

BIWEEKLY IN-OFFICE INJECTABLE TREATMENT OF STRIAE DISTENSAE VS A LONG-TERM DAILY USE OF TOPICAL VITAMIN C

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Summary

The treatment of striae distensae (SD) is difficult, generally unsatisfactory, and no placebo-controlled study has been carried out to ascertain the effect of different topical treatments.

The aim of this study was to control the activity of both an office injectable treatment and a topical treatment of water solutions of vitamin C, betaglucan and hyaluronic acid (active A).

A single blind placebo-controlled randomized comparative clinical study was performed on 66 women aged between 18-24, with SD localized over the abdomen and buttocks. The subjects were divided into 3 study groups. Active B was applied at home twice a day for 16 weeks to 24 patients (group A). Twice a week they received also dermal injection of active A for the entire period. 22 patients in group B applied, twice a day, active B for 16 weeks. The remaining 20 patients in group C applied a placebo solution (distilled water) twice daily during the same period.

The differences between the results in the different groups were statistically significant at week 12 and 16 ($p < 0.05$) both by visual score and by istological control performed. However, the combined use of injection and topical application (group A) provided superior results (+57%, $p < 0.05$) compared with the group B (topical treatment only) (+32% $p < 0.05$ vs. placebo). No side effects were observed during the treatment period, except a light burning at the moment of the injection. No results from placebo.

The combined topical and injectable use of vitamin C, betaglucan and hyaluronan seems to be effective to stimulate cell proliferation provided that the right concentration of the active with the right carrier is used.

Riassunto

Il trattamento delle striae distensae (SD) è difficile, scarso di risultati positivi e non è stato mai condotto uno studio di verifica confrontato con il placebo per controllare gli effetti di diversi trattamenti topici.

L'obiettivo di questo studio è stato quello di controllare per 16 settimane l'attività svolta da un trat-

tamento iniettivo e/o topico di una soluzione acquosa di vitamina C, betaglucano e acido ialuronico. È stato eseguito uno studio clinico a doppio cieco randomizzato su 66 donne di età compresa tra 18-24 anni con presenza di SD localizzate su addome e glutei.

I soggetti sono stati suddivisi in 3 gruppi.

ACTIVE B è stato applicato localmente a casa due volte al giorno per sedici settimane su 24 soggetti del gruppo A che, due volte alla settimana, venivano anche trattati con applicazioni sottocutanee di un prodotto analogo sterile ed apirogeno (ACTIVE A).

22 pazienti del gruppo B venivano trattati due volte al dì con la sola soluzione topica (ACTIVE B).

Ai restanti 20 soggetti (gruppo C) veniva applicata localmente la soluzione placebo (acqua distillata).

I dati ottenuti alla 12^o ed alla 16^o settimana, controllati clinicamente ed istologicamente, sono risultati statisticamente significativi ($p < 0.05$) nei diversi gruppi.

Comunque l'uso congiunto delle applicazioni topiche e di quelle iniettive (gruppo A) è risultato superiore del 57% ($p < 0.05$) se paragonato con il solo uso topico (+32% $p < 0.05$).

Non sono stati osservati effetti secondari .

L'uso congiunto topico ed iniettivo della vitamina C, del betaglucano e dell' acido ialuronico sembra possa considerarsi quale ottimo biostimolante cutaneo se utilizzato nei tempi e nei modi giusti.

INTRODUCTION

The treatment of striae distensae (SD) is difficult, generally unsatisfactory, and no placebo-controlled study has been carried out to ascertain the effect of different topical treatments (1-7).

AIM

The aim of this study was to control the activity on striae distensae of both an office injectable treatment (active A) and a topical one (active B) by the use of water solutions of vitamin C, beta-glucan and hyaluronic acid. As matter of fact it seems that this treatment increasing the secretion of growth factors and stimulating cell proliferation, may improve the appearance of SD (8).

MATERIAL AND METHODS

Material

1. *Active A*: hyaluronic acid, sodium salt 2 mg, sodium- carboxymethyl betaglukan 0,1 mg, ascorbic acid 0,5 mg, arginine 1 mg, sodium chloride 9 mg, sterile water for injectable solution q.b. at 1 ml, pH 7 ⁽¹⁾;
2. *Active B*: aqua, sodium ascorbyl phosphate, 3-aminopropyl-L-ascorbyl phosphate, carboxybetaglukan, hyaluronic acid ⁽²⁾;
3. *Placebo*: distilled water solution;
4. *Cleansing foam*: Aqua, decyl glucoside, glycerin, chlorexidine digluconate, sodium hydroxymethylglycinate, methyl gluceth-20, lactic acid, triclosan, piroctone olamine, linseed acid, disodium EDTA, parfum⁽³⁾;
5. *Scrub*: Aqua (Water), Decyl Glucoside, Glycerin, Hydrogenated Jojoba Oil, Trideceth-9, Potassium Azelaoyl Diglicinate, Peg-5 Octanoate, Glycine, Carbomer, Sodium Hydroxymethylglycinate, Polyethylene, Phosphatidylcholine, Propylene Glycol, Phenoxyethanol, Arginine, Aloe Barbadosis (Aloe Barbadosis Extract), Alcohol⁽⁴⁾.

