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Case Series

Efficacy and safety of hair serum containing Greyverse, EUK 134 and Amisol trio in premature greying of hair

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ABSTRACT

Greying of hair, also known as achromotrichia or canities, is a part of ageing. Premature canities is a widespread, poorly characterised dermatological condition with little clinical and demographic information. We conducted this study to evaluate the efficacy and safety of hair serum containing Greyverse, EUK 134 and Amisol trio in premature greying of hair. Ten cases of premature canities (onset before 25 years of age) were recruited from the outpatient department at Cutis Academy of cutaneous sciences, Bengaluru. The participants were recruited after written informed consent from patients (>18 years age); whereas in patients <18 years age, it was provided by their parents/guardians. The Revgrey® hair serum formulation was asked to be applied twice daily for three months and its efficacy and safety was analyzed during follow-up at day 30 and 90. In our study, we found that the mean age of onset of greying was 14.9±4.33 years. The frontal region was the earliest affected area. The investigator's assessment and patient's self-assessment was recorded after completion of the treatment at 12 weeks. The investigator's assessment revealed that 4 patients (0.4%) showed slightly increased recovery of hair while 3 patients (0.3%) showed moderately increased recovery of hair. The small sample size of the study was its limiting factor in arriving at a definite conclusion. We concluded that application of Revgrey® hair serum formulation in males and females suffering premature greying of hair is both safe and beneficial.

Keywords: Premature greying of hair, Greyverse, EUK 134, Amisol, Canities, Ageing

INTRODUCTION

Greying hair, commonly known achromotrichia, is a physiological phenomenon called "canities" and is a part of ageing. [1] In white population, age related hair greying onsets at the age of 34.2±9.6 years whereas it is delayed in black population (43.9±10.3 years). In Japanese this phenomenon onset between 30-34 years in men and between 35-39 years in women.[2] The hairs in beard and moustache areas have earliest onset greying, as compared to scalp or body hairs. In the Indian population there is no age range for greying. Premature canities refers to greying that starts before the typical age of onset. If hair begins to grey before the age of 20 in Caucasians or before the age of 30 in Africans, it is considered premature greying.[3] The definition of premature canities is unspecified in Asian population, but in India, canities in less than 25 years of age is considered premature.[4]

The advantages of pigmented hairs are numerous. Gray hair is generally coarser, stiffer, and less manageable than pigmented hair requiring more ultraviolet (UV) protection as compared to dark or brown hairs. Toxic metal buildup from fish ingestion, that concentrate heavy metals, is prevented by the selective and ardent binding of poisons and metals to melanin pigment, notably in humans living along seacoasts and river banks.[5] Furthermore, reactive quinone intermediates produced during the formation of melanin have strong antibacterial capabilities. Also, deep dark or black hair helps with ion transport and salt balance and protects against sunstroke. Premature hair greying occurring before the age of 40 years has been shown to be an important predictor of low

bone density and osteopenia. Premature greying of hair to be a significant risk factor for CAD has been reported by various authors. Risk of myocardial infarction has been reported to be directly proportional to the extent of greying of hair in men.[6]

The 5-10% of the world's population, primarily from northern Europe, lacks the eco-friendly brown–black hair.[7] Mutations in the melanocortin-1 receptor (MC1R) gene are thought to be responsible for the white-blonde and yellow-blonde hair colors seen in people living in northern European countries with less sunshine.

Premature hair greying or canities has severe negative impacts on an individual's appearance, self-esteem and social acceptance.[8]

Though a common entity, the treatment of premature canities is still far from satisfactory. Calcium pantothenate 200 mg daily, para-aminobenzoic acid (PABA) 100 mg thrice daily has been reported to cause darkening of the hair, but their therapeutic efficacy is not guaranteed. Relapse is common after drug cessation. Hair colorants are presently the mainstay of recovering lost hair colour. There is a definite lacuna in the treatment options of this condition.

Repigmenting formula Revgrey® hair serum contains Greyverse, EUK 134, and Amisol trio. Greyverse is α-MSH biomimetic tetrapeptide (PTP20) which helps in re-pigmentation of grey hair PTP20 promotes pigmentation of hair by increasing melanin synthesis (improving TRP-1 synthesis), increasing melanosome transfer from melanocyte to keratinocyte cells and increased expression of MCIR and MITF (key melanogenesis genes). By boosting catalase activity and TRP2 production, PTP20 also aids in reduction of oxidative stress.[9]

EUK 134 is a powerful antioxidant that lowers oxidative stress by simulating the actions of enzymes-catalase and superoxide dismutase (SOD).

