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Use of a specific anti-stretch mark cream for preventing or reducing the severity of striae gravidarum. Randomized, double-blind, controlled trial

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Synopsis

Few studies have tested the efficacy of commercially available cosmetic products for preventing *striae gravidarum*. Therefore, the objective of this study was to evaluate efficacy on prevention of *striae gravidarum* using a specific anti-stretch mark cream containing hydroxyprolisilane-C, rosehip oil, Centella asiatica triterpenes and vitamin E. A randomized, double-blind, placebo-controlled trial was conducted between November 2009 and April 2011. Pregnant women were included and classified as *treated group* (emollient and moisturizer containing hydroxyprolisilane C, rosehip oil, *Centella asiatica* triterpenes and vitamin E) and *control group* (cream without the active ingredients). Overall incidence of stretch marks during pregnancy was 33.3% for the control group and 37.6% for the treated group (n.s.). Severity of previous stretch marks significantly increased in the control group during the study (17.8%, $P = 0.001$), but not in the treated group (6.3%, ns). In women who developed new stretch marks during the study, there was a significantly greater 'difference in severity' (between baseline and maximum severity) in control group vs. treated group (0.47 [0.57] vs. 0.14 [0.60], $P = 0.031$). In women without previous striae, incidence of these marks was significantly lower for the *treated group* patients compared with *control group* (5.6% vs. 35%, $P = 0.031$, OR: 9.2 [95% CI: 1.0–83.3]). The use of the anti-stretch mark product is proved to be effective in reducing severity of the striae during pregnancy, prevents the appearance of new striae and halts progression of those already present. In women who had no striae at baseline, use of the anti-stretch mark cream was more effective than placebo in preventing new stretch marks.

Résumé

Peu d'études ont testé l'efficacité de produits cosmétiques disponibles sur le marché pour prévenir les *striaegravidarum (*vergetures). Par conséquent, l'objectif de cette étude était d'évaluer l'efficacité de la prévention des *stries gravidarum* en utilisant une crème spécifique anti-vergetures contenant Hydroxyprolisilane-C, l'huile de l'églantier, des triterpènes de*Centella asiatica* et de la vitamine E. Une étude randomisée, en double aveugle, contrôlée par placebo a été menée entre Novembre 2009 et Avril 2011. Les femmes enceintes ont été incluses et classéesdans le groupe traité (émollient et hydratant contenant Hydroxyprolisilane C, l'huile d'églantier, des triterpènes de *Centella asiatica* et de la vitamine E) et le groupe témoin (crème sans les ingrédients actifs). L'incidence globale des vergetures pendant la grossesse était de 33.3% pour le groupe témoin et 37.6% dans le groupe traité (ns). La sévérité des vergetures préexistantes augmentait de façon significative dans le groupe contrôle lors de l'étude (17.8%, $P = 0.001$) mais pas dans le groupe traité (6.3%, ns). Chez les femmes qui ont développé des nouvelles vergetures pendant l'étude, il y avait une différencede sévérité nettement plus grande (entre le début et le degré maximal) dans le groupe contrôle *vs.*le groupe traité (0.47 [0.57] vs. 0.14 [0.60], $P = 0.031$). Chez les femmes sans vergetures préexistantes, l'incidence de ces marques était significativement plus faible chez les patients du groupe traité par rapport au groupe témoin (5.6% vs. 35%, $P = 0.031$, OR: 9.2 [IC à 95%: 1.0 à 83.3]). Le produit anti-vergetures est prouvé être efficace dans la réduction de la gravité des stries pendant la grossesse, et il empêche l'apparition de nouvelles vergetures et la progression s'arrête de celles déjà présentes. Chez les femmes qui n'avaientpas de stries au départ, l'utilisation de la crème anti-vergetures a été plus efficace que le placebo dans la prévention de nouvelles vergetures.

Introduction

Striae gravidarum are linear depressions of the skin caused by fibroblast dysfunction [1]. Stretch marks may be the result of mechanical factors (stretching of the skin owing to the development of subcutaneous structures such as interstitial adipose tissue or muscle development) or biochemical factors (i.e. because of excessive glucocorticoid levels, which inhibit the activity and proliferation of fibroblasts [2]). Stretch marks may appear at any stage of life and can be related in some cases to genetic predisposition [3]. Also, striae frequently occur during adolescence and pregnancy: in approximately 27% of adolescent [2], and between 60% and 90% of women develops them during pregnancy [3], [4] as a result of a combination of mechanical and hormonal factors (increased steroid hormones [2]). For *striae gravidarum*, some authors have suggested that variables such as age, weight gain during pregnancy or family history may also be risk factors for this skin problem [4].

