PROTECTIVE EFFECT OF A BROADSPECTRUM UVA-UVB SUNSCREEN IN THE RETINOID THERAPY DURING SUMMER SEASON

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OBJECTIVE OF THE STUDY

To verify usage a broadspectrum UVA-UVB sunscreen for targeted skin protection at patients with acne nodulocystica gravis or acne conglobata treated during summer months by Roaccutane® Roche caps.

DEFINITION AND TYPE OF THE PERFORMED STUDY

Type of the study - IV - post-registration observance.
Blind; patients randomised into two groups with and without application of the Anthélios XL60+ cream.

MATERIAL AND METHOD

Division of the patients into two groups:

Group I : application of Anthélios XL60+ cream during the whole term of Roaccutane® caps therapy.
Group II : restricted application of Anthélios XL60+ cream to a specified place at the forearm during one specified week, when observation took place.

Locality of observing the effect of protection against the UV radiation:

Volar area of the left forearm, demarcated area of 5 x 5 cm to observe the effect of applying Anthélios XL60+ cream or a blind excipient.

Prerequisite:

Before assigning any patient into the study, skin photo-type was determined and a photo-test was carried out (to assess degree of the erythema occurring by exposure to the source of UV radiation gluteal area). As a source of radiation in the photo-test carried out, a mercury discharge lamp 125 W (mountain sun) was chosen.

Workplace : Department of Dermatovenerology, Svidnik, Slovak Republic.
Number of patients : 26 (14 males, 12 females)
Average age : men 19,64 year, women 20,5 year
Diagnosis : acne nodulocystica gravis, acne conglobata
Duration of the disease : in average: men 3.57 years, women 3.33 years
Duration of the treatment : in average: men 151 days, women 113 days
Photo-type : I - 4 patients (2 males, 2 females)
II - 20 patients (10 males, 10 females)
III - 2 patients (male)

Inclusion criteria:

- activation of the basic disease, apparent symptoms of bacterial infection (pustules, nodules)
- apparent and severe symptoms corresponding with the assessment according to Cook scale 6-10
- lack of oral treatment by antibiotics, chemotherapeutics or retinoids one month before assignment into the study
- resistance to the treatment applied so far

Exclusion criteria:

- hypersensitivity to components of the products (Roaccutane® Roche, Anthélios XL60+ (La Roche-Posay Pharmaceutical Laboratories), Ceralip (La Roche-Posay Pharmaceutical Laboratories)
- hypersensitivity to parabens
- patients with extremely sensitive skin
- patients under 15 years of age
- pregnancy, lactation

Duration of the study: 4 months
Randomisation : at assignment into the study
Oral drugs used : Roaccutane® Roche caps. 10 and 20 mg
Term of application : 1-3 months, according to individual response
Local agents used : options: Acnefug® EL, Acnefug® liquid N, magistraliter ointments with ichthammol Acidi salicylici, resorcini, or Skinoren® (azelain acid), in justified cases
ointments with antibiotics; Effaclar, Effidrate; soap with Ichthammol SANO 5%, 8% Thermal water La Roche-Posay
Other : mechanical cleaning
Targeted protection against solar radiation : Anthélios XL60+ cream
Special protection lips : Ceralip
Term of application : during usage of Roaccutane® Roche caps.
Recommended personal hygiene agents : non-irritating local agents, not to combine the recommended treatment with other products
Checks : at two-week intervals

RESULTS

Tolerance and adverse effects:

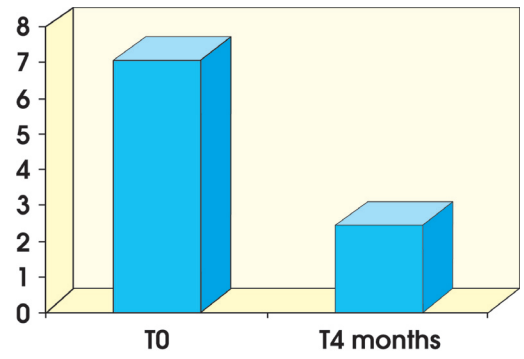
A broadspectrum UVA-UVB sunscreen induces no adverse effects (very good tolerance in all patients).
Patient satisfaction: excellent 96%, very good 4%
Roaccutane® Roche, 4 patients with headache and nausea

