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RESEARCH ARTICLE

Q – SERA HAIR SERUM PRESCRIBER'S OBSERVATION AND MONITORING REPORT – REPORT ON ANALYSIS OF DATA FROM MULTIPLE INVESTIGATORS

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ABSTRACT

Telogen effluvium is diffuse hair loss from the scalp lasting for 6 months but is self-limiting. The present study was undertaken to analyze data obtained from multiple investigator prescribing Q – Sera Hair Serum (combination of Biochanin A, Acetyl Tetrapeptide-3, Bioactive Signaling Molecules (Cytokines), Ethylpanthenol and Inositol) for diffuse hair loss. The subjects were on once daily application of Q – Sera Hair Serum for 21 days. The effectiveness of the product was based on reduction in number of hair loss and overall improvement as assessed by the investigators. 89.36% of the subjects reported reduction in the daily hair loss within 21 days. The percentage of improvement in the overall appearance of the hair was 61% according to the investigator's assessment. Thus this prescriber's observational study found the product Q – Sera Hair Serum to be effective in improving hair loss as a short term therapy.

INTRODUCTION

Telogen effluvium[TE] is a scalp disorder characterized by the thinning or shedding of hair resulting from the early entry of hair in the telogen phase [1,2]. TE is a diffuse hair loss which occurs 3 months after a triggering event and is self-limited in time [3].

TE was first described by Kligman in 1961. It is most common cause of diffuse hair loss. A wide variety of potential triggers have been implicated in the pathogenesis of TE. By definition TE is non-scarring diffuse hair loss from the scalp that occurs 3 months after a triggering event and is usually self-limiting, lasting for 6 months.A wide variety of potential triggers have been implicated in the pathogenesis of TE. TE occurs if a significant number of anagen hairs are triggered to stop growing prematurely by any stimulus and subsequently enter catagen phase followed by telogen phase [4-12].

The most important aspect in the management of TE is counseling the patient about the natural history of the condition. Normal hair cycle and relationship between triggers and timing of hair loss should be explained. Attempts should be made at identifying the specific cause and once identified they have to be corrected. Hair shedding takes 3-6 months to cease after which regrowth can be noted in 3-6 months on removal of triggers, but cosmetically significant regrowth can take 12-18 months [14-15]. Stress is one of the major contributing factors for telogen effluvium. There is no specific therapeutic intervention which could prevent stress induced premature onset of catagen [16]. Psychological counseling being the least invasive and easy to address the psychological impact is considered as the best and safest treatment [14]. The patient needs a brief discussion on the diagnosis and treatment options. Potential therapeutic options include the following depending on the pathogenesis of TE [11]

1. Inhibition of catagen
2. Induction of anagen
3. Inhibition of exogen.

Q – Sera Hair Serum combines the benefits of Biochanin A, Acetyl Tetrapeptide-3 and Bioactive Signaling Molecules (Cytokines) in combination with Ethylpanthenol, Inositol and the sulfur-rich amino acids Acetyl Cysteine and Acetyl Methionine to simultaneously address multiple factors involved in the progression of pattern alopecia. The Q – Sera Hair Serum acts on recessing hair by limiting hormonal influence through inhibition of 5-α-reductase activity, preventing aggravation of hair loss due to micro inflammation and supporting hair growth through stimulation of ECM protein synthesis.

The Q-Sera Hair Serum preparation is being marketed in India. The present study was conceived to assess the efficacy of Q-Sera Hair Serum in reducing the hair loss in Indian men and women within a span of 21 days, and user satisfaction on that count, on an observational basis.

MATERIALS AND METHODS

Study subjects suffering from Alopecia were recruited by prescribers (dermatologists) in different urban centers of India. Both male and female subjects suffering from hair loss were eligible, provided they did not have any contraindication to Q-Sera Hair Serum therapy.

The no. of hair loss daily was taken at recruitment and subjects were placed on topical Q-Sera Hair Serum therapy. This Q-Sera Hair Serum was used in a manner consistent with the product's prescribing information. Q-Sera Hair Serum had to be applied once daily for 21 days. Subjects were treated for 21 days with follow-up at day 0 and day 21 interval. At each visit body weight and blood pressure were recorded and effectiveness of the treatment in relation to sign – symptoms was assessed under the following heads:

No. of Hair loss Daily	Subjective questionnaire	Adverse event
	1.Since the start of treatment, how effective has the treatment been in slowing down the rate of hair loss. 2.Investigators' Global assessment on the overall appearance of hair	

The first question was scored on a 3-point scale – Effective, Not effective and No opinion either way.