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There is no totally effective treatment to remove striae once they have formed. Skin's elastic capacity has been proposed as an important factor associated to their appearance [4], so preventive treatments are mainly based on maintaining and improving the dermis structure. Fibroblast stimulators and healing agents are used to increase production of collagen and elastin fibres (i.e. extracts of *Centella Asiatica* [5] and rose hip oil [6]) as well as substances that provides a source of amino acids to help regenerate collagen and elastin fibres such as hydroxyprolisilane-C, which supplies hydroxyproline and aspartic acid.

Few studies have tested the efficacy of commercially available cosmetic products for preventing *striae gravidarum* [2]. Here, we describe a randomized, double-blind, controlled trial designed to evaluate the preventive efficacy of a specific anti-stretch mark cream containing hydroxyprolisilane-C, rosehip oil, Centella asiatica triterpenes and vitamin E during pregnancy.

Materials and methods

This randomized, double-blind, placebo-controlled trial was conducted between November 2009 and April 2011 at the Mother-child University Hospital of Canarias. All materials for the study were reviewed and approved by the hospital's Clinical Research Ethics Committee.

Women aged over 18 who were attending the gynaecology clinic at week 12 ± 2 of pregnancy and who agreed to participate were included in the study. Patients with previous skin diseases, other than striae, affecting areas where the cream should be applied (abdomen, thighs, hips, buttocks and breasts) and patients who refused to discontinue other creams or lotions in those areas were excluded. Characteristics and objectives of the study were explained in detail prior to inclusion in the study. All participants provided written informed consent.

The active treatment used was *Velastisa Anti-Stretch Marks* ISDIN, a commercially available emollient and moisturizer containing hydroxyprolisilane C, rosehip oil, *Centella asiatica* triterpenes and vitamin E, registered as a cosmetic product. Placebo was a cream with similar composition to treatment and emollient properties, but without the active ingredients listed above.

Tars with creams were labelled with a code number and also a code number was assigned to every patient. The cream tubes were consecutively assigned to each participant by the researcher. Assignation of product (treatment or placebo) was established by a computer-generated random sequence, which was known only to the CRO and was not revealed until the data analysis stage. Randomization was performed at a ratio of 1:1.

Both groups (treatment or placebo) should use the cream at least twice a day, preferably after bathing and at bedtime on the abdomen, buttocks, hips, thighs and breasts.

Study protocol included six control visits: initial (12 ± 2 weeks of pregnancy), four follow-up visits (24 ± 2, 32 ± 2, 36 ± 2 and 40 ± 1 week of pregnancy) and a final visit (30 days ± 5 days after delivery). On the initial visit, data for anthropometric characteristics, pregnancy history, presence and severity of stretch marks prior to current pregnancy, previous use of anti-stretch mark products and family history of stretch marks were recorded in a Case Report Form (CRF). During the following visits (weeks 24, 32, 36, 40 and final visit), appearance of new stretch marks and their severity were recorded, along with participants' compliance with recommended application regimen, number of applications per day and adverse reactions to the cream. During the last two visits (week 40 and final), subjective evaluation of the cream's effectiveness and tolerability and its cosmetic properties was also obtained.

Severity of previous stretch marks and new stretch marks during the study was assessed using an ordinal scale from 0 to 3 (0 = no marks, 1 = few and thin marks, 2 = many thin marks or few thick marks and 3 = many thick marks) [2].

Presence and severity of stretch marks at initial visit was taken from pre-pregnancy assessment visit. To determinate '*difference in severity*', a comparison was made between '*maximum severity*' recorded during the follow-up visits and *baseline severity*. These results were used to compare changes in the severity of the striae between the two study groups.

Participants' subjective overall ratings of effectiveness, tolerability and cosmetic properties were scored on a scale of 0 to 3 (0 = poor, 1 = medium, 2 = good, 3 = excellent) for each of the parameters.

