator and finasteride is a 5α reductase inhibitor. However, they are neither a catagen-inhibitor

nor anagen inducer and both are approved by FDA for use in only AGA and Female Patterned Hair Loss (FPHL).[8,10]Hence, they have no role in TE to cause hair regrowth. Nutritional supplements only aid the process of hair growth but no controlled studies are available. PRP therapy causes good results in Androgenetic Alopecia but has not been found to have any role in acute TE. A new treatment called CNPDA (combination of caffeine, niacinamide, panthenol, dimethicone, and an acrylate polymer) reported by Davis et al, for hair thinning only shows 10% improvement. Hence, so far there is no definitive treatment with quantifiable results available for TE.[8,10,26]

In 2010, Kapoor and Shome invented a recombinant, bioengineered hair growth formulation called QR678 Neo® containing plant-based growth factors. QR678 Neo® has growth factors such as vascular endothelial growth factor, basic fibroblast growth factor, insulin-like growth factor-1, keratinocyte growth factor, and copper tripeptide 1 or their biomimetic peptides which when administered into the scalp decreases the number of vellus hair, increases the terminal hair and hair shaft diameter. It also causes hair regrowth where the hair follicle is present but in dormant stage.[12,13]

It has been used for hair growth in the treatment of alopecia areata, post chemotherapy hair loss, females suffering hair loss due to PCOS, and posthair transplant patients. It has also been compared with Minoxidil and finasteride topical application, and also with PRP therapy and has proven to be safe and efficacious and have also confirmed on hair pull test that it significantly decrease hair fall in around 83% of patients.[12–17]

QR678Neo® therapy is done as an outpatient procedure with no adverse effects and no disruption of existing hair.[14–17]

QR678Neo® therapy contains biomimicking peptides, mimicking growth factors such as VEGF which is essential for angiogenesis and vascular permeability and thus increasing the vasculature around hair follicle; IGF-I regulates cellular proliferation and migration during hair follicle development; and bFGF promotes anagen phase in resting hair follicles.[10]

In this study, we found excellent response for reduction in hair fall and improvement in hair growth in 89% of the patients. On videomicroscopic assessment, there is significant improvement in hair density after 4thsession and 1 month after 8th session, ($p = 0.048$).

Patient satisfaction scores for growth of hair, amount of noticeable hair, visibility of the scalp, and rate of hair loss were 4.5, 4, 4.25, and 5 respectively. Only 5% patients showed no improvement with QR678Neo® therapy. None of the patients reported of worsening of hair loss after the QR678Neo® therapy.

5 | CONCLUSION

The Covid-19 stress-induced persistent TE can be daunting on the patients post-Covid-19 as they are recovering from that stress, trauma, and hospitalization. Excessive hair fall conditions such as TE induced by Covid-19 have not been widely studied and hence treatment modalities currently present, fail to give justice to this new onset factor of excessive hair loss due to Covid-19. This study suggests a definitive and quantifiable role of QR678Neo® hair growth formulation in the Covid-19-induced persistent TE patients for significant improvement in hair density and hair count, and also reduces the hair fall. It should be further evaluated in a larger group of such patients, and in non Covid-19 cases of TE as well.

CONFLICT OF INTEREST

The authors state no conflict of interests.

AUTHOR CONTRIBUTION

Debraj Shome—Development and conceptualization of study and support in manuscript writing. Rinky Kapoor—Development and conceptualization of study and support in manuscript writing. Monika Surana—Conceptualization of study, literature review and manuscript writing. Sapna Vadera—Manuscript assistance. Ronak Shah—Statistical analysis.

ETHICAL STATEMENT

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to and the appropriate ethical review committee approval has been received. All necessary consents were taken from patient during this study.

DATA AVAILABILITY STATEMENT

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

ORCID

Debraj Shome https://orcid.org/0000-0003-2163-1170

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