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· Abstracts of the 10th Congress of the
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· 10–14 October 2001
· Munich, Germany

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Skin and Environment – Perception and Protection

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adipose panniculus and limitation of the fingers extension. Radiology confirmed osteopenia.

Comments Topical steroid potency must be enough to reach therapeutic effect evaluating the results periodically in chronic or inflammatory dermatoses. Lack of communication between General Doctors and Specialists may cause irreversible side-effects as those our patient present.

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P24-6

Cumulative irritancy potential of calcitriol ointment versus calcipotriol ointment and cream in healthy subjects

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Background Several vitamin D derivatives have been marketed for topical treatment of psoriasis (Calcipotriol, Tacalcitol and more recently, Calcitriol). The efficacy of these compounds has been demonstrated in several clinical studies. However, certain of these available products have been associated with unwanted effects such as local skin irritation.

Objectives The purpose of this study was to evaluate the local tolerance after repeated topical occlusive application over 21 days of 3 marketed products, calcitriol 3 µg/g ointment, calcipotriol 50 µg/g ointment and calcipotriol 50 µg/g cream in healthy volunteers.

Methods This study was conducted as a single center, randomized, evaluator-blinded, controlled, intraindividual comparison involving healthy volunteer subjects. All 25 subjects received the 3 products (calcitriol ointment, calcipotriol ointment and calcipotriol cream) and the negative control (white petrolatum). The test consisted of 21 days of occlusion for the test products (15 applications, 15 scorings, 21 occlusion days) distributed as five applications per week (every day except week-ends), for three consecutive weeks.

Results Only one subject prematurely interrupted his participation at Day 11 for personal reasons unrelated to the study. The Mean Cumulative Irritation Index (MCII) of Calcitriol 3 µg/g ointment (0.18) was slightly higher than those of white petrolatum (0.12) and lower than the MCII of the two Calcipotriol 50 µg/g formulations (0.23 for the cream and 0.50 for the ointment).

Conclusions Calcitriol 3 µg/g ointment, Calcipotriol 50 µg/g cream and white petrolatum were classified as non-irritant. Calcipotriol 50 µg/g ointment was classified as slightly irritant with a M.C.I.I. higher than 0.25 which is consistent with the clinical experience with this formulation.

Seventeen Adverse Events (10 headaches, 3 pains, 1 sore throat, 1 venous insufficiency, 1diarrhea and 1 dyspepsia) were observed in this study and were judged to be unrelated to the tested formulations.

P24-7

Daily changes of circulating immune complex in patients with psoriasis during the process of treatment by plasmapheresis and hyperbaric oxygenation

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The aim of this research work was to study the changes of daily dynamics of circulating immune complexes in the serum of blood during the process of treatment by plasmapheresis and hyperbaric oxygenation in patients with psoriasis. Twenty-six patients with psoriasis (seven males and nine females, 19–48 years) were examined. They mainly suffered from severe and wide spread forms of this disease and were recalcitrant. The duration of psoriasis exceeded 30 years in most of the patients. Plasmapheresis was made manually by using refrigerating centrifuge K – 70/Germany with sets of double or single plastic containers of 'Gemakon – 500/300' and 'Gemakon – 500¢ types and one-single system for blood transfusion. Hyper-baricoxygenation was carried out in the pressure chamber. The patients were in sitting position and breathed oxygen through the masks. The temperature was about 230–290 C in the pressure chamber during the treatment. The most of the air was no less than 65% the oxygen containing in the air was from 21% till 23%, carbon dioxide – 0.03% no more than assumed normal. The course of treatment of hyperbaric oxygenation was from 5 to 10 procedures conducted daily except Sunday. During the treatment the observations were carried out for changes of daily dynamics of circulating immune complexes. It was marked that plasmapheresis and hyperbaric oxygenation render immunocorregating action manifesting itself in normalization of studied parameters. At first the increased contains of circulating immune complexes ,carrying out of plasmapheresis and hyperbaric oxygenation enable to reduce their concentration twice to the end of the first procedure. Six – 12 hours later after the procedure the containing of the circulating immune complex is weakly increased it is connected with going them out from tissues of effectors. At the following observation they determined further reduction of circulating immune complexes by the end of the first day, after the third procedure its containing was one third of the starting form. Thus carrying out early therapy at the patients with psoriasis refracted to it can lead to the reduction of circulating immune complex which is accompanied by significant improvement of the basic skin process. Effectiveness and security of this method allows to consider sensible use of it at the therapy of severe forms of psoriasis.