Compliance was determined using the total number of applications and the percentage of days using the cream. This way, we can classified as 'Compliant' those who performed two applications or more per day or applied the cream on at least 85% of the days, and as 'non-compliant' those who did not meet any of these conditions.

Statistical analysis

Statistical analyses were performed using the statistical software SPSS 13.0 for Windows.

Continuous variables were summarized by the number of valid cases (n), means and standard deviation (SD), extreme values (minimum and maximum) 25th and 50th percentiles (median) and 75th percentile. Categorical variables were summarized by the number of valid cases and percentage of each class.

With regard to the objectives of the study, categorical variables were studied using Chi-square tests for independent samples or the McNemar test for related samples. Numerical or ordinal variables were analysed using the Mann-Whitney *U*-test for independent samples and the Wilcoxon signed ranks test or the sign test for related samples.

Results

A total of 198 women in their 12th week of pregnancy were included (97 in the control group and 101 in the treated group), with a mean age (SD) of 30.12 (5.07) and 30.35 (5.5) years respectively (ns). Of these, one hundred and eighty-three performed at least one follow-up visit (90 and 93 respectively). Obesity (BMI ≥ 30) (n. s) was reported in 16.3% of control women and in 11.2% of treated women prior to pregnancy; 43.3% of control women and 45.5% of treated women were primiparous (ns). (Table I)

Prevalence of pre-pregnancy stretch marks was a 77.3% for the control group and a 79.2% for the treated group (ns). Main related causes were weight increase (42.5% vs. 36.3%, ns), puberty (32.9% vs. 33.8%, ns) and previous pregnancies (32.9% vs. 35%, ns). Severity of previous marks was 1.35 (control group) and 1.38 (treated group) (ns). Striae was evaluated as 'few and think marks' by 68.9% of control women and 65% of treated women, 'many thin marks or few thick marks' by 27% of control women and 35% of treated women (ns), and as 'many thick marks' by 4.1% of control women and 2.5% of treated women (ns). (Table I)

Table I Characteristics of the sample

	Control* Mean (SD)	Treated*
Mean (SD)		
Age	30.12 (5.07)	30.35 (5.50)
Menarche (years)	11.99 (1.39)	12.45 (1.99)
Height (cm)	162.63 (6.10)	163.78 (6.54)
Weight (kg) prior to pregnancy	66.58 (14.73)	64.66 (12.43)
Weight (kg) at initial visit	68.57 (13.79)	67.49 (12.09)
Body mass index (BMI) prior to pregnancy	25.11 (5.29)	24.22 (4.83)
	n (%)	
Obesity (BMI $\geq$ 30)	15 (16.3%)	10 (11.2%)
First pregnancy	42 (43.3%)	46 (45.5%)
Prevalence of striae	75 (77.3%)	80 (79.2%)
Severity of previous striae		
1 – Few and thin marks	51 (68.9%)	52 (65.0%)
2 – Many thin marks or few thick marks	20 (27.0%)	26 (32.5%)
3 – Many thick marks	3 (4.1%)	2 (2.5%)
Cause of striae		
Weight gain	31 (42.5%)	29 (36.3%)
Puberty	24 (32.9%)	27 (33.8%)
Previous pregnancies	24 (32.9%)	28 (35.0%)
Current pregnancy	1 (1.4%)	–
Other causes	–	1 (1.3%)
Use of body creams or lotions	61 (65.6%)	69 (71.1%)

n = 198
*No significant differences were found between the two samples

Of the 183 women with at least one follow-up visit, 174 of them (86 vs. 88) attended to the 24 weeks of pregnancy visit, 162 (79 vs. 83) attended to the 32-week visit, 133 (65 vs. 68) to the 36-week visit, 45 (24 vs. 21) to the 40-week visit and 46 (27 vs. 19) to the final 30 days postpartum visit.

