Evaluation of Calmapherol SC efficacy in the treatment of atopic dermatitis. Therapy of atopic dermatitis.

Summary

Introduction: Atopic dermatitis (AD) is a chronic skin disease whose main symptoms are skin lesions, dry skin and itching as well as periods of exacerbation and remission. Clinical symptoms of AD have a significant socioeconomic impact. Key elements of AD treatment are skin care and aggressive anti-inflammatory therapy, when needed. Taken together, they reduce AD symptoms.

Aim: The aim of the study was to assess the effectiveness of Calmapherol SC in AD therapy.

Materials and methods: The study included 77 patients with diagnosed AD. The effectiveness of Calmapherol SC in the treatment of AD was evaluated during one control visit based on the assessment of severity of skin lesions after applying Calmapherol SC. Patients also assessed the severity of itching and sleep disorders.

Results: The improvement of skin condition was observed after therapy with Calmapherol SC in all patients included in study. Statistically significant reductions of AD symptoms were observed during a control visit after therapy with Calmapherol SC. Moreover, the reduction of itching and sleep disorder was also observed.

Conclusion: Calmapherol SC is an effective non-steroidal cream in the topical treatment of AD. The results support the use of Calmapherol SC in the skin care therapy of patients with AD.

Keywords: atopic dermatitis, atopic dermatitis therapy, skin care, Calmapherol SC, SCORAD.

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Atopic dermatitis (AD) is a chronic, recurring inflammatory dermatosis that can co-exist with other atopic, Ig-dependant diseases, that is food allergy, allergic rhinitis or asthma. AD is the result of complex interactions between genetic, epigenetic, environmental and immunological factors, coupled with the defect of skin barrier and is characterized by the occurrence of periods of exacerbation and remission (1-3).

From the perspective of doctor's practice the AD is commonly diagnosed in case of children aged 5 or less. It is worth stressing that this disorder can significantly lower both the quality of life of patients, and that of their families, leading to serious socioeconomic consequences (4-8). This means that an efficient AD therapy should first of all swiftly eliminate the symptoms of disorder in order to improve patient's quality of life and prevent exacerbations. Due to the exacerbative and chronic nature of the disorder the cooperation between the patient and doctor becomes an important element of AD therapy.

Pursuant to the current guidelines of Dermatology Section of Polish Society of Allergology and the Allergology Section of Polish Society of Dermatology, as well as international standards, AD therapy should include the connection of appropriate daily skincare with emollient therapy, avoiding exposition to irritating factors and allergens and anti inflammatory therapy (9,10).

Care processes are a very substantial part of AD treatment (10). Regular skin greasing positively influences the soothing of inflammatory reaction and reduces itchiness. Additionally skincare with local use of emollient, 3-4 times a day can reduce the need for topical use of glucocorticosteroids (10,11). Another group of topical preparations, that due to their content of active substances have both treatment and care properties, are the cosmeto-pharmaceutics. They rebuild the epidermal barrier, returning its natural function, decreasing local inflammatory reaction in AD (10).

Calmapherol SC is a non-steroid cream containing:

• glycerophosphoinositol salt of choline (GPI) – lecithin derivative – an innovative active plant ingredient; GPI salts play an important role in control of the inflammatory process, by supervising the excretion of fatty acids; they have action directed to reduction of skin irritation and redness, also showing soothing action.

• zinc oxide, zinc sulfate, copper sulfate – antibacterial, anti inflammatory and regenerative action; with mending effect especially on irritation; efficiently reduces the inflammatory reaction of skin;

• vitamin E – restores the natural protective functions of skin, improves its moisturization and prevents loss of fluid; has regenerative effects on irritated, sensitive and dry skin; reduces the feeling of roughness and skin tension, soothes redness;
• alantoin – with soothing effects; its action supports epidermal regeneration process.

Aim of research

Thea im of present study was to evaluate the efficacy of Calmapherol SC in AD treatment, with use of the SCORAD – AD scoring system.

Materials and methods

77 patients, including 14 children aged 3 to 17 and 63 adults with age ranging from 20 to 62 years were qualified for the open application process. The decision to qualify the patient was made by dermatologist, based on diagnostic criteria proposed by Hanfin and Rajka, including data from initial interview, clinical image of skin changes and selected laboratory parameters. Duration of disease among the patients included in the panel was: ≤ 1 month – 18% patients; ≤ 1 year – 48% patients; > 1 year – 34% patients.

