REVIEW

Evaluation of a new topical cream to psoriasis treatment: randomized clinical trial

Elizabeth Benites[1,2] · Esmeralda Carrillo[3,4,5] · Martha Heras[2,6] · Doménica Bourne[7]

Abstract

The aim of this study is to develop a new topical cream for psoriasis and to test its results. Experimental clinical trial. Phase I: hypersensitivity test in 100 healthy volunteers. Phase II: 120 patients, prospective, analytical differential study in hospital. In phase I, 99% health persons did not show any reaction. In phase II, the 120 patients selected in two groups, group A-new cream and group B-corticosteroid, the paired samples calculated T-value in group A was: 19.144 for erythema, 6.725 in infiltrate, 12.475 in desquamation and in pruritus 10.863, PASI 14.662 and BSA 19.083 which are higher than 1.96 the result was 0.000 less than P 0.05 highly significant after treatment group B control group, showed the T values, erythema 7.590, infiltrate 10.573, desquamation 7.311, pruritus 3.615, PASI 2.631, BSA 4.411. The T-values which are higher than 1.96 were 0.000 less than P 0.05 highly significant after treatment. In the Pearson correlation for cases and controls, association values were observed for SBA 0.042 before treatment and 0.008, after treatment, in PASI 0.021, before treatment and 0.008 after treatment. The results examined by hypotheses and cross-tabulations are highly significant in groups A and B separately, and when group A is tested against group B by means of cross-tabulations, they show differences after treatment. In the logarithmic regression for the associated risk factors, the odds ratio values of BMI 1.113>OR 1 and urea 1.439>OR 1. The elevation of these two parameters may affect the exposed group. When comparing the group, A and group B, the symptoms of erythema, infiltrate, desquamation, pruritus, PASI index and SBA were found to decrease with the group A/new cream after treatment. Further studies in larger populations are suggested, the new cream has been shown to reduce the clinical symptoms of psoriasis.

Keywords Erythema · Infiltration · Desquamation · Index of severity of the injuries [PASI] · Area of affected surface [SBA]

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Abbreviations

HTMC	Hospital "Teodoro Maldonado Carbo"
Cream A	New topical cream
Cream B	Corticosteroid cream (Betamethasone)
CEISH	Committee on ethics in human beings
PASI	Index of evaluation of the degree of severity of the injuries.
BSA	Area of affected surface
T test	T student to hypothesis
Cw6, B13, B17	Human leukocyte antigens
WHO	World health organization
ICD-10 L40	The international classification of psoriasis
Soralex	(Exfoliating cream) Sanitary registration number: 129-CO-001-REQ-02-2023-01078 ARCSA, Ecuador

Introduction

Psoriasis is an autoimmune inflammatory disease that causes the cells of the last layer of the skin, keratinocytes, to grow much faster than normal, every three or four days instead of 28 days, as happens with the cells of a healthy person, leading to psoriatic. This disease affects almost 138 million people worldwide, the prevalence of this type of disease worldwide is around 2–3%, causes itching or painful patches of thickened skin, reddened with silvery scales that appear on different parts of the body (Parisi 2013). This disease does not respect factors of age, sex, origin, socioeconomic or cultural, its maximum incidence is between 20 and 50 years (Gibbs 1996). The cause of psoriasis is unclear, but it is known to involve immune stimulation of epidermal keratinocytes; T cells appear to play a central role. Family history is common, and some human leukocyte genes and antigens (Cw6, B13, B17) have been associated with psoriasis (Reich 2012). There are different types of psoriasis: Erythroderma with the redness of the skin is very intense and covers a large area. Guttate (guttate): small red to pink spots appear on the skin. Inverse: skin redness and irritation occur in the armpits, groin and between the overlapping skin. Plaque: Thick, red patches of skin covered by silver to white scales. This is the most common type of psoriasis and affects around 80% of psoriasis sufferers. Pustular: white blisters surrounded by red, irritated skin (Martin et al. 2012).