At the 24-week visit, 23.2% (control) and 20.7% (treated) of women presented new stretch marks. These findings were also reported for both groups at the 32-week visit (15.6% and 22.8% respectively) (ns), 20.3% and 13.6% (ns) at the 36-week visit, 13.6% and 14.3% (ns) at the 40-week visit and 11.1% and 11.8% (ns) at the final visit. Overall incidence of stretch marks during pregnancy was 33.3% for the control group and 37.6% for the treated group (n.s.). (Table II)

In the control group, initial severity of stretch marks was 1.07 (0.73) and maximum severity was 1.26 (0.75) ($P = 0.001$, 95% CI: 8.3–28.3%). In the treated group, initial severity was 1.11 (0.73) and maximum severity corresponded to 1.18 (0.79) (P = ns, 95% CI: −1.5–15.1%). Therefore, the severity of striae increased significantly during the study in the control group (17.8%, $P = 0.001$), but not in the treated group (6.3%, ns). (Table II)

In women who developed new stretch marks during the follow-up, 'difference in severity' was significantly higher in control group than in treated group (0.47 [0.57] vs. 0.14 [0.60], $P = 0.031$) (Table II) (Fig. 1). Fifty per cent of control presented increased severity of stretch marks compared with 25.7% of treated women ($P = 0.043$, OR: 2.89 [95% CI: 1.02–8.19]).

For women who had no previous striae ($n = 38$), overall incidence of stretch marks during pregnancy was significantly lower for the treated group (5.6% vs. 35%, $P = 0.031$, OR: 9.2 [95% CI: 1.0–83.3]). (Table II)(Fig. 2)

Table II Incidence and severity of striae gravidarum

Characteristics		No new striae	New Striae	*P*
History				
Previous Striae	Control	60 (66.7%)	30 (33.3%)	0.325
	Treated	58 (62.4%)	35 (37.6%)	
No previous striae	Control	13 (65%)	7 (35%)	0.045
	Treated	17 (94.4%)	1 (5.6%)	
Severity				
Maximum vs. Previous		Mean (SD)	% Change (95%CI)	
	Control (N = 87)			0.001
	Previous striae	1.07 (0.73)	17.8 (8.3 to 28.3)	
	Striae during study	1.26 (0.75)		
	Treated (N = 93)			0.106
	Previous striae	1.11 (0.73)	6.3 (−1.5 to 15.1)	
	Striae during study	1.18 (0.79)		
Difference in severity				
Compliant women	Control (*n* = 73)	0.21 (0.41)	(0.11 to 0.3)	0.029
	Treated (*n* = 83)	0.06 (0.39)	(−0.03 to 0.15)	
New striae	Control (*n* = 30)	0.47 (0.57)	(0.25 to 0.68)	0.031
	Treated (*n* = 35)	0.14 (0.6)	(−0.06 to 0.35)	
Primiparous women	Control (*n* = 14)	0.57 (0.65)	(0.2 to 0.94)	0.047
	Treated (*n* = 17)	0.18 (0.53)	(0.1 to 0.45)	
Users of body lotions	Control (*n* = 55)	0.22 (0.42)	(0.11 to 0.33)	0.014
	Treated (*n* = 65)	0.05 (0.33)	(−0.03 to 0.13)	

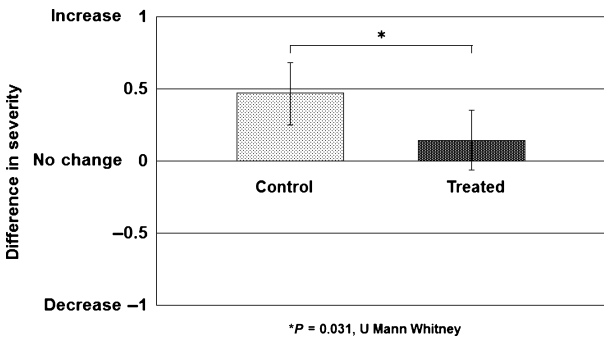

Figure 1 Difference in severity in women with striae.

In primiparous who developed new stretch marks, the 'difference in severity' was significantly higher in control group than in the treated group (0.57 [0.65] vs. 0.18 [0.53], $P = 0.047$). (Table II)

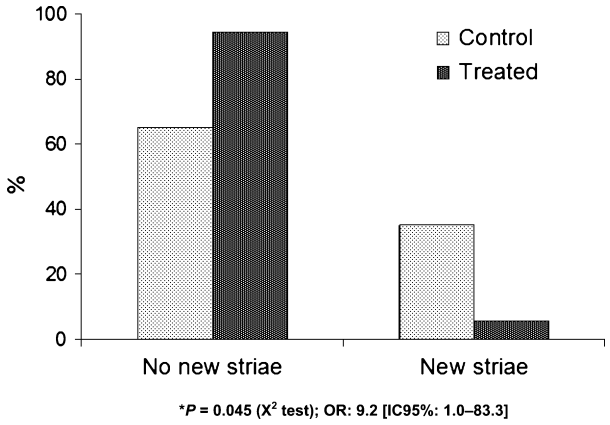

Figure 2 Incidence in women without previous striae.