The research was in form of open, non-randomized clinical survey of "real-life" type. Calmapherol SC was ordered to the patients included in the survey, to be used topically and left till absorption at least 2 times a day, after previous cleaning and drying of skin surface. The evaluation of patient's skin condition was made by dermatologist at the beginning of survey (prior to use of Calmapherol SC) and during one follow-up appointment – after 1 month ± 2 weeks from the initial appointment (after use of Calmapherol SC). The intensity of lesions among AD patients, both children and adults, was evaluated through intensification of swelling, scabs, erythema, excoriations, decortications and lichenifications measured on a 0 to 3 scale. The intensity of itchiness and sleep disorders was also subjectively measured on a 0 to 10 scale. Percentage scale was used to evaluate the area of each part of the body that shows lesions, divided in front and rear parts of: head, upper limbs, torso, lower limbs. In case of hands only frontal part was considered and the evaluation of groin area only concerned adult patients. Based on the results of evaluation of intensification degree of skin lesions, the SCORAD index was calculated for the patients with use of SCORAD calculator. SCORAD is both a system and a tool to evaluate the intensification of AD. The results were subjected to statistical analysis. Linear variables were presented as mean values and the standard error of mean (Mean

± SEM). Normality of distribution was verified with use of Saphiro-Wilk statistical test. In order to compare the linear variables in dependant groups, showing a near normal distribution of values, the t-Student test was used.

Results

During the present research improvement of skin condition was observed among all patients, coupled with lowered AD intensification. The statistically significant reduction of AD symptoms during the follow-up appointment was proven, after the introduction of topical treatment with Calmapherol SC. During the first appointment the AD symptoms were evaluated as: erythema 2.1 ± 0.10; excoriations 0.90 ± 0.08; lichenification 1.32 ± 0.10; swelling 1.03 ± 0.08;

