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Research Article

Efficacy of Compound GV-350 with Tricofer® Iron, Cystine and Biotin in the Management of Telogen Effluvium in Women with Iron Deficiency

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Abstract

Objective: Iron deficiency without anaemia can induce Telogen Effluvium (TE). Traditional oral iron salts are poorly and erratically absorbed. The present study investigated whether treatment with GV-350 (30 mg Tricofer®, 500 mg cystine, 250 µg biotin daily) on an empty stomach for 3 months improved iron status and TE in 20 iron- deficient women (ferritin <40 ng/mL).

Methods: Blood tests to measure iron status were performed. Safety (adverse events), impact of the TE in the quality of life (Hair-Specific Skindex-29 score; HSS-29) and percentage of surface covered by hair before and after treatment (photographs, N=8) or phototrichogram (N=3) were also measured. Dermatologists and patients provided a global assessment of the efficacy and tolerability of GV-350.

Results: After 3 months of treatment, iron status improved significantly with increases in serum iron (68.7 ± 18.4 to 83.9 ± 25.2 µg/dL; $p<0.05$), ferritin (26.1 ± 11.2 to 43.8 ± 40.5 ng/mL; $p=0.025$), transferrin saturation index (TSI; 21.8 ± 6.2 to 31.3 ± 7.9 %; N=14, $p<0.01$), red blood cells (4.2 ± 0.2 to 4.3 ± 0.2 x10^6/µL; $p<0.025$) and haemoglobin (12.9 ± 0.7 to 13.1 ± 0.8 g/dL; $p=0.053$). This was accompanied by an improvement in the results of the phototrichogram, hair surface area and satisfaction (efficacy and tolerability). Impact of TE in overall quality of life was reduced by 53% (vs. baseline), but also in its three dimensions: emotional, functional and symptomatic. There were no treatment-related adverse events.

Conclusion: We conclude that compound GV-350 taken on an empty stomach for 3 months is adequately absorbed, improving iron deficiency, the clinical symptoms of TE and the quality of life of patients, with good tolerability.

Keywords: Telogen Effluvium; Iron Deficiency; Ferritin; Iron Supplementation; Tricofer®; Hair-Specific Skindex-29

Abbreviations

HSS-29: Hair-Specific Skindex score with 29 items; TE: Telogen Effluvium; TSI: Transferrin Saturation Index

Introduction

Telogen Effluvium (TE) is a widespread and diffuse form of hair loss and thinning that frequently occurs in a woman's middle age. The life cycle of a hair follicle consists of several stages of varying duration. Iron participates as a regulator of hair follicle activity (proliferation, energy metabolism, follicle oxygenation, growth). Low iron availability in the hair follicle due to a decrease in circulating iron, as occurs in iron deficiency or anaemia, contributes to a shift of the hair cycle from the anagen towards the telogen phase, which, maintained over time, induces a progressive miniaturization of the hair and even a decrease in hair density

(Cranwell 2019, Asghar 2020, Hughes 2024). Ferritin is the reserve for iron stores in the human body. Iron stored in ferritin is mobilized to the blood stream in response to a drop in peripheral iron levels or an increased demand that is not compensated by circulating iron levels.

In 1990 Rushton (Rushton 1990) established the hypothesis of the diffuse alopecia process, based on clinical evidence and in which there was a 71% reduction of follicles in the anagen phase, with the consequent increase of 72% of hair in the telogen phase, with the presence of miniaturized hairs and over time the hair density was reduced. Kantor and cols (Kantor 2003) analysed the parameters related to iron metabolism in women with different forms of alopecia and found that women (≤40 years) with Androgenetic Alopecia (AGA), Telogen Effluvium (TE) and Alopecia Areata (AA), had lower iron deposits than women of the same age without alopecia, this difference being statistically significant. It has been reported that between 20 and 25% of women with TE have iron deficiency (in the absence of anaemia), with ferritin levels below 40 ng/mL (Rushton 1990, Rushton 2002a, Rushton 2003, Deloche 2007, De Viragh 2013). Ferritin levels considered normal constitute a wide range (15-291 ng/mL). Although a ferritin of 40 ng/mL does not indicate anaemia, several studies agree that levels below this threshold can trigger the hair to enter the telogen phase (its growth cycle stops and consequently shedding occurs). Maintaining the cause of effluvium for a long time (chronic telogen effluvium) also has an impact on the quality of the hair, observing the progressive miniaturization, with a greater proportion of hairs in the telogen phase, in addition to the decrease in hair density on the scalp. Iron supplementation is a therapeutic option in order to rise ferritin levels. However, oral iron absorption is low and erratic, being influenced even by food. Traditional iron salts are usually administered at high doses to ensure enough iron absorption, but cause irritation in contact with the gastrointestinal mucosa leading to the common adverse gastrointestinal symptoms that characterize these treatments (diarrhoea, constipation, nausea, stool coloration, etc.), that result in a poor adherence to treatment (Cancelo- Hidalgo 2013, Pantopoulos 2024, Dhanvijay 2025).