¹ Trade name HCG 2000

² Trade name HCG 1000

Clinical Methodology

A single 4 months blind placebo-controlled randomized comparative study was performed on 66 women aged between 18-24, with SD localized over the abdomen and buttocks.

The subjects were randomly divided into 3 groups:

1. *Group A*: composed of 24 patients, applied Active B at home twice a day for 16 weeks. Twice a week and for the entire period, they received also dermal injection of Active A. The product was applied directly on the SD area cleaned both by a supplied cleansing foam ⁽³⁾ and a scrub ⁽⁴⁾.
2. *Group B*: composed of 22 patients, applied Active B the same period and the same way.
3. *Group C*: composed of 20 patients, applied the Placebo solution.

In conclusion all the three groups applied at home on the skin ACTIVE B or PLACEBO and only 1 group (group A) was treated also by injection with ACTIVE A.

Patients

Each patient, supplied with identical vials containing ACTIVE B or PLACEBO, was instructed to apply them on the SD pre-cleansed area (cleansing foam + scrub) twice a day for all the study period. The patients were also instructed to not use any other skin care product.

Skin Biopsies

Biopsies specimen were taken from a SD area, sectioned into 1-mm wide strips, fixed in formalin at 4°C for 18 hours and transferred to ethanol for further fixation, and paraffin embedded. Three-micrometer sections were studied by means of SEM or normal histology.

³ Trade name ALFA 4 Micospuma

⁴ Trade name KERATOTAL SCRUB

Injection Methodology

ACTIVE A was injected by using a linear threading puncture technique with a 30-gauge needle. For each SD skin area was used from 1 to 4 ml of the product diluted with 3 percent carbocaine.

Prophilometry

Prophilometry of the SD areas was carried out by scanning the surface of its skin replica and quantitatively determining its microtopography according to Makky et al (9,10). The impression of the SD area was taken by using the SIFLO® rubber (Flexico Development Ltd., London, UK) and the quantitative topographic measurement of the surface microrelieves was determined by the Confocal Laser Scanning Microscope (CLSM) (11,12).

The obtained results are reported on Fig. 1.

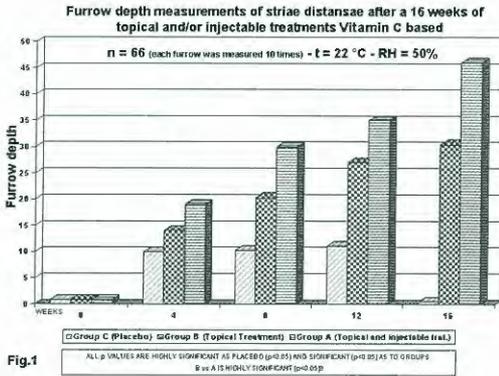


Fig.1

Clinical and Histological Evaluation

Obtained results, performed on the first day (baseline) and at week 4, 8, 12 and 16 (end of treatment) were evaluated with a visual score-method, sequential photographs and biopsies in two patients.

Clinical evaluations included the efficacy for reduction of color and appearance of the STRIAE

DISTENSAE as well as the skin tolerance after the application phase.

0 = normal color and dermatoglyphic pattern;
 0.5 = white/pinkish color and dermatoglyphic pattern less evident

1 = pink color, moderately flat skin

2 = intense pink color, flat skin

3 = violaceous color, flat skin

The obtained clinical results are reported on Figure 2.

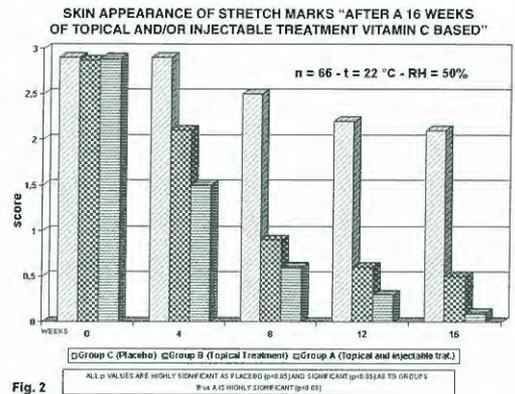


Fig. 2

STATISTICAL ANALYSIS

Mean and standard error of the mean were calculated for all data. The student *t* test was used for comparison between groups with a *p* value less than 0.05 considered significant.

RESULTS AND COMMENTS

As it is seen on Figure 1 and 2 the combined use of injection and topical application (GROUP A), both by the visual score and the profilometry method showed that this treatment protocol improves the striae inducing the neoformation of the dermatoglyphic pattern of a bi-dimensional skin surface topography rich in micro and macrorelieves. Moreover the bioptic result showed also an increased production of elastin and normalization of histologic architecture of the cell component (Fig. 3 and 4).