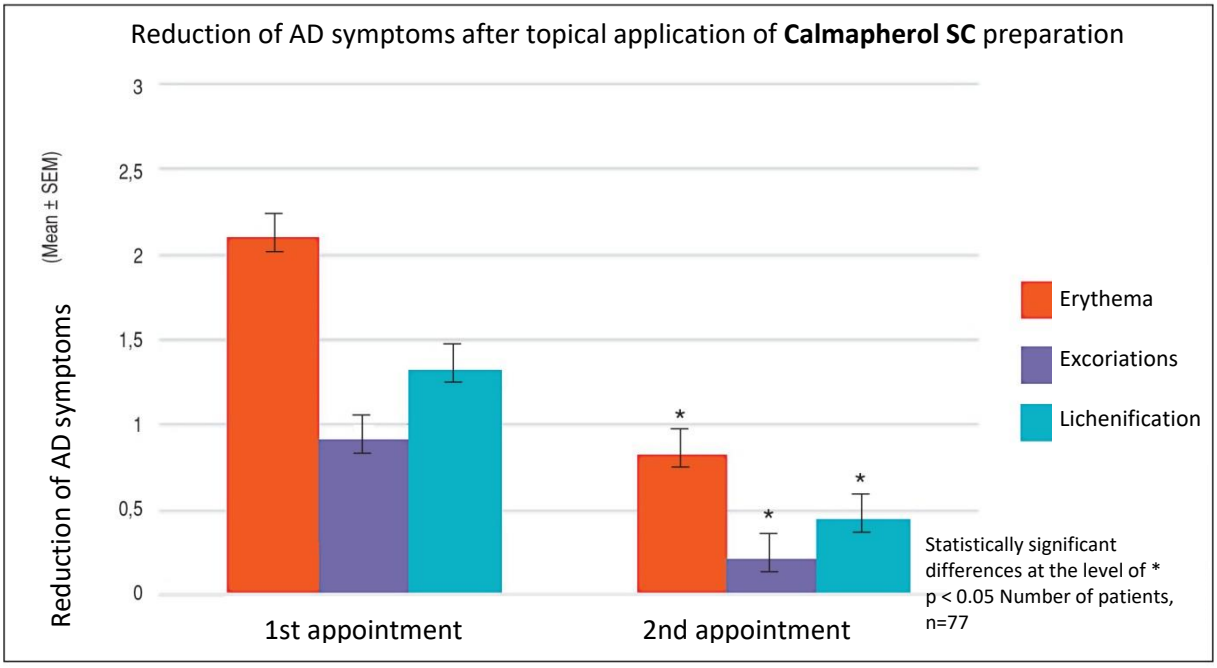

Figure 1a. Reduction of AD symptoms (erytema, excoriations, lichenification) after introduction of topical therapy with Calmapherol SC. The results were averaged and presented as means±standard error of mean (Mean ± SEM) for erythema, excoriations, lichenifications, prior and after topical Calmapherol SC terapy, respectively; and subjected to statistical analysis. Statistically significant differences at *p < 0,05 were proven

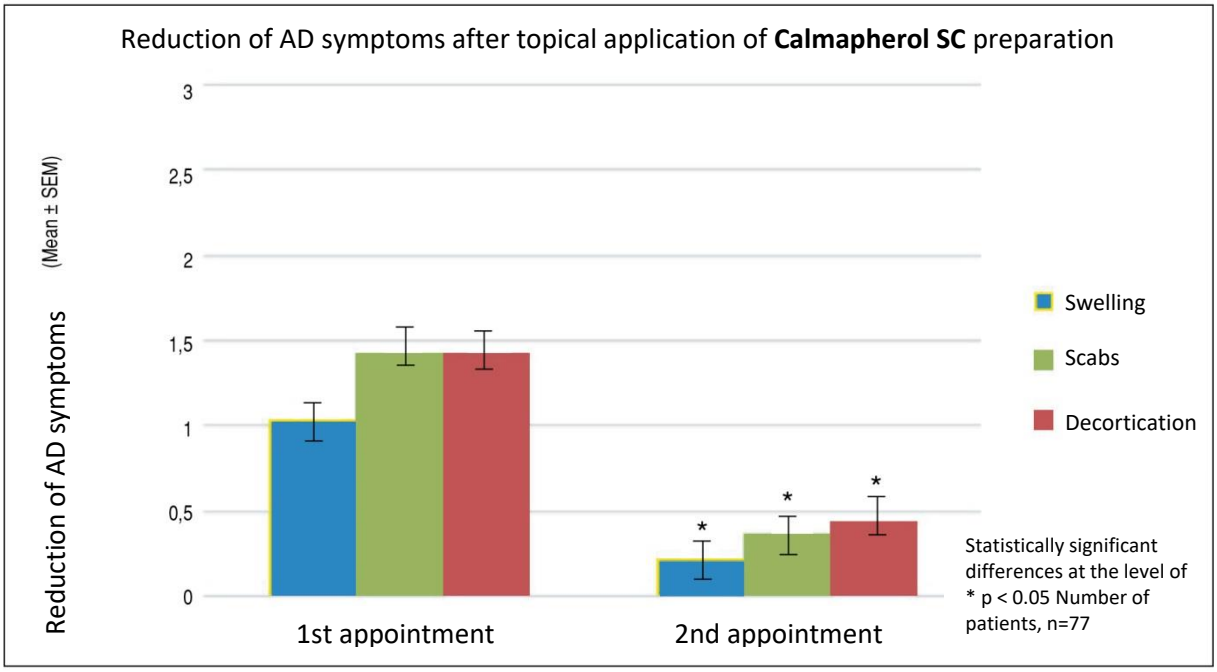

Figure 1b. . Reduction of AD symptoms (swelling, scabs, decortication) after introduction of topical therapy with Calmapherol SC. The results were averaged and presented as means±standard error of mean (Mean ± SEM) for swelling, scabs, decortication, prior and after topical Calmapherol SC terapy, respectively; and subjected to statistical analysis. Statistically significant differences at *p < 0,05 were proven

scabs 1.46 ± 0.10; decortication 1.43 ± 0.08. The analysis of results from evaluation of patients' skin lesions showed statistically significant reduction of AD symptoms, which were: erythema 0.81 ± 0.08; excoriations 0.21 ± 0.05; lichenification 0.43 ± 0.07; swelling 0.21 ± 0.05; scabs 0.36 ± 0.06; decortications 0.43 ± 0.06. Reduction of AD symptoms, as evaluated during follow-up appointment following the introduction of topical Calmapherol SC therapy is presented in figures 1a and 1b.