Treatment depends on the type of lesion and its complications; retinol, corticosteroids, vitamins and salicylates, phototherapy, cyclosporine, immunosuppressants, cytokines, monoclonal antibodies and others are used. Hygienic, dietary and sanitary preventive measures are recommended (Hani 2010). Psoriasis presents many complications that affect patients' quality of life with genetic, environmental, and lifestyle predispositions. The lack of response to treatments causes patients to visit several specialists due to their physical discomfort, psychological suffering that sometimes leads them to attempt suicide, since their physical appearance generates rejection in society, affecting their family, work, and economic life (Rendon and Schakel 2019). There are several alternative treatments that claim to relieve symptoms for psoriasis, such as special diets, creams, dietary supplements, and herbs. The effectiveness of any of these treatments is not proven. But some alternative treatments are generally considered safe and may be helpful for some people by reducing signs and symptoms, such as itching and peeling. These treatments would be best suited for people with milder, plaque disease, but not for those with pustules, erythroderma, or arthritis (Krueger et al. 2001).

Different single or combined treatments are approved by regulatory agencies such as the FDA and the EMEA. Still, at the same time, they are harmful in the medium and long term, presenting resistance and abandonment of conventional treatments and their high economic cost, especially in the moderate and severe forms (Armstrong and Pathophysiology 2020). This disease is characterized by relapses and remissions that affect the quality of personal, family, work and social life, including severe depressive disorders (Armstrong et al. 2012). There are also natural treatments, alone or in combination, already marketed, that are offered as "alternative medicine" (Şenel 2022). For this reason, we set out to develop a new topical cream with the following natural ingredients: salicylic acid, animal lard, sublimated sulfur, triple aluminum sulfate, petroleum jelly and bay essential oil

A. *Pork fat* - Whose components are oleic acid, stearic acid, palmitic acid, as it is a lipid of animal origin it has a considerable amount of saturated fatty acids and cholesterol, it has moisturizing and repairing properties, and therefore contributes to the development and hormonal functioning of humans and animals. Cholesterol is a biochemical precursor of hormones such as DHEA, testosterone, progesterone, estrogen, prolactin, cortisol, cholecalciferol (vitamin D3) (Feingold 2009).

B. *Salicylic acid* - Industrially obtained from carbon dioxide and sodium phenoxide by electrophilic substitution and subsequent liberation of the acid from its salt by addition of a strong acid. This is the well-known Kolbe-Schmitt synthesis. It is used to treat skin diseases characterized by desquamation or overgrowth of skin cells, such as psoriasis (a skin disease in which red, scaly patches form on certain areas of the body). By softening and loosening dry, scaly or thickened skin to facilitate its shedding or removal (Cuellar et al. 2018).

C. *Flower washed sulphur* - Obtained from sublimed Sulphur by treatment with ammoniated water to eliminate

the remains of acidity and impurities and subsequent washing with boiling distilled water. It is a fine, dry, lemon-yellow, odorless, tasteless powder. Practically insoluble in water. Sparingly soluble in alcohol, ether and glycerin; somewhat more soluble in turpentine and other volatile oils. Almost totally insoluble in carbon sulphide. Disinfectant and antimicrobial properties due to its active principles, used in smaller doses on the skin (Gupta and Nicol 2004).

D. *potassium aluminum sulfate* - A type of triple sulphate Al2(SO4), composed of the sulphate of a trivalent metal, such as aluminum, and another of a monovalent metal. It is a stone of volcanic origin extracted from quarries, composed of aluminum sulphate and potassium sulphate (the most frequent), components that give it astringent, antibacterial and healing properties (Hyung-Sik Seo 2012).

E. *Vaseline* - Also known as petroleum jelly, a homogeneous mixture of long-chain saturated hydrocarbons, usually chains of more than 25 carbon atoms, obtained from the refining of a heavy fraction of petroleum, has softening, moisturizing and moisturizing properties (Penven et al. 2005).