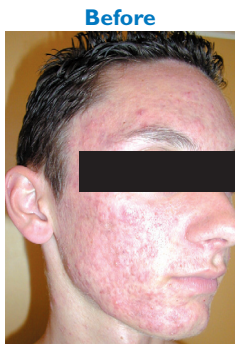
Efficacy:

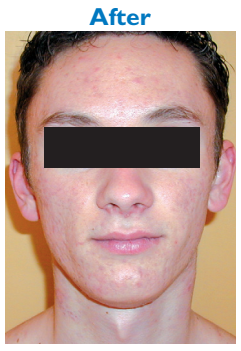
Roaccutane® local finding evaluation (Cook index scale):

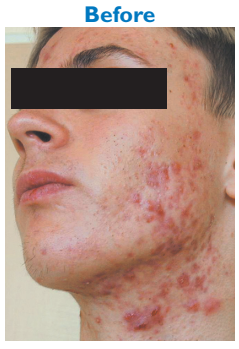
Before treatment:	degree 9 -	3 patients	(1 male, 2 females)
	degree 8 -	8 patients	(4 males, 4 females)
	degree 7 -	4 patients	(3 males, 1 female)
	degree 6 -	11 patients	(6 males, 5 females)
After treatment:	degree 6 -	1 patient	(1 female)
	degree 3 -	11 patients	(6 males, 5 females)
	degree 2 -	14 patients	(8 males, 6 females)

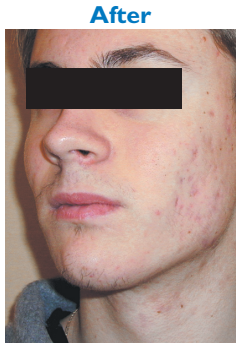
Cook index (mean values)

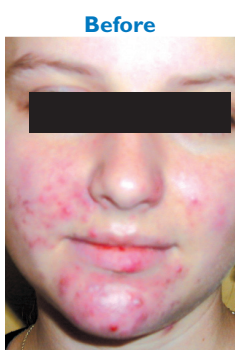


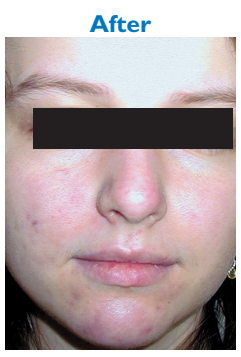












DISCUSSION

The effect of the broadspectrum UVA-UVB sunscreen in the course of the whole treatment by Roaccutane®, has been consonantly assessed both by the dermatologist and the patients as perfect protection (96%). One female patient (who interrupted the treatment) considered its effect as indistinct (4%). Adverse effects such as irritation or agent intolerance were not reported at any patient. Evaluation of the response with a weekly application of a blind excipient at 12 patients (6 females, 6 males) has confirmed in full excellent effects of the broadspectrum UVA-UVB sunscreen. In the group of men, two patients with photo-type I showed an apparent erythema on the third day of placebo application and a burning erythema on the seventh day, in general the patients with photo-type II reported the same result, but the burning was not so distinct. In the group of women, one female patient, who interrupted the treatment, has been excluded from the study. In total, 5 women with placebo application were evaluated (showed the most distinct response there was burning of the treated place on the 7th day), and four with photo-type II. The changes at other women were in general identical with the changes at men. One woman showed basically the same response for the whole week.

CONCLUSION

The need for targeted use of photo protective agents enabling stay at the sun without risk of origination of adverse effects, can be traced back to 1920s. The efforts of research and producers concentrate on preparing such photo protective agents for external use, which would potentiate the influence of natural pigmentation and restrict harmful impact of solar radiation. The majority of the photo protective agents used nowadays is a combination of UVB and UVA filters, often containing also a physical UV-blocker. So these agents are convenient mostly for people with photo-type I and II.
The performed study has in full scope justified the idea, that in case of targeted use of sunscreens with both high SPF and UVA-PF and good cooperation with patients, the trouble-free treatment by systemic retinoids is possible even in summer months.

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