After an analysis of evaluation of intensification if itchiness after use of Calmapherol SC the statistically significant reduction of itchiness was proven, from 4.62 ± 0.21 to 2.29 ± 0.19 in case of AD patients (Figure 2).

What was subject to subjective evaluation of patients was also the intensity of sleep disorders on a 1 to 10 scale. During the first appointment the sleep disorders measured were on average 1.77 ± 0.19. After introduction of topical Calmapherol SC therapy statistically significant reduction of intensity of sleep disorders, to 0.71 ± 0.12 was observed. Figure 3 presents the reduction of sleep disorders after introduction of topical Calmapherol SC therapy.

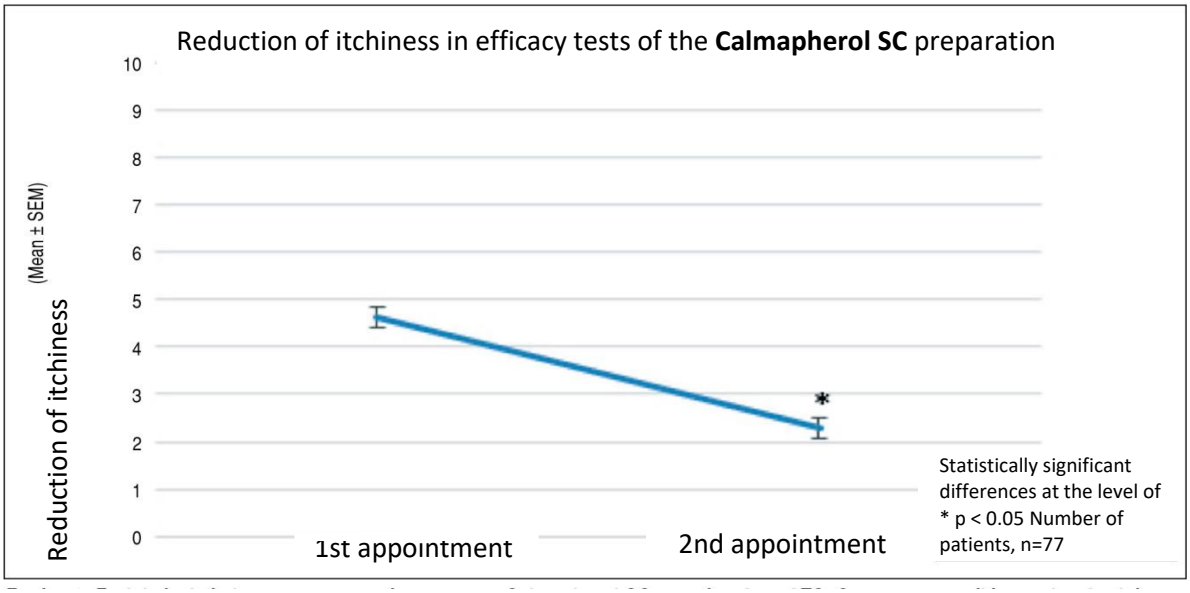

Figure 2. Reduction of itchiness after use of Calmapherol SC in AD patients. The results were averaged and presented as means±standard error of mean (Mean ± SEM) for itchiness intensity prior and after topical Calmapherol SC terapy, respectively; and subjected to statistical analysis. Statistically significant difference at *p < 0,05 was proven