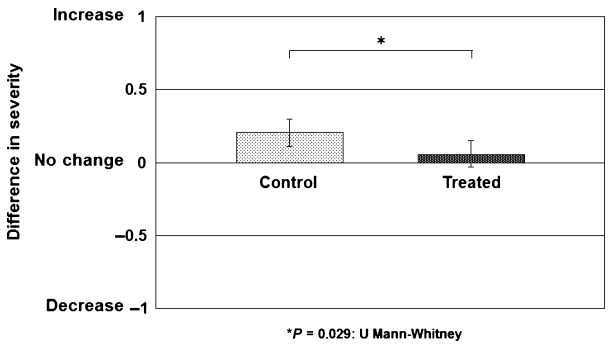

Figure 3 Difference in severity in compliant patients.

According to compliant women subgroup (n = 156), differences in severity were significantly higher in control group than in treated group (0.21 [0.41] vs. 0.06 [0.39], P = 0.029). (Table II) (Fig. 3)

Finally, in women who regularly use creams or lotions, 'difference in severity' was significantly lower in the treated group than in control group (0.22 [0.42] vs. 0.05 [0.33], P = 0.014). (Table II)

No significant differences were found between the control and treated group regarding their subjective assessments of the cream's effectiveness and tolerability or its cosmetic properties.

Adverse reactions were reported for both groups: 5 of 90 from the control group had adverse reactions to the cream (redness and pruritus, 'red abdomen', dry skin, itching and one unspecified adverse reaction), and 3 of 93 from the treated group presented adverse reactions (one with chest rash and two with unspecified reactions).

Discussion

The study has shown a positive effect of the anti-stretch mark cream in the reduction of *striae gravidarum* severity and a significantly change in their overall incidence in those women without previous history of striae.

Overall incidence of stretch marks during pregnancy for this study was lower than previously reported in the literature [4]. Also, the use of anti-stretch mark cream may have a protective effect against appearance of striae in women with no previous history of them. These protective effects findings are higher than other studies [2]. In addition, our findings differ with the protective effect against the appearance of striae in women with history of striae during puberty reported by Mallol *et al.* [2], although the small size of the two samples may have influenced the results.

The main limitation of this study was the type of placebo (vehicle) used that, according to dermatology studies, has itself an important effect. The cream used for the control group has emollient and moisturizing properties and presents similar tolerability and cosmetic profiles as the anti-stretch cream as a real-life comparator. This kind of product also has been proposed as an option to prevent the appearance of *striae gravidarum*.

Conclusions

Overall incidence of stretch marks in women without previous history of striae was lower in the group in which the anti-stretch mark cream was administered. In fact, use of anti-stretch mark cream may reduce the likelihood of developing stretch marks by up to nine times in women without previous history of stretch marks.

Severity of stretch marks appearing during pregnancy with the use of the anti-stretch mark cream was lower; also, there was a lower increase in comparison with placebo group.

In women who developed new striae, difference in severity vs. baseline severity was also lower in the treated group. With the use of anti-stretch mark cream, severity of the new striae was three times more likely to remain unchanged or to decrease with respect to the baseline situation.

The use of the anti-stretch mark cream more than twice a day or on at least 85% of the days was associated with a greater reduction in the severity of the striae than with the use of placebo. Furthermore, in women who regularly use creams or lotions, the anti-stretch mark cream achieved a greater reduction in striae than placebo, suggesting that the sustained use of this cream is more efficient in reducing striae.

The use of the anti-stretch mark product proved to be effective in reducing the severity of the striae during pregnancy, preventing the appearance of new striae and halting the progression of those already present. In women who had no striae at baseline, the use of the anti-stretch mark cream was more effective than placebo in preventing the occurrence of new stretch marks.

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