F. *Laurel essential oil* - Owes its analgesic properties to three chemical components: eugenol, chavicol and myrcene, it is used as a skin tonic, relieves muscle or joint pain and neuralgia, reduces stress and anxiety (Viciolle and Castilho 2012).

In this study our objective is: Check the hypersensitivity to its components, the effectiveness of the new product made with the six elements, evaluate its effectiveness compared to a commercial topical cream. Hypothesis. Will the new formula made with natural products be able to reduce the characteristic clinical signs of Psoriasis?

Methodology

Place of preparation

Laboratory José F. Quiróz Pérez CIA.LTDA. "La Salud" Pharmacy (FLS), Guayaquil. Address: Mapasingue oeste Mz 48 Avenida 3era, entre la calle 2da y 3era, Guayaquil, Ecuador.

Laboratory materials

Morter. Beaker of 1000 ml. Beaker of 250 ml. and Computer and printer. All ingredients are purchased from the chemical market.

Preparation of the complete formula

Pulverize the alum in a mortar, crush the Sulphur and salicylic acid and mix all the powders in a 1000 ml beaker. In a 250 ml add petroleum jelly, bay leaf oil and add to the 100 ml beaker. Finally add the lard and mix until a homogeneous miss is obtained.

Quality control

Analysis of organoleptic properties (color, odor, appearance, and consistency), physical properties (determination of consistency), physical properties (determination of extensibility) of the final products.

Inclusion criteria

Patients receiving medical attention in Dermatology at the Teodoro Maldonado Carbo Hospital of the IESS Patients diagnosed with mild and moderate psoriasis in any of its locations with or without treatment. Over 12 years old. Patients who do not have malignant tumor pathology in the skin, autoimmune or other disabling pathologies.

Exclusion criteria

Patients who do not receive care in the Dermatology of the Teodoro Maldonado Carbo Hospital of the IESS. Patients corresponding to other skin pathologies. Patients under 12 years of age. Patients suffering from psychiatric disorders due to other pathologies that could interfere with the database and evaluation of quality of life. Patients with malignant tumor pathology in the skin, autoimmune or other disabling pathologies.

Approval of CIESH and TMC hospital

The research protocol was approved before the start of this work by the Institute of Research and Innovation of Integral Health of the Catholic University of Guayaquil, Ecuador. The informed consent was approved in the document Number HLV.DOF-CEISH-004 in January 31 of 2020, by the Research Ethics Committee of the Luis Vernaza Hospital in Guayaquil, Ecuador. The sampling of patients with psoriasis was approved by the management of the Luis Vernaza Hospital in Guayaquil in October 1 of 2021.

Selection of the sample

Our study population consisted of 173 patients from the Teodoro Maldonado Carbo Hospital with a diagnosis of psoriasis, 120 patients with mild and moderate psoriasis were selected by statistical calculation of population

Table 1 Hypersensitivity test in 100 healthy subjects with the 5 formulations and complete formula to psoriasis disease

Elaborate Formula By Elizabeth Benites

Fase I Fórmula # 1		Fase I Fórmula # 2		Fase I Fórmula # 3		Fase I Fórmula # 4		Fase I Fórmula # 5		Fase II Fórmula total	
20 healthy subjects		20 healthy subjects		20 healthy subjects		20 healthy subjects		20 healthy subjects		60 healthy subjects	
Promoter code: ICD10.L40.0-001		Promoter code: ICD10.L40.0-002		Promoter code: ICD10.L40.0-003		Promoter code: ICD10.L40.0-005		Promoter code: ICD10.L40.0-004		Promoter code: ICD10.L40.0-006	
Ingredients	gr.	Ingredients	gr.	Ingredients	gr.	Ingredients	gr.	Ingredients	gr.	Ingredients	gr.
Salicylic acid	0.89	Salicylic acid	0.89	Sulphur	5.10	Sulphur	5.10	Salicylic acid	0.89	Salicylic acid	0.89
Sublimed alum	0.77	Sulphur	5.10	Sublimed alum	0.77	Salicylic acid	0.89	Sblimed alum	0.77	Sublimed alum	0.77
Solid vaseline	45.00	Solid vaseline	45.00	Solid vaseline	45.00	Pork fat c sp	45.00	Pork fat c sp	45.00	Pork fat c sp	45.00
Bay laurel oil	0.75ml					Bay laurel oil	0.75ml			Solid vaseline	45.00
										Sulphur	5.10
										Baylaurel oil	0.75ml