P24-8

Down-regulation of 12-hydroxyeicosatetraenoic acid receptors in psoriatic epidermal cells by UV 313 nm

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UV-light induces different changes in skin which may be shown by electron microscopic examination. DNA damage or apoptosis are well-known as disturbances caused by UV-radiation. On the cell surface, receptors could be also affected during the treatment with arteficial UV sources or during the skin irradiation for cosmetic reasons. Because 12-hydroxyeicosatetraenoic acid (12-HETE) is considered to be the main epidermal eicosanoid and it is assumed to have both pathophysiological effects in inflammatory skin diseases such as psoriasis and atopic eczema and a physiological role in the cutaneous biology we decided to show the UV-light effect on 12-HETE cell curface receptors. Therefore, the effects of single and repeated irradiations with selected UV-B light of 313 nm from Waldmann F 85/100 W – TL-01 bulb on the 12(S)-HETE receptors in psoriatic epidermal cells were studied in the present work. UV-light *in vivo* (0.5 J/m²) and *in vitro* (50–150 J/m²) induced a down-regulation of 12(S)HETE receptors in a dose-dependent manner. The above described effect occured after a latency period of 6 h and reached its maximum at 7.5 h. *In vitro*, a single UV irradiation (150 J/m²) or repeated irradiation (50 J/m²) developed a 55% receptor down-regulation (Bmax), however, the receptor affinity remained unchanged. The down-regulation of 12-HETE receptors on keratinocytes developed after the UV-B iradiation may contribute to the explanation of its effects in phototherapy or photoaging.

P24-9

Effects of bathing and Peloid Prolom Banja on symptoms psoriasis vulgaris

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Prolom Banja is located in southern Serbia, at an altitude of 598 m above sea-level, in a mountainous area with volcanic origins. Its mineral water contains

alkaline, oligomineralic, hypothermic and hydrocarbonatic which contain the following elements, sodium and silicium. Patients afflicted with psoriasis have used them for many years. The aim of the study was to examine the effects of water and peloid from Prolom Banja on psoriasis vulgaris. Spa therapy (2 × 20 min bathing, 1 × 20 min peloid and 2 × daily neutral cream) was applied to 35 patients with psoriasis vulgaris. The Pasi score for erythema, infiltration and desquamation were calculated before therapy and after 7 days in 35 patients (group I), after 7 and 14 days in 17 patients (group II), after 7, 14 and 21 days in 20 patients (group III) and 7, 14, 21 and 28 days in 9 patients (group IV). The PASI score is calculated by the known formula with regard to erythema, infiltration and desquamation affected parts of the body (head, torso, arms and legs). Aside from effects of therapy on the total score we also examined symptoms and improvements, shown in percentages. Results were presented in percentages of improvement of score: up to 20% = weak, 21–40% = satisfactory, 41–60% = good, 61–80% = very good and more than 80% = excellent. At the end of the study groups I, II and III had a pasi score improvement which was graded as satisfactory 25.69%, 28.69% and 38.75% and group IV received 46.62%. Improvement of erythema in groups I and II was declared poor (15.68% and 14.64%), satisfactory in group III (33.33%) and good in group IV (41.05%). Improvement of infiltration for groups I and II was considered weak (15.68% and 14.64%), for group III satisfactory (33.33%) and for group IV good (41.05%).Improvement of desquamation for groups I and II was graded as satisfactory(38.26% and 39.50%) and for groups III and IV as good (42.11% and 46.96%). Spa therapy and Prolom Banja (bathing and peloid) have favourable effects on symptoms of psoriasis vulgaris. Most favourable improvements achieved in desquamation, followed by infiltration and erythema. Best results are received with a treatment period of 21–28 days.

P24-10

Efficacy and safety comparison of psoriasis maintenance therapy with either calcitriol or calcipotriol ointments

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Objectives This study aimed to assess the efficacy and safety of calcitriol 3 μg/g ointment vs. calcipotriol 50 μg/g ointment (twice daily) as maintenance therapy following 2 or 4 weeks of combination therapy of either product with clobetasol propionate 0.05% cream (once daily) in mild to moderate chronic plaque-type psoriasis.

Methods This multicentre, randomised, parallel group, investigator blinded study was performed in 14 centres. The total duration of treatment for each subject was 12 weeks (including 2 or 4 weeks of combination therapy). The primary efficacy evaluation parameter was investigator Global assessment of improvement recorded on a scale from – 1 (worse) to 5 (clear).