Amisol trio is cuticle repair and conditioning substance made of soy phospholipids, glycolipids, sterols and soybean oil. On hair cuticle, it creates biofilm that heals cuticle, decreases split ends, guards against dry scalp.[10]

The aim of this study was to examine effectiveness and safety of the hair serum containing Greyverse, Euk 134, and Amisol trio in preventing premature greying of hair.

CASE SERIES

This was an open labelled, single arm, interventional case series study to examine the efficacy of Revgrey® hair serum in preventing premature greying of hair. This study was conducted after the institutional ethics committee's approval. The participants were recruited after written informed consent from patients (>18 years age); whereas in patients <18 years age, it was provided by their parents/guardians. Verbal consent was also taken from children between 7-18 years age.

The study duration was of 6 months and the treatment duration was of 12 weeks. The patients (<25 years of age) with greying of hair were included in the study based on the following selection criteria:

Inclusion criteria

Patients aged less than 25 years diagnosed with premature canities attending the OPD. Patients who were willing to appear for regular follow-ups and follow the prescribed treatment regularly. Parents/guardians (legally authorized representative [LAR]) willing to provide written informed consent for patients aged less than 18 years. Patients between 18-25 years of age willing to provide written informed consent included in the study.

Exclusion criteria

Patients known to be allergic to any of the components of the study medications. History of any chronic systemic disease like rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis. Patients with known malignancy or those on chemotherapy. Patient refusal and participated in clinical trial in last 90 days were excluded.

A total of 10 patients were enrolled in study. Diagnosis was based on detailed history and clinical examination.

The study intervention included application of Revgrey® hair serum on the scalp twice daily, oral nutritional supplement to be taken once daily for 3 months (not containing calcium pantothenate and PABA), daily washing with shampoo containing zinc pyrithione and study period included 3 visits. The baseline findings at day 0 and findings on follow-up at day 90 were documented. The efficacy assessment was done by the investigator and through patient self-assessment score.

The efficacy assessment included clinical photographs and Trichoscopy with video-dermoscope (Fotofinder) at 50 X magnification, before and at the end of study period (Day 0 and 90), to analyse the outcome. The scalp is divided into 5 parts: frontal region, vertex, left temporal, right temporal and occipital region. One point with maximum greying of hair was chosen clinically in each of these areas for trichoscopy. Same points were chosen for follow-up analysis on day 90. Manual counting of white hair using Smart count mode was also done.

Statistical analysis

The efficacy of data at each time point was summarized as Mean ± SD. The efficacy data was then compared between time points using Wilcoxon signed rank test. The safety data was presented as proportions. All analysis were conducted at 5% significance level. The data was analyzed using MS excel 365 and SPSS version 22.

Of the total 10 subjects enrolled in the study, 2 (20.0%) were females and 8 (80.0%) were males. The mean age of study sample was 14.9 (±4.3) years, Table 1. The mean number of white hairs in frontal region was 9.22 (±4.33) while on day 90 it was 8.88 (±6.15). Mean change from the baseline was found to be -0.34 and p=0.8074.

The mean value of number of white hairs in vertex region was 9.33 (±4.12) while on Day 90 it was 7.22 (±3.76). The mean change from the baseline was found to be -2.11 and the p=0.0142.

The mean value of number of white hairs in right temporal region was 9 (±4.34) while on Day 90 it was 6.3 (±3.43). The mean change from the baseline was found to be -2.7 and the p=0.0962.

The mean value of number of white hairs in left temporal region was 8.66 (±4.84) while on Day 90 it was 6.88 (±3.72). The mean change from the baseline was found to be -1.78 and the p=0.1614.

The mean value of number of white hairs in occipital region was 9.22 (±5.60) while on day 90 it was 7.77 (± 5.99). The mean change from the baseline was found to be -1.45 and the p=0.0827 as seen in Figure 1, Table 2.