proportions with a margin of error of 5% and a confidence level of 95%. Of which 60 patients were randomly applied the new formula and 60 patients with corticosteroid as a control group.

Study design

This study was experimental clinical tries, randomized, double-blind controlled. Patients were asked to report any adverse event and concomitant medications since their previous visit. Additional safety assessments included PASI improvement response at 10 days after application.

Methodology clinical tries

The methodology used was a randomized, prospective, observational, descriptive, differential analytical clinical trial. For the interpretation of the results, descriptive and undifferentiated statistical tests were performed. Data visualization methods using histograms, normality curves and Q–Q plots and the Shapiro–Wilk normality test were used to assess the distribution of continuous variables with mean and standard deviation as measures of central tendency and dispersion for normally distributed variables, while the median and range were interquartile. Finally, to evaluate the differences between the means of the continuous variables, for those with normal distribution, the student's t test was used, while the nonparametric Mann-Whitney U tests were used to show the differences between the medians of the abnormally distributed continuous variables. For categorical variables, Pearson's chi-square test was used to assess the differences between them. All statistical and graphical analyses were performed using IBM SPSS Statistics for Windows, version 24 (IBM Corp., Armonk, N.Y., USA) and GraphPad Prism 8 version 8 (La Jolla, California, USA).

Phase I study: evaluation of hypersensitivity

It was carried out in 2019 at the intradomicile level in 100 healthy subjects, 5 formulas were elaborated with different components (Table 1), 20 subjects were randomly selected for each formulation, the application of the cream was on the back of the forearm, the control was carried out 24 h after its application. It was found that they did not present secondary reaction or hypersensitivity to any of the components of each formulation (Fig. 1).

Phase II study: randomized clinical trial with the complete formula (Fig. 2)

Place and date of the clinical trial in patients with psoriasis The selection of outpatients and their application was carried out in February to December 2022 from the Dermatology Service of the "Teodoro Maldonado Carbo" Hospital in the city of Guayaquil.

Clinical treatment

100% of patients live in a humid tropical climate with a temperature of 32 ℃+/−5, are affiliated to social security, in this study no systemic or biological treatments were administered to randomly selected patients.

Her oral treatment consisted of administering Vit D1 tablet daily, antihistamine, 1 tablet at night for pruritus. The cream with the complete formula was applied to group A,

Fig. 1 Patient with psoriasis evaluated before and after the application of the topical cream to psoriasis disease