Tricofer® (Laboratorios Viñas, S.A. Barcelona, Spain) is a liposomal iron consisting of ferric pyrophosphate contained in a liposome, which minimizes irritation of the gastrointestinal mucosa by direct contact, ensuring good adherence to treatment. Once it reaches the liver, it is released from the liposome and is available to be mobilized to the blood stream or stored in ferritin. The GV-350 compound contains Tricofer®, but also L-cystine and biotin, both compounds with a trichogenic function that contribute to the maintenance of normal hair (Galmes 2023). We hypothesized that iron supplementation with Tricofer® together with the cystine and biotin of the GV-350 compound, shall favour an improvement in the TE of female patients with baseline ferritin below 40 ng/mL. The main objective of the present study was to assess the evolution of the iron status, as well as to clinically improve the TE of women with iron-deficiency and establish a possible relationship between clinical improvement and that of iron blood tests. Secondary objectives consisted of the assessment of tolerability (and safety) and the impact of TE in quality of life of these patients.

Methodology

Study Design

This study was approved by the Ethics Committee for Drug Research of the International University of Catalonia (Barcelona, Spain) on 14 January 2021. All patients provided their signed written informed consent. The study design was open, prospective, phase III, controlled with their baseline clinical condition. Participated 6 dermatologists from 6 Health Centres in Spain. The research was conducted in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) and the principles outlined in the Declaration of Helsinki. Consent to participate was obtained from patients from case series.

Participants/Subjects

Sample size estimation was performed with the GRANMO Sample size and Power Calculator, developed by the Program of the Girona Heart Registry (REGICOR), IMIM, Barcelona (available in https://www.datarus.eu/en/applications/granmo/). Taking into consideration the limited treatment duration and the erratic iron absorption, we estimate that an initial proportion of 100% cases will present ferritin levels below 40 ng/mL and this proportion will decrease to 50% after treatment. Accepting an alpha risk of 0.05 and a power of 0.8 in a two-tailed test, with an anticipated drop-out rate of 10%, a total of 19 subjects were estimated necessary to recognize a statistically significant difference. This value was rounded to 20 cases. Twenty adult women with TE, aged between 18 and 75 years, with baseline serum ferritin levels between 5-40 ng/mL (confirmed with blood test) and at least 3 months of history of diffuse hair loss, were selected. Other types of alopecia, cases with severe iron deficiency anaemia, severe

systemic disease or pregnant women were excluded. Other concomitant treatments were allowed as long as they were not intended for their TE nor iron supplementation. All patients were assessed for the screening criteria confirming ET diagnose and ferritin levels. Patients were instructed to ingest 2 capsules of GV-350 together each day (30 mg Tricofer®, 500 mg cystine, 250 μg biotin daily doses) on an empty stomach, at least 30 minutes before breakfast or lunch, on a daily basis for 3 months. Patients were evaluated in a screening visit, a baseline control to record parameters before treatment and a final control visit after 3 months, at the end of treatment.