Investigator's assessment reported that subject with slight increase in recovery of hair were 4 (0.4%), moderate increase in recovery of hair were 3 (0.3%), great increase in recovery of hair were 1 (0.1%), no change in recovery of hair were 1 (0.1%), slightly decreased in recovery of hair were 0 (0.0%), moderately decreased in recovery of hair were 1 (0.1%) and greatly decreased in recovery of hair were 0 (0.0%) as seen in Table 3. The results from self- assessment can be seen in Table 4.

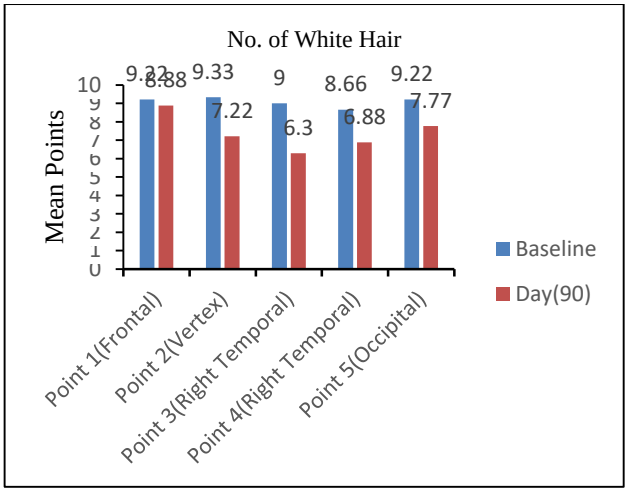

Figure 1: Number of white hair.

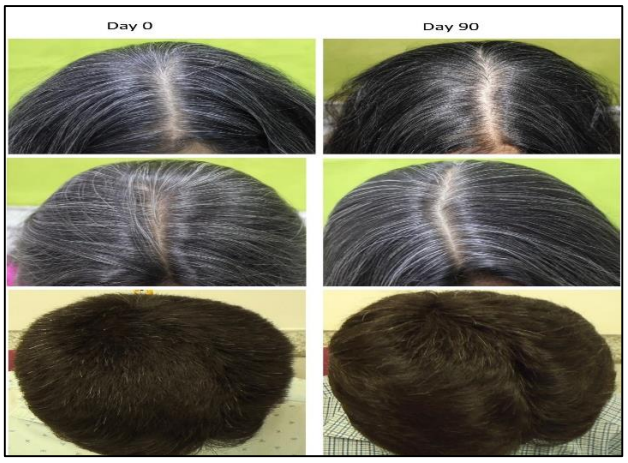

Figure 2: Results-pre and post Revgrey® hair serum use.

Table 1: Summary statistics of demographics of all subjects.

Parameters	Count, (n=10)
Age (Years)	
Mean	14.9
Standard deviation	4.33
Minimum	6.00
Maximum	19.00
Gender, n (%)	
Male	8 (0.8)
Female	2 (0.2)

Table 2: Summary statistics of umber of white hair.

Parameters	Count, (n=10)	
Point 1 (Frontal)	**Baseline**	**Day (90)**
Mean	9.22	8.88
Standard deviation	4.33	6.15
Median	15.5	9.00
Minimum	6.00	3.00
Maximum	19.00	22.00
Mean change from baseline	-0.34	
Intra group p value	0.8074	

Continued.

Parameters	Count, (n=10)	
Point 2 (Vertex)	**Baseline**	**Day (90)**
Mean	9.33	7.22
Standard deviation	4.12	3.76
Median	9.00	6.00
Minimum	5.00	3.00
Maximum	18.00	12.00
Mean change from baseline	-2.11	
Intra group p value	0.0142	
Point 3 (Right temporal)	**Baseline**	**Day (90)**
Mean	9.00	6.3
Standard deviation	4.34	3.43
Median	7.00	5.5
Minimum	6.00	2.00
Maximum	18.00	13.00
Mean change from baseline	-2.7	
Intra group p value	0.0962	
Point 4 (Left temporal)	**Baseline**	**Day (90)**
Mean	8.66	6.88
Standard deviation	4.84	3.72
Median	8.00	7.00
Minimum	2.00	2.00
Maximum	17.00	13.00
Mean change from baseline	-1.78	
Intra group p value	0.1614	
Point 5 (Occipital)	**Baseline**	**Day (90)**
Mean	9.22	7.77
Standard deviation	5.60	5.99
Median	9.00	7.00
Minimum	2.00	1.00
Maximum	20.00	19.00
Mean change from baseline	-1.45	
Intra group p value	0.0827	

Seven point assessment based on physician's assessment of global photography, Slightly increased +1, moderately increased +2, greatly increased +3, no change 0, slightly decreased −1, moderately decreased −2, greatly decreased −3.