Fig. 2 The protocol study: evaluation of a new topical cream in psoriasis: a randomized clinicla trial
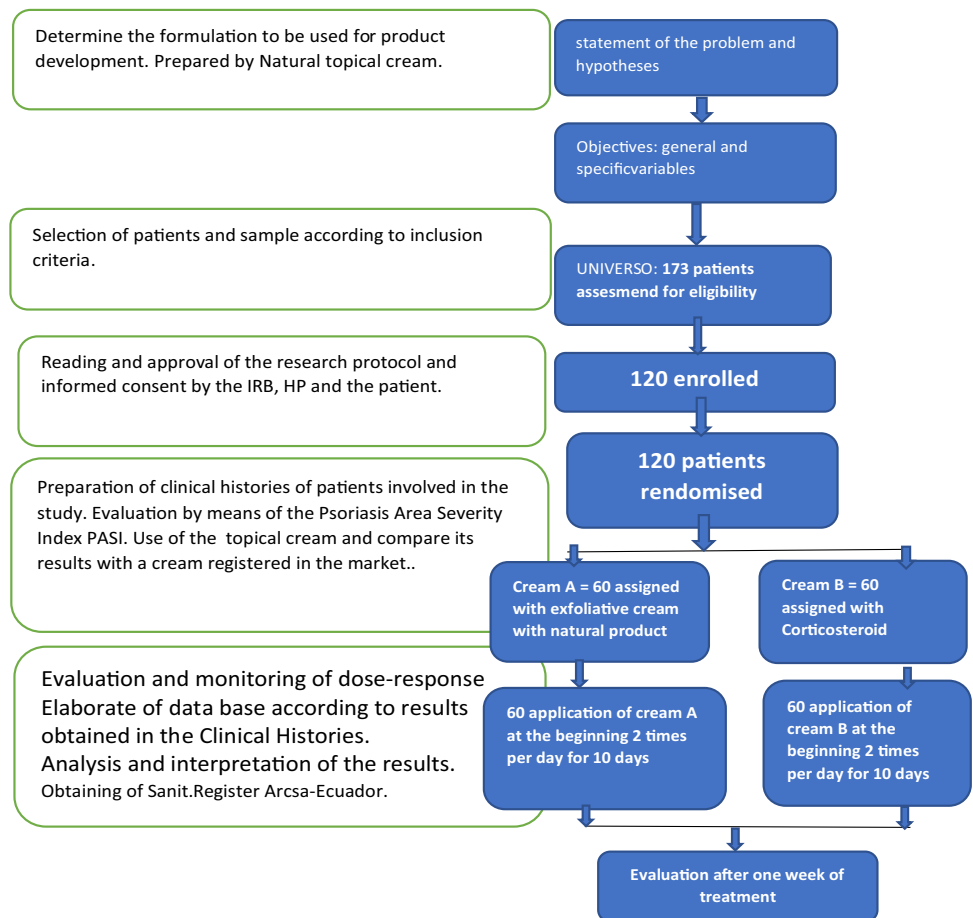
Table 2 Patient demographics and clinic characteristics at baseline. *Source* Teodoro Maldonado Carbo Hospital

	Cream A (N=60)	Cream B (N=60)
Males	40 (66.7%)	27 (45%)
Females	20 (33%)	33 (55%)
age (year)	48.78 (12–84)	56.90 (22–80)
BMI	24.5	30-Apr
Glucose	86	102.5
Urea	24.8	27
weight	69Kg	76.5 Kg
size	1.6 cm	1.6 cm
Systolic BP	120 mm Hg	129 mm Hg
Diastolic BP	70 mm Hg	80 mm Hg
Leukocites	6.58	7.2

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and the corticosteroid to group B, twice a day in the affected areas, the control was performed at 10 days after treatment.

Results

In the descriptive observational study

Group A 66% are male and 44% female, their mean age is 48.78 years (12–84), weight 69 kg and height 1 mt 60 cm, BMI 24.5. The mean laboratory parameters were glucose 86, urea 24.8, BP 120/70 and leukocytes 6.58. Group B 45% are male and 55% female, mean age was 56.90 years (22–80), weight 76.5 kg and height 1 mt 60 cm. The mean in laboratory parameters BMI 30.4, glucose 102.5, urea 27, BP 129/80 and leukocytes 7.2 (Table 2).

In terms of occupation, group A, 71% are employees and 10% pensioners, 6.7% professionals, 5% operators, 3.3% teachers and 3.3% housewives, and group B 14.8% administrative and 10% pensioners36.1%, professionals 6.6%, operators 26.2%, teacher 3.3% and housewives 11.5%. The ethnic factor group A 50% are mestizo, 20–25% indigenous, 10–12% black and 3–5% white and group B 48–55% are

Table 3 The ethnic factor. *Source* Teodoro Maldonado Carbo Hospital

	Group A (%)	Group B (%)
Mixed race	50	48–55
Indigenous	20–25	21–25
Black	10–12	7–9
White	3–5	2–12

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mestizo, 21–25% indigenous, 7–9% black and white 2–12% (Table 3).