Data Collection

The information obtained during the study was incorporated into a paper case report form. Policy for protection of sensitive data was applied and data was pseudonymized, only the researchers were able to trace their identities. Analysis of the results was carried out at the end of the study. The evolution of the different parameters and variables obtained during the study was studied. Blood tests were performed to assess evolution of the iron status during treatment (serum iron, serum ferritin, transferrin saturation index, red blood cells and haemoglobin) comparing differences between the baseline and final visit. The impact of TE on patients' quality of life was evaluated. To this end, a validated score for this purpose focused on alopecia was applied, the Hair Specific Skindex of 29 items or questions translated into Spanish (Chren 1997, Guerra-Tapia 2018). This score focuses on three dimensions: One functional with 12 items (social life, isolation, sexuality, work, hobbies), other emotional with 10 items (embarrassment, annoyance, depression, frustration) and a symptomatic dimension with seven items (itching, pain, irritation). Each item has a Likert-like response scale with possible options, 0 (never) to 4 (all the time). The questions refer to the previous four-week period. High scores indicate worse quality of life. The score for each dimension is obtained by transforming the sum of the responses on a linear scale from 0 (no impact on health-related quality of life) to 100 (maximum impact on health-related quality of life). An overall score is obtained by the same transformation. The scale allows stratifying the degree of affectation in quality of life: without affectation (<20), mild (20-30), moderate (30-40) and severe (≥40). Intra- individual statistical significance between baseline and final visits was assessed using a Student's t-test for paired data. Photographs were taken maintaining the conditions of light, focal length, number of magnifications and location in 8 of the 20 patients, before and after treatment. The percentage of surface covered by hair was calculated using Image J software (version 1.54b of open-source public domain). The photographs were transformed into a grayscale. By adjusting the threshold, the pixels corresponding to hair or the entire image were obtained, allowing the percentage to be calculated. If more than one image of the same visit was available, all of them were assessed and the average was taken. Phototrichogram was performed when available, to quantify hair density, terminal hair count, vellus count and the ratio of terminal/vellus hair in the same spot. In the final visit, adverse events and adherence to treatment (good if >80%) were also recorded and dermatologists and patients provided a global assessment of the efficacy and tolerability of GV-350.

Data Analysis

Data were included in an excel database and statistically analysed with this same program. The statistical analysis is mostly based on basic descriptive data and statistical tests (t- test for means of two paired samples, chi-square test). Qualitative results were expressed as percentages with respect of total cases. Quantitative data were expressed as the mean of the total and its standard deviation. Intra-individual statistical significance between baseline and final visits was assessed using the student's t-test for paired data and the p- value for 1 tail. The comparison between the opinion of the researchers and that of the patients was verified by means of a chi-square test. A $p<0.05$ value was considered statistically significant and a $p<0.01$ value was considered very significant. The numerical results were summarized in the form of table or boxplot. Increases (%) vs. baseline mean values were calculated as 100x(final-basal)/basal.

Results

A total of 20 women aged 28 to 54 years (mean age: 43.1 ± 11.2 years) were included, with a mean duration of TE of 12.3 ± 11 months. A 30% of the sample (N=6) indicated that the onset was abrupt, while for 70% (14 patients) it was gradual. Along with iron deficiency, 8 women were associated with stress as an added factor to their alopecia (1 also with anxiety), in three others childbirth and in separate cases breastfeeding, perimenopause, COVID-19 infection or a poor diet (this case also showed signs of untreated mild depression). The 85% of cases (N=17) were not taking any concomitant medication. Three patients also received another treatment that did not interfere with GV-350: one case of HRT (hormone replacement therapy) due to perimenopause, one case of Valacyclovir (500 mg) and another case of Melatonin (10 mg). All patients completed the 3-month treatment and could be evaluated (Table 1).

	Mean ± SD	N (%)
Age (years)	43.1 ± 11.2	20 (100%)
TE duration (months)	12.3 ± 11.0	20 (100%)
Onset of the TE	**N (cases)**	**% of total**
Abrupt onset	6	30%
Gradual onset	14	70%
Mood distress, stress, depression	**N (cases)**	**% of total**
Yes	9	45%
No	11	55%

Table 1: Patient characteristics.