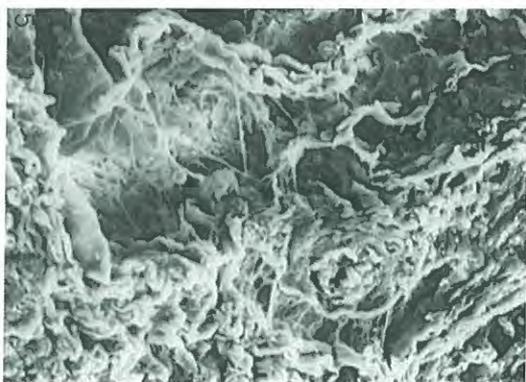


Fig. 3

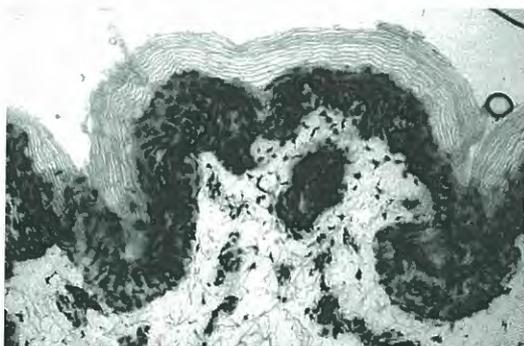


Fig. 4

What is interesting to underline is that the combined use of injection and topical application (GROUP A) provided superior results (+ 57%, $p < 0.05$) compared with the topical treatment only (GROUP B).

On the other side the topical treatment (GROUP B), compared to PLACEBO (GROUP C), showed to perform an interesting activity both on the deratoglyphic pattern and on the collagen bundles organization (+ 32%, $p < 0.05$).

As matter of fact, both the treatments, topical and by injection, showed to ameliorate and to improve the striae that change in color appearing less evident. Moreover the combined solution used containing vitamin C, betaglucan and hyaluronic acid has been shown to normalize collagen bundles, to increase elastin production

and stimulate both fibroblasts and cell proliferation (Fig. 3 and 4).

No side effects were observed during the treatment period, except a light burning at the moment of the injection.

CONCLUSIONS

From the obtained results from this first placebo-controlled study it seems realistic to state that this balanced solution of different active compounds, such as vitamin C, hyaluronic acid and betaglucan able to normalize the histologic architecture of the dermis and epidermis together with the dermatoglyphic skin pattern, may be successfully in the treatment of striae distensae and dermal scars.

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References

1. **Scoggins RB. (1979)** Skin changes in pregnancy. In: *Dermatology in General Medicine*. 2 ed. T.B. Fitzpatrick et al.. New York, Mc Graw-Hill, p. 1363
2. **Lawley tj. (1987)** Skin changes and diseases in pregnancy. In: *Dermatology in General Medicine* 3 ed. T.B. Fitzpatrick et al.. New York, Mc Graw-Hill, p. 2082
3. **Chernosky M, Knox J. (1964)** Atrophic striae after occlusive corticosteroid therapy. *Arch. Dermatol.* **90**: 15-19
4. **Arem AJ, Kischer CW. (1980)** Analysis of striae. *Plast reconstruct Surg.* **65**: 22-29
5. **Shev HM, Yu HS, Change CH. (1991)** Mast cell degranulation and elastolysis in the early stage of striae distensae. *J. Cutan Pathol.* **18**: 410-416
6. **Zheng P, Lavker RM, Kligman AM. (1989)** Anatomy of striae. *Br. J. Dermatol.* **112**: 185-193
7. **Tsuji T, Sawabe M. (1988)** Elastic fibers in striae distensae. *J. Cutan Pathol.* **15**: 215-222
8. **Monteleone F, Biagini G. (2001)** Striae atrofiche: effetti di una biostimolazione intralesionale. In print on *Kosmetica*
9. **Makki S (1987)** Méthodes d'étude quantitative de la microtopographie de la peau humaine: évaluation de l'efficacité des produits dermo-cosmétiques. Thèse: *Sci. Pharm*: Besancon
10. **Makki S, Ettaleb A, Millet J, Humbert P (2000)** Cosmetic efficiency assessment through Confocal Laser Scanning Microscopy. *J Appl. Cosmetol.* **18**: 105-111
11. **Mignot J (1995)** Three-dimensional evaluation of skin surface: micro and macro-relief. In: *Non-invasive Methods and the skin*, Boca Raton, CRC-Press, p.107-119
12. **Rajadhyaksha M, Grossman M, Esterowitz D, Webb RH, Anderson R (1995)**, In vivo Confocal Scanning Laser Microscopy of human skin: Melanin Provides strong contrast, *J. Invest Dermatol.*, **104**: 946-52

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