Analytical study

Applying Student's T. in the symptoms before and after treatment to group A with the new formula, the calculated value of T of paired samples is 19.144 for erythema, 6.725 in infiltrate, 12.475 in desquamation and in itching 10.863, also in PASI 14.662 and BSA in 19.083 that are higher than 1.96 accepting the alternative hypothesis whose Probability result was $0.000 < P\ 0.05$. Being statistically significant after treatment versus group B corticosteroid as control group, showed the following behavior in the T values, erythema 7.590, infiltrate 10.573, desquamation 7.311, itching 3.615, PASI 2.631, BSA 4.411. Accepting the alternative hypothesis whose Probability result was $0.000 < P\ 0.05$ in significant value after treatment (Table 4).

In the box plot, it is observed that group A presented a much lower BSA severity scale in relation to group B (Fig. 3). As in the box diagram, group A presented a decrease in clinical symptoms in relation to group B control (Fig. 4).

In Pearson's correlation for cases and control versus BSA, a significant level of $0.042 < P\ 0.05$ was observed (Table 5) and after treatment the probability is less than $0.008 < P\ 0.05$ (Table 6), finding a great difference with the standard treatment.

In the Pearson correlation for cases and control vs PASI (Table 7) a significant level $0.021 < P\ 0.05$ is demonstrated, and in the Ch2 test in cases and control VS PASI after

Table 4 Demographic table, use of statistical mean in natural topical cream *Source* Teodoro Maldonado Carbo Hospital

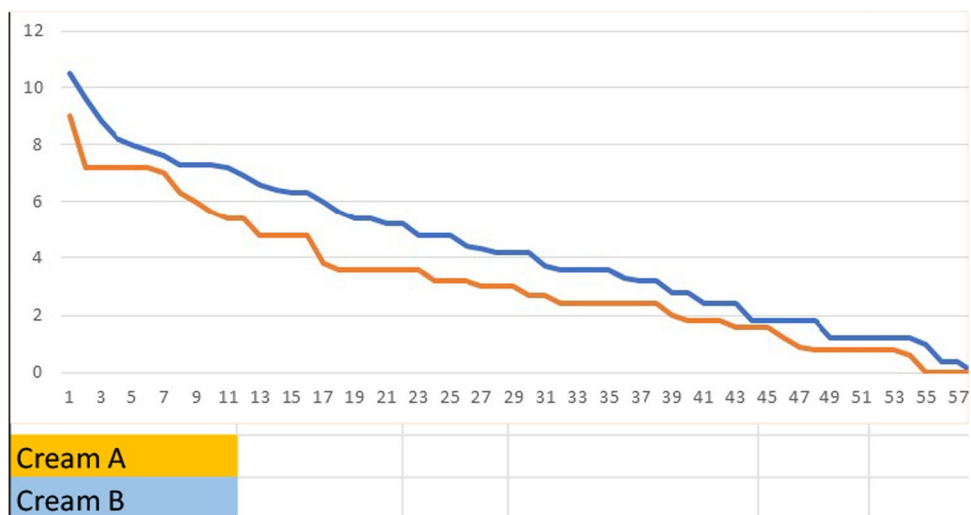|	Before treatment		After Treatment		Value P= 0.05
	Women 20	Men 40	Women 33	Men 27	
Sex	Half	Half	Half	Half	
Erythema	2.60	2.65	2.36	2.26	0.000
Infiltrate	2.35	2.53	2.27	1.22	0.000
Desquamation	2.40	2.63	2.82	2.63	0.000
Itching	2.65	2.18	2.73	2.56	0.000
PASI	10.87	11.05	10.14	9.39	0.000
BSA	19.55	19.13	20.24	19.85	0.000