Evolution of Iron Metabolism Parameters

Serum iron levels increased from a mean 68.7 ± 18.4 μg/dL to 83.9 ± 25.2 μg/dL (N=20; p<0.05). The mean basal ferritin also increased after treatment with GV-350 from 26.1 ± 11.2 ng/mL to 43.8 ± 40.5 ng/mL (N=20; p<0.05). Transferrin Saturation Index (TSI (%)) was measured in 14 of the 20 cases, with mean values from 21.8 ± 6.2% at baseline augmented to 31.3 ± 7.9% at the end of treatment (N=14; p<0.01). The number of red blood cell at baseline was of 4.2 ± 0.2 x10⁶/μL and changed to 4.3 ± 0.2x10⁶/μL after 3 months of treatment (N=20; p<0.05). Haemoglobin baseline levels were of 12.9 ± 0.7 g/dL and increased to 13.1 ± 0.8 g/dL at the final control (N=20; p-paired=0.053). The results of the iron metabolism parameters are summarized in Table 2, Fig. 1.

Parameter (units)	Mean ± Standard Deviation		p-paired (1 tail)	N	Rank Normality
	basal	final			
Red blood cells (x10⁶/μL)	4.2 ± 0.2	4.3 ± 0.2	0.014	20	3.8 - 5.3
Haemoglobin (g/dL)	12.9 ± 0.7	13.1 ± 0.8	0.053	20	11.5 - 16
Serum Iron (μg/dL)	68.7 ± 18.4	83.9 ± 25.2	0.032	20	50 - 170
Ferritin (ng/mL)	26.1 ± 11.2	43.8 ± 40.5	0.012	20	15 - 291
Transferrin saturation index (TSI, %)	21.8 ± 6.2	31.3 ± 7.9	0.002	14*	25 - 45
* Missing data: TSI was not assessed in 5 cases, nor in 1 baseline, consequently, statistical analysis corresponds to 14 complete cases.					

Table 2: Evolution of the analytical parameters of iron status in blood.

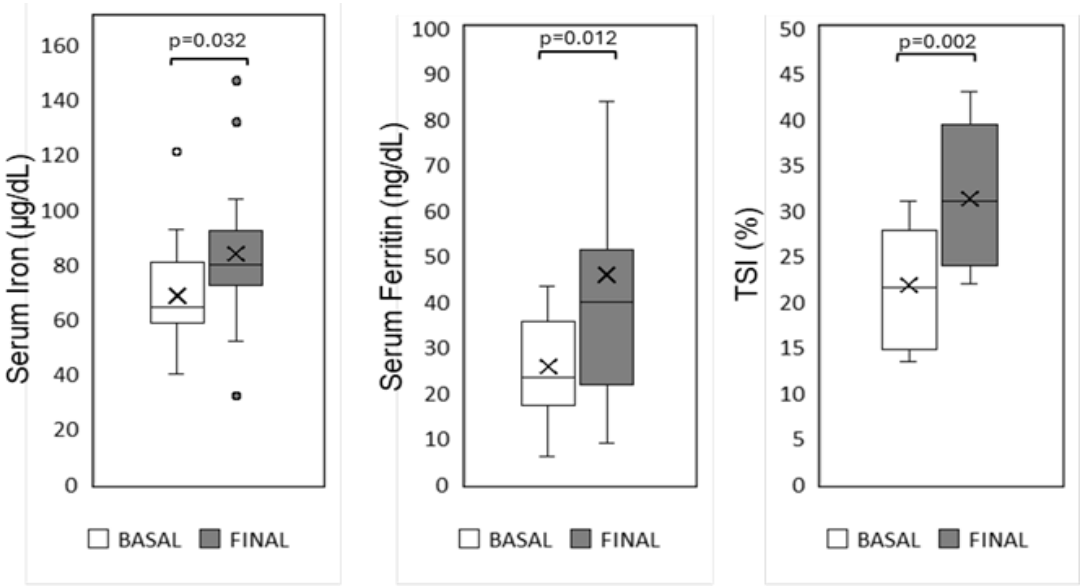

Figure 1: Boxplot of the evolution of serum iron, ferritin and Transferrin Saturation Index (IST), before (white) and after 3 months of treatment with GV-350 (grey). A p<0.05 was considered statistically significant.