The second question was scored on a 3-point scale – Improved, Stayed the same and Deteriorated.

At the final follow-up visit subjects were queried as to their overall opinion on Q-Sera Hair Serum – fair, good or very good.

This being an observational study of an established safe product in routine clinical use, no laboratory tests were done exclusively to monitor safety of Q-Sera Hair Serum therapy. Prescribers did not maintain any concomitant medication record as part of the study.

RESULTS

50 subjects were recruited by 15 different prescribers in different parts of India from January, 2015 to August, 2015. Of these the records of 47 were found to be evaluable. The 3 non-evaluable subjects did not report for follow-up after the study initiation visit and therefore did not complete the study.

The mean age was 30.08 ± 10.48 years [Mean ± Standard deviation] for 46 subjects.

Table 1 Body weight and blood pressure profile of the study subjects

	Pre - treatment	3 weeks
Weight [kg]	51.22 ± 30.34	NA
Systolic BP [mm Hg]	122.46 ± 62.18	122.87 ± 60.613
Diastolic BP [mm Hg]	79.38 ± 40.24	82.5 ± 39.71

Table 2 depicts the effectiveness of the treatment based on the subject questionnaire and the improvement based on physician's assessment.

Since the start of the treatment, how effective has the treatment been in slowing down the rate of hair loss	Visit 2 (n = 47)
Effective	44 (93.61%)
Not effective	3 (6.38%)
No opinion either ways	0 (0.0%)
Investigator's assessment of improvement from Visit 1	**Visit 2 (n = 31)**
Improved	19 (61.29%)
Stayed the same	12(38.70%)
Deteriorated	(00.00%)

Daily Hair loss

89.36% [n = 42] of the subjects had reduction in daily hair loss.

CONCLUSION

Telogen effluvium is the loss of telogen hair due to abnormal hair cycling [17]. Excessive daily shedding of approximately 100–200 telogen hairs is typically seen. Possible causes of acute telogen effluvium include systemic disease, drugs, fever, psychoemotional stress, weight loss, delivery, iron and Vitamin D deficiency, inflammatory scalp disorders, interruption of oral contraceptives, and iron deficiency [18]. Treatment for telogen effluvium should be focused on the cause [19].

Major reasons of hair loss in TE include loss of Extracellular Matrix (ECM) proteins in the follicles and localized inflammation. The size of hair follicle is thought to be determined by the volume of its dermal papillae which depends on the number of cells and on the volume of the ECM. Acetyl tetrapeptide 3 has shown effect in significant stimulation in the synthesis of both ECM proteins and increase in Type III collagen [20].

Several different cytokines and chemokines have been discovered in human milk in the past years, and the list is growing very rapidly. Milk contains increasingly complex network of chemo - attractants, activators, and anti-inflammatory cytokines are present in human milk [21].

Milk mainly contains the following cytokines: [21, 22] IL – 1 B, IGF-1,bFGF, PDGF,KGF TNF –alpha IL-6IL -10 anti-inflammatory IFN gamma M-CSF GM- CSF.

Cytokines (IGF-1, bFGF,PDGF KGF) which are present in milk increases hair growth [23].

The use of Q-Sera by men and women suffering from alopecia, results in substantial improvement in their daily hair loss count within 20 days of using the product. The therapy proved to be effective for 93.61 % [n = 44] of subjects. According to the investigator's assessment the percentage of improvement in the overall appearance of the hair was 61% [n = 31].

There was no alteration of body weight and blood pressure during the study. Neither are these to be expected from the pharmacological profile of the preparation. No adverse event was reported. The study was not designed to evaluate laboratory parameters.

The beneficial effects of the product influenced most of the study subjects favorably.

Overall, the current prescriber's observational study supports the impression gained from other trials that topical Q- Sera Hair Serum is effective in improving hair loss on short-term therapy as early as 20 days without tolerability problems.

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