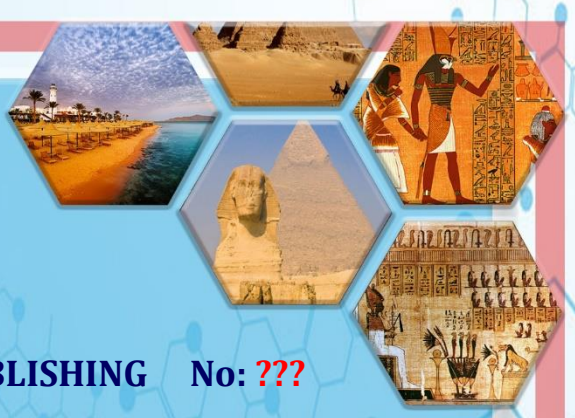

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Development of Safe Dermotologic Preparation With Account of Natural Constituens of Skin

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Introduction

Recently incidence and prevalence of inflammatory skin diseases became very high. For example, in some countries up to 25% of the population suffers from the dermatosis. The incidence rate of dermatosis among the children far outweighs the incidence rate of dermatosis among the adults.

Modern therapy of dermatosis is aimed to suppress inflammatory process and immune response. Main preparations for local treatment of dermatosis are glucocorticosteroids (GCS) that have anti-inflammatory, immunosuppressive, antipruritic action; conversely these medications can cause steroid adermotrophia due to long term usage. Vasoconstrictor effect of GCS, suppressing proliferative reparative processes, reinforcement of dystrophic changes of collagen and elastic fibres is a signifficant in the development of adermotrophia. Therefore skin looses elasticity, it becomes hyposthenic, dry and thin. Skin barrier function disturbs that results in hyperpermeability of epidermis for toxins, microorganisms. That's why up to date treatment of dermatosis is paid particular attention. It is known that disturbance of hydrolipidic film is caused by lack of lipids in it (in particular, ceramides), that results in skin laxity, increase in transepidermal water loss, penetration of allergens that causes development of irritation. In this regard usage of medications for treatment of dermatosis that heal and restore skin barrier function is very essential. Thus, the problem of treatment of dermatosis remains unaddressed that gives evidence of practicability of the development of new efficient and safe preparation for dermatology.

The goal of this work was investigation of atrophic action of the developed combination dermatologic preparations in order to increase safety of glucocorticosteroid therapy through the introduction of ceramides into the composition of preparations.

Materials and methods

Investigation of the influence of nonfluorinated GCS (mometasone, methylprednisolone) and their combinations with ceramides and with fluorinated GCS (betamethasone); their combination with ceramides on the occurrence adermotrophia at the long-time application of these preparations (six weeks) on the healthy skin of guinea pigs (4x4 cm^2). 55 guinea pigs (body mass 600 – 850 g) were used in the experiment. All manipulations with animals were performed in accordance with bioethical regulations.

Atrophic action was estimated using macroscopic (state of the change of skin, depth of skin fold, skin moisture) and microscopic (depth of epidermic layer) parameters. Skin state of the investigated animals on the treated skin areas were estimated visually in points every day. Depth of skin fold, temperature and moisture of horny layer of skin was measured using apparatus «Digital Moisture Monitor For Skin», Japan. The depth of epidermic layer (c.u.) was measured using microscope «Micros 400», Austria.

Results and discussion

According to the results of macro- and microscopic studies it has been established that the most pronounced steroid adermotrophia is observed after application of multicomponent crème «Betamethasone» and a shade less after application of ointment «Methylprednisolone». Obtained data proves that fluorinated GCS is more capable of causing side effects of medicinal products. After application of «Mmometasone» atrophic changes in the skin were not practically observed.

Table 1

Influence of preparations on the atrophic changes in the skin after their long-lasting application

Study group		Change of skin state	Depth of skin fold	Skin moisture	Depth of epidermic layer
Creme	Placebo	0.1	□1.1	1.0=IC	□1.4
	Ceramides	1.0	□1.2*	□1.2*	□2.3**/***
	BM	3.4**	□1.1	□1.2*	□1.5***
	BM + C	0.2	□1.1	□1.1*/**	□1.3**
	MF	1.3	1.0=IC	□1.2	□1.1
	MF + C	1.2	1.0=IC	□1.1*/**	□1.1
	MPA	2.0	□1.1	□1.1	□1.1
	MPA + C	1.8	□1.1	□1.1*/**	□1.1**
Ointment	MPA	2.1	□1.1*	□1.1	□1.6***
	MPS + C	1.6	□1.1*	□1.1*/**	□1.5**/***

Notes

Change of parameter in times (increase □ or □ decrease) in comparison with primary data (depth of skin fold, skin moisture) / with intact control (depth of epidermic layer); * – deviation is statistically significant relating to primary data, p □ 0.05; ** – deviation is statistically significant relating to the same preparation without ceramides, p □ 0.05; *** – deviation is statistically significant relating to the group of intact control, p □ 0.05; IC – intact control, MF – mometasone furoate, MPA – methylprednisolone aceponate, C – ceramides.

After application of crème «Ceramides» proliferative process acceleration (2.3 times greater in comparison with intact control) and increase in skin moisture (1.2 times greater in comparison with primary data) was observed (Table 1). Ceramides after addition to the investigated GCS gives them selective effect. It was shown that after long-lasting application of investigated preparations with ceramides on the guinea pigs' skin they showed maximal safety in comparison with their multi-component analogues. Reducing the risks from the occurrence of adermotrophia in these experiments was gained by the positive influence of ceramides on the skin trophism and the processes of natural regeneration of its structure.

Conclusion

Obtained data are very important for practical medicine and pharmacy because they allow developing dermatologic preparations with new level of safety (especially in pediatrics) and open new promising trend for improvement of existent local GCSs made in Ukraine.