Evolution of the Hair Specific Skindex-29 Quality of Life Scale

The impact of TE on patients' quality of life was evaluated by applying the 29-item Hair- Specific Skindex scale (HSS-29). The patients showed different degrees of impairment of quality of life as a result of TE. Table 3 and Fig. 2 summarize the mean values obtained before and at the end of treatment, both globally and for each separate dimension. All the means improved with respect to the baseline visit, going from moderate to no affectation in the emotional and symptomatic dimensions and from mild to no affectation for the functional dimension and the patient's global assessment. These improvements at the end of treatment were statistically very significant.

Valued Dimension	Mean ± Standard Deviation		P-Paired	N	Qol Affectation Basal To Final
	Basal	Final			
Functional	23.2 ± 24.3	12.4 ± 20.5	2.8x10-3	20	Mild to Absent
Emotional	35.3 ± 23	18.3 ± 19.1	7.7 x10-5	20	Moderate to Absent
Symptomatic	33.6 ± 20.7	8.3 ± 7.1	2.5 x10-5	20	Moderate to Absent
Global	29.9 ± 19.3	14.1 ± 16.2	4.9 x10-5	20	Mild to Absent
Degree of impact on quality of life: not affected (<20), mild involvement (20-30), moderate (30-40) and serious (≥40).					

Table 3: Evolution of the impact of TE on patients' quality of life (Hair Specific Skindex-29 score), before and at the end of treatment.

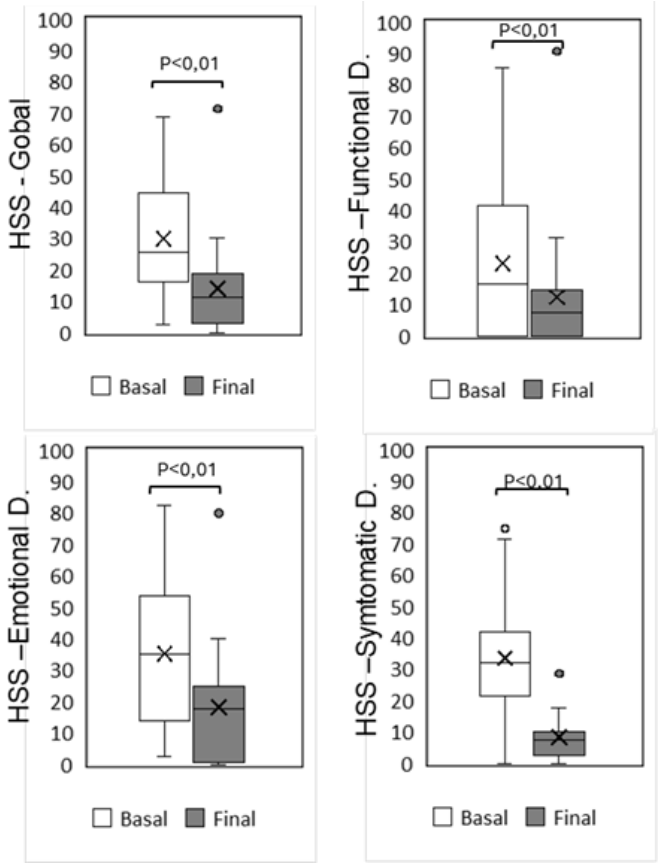

Figure 2: Boxplot of the Evolution of the impact of TE on patients' quality of life (Hair Specific Skindex score-29; HSS), before (white) and at the end of treatment (grey), both global assessment and functional, emotional and symptomatic dimensions.

Phototrichogram Results

This test was performed on only 3 of the 20 patients, therefore no statistical conclusions can be drawn. However, it should be noted that all the parameters assessed improved in all 3 cases, as shown in Table 4. The mean hair density increased by 11.9% compared to baseline. This increase is confirmed by the 18% rise in the average of terminal hairs and the 5.6% decrease in the average vellum, which gives an increase in the ratio of terminal hairs to vellum of 19.4%.

Parameter	Mean ± Standard Deviation		Increase Vs. Baseline (%)
	Basal	Final	
Hair density (n hairs/cm²)	70 ± 11.1	78.3 ± 8	11.9
Terminal hair count	52.3 ± 9.8	61.7 ± 8.7	18.0
Vellum hair count	17.7 ± 4	16.7 ± 1.5	-5.6
Terminal hairs to vellum ratio	3.1 ± 0.9	3.7 ± 0.7	19.4
No statistical assessment provided due to the reduced number of cases (N=3).			