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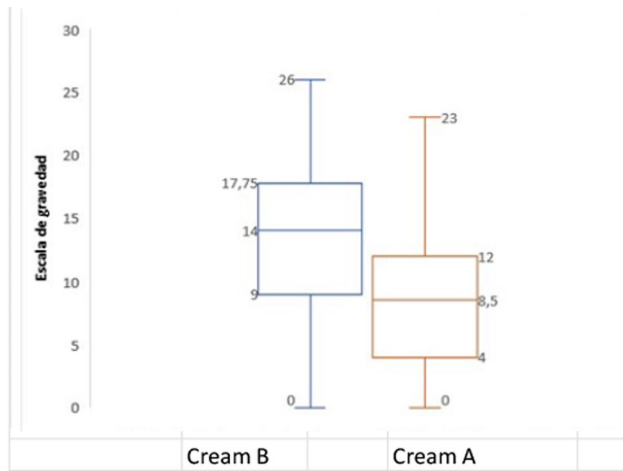
Fig. 3 Decrease in psoriasis servity by applying the natural topical cream (cream A) versus corticosteroid treatment (cream B). In the box plot showed that patient with the natural topical cream have a much lower BSA severity scale than patients who used corticosteroid

treatment the difference is less than $0.008 < P\ 0.05$, the dose-response association is lower with the new formula (Fig. 4). In the logarithmic regression for associated risk factors, the Odds ratio values determine the association with the risk or protection of the studied variables of BMI $1.113 > OR\ 1$ where it is evident that there is a risk of complications due to overweight 1.11 times higher than those who are not exposed. (Table 8) the same can be said with urea values $1.439 > OR\ 1$ considering a risk factor for comorbidities in patients with psoriasis than those who are not exposed (Fig. 5).

Table 5 Correlation between cases and controls versus BSA. *Source* Teodoro Maldonado Carbo Hospital

	Value	Df	Meaning asyntolic (two-wayl)
Pearson's Chi-square	37.229[a]	24	0.042
Likelihood ratio	46.832	24	0.004
Linear by linear association	7.000	1	0.008
N of valid cases	120		

[a]42 boxes (84.0%) have expected a count less than 5. The mínimum expected count is 0.50

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Table 6 Association between case control versus TBSA. *Source* Teodoro Maldonado Carbo Hospital

	Value	df	Meaning asyntolic (two-wayl)
Pearson's Chi-square	41.140[a]	22	0.008
Likelihood ratio	51.771	22	0.000
Linear by linear association	3.360	1	0.067
N of valid cases	120		

[a]40 boxes (87.0%) have expected a count of less than 5. The minimum expected count is 0.50

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Discussion

Discussion and conclusion

This study confirmed our hypothesis with the new topical cream did reduce the characteristic clinical signs of psoriasis after treatment.

In the categorical variables with the new products, its effectiveness was verified at 10 days of treatment (Fig. 5). When comparing the new cream vs the corticosteroid cream,

Fig. 4 PASI behavior with treatment with the natural topical cream (cream A) versus treatment with corticosteroid cream (cream B)

Table 7 Case and control versus PASI after treatment. *Source* Teodoro Maldonado Carbo Hospital

	Value	Df	Meaning asyntolic (two-wayl)
Pearson's Chi-square	68.781[a]	47	0.021
Likelihood ratio	93.428	47	0.000
Linear by linear association	6.352	1	0.012
N of valid cases	120		

[a]92 boxes (95.8%) have expected a count less than 5. The minimum expected count is 0.50

Developed: Benites E, Bourne D

it was shown that its application decreases the clinical symptoms of psoriasis in the skin, the alternative hypothesis is accepted being the results of erythema, infiltrate, desquamation, itching, the PASI index and the SBA their values were very significant after treatment. Conclusion. New studies are recommended in other types of diseases of desquamative origin to evaluate the effectiveness in relation to the time-response to treatment with this new topic cream (Fig. 1).