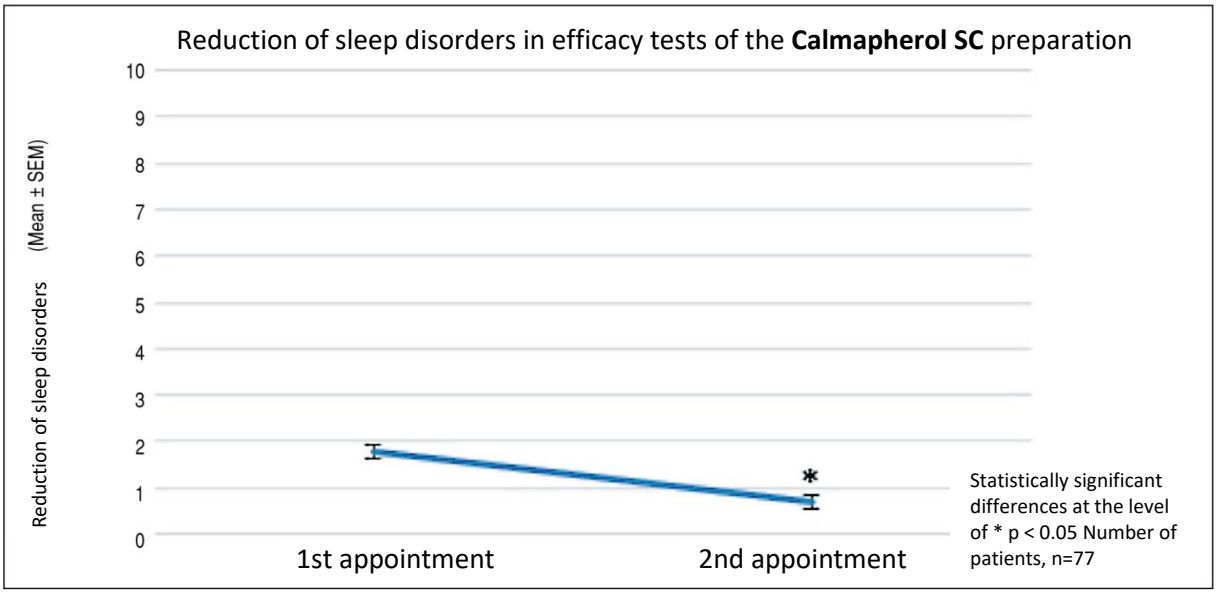

Figure 3. Reduction of sleep disorders after use of Calmapherol SC in AD patients. The results were averaged and presented as means±standard error of mean (Mean ± SEM) for intensity of sleep disorders prior and after topical Calmapherol SC terapy, respectively; and subjected to statistical analysis. Statistically significant difference at *p < 0,05 was proven

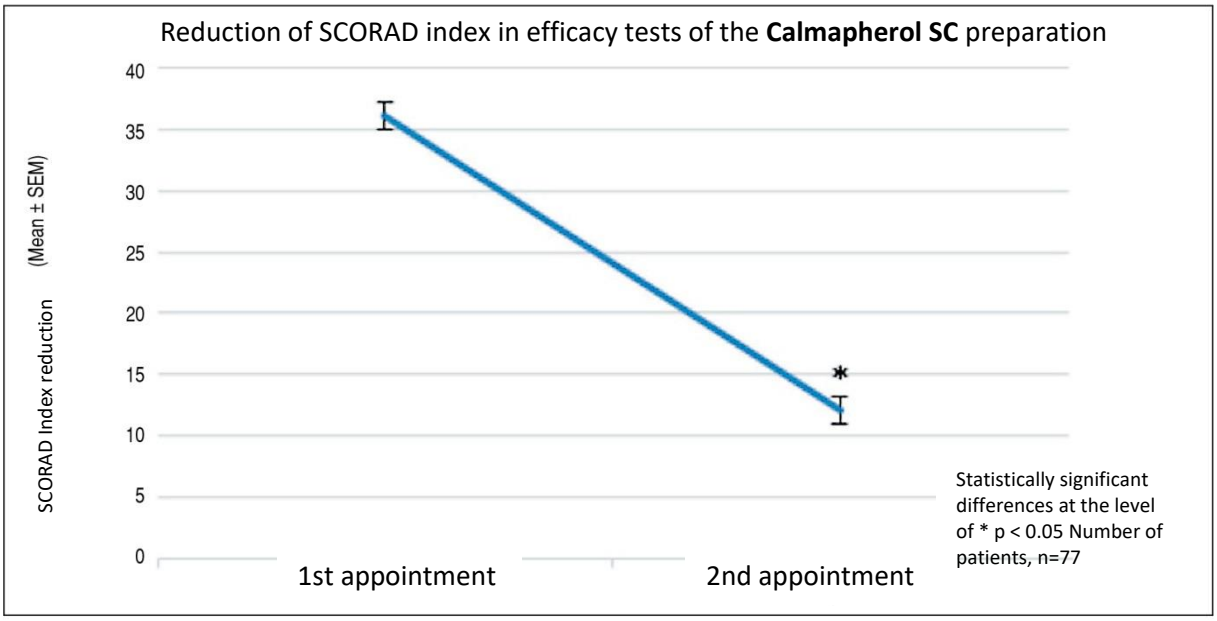

Figure 4. Reduction of SCORAD index after use of Calmapherol SC in AD patients. The results were averaged and presented as means±standard error of mean (Mean ± SEM) for AD intensity – SCORAD index prior and after topical Calmapherol SC terapy, respectively; and subjected to statistical analysis. Statistically significant difference at *p < 0,05 was proven