Table 4: Evolution of the parameters measured with a phototrichogram.

Photographs and Percentage of Surface Covered by Hair

Photographs were taken in 8 of the 20 patients, before and after treatment and the percentage of surface covered by hair was calculated. The results indicate that this percentage increased from 50.7 ± 11.8% to 54.3 ± 11.5%. This represents a relative increase of 7.1% compared to the baseline mean. The t-test for means of two paired samples showed that the increase was statistically very significant (N=8; p=0.0025) (Fig. 3).

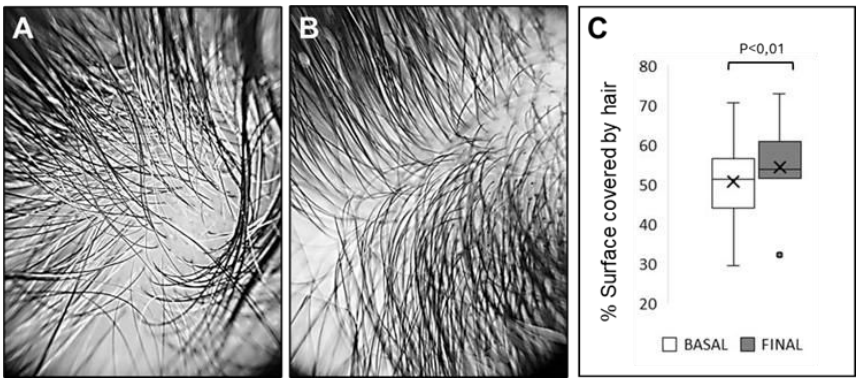

Figure 3: Photographs of a representative case, (A) before and (B) after treatment with GV-350. (C) Boxplot of the surface covered by hair in photographs from 8 patients, before (white) and at the end of treatment (grey).

Global Assessments of Investigators and Patients

In relation to efficacy (Fig. 4), the researchers considered it good in all patients (100%, N=19), while 95% (N=18) of the patients considered it good and 5% (N=1)) fair. One case did not answer this question. The Chi-square test confirmed that the responses did not show statistically significant differences (p=0.598) between physicians and patients. Regarding tolerability (Fig. 4), the opinions were repeated: 100% of the patients (N=20) presented good tolerability to GV-350 according to the physicians, while 95% (N=19) of the patients considered it good and 5% (N=1)) fair. Again, the Chi-square test confirmed that the responses of physicians and patients did not show statistically significant differences (p=0.599) between them.

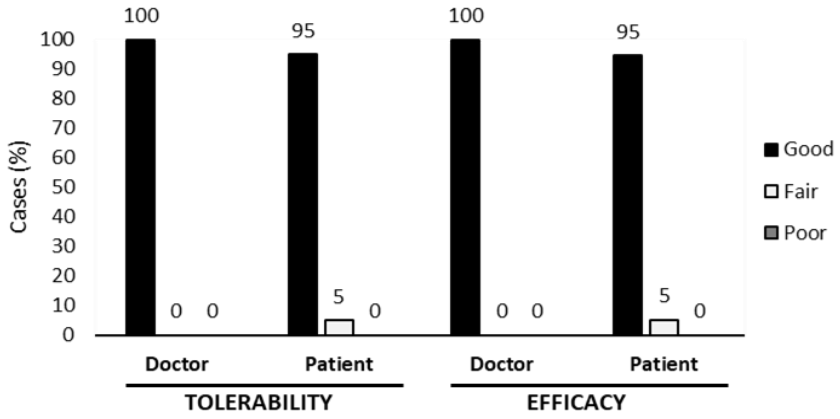

Figure 4: Bar graph summarizing physicians' and patients' global assessments about the efficacy and tolerability of GV-350. Data expressed as a percentage of cases with respect to the total.

Adverse Events

During the study, a case of mononucleosis was recorded, whose relationship with the treatment under study was considered by the researcher to be remote. No other events or adverse reactions were recorded during the test.