Results 125 subjects were included (61 in the calcitriol group and 64 in the calcipotriol group); the mean age was 50 years. The characteristics of psoriasis at baseline (Body Surface Area [BSA] and Psoriasis Area Severity Index [PASI]) were comparable between the 2 groups (BSA = 13% and PASI = 7). An excellent efficacy was demonstrated in both groups at the end of the combination therapy with clobetasol propionate cream (54% had at least marked improvement in the calcitriol group as compared to 59% in the calcipotriol group). The efficacy further improved during the 8–10 weeks of maintenance therapy with either calcitriol or calcipotriol. Degree of global improvement showed no significant difference between the 2 groups at any study visits (at week 12, the percentage of patients with marked improvement, almost cleared and cleared was 78.7% and 87.6%, for calcitriol and calcipotriol, respectively). The percentage of relapse during the maintenance phase was not different between both groups (25% and 20%, for calcitriol and calcipotriol, respectively). The incidence of adverse events was comparable in the two groups.

Conclusions This study shows that in chronic plaque psoriasis both calcitriol and calcipotriol ointments are useful in maintaining the good efficacy obtained after a short combination with clobetasol propionate preparations.

P24-11

Efficacy and safety of a new clobetasol short-contact therapy versus calcipotriol solution in the treatment of scalp psoriasis

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Introduction An original, short-contact, rinsed-off formulation containing 0.05% clobetasol propionate has been developed to provide a dosage form suitable for the treatment of scalp psoriasis. This formulation can be applied to wet or dry scalp skin, left for a short length of time, then rinsed off with water.

Objectives To evaluate the efficacy and tolerance of a rinsed-off scalp formulation containing clobetasol propionate 0.05% using different treatment/application regimens in scalp psoriasis, compared to calcipotriol 0.005% scalp solution.

Methods This was an investigator masked parallel group study, where 59 patients with scalp psoriasis were randomly assigned to receive 3 weeks of treatment with either Clobetasol scalp formulation (once daily, 3 dosage regimens: 15 min dry scalp, 10 min dry scalp, 10 min wet scalp) or Calcipotriol scalp solution, twice daily.

Results There was a decrease in the mean total score of psoriasis symptoms between Baseline and Week 3 in all treatment groups (–64%, –55.5%, –69% and –42%, in the 15′ dry, 10′ dry, 10′ wet and calcipotriol groups, respectively). However, improvement of symptoms was higher in the 3 clobetasol groups than in the group using calcipotriol scalp solution. In addition, the global improvement was significantly greater for both 15′ dry and 10′ wet clobetasol groups as compared to calcipotriol scalp solution (71%, 67% and 27% of the subjects had at least marked improvement, in the 15′ dry, 10′ wet and calcipotriol groups, respectively ($P = 0.05$)). Tolerance of treatments was good.

Conclusions The results showed that short-contact, rinsed-off clobetasol propionate 0.05% preparation had a significantly better therapeutic effect on scalp psoriasis than calcipotriol scalp solution. Short-contact, rinsed-off clobetasol propionate represents a novel approach to the treatment of scalp psoriasis.

P24-12

Efficacy of Bettamousse™ on scalp psoriasis: the SCALE trial: a randomised controlled, cross-over study

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Background Scalp is a common localisation of plaque psoriasis. Corticosteroid-based lotions are the most widely utilised therapy in this clinical setting. A new formulation of betamethasone valerate 0.1% in thermophobic, low-residue foam vehicle (Bettamousse™, Mipharm, Italy) (BM) is available for the topical treatment of scalp derrmatoses.

Aim of the study In a multicentre (25 Dermatology Clinics randomised, cross-over study, the efficacy, safety and patient acceptability of BM, as. compared with standard therapies (ST) (i.e. corticosteriods or vitamin D analogues) in scalp psoriasis were evaluated. ST were chosen by each centre according to their common therapeutic protocol for scalp psoriasis.

Patients and methods 154 patient with moderate to severe scalp psoriasis participated to the trial. After a 2-week run-ii period, each active treatment (BM or ST) was applied for 4 weeks with a wash-out period between the two-active treatments phases of at least 4 weeks. Efficacy was evaluated analysing a 'target' lesion for erythema, scaling, itching and burning using a five-point grading score. Patient acceptability was evaluated using a 13-point Finlay-Khan-modified questionnaire at the end of each treatment period. Safety was evaluated recording any adverse event occuring during study duration. BM was applied twice daily, ST were applied according to approved scheduled regimen.

Results 151 patients concluded the study. At baseline, clinical scores of erythema scaling, itching and burning were 1.5 ± 0.8, 2 ± 0.8, 1.7 ± 0.8, and