Table 3: Summary statistics of investigator's assessment.

Parameters	Count, (n=10)
Slightly increased	4 (0.4%)
Moderately increased	3 (0.3%)
Greatly increased	1 (0.1%)
No change	1 (0.1%)
Slightly decreased	0 (0.0%)
Moderately decreased	1 (0.1%)
Greatly decreased	0 (0.0%)

Table 4: Summary statistics of patient's self-assessment.

Parameters	Count, (n=10)
No improvement	2
1%-25% improvement	2
26%-50% improvement	2
51%-75% improvement	3
76%-100% improvement	1

DISCUSSION

Hair are important in terms of appearance and self-perception. The two components of hair ageing are weathering of the hair shaft and follicle ageing. Weathering of the hair shaft is the deterioration of the fibres of hair that extend from the root to the tip. Greying, or reduced melanocyte activity, is a result of ageing hair follicles. Greying of hair is a physiological phenomenon which is regarded as a sign of ageing.

The study by Sehrawat et al showed the "50" rule of thumb, which states that 50% of people will have at least 50% grey hair by the age of 50.[11] It was also predicted that between 6%-23% of people in the world have 50% of their hair grey by the time they are 50 years old.

Sonthalia et al reported the mean age at onset of premature greying was 10.2±3.6 years (range: 5-19 years), with an almost equal gender distribution while in our study, the age of participants was 14.9±4.33 years (mean ± SD).[12] The minimum age of participants was 6 and the maximum age of participants was 19 and the

number of male participants in the study were 8 and female participants were 2.

Bath et al study involved 35 children, 11.5% had mild greying of hair, 65.7% had moderate greying of hair, and 23% had severe greying of hair.[13] The mean age of cases was 16.8 years and mean age of onset of premature greying was 15 years. Male to female ratio was 1: 1.1 indicating no sex predilection. All the children had a moderate built and nourishment. Parental history of premature greying was present in 42.6% of patients and sibling's involvement was seen in 14.2% of patients. It is interesting to observe that 8 (22.85%) cases also had vitiligo lesions in the body. In our study, male to female ratio was 4:1 and the number of white hair seen in different region were different for each participant.

The study by Majeed et al reported that the anagen-telogen ratio did not alter significantly, but TrichoScan® measurements of hair density, hair growth rate, vellus, premature greying of hair and terminal density showed substantial improvements over baseline at all study time points.[14] The scale grade changed in direct proportion to the change in hair density. In our study regular application of hair serum containing Greyverse, Euk 134 and Amisol trio has shown its efficacy in preventing premature greying of hair and more than three participants were found to have good results with its use, as seen in Figure 2.

Decraene et al proved in his study that primary human keratinocytes are shielded from oxidative damage by EUK-134 while in our study EUK 134 proved to be as a powerful antioxidant that lowers oxidative stress by simulating the actions of enzymes-catalase and superoxide dismutase (SOD).[15]

The study conducted by Kwon et al showed that lugworm autolysate is having a conditioning effect as it improved the hair strength while in our study amisol trio made of soy phospholipids, glycolipids, sterols, and soybean oil showed that it repairs the cuticle and is also having a conditioning property.[16]

CONCLUSION

The innovative Revgrey® hair serum is proposed to be an acceptable solution to control premature greying of hair. It is light, safe, and soothing on the scalp as it contains Greyverse, EUK 134 and Amisoltrio. More than 70% of the study population admitted that the test product was effective in controlling greying of hair, that lead to an improvement in their self-esteem and quality of life. There were no adverse events during the study. The small sample size of the study was its limiting factor. This study fairly demonstrates that using the Revgrey® hair serum formulation in males and females suffering premature greying of hair is both safe and beneficial, but further studies with larger sample size are required to assess its efficacy.

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