Limitation

The Teodoro Maldonado Carbó Hospital in Guayaquil belongs to the Social Security Institute (IESS), affiliates must request medical attention through a call center. The

Table 8 Logarithmic regression for associated risk factors. *Source* Teodoro Maldonado Carbo Hospital

	VARI-ABLES	Groups A & B	Error estándar	Wald	gl	Sig.	Exp(B)	95% C.I. para EXP(B) Inferior	Superior
Step 1	Sex	−.793	.457	3.006	1	.083	.453	.185	1.109
	Age	−.025	.016	2.370	1	.124	.975	.945	1.007
	Weight	−.068	.038	3.187	1	.074	.934	.867	1.007
	BMI	3.841	3.049	1.586	1	.208	46.552	.118	183
	Glucose	.107	.057	3.465	1	.063	1.113	.994	1.245
	Creatinine	−.008	.005	1.970	1	.160	.992	.982	1.003
	Urea	.281	.336	.699	1	.403	1.324	.685	2.559
	Constant	.364	.174	4.388	1	.036	1.439	1.024	2.022
	Sex	−4.505	4.911	.842	1	.359	.011		

Variables specified in step 1: SEX, AGE, WEIGHT, HEIGHT, BMI, GLUCOSE, CREATININE, UREA.

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Fig. 5 Factor de Risk in two group A and B
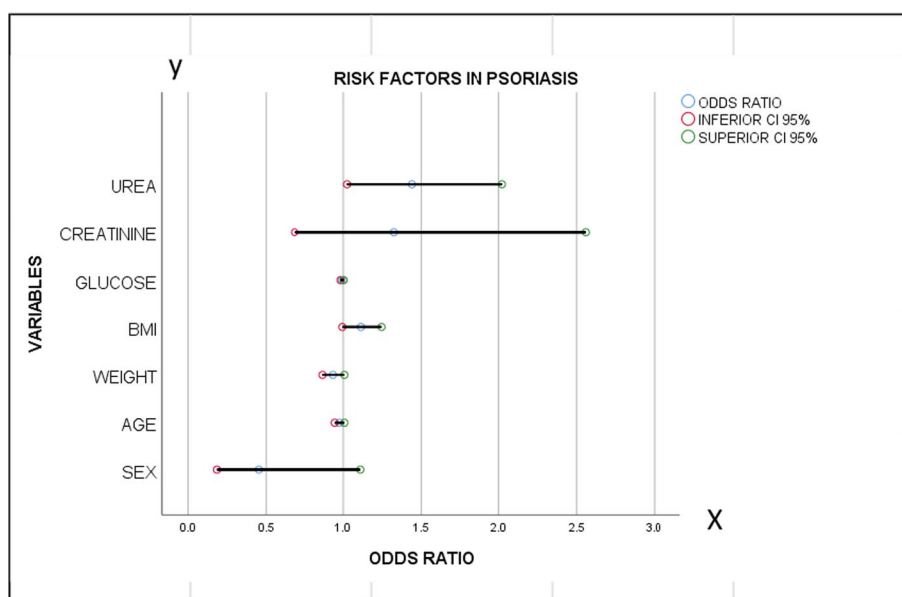
affiliate can go without an appointment to the 10 day for control, the researcher maintains digital communication with patients living in the city but, has limited with those living in marginal urban and rural areas due to problems of transfer or work permits, however contact was maintained through video-consultation to evaluate the response to treatment.

Data availability Data supporting the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Ethical approval Ethical aspects were considered in the 120 patients with psoriasis, likewise the confidentiality of medical records and the non-disclosure of patient names will be maintained, informed consent was requested in healthy subjects and also in patients. The database will be compiled in Excel format and will only be used in this study for statistical purposes to evaluate and compare the results.

Conflict of interest All authors have critically read this manuscript and have made their revisions and have had full access to all study data and assume responsibility for data integrity and accuracy of data analysis and have now all approved this final version for submission. All authors agree to be responsible for the future integrity of this study. This material is original research that has not been previously published and has not been submitted for publication elsewhere while it is being considered. All authors of this original article have no conflict of interest to declare.

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