Adherence to Treatment

Adherence to treatment was considered good if more than 80% of treatment was completed. With the exception of two patients who stopped taking 25 and 30 of the 180 capsules that completed the treatment (86% and 83% adherence, respectively), all other patients in the study completed the therapy adequately. The two patients were also included in the final statistical analysis, exceeding the 80% threshold.

Discussion

Iron participates as a regulator of hair follicle activity (proliferation, energy metabolism, follicle oxygenation, growth). Low iron availability in the hair follicle in the event of a decrease in circulating iron, as occurs in iron deficiency or anaemia, can induce Telogen Effluvium (TE) (Deloche 2007, Elston 2010, Cranwell 2019). Traditional oral iron salts are poorly and erratically absorbed. We hypothesized that iron supplementation with Tricofer® (30 mg iron element/day) together with the L-cystine (500mg/day) and biotin (250μg/day) of the GV-350 compound, would improve the TE of female patients with baseline ferritin below 40 ng/mL. Our present study has shown that GV-350 is effective and safe in the oral management of these women, improving the initially altered iron metabolism parameters, while producing a clinical improvement in their effluvium as demonstrated in the cases studied by phototrichogram and the surface covered with hair. This was supported by the patient's global assessments on the GV-350 efficacy and tolerability. Moreover, the impact of TE in the quality of life of these women assessed with the Hair Specific Skindex-29 scale was reduced.

Diffuse alopecia is characterized by a reduction of follicles in the anagen phase and an increase of hair in the telogen phase, presence of miniaturized hairs and reduced hair density over time (Rushton 1990). There is evidence that pre-menopause women with androgenetic alopecia, Telogen Effluvium (TE) and alopecia areata, had statistically significant lower iron deposits than women of the same age without alopecia (Kantor 2003). Between 20 to 25% of women with TE have iron deficiency in the absence of anaemia, with ferritin levels below 40ng/mL (Rushton 1990, Rushton 1992, Rushton 2002a, Deloche 2007, De Viragh 2013). Several studies coincide that levels below this threshold can trigger the hair to enter the telogen phase. Under the study conditions, our results in the evolution of the iron status have been very favourable, since all the analytical parameters have improved significantly. Particularly relevant were the increases with respect to the baseline mean in serum ferritin levels (68%), serum iron levels (22%) and in the transferrin saturation index (44%). Rushton and cols already published that iron supplementation rises ferritin levels above 40 ng/mL, improves hair quality, increases the percentage of hairs in the anagen phase and decreases that in telogen phase, resulting in more hair density (Rushton 2002b, Trost 2006, Lin 2023). They also published that iron supplementation may favour the response to other specific treatments for alopecia (Rushton 1992). We did not include other treatments for alopecia, however the trichogenic benefits of supplementation with biotin and cystine, are well known. The hair shaft is composed almost entirely of protein (primarily keratin). Keratin has a high cystine content; and its structure resilience increases with the amount of cystine. The involvement of biotin in protein synthesis and more specifically, in keratin production, explains its contribution to healthy nail and hair growth; more evident in patients with biotin deficiency such as pregnancy, malnutrition, medication effects and biotinidase deficiency (Patel 2017, Galmes 2023). In the present study, although it was only measured in 3 patients, hair density improved by 12% and the number of terminal hairs by 18%, increasing the ratio of terminal hairs to vellum by 19%. In the same way, the photographic assessment of the surface covered by hair carried out in another 8 patients showed a significant increase of 7.1%. TE has cosmetic implications that can impact negatively in the quality of life of patients. For this reason, it is even recommended to address the need to use psychological tests in the field of dermatology (Costeris 2021). To assess the impact of TE hair loss in quality of life of our patients we used the validated 29-item Hair-Specific Skindex questionnaire. This questionnaire not only assesses the global impact, but also different dimensions that focus on functional questions (social life, isolation, sexuality, work, hobbies), emotional items (embarrassment, annoyance, depression, frustration) and a symptomatic dimension (itching, pain, irritation). The scale allows stratifying the degree of affectation in quality of life. In our study we observe that the favourable analytical results and the clinical improvement of the effluvium have impacted positively in the evolution of the quality of life. All the means improved with respect to the baseline visit, decreasing from moderate to no affectation in the emotional and symptomatic dimensions and from mild to no impact for the functional dimension and the patient's global assessment. The Hair- Specific Skindex-29 score, was statistically significant reduced by 53%