Mean SCORAD index, as measured on the basis of skin condition, intensity of itchiness and sleep disorders was 36.1 ± 1.35 during the first appointment and 12.1 ± 0.9 during the follow up. The analysis of results proved statistically significant reduction of SCORAD index (Figure 4).

Discussion

3 elements contribute to the preservation of proper function of epidermal barrier: proper development of stratum corneum, including cornified envelope, network of Langerhans cells and tight junctions (12). The bonds of keratinocytes in the stratum corneum is stabilized by different lipids: ceramides (40-50%), cholesterol (25-30%) and free fatty acids (10-20%). They form perfect protection from water loss from epidermis, and from potential penetration of antigens (13,14).

Due to the complex, multi-factor and not fully understood pathology of AD the therapy of this disorder utilizes complex approach. Treatment is thus oriented on factors participating in etiolopathology of the disease. What is stressed among the factors influencing the development of AD are the defects of the epidermal barrier. Defects of cornified envelope proteins were in recent years declared the central point of pathogenesis mechanism of AD skin lesions

and the first step in atopic cascade (14,15). Among other reasons behind the defect of epidermal barrier in case of AD patients we can also name: mutations of the filaggrin – that is the protein building the cornified envelope – gene, and disorders of lipid metabolism and composition in stratum corneum. What can also influence the deficiencies of epidermal barrier are: disorders in tight junction structures, increased activity of serine protease, overproduction of type Th2 cytokines, inhibition of antibacterial peptides function. These disorders cause increased permeability of the epidermal barrier in case of AD patients, as well as lowered integrity of stratum corneum (16). This triggers a range of pathological processes, leading to appearance of clinical symptoms of AD.

Therapeutic standards of AD therapy stress, that the basis of treatment is to join proper skincare with avoidance of exposition to irritating factors and allergens, coupled with anti inflammatory treatment. What is also sginificatnt, according to guidelines of European Academy of Dermatology and Venereology is fighting the defect of epidermal barrier by its protection and repair, and the reduction of the sub-clinical dermatitis in the AD therapy (10). There are literature sources indicating, that proper skincare in case of children suffering from AD can halt the development of atopic cascade, and thus the AD itself. Still this issue requires further research (17,18).

What is also stressed in treatment of AD is the topical treatment of skin lesions with use of corticosteroids. It is worth remembering, that the results of clinical research indicate large personal differences in their absorption and action. We should be particularly cautions in case of corticosteroid therapy in case of children, due to the difference of absorption abilities resulting from differences in the anatomical structure of infant and adult skin. The general rule for using steroid substances is their short application (few days only) and replacement with weaker ones once improvement is observed. The literature also suggests that prolonged corticosteroid therapy leads to development of allergic reaction to those substances by 13% of total number of patients. Corticosteroid therapy also bears the risk of side effect, e.g. the thinning of epidermis (19). This forced us to search for new therapeutic options for topical treatment of AD. Proper skin care includes procedures aiming at restoring and then preserving proper moisturization and reconstruction of the lipid barrier of skin. The care procedures should be based on use of hypoallergenic cosmeto-pharmaceuticals in form of creams, suspensions, soaps rich in moisturizing and soothing agents. Calmapherol SC has additional anti inflammatory and itchiness reducing properties, while also making the skin more elastic and providing a protective skin film.

Conclusion

The Calmapherol SC preparation is a non-steroidal cream that is effective in topical therapy of AD. The results of study confirm the justification for use of the Calmapherol SC preparation for skincare of AD patients. Due to the novel and rich composition it is highly efficient in AD therapy. This preparation can be used both in children and adults. It shows anti itchiness and anti inflammatory properties. Apart from its highly efficient care effects the conducted study also proved the reduction of sleep disorders in AD patients using the Calmapherol SC preparation.

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