with respect to the basal, minimizing the impact of alopecia after three months of treatment. Traditional iron salts are usually associated with adverse gastrointestinal symptoms such as diarrhoea, constipation, nausea, stool coloration, etc.), that result in a poor adherence to treatment (Cancelo-Hidalgo 2013, Pantopoulos 2024, Dhanvijay 2025). The absorption of oral iron is low and erratic, depending on different factors such as the iron status itself, its intake or not on an empty stomach, the iron salt used, the presence of alteration in the intestinal mucosa, etc. To ensure the adequate absorption of the iron in the GV-350 compound, a trivalent liposomal salt, Tricofer®, has been used. It has a lipid envelope that facilitates intestinal absorption, while protecting the salt from direct contact with the mucosa, improving its tolerability. On the other hand, to avoid the possible interaction of food in its absorption, patients were asked to ingest the capsules on an empty stomach. Our data demonstrates that GV-350 product is well tolerated, as indicated by practically all patients, even when ingested on an empty stomach, which confirms the protection of Tricofer® and this has contributed to the adequate adherence of patients during the 3 months of treatment. Furthermore, no adverse reactions were recorded associated with the study treatment. This contributed to complete treatment with acceptable adherence in all cases.

This research has some limitations. As it is a single-arm study, participants act as their own controls, making it difficult to establish causality. Besides, TE is usually self- limiting, even though the recovery process can take many months. The median duration of TE in our cases was of 7 months (IQR: 6-13.5 months). In our study, ferritin levels were confirmed and treatment with GV-350 was performed, the clinical setting of TE improved significantly in the final control visit. Despite the duration of the TE and treatment with iron for only 3 months, the possibility of a spontaneous resolution cannot be disregarded. Another limitation is the small sample size and few cases with evidence on the clinical evolution of the TE. The selection criteria were strict, which, despite telogen effluvium being a common condition, made participant inclusion difficult and justifies the final number of subjects. However, we consider it adequate for a preliminary exploratory study. The main objective of this study was to demonstrate whether the GV- 350 compound could improve the iron status on an empty stomach, however, photographs or phototrichogram were only performed by some researchers. Taking this present data as preliminary, a future Randomized Controlled Trial (RCT) should be conducted for confirmatory evidence. Finally, even though quality-of-life improvement is significant, psychosocial confounding factors (placebo response, natural remission of TE) should be acknowledged. Regarding limitations, we note that many are shared with other studies on TE, especially considering its potentially self-resolving nature when a specific cause is present. However, in this study, which focuses on effluvium associated with low ferritin levels, we have an objective measure -ferritin- that showed improvement, which has a direct and close relationship with the pathophysiology of effluvium.

Conclusion

The results of this study show that the GV-350 compound at the dose of 30 mg of Tricofer®, 500 mg of L-cystine and 250µg of biotin per day, ingested on an empty stomach for 3 months, is effective in the treatment of chronic telogen effluvium in iron deficiency (non-anemic) women, improving iron status, clinical signs of TE and patients' quality of life, with a very good tolerability and safety profile.

Conflicts of Interest

This research was sponsored by Laboratorios Viñas, S.A; which complies with the Good Practice Code for the Pharmaceutical Industry (Farmaindustria Code). Dr. Irene Lopez- Vilchez, Dr. Cleofé Zaragozá and José Luis Galmés Olmos, from the Clinical Research Department of Laboratorios Viñas prepared the study design and participated in the study monitorisation. They performed the transcription of the CRF data into the database and made the statistical analysis. Based on the final study report that contained the raw data attached for transparency, prepared the manuscript draft to be critically reviewed by the authors.

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None.

Informed Consent Statement

Informed consent was obtained from the participants involved in this study.

Authors' Contributions

RGS participated in the preparation of the study design. The rest of the authors participated in the inclusion of cases and data collection according to the study protocol. RdRG provided Phototrichogram results in his 3 cases. MBdT and ANG provided pictures for the assessment of surface covered with hair in their 8 cases. All authors performed a critical review of the manuscript. All authors provided their final approval of the version to be published. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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