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EVALUATION OF THE EFFICACY OF AN OINTMENT CONTAINING GOOSE FAT, EXTRACT ALOE, AND BETAMETHASONE IN PRECLINICAL STUDIES FOR THE TREATMENT OF ALLERGIC DERMATITIS

Feruza R. Karimova – Ph.D., associate professor
Bukhara state medical institute (Bukhara. Uzbekistan)
feruza_karimova@bsmi.uz

Abstract. *This preclinical study, based on modern scientific principles, assessed the biological safety and regenerative efficacy of a topical ointment composed of goose fat, aloe, and Betamethasone. The experiments were conducted using a full-thickness excision wound model in albino rats. The ointment demonstrated no signs of acute toxicity, with treated animals showing stable clinical behavior and body weight. Application of the formulation led to significant acceleration of wound healing, with complete closure observed by day 14. Comparative analysis indicated superior efficacy of the experimental ointment compared to standard treatments. These findings confirm the high regenerative potential and safety profile of the goose fat-based formulation and support its relevance for further clinical development.*

Key words: Goose fat, extract aloe, betamethasone, topical ointment, preclinical study, skin wound, regenerative activity, biological safety, toxicity, excision model.

The urgency of problem: According to the World Health Organization (WHO), allergic skin diseases, including atopic and contact dermatitis, affect 10–20% of the global population. Data from The Global Burden of Disease Study (2019) indicates that skin diseases rank among the top ten in terms of overall disease burden, with atopic dermatitis being a leading condition within this category [1,5,7,8]. The prevalence of severe atopic dermatitis (SAD) in children in Europe and the USA varies between 15–25%, while in adults it ranges from 2–10%. While biological agents like Dupilumab have proven effective in treating these conditions, their high cost — approximately $35,000–$40,000 USD per patient annually — often limits their widespread implementation in clinical practice. Furthermore, long-term use of synthetic antihistamines (e.g., loratadine, cetirizine) can lead to various side effects such as drowsiness, decreased concentration, and dry mouth [2,3,6,7].

The aim of the study was to conduct preclinical trials to determine the toxicity of an ointment containing goose fat + aloe extract + betamethasone used in the treatment of allergic dermatitis or steroid-responsive dermatoses.

Research methods and methodology. Our research methodology was developed with due consideration for various principles of modern scientific knowledge, ensuring it was adequately aligned with the defined objectives. The planned and conducted studies, based on general scientific and specific methods, aimed to address the stated research tasks**.**

All experiments were conducted on healthy animals that underwent a minimum of 10–14 days of quarantine. Acute toxicity was studied by administering the test samples dermally, following an established standard method. For this purpose, outbred white rats (male and female) weighing 18–22 g were used. Each group consisted of 6 animals, totaling 30 animals across all groups.

One day prior to the experiment, the fur on a 1x1 cm area of the animals' dorsal region was carefully trimmed.

The test samples, in the form of low-concentration ointments, were applied topically to the animals at varying doses:

Ointment 1: goose fat + aloe, 0.1% ointment, at a dose of 25 mg/kg (0.5 ml/20 g).

Analysis of the animals' clinical status, behavior, weight changes, condition of the skin and mucous membranes, and vital signs revealed that these modifications of the preparation did not lead to lethality even at the highest doses tested. Consequently, all investigated formulations were assessed as non-toxic based on acute toxicity indicators, and their approximate LD_{50} levels do not exceed the

maximum doses applied. This indicates that the goose fat-based ointment modifications are promising from a biological safety perspective at the preclinical stage.

Animals were kept in specialized cages under continuous observation for the first hour. They were then examined hourly for the subsequent 24 hours, and thereafter, their general condition was monitored once daily for the next 13 days (total observation period was 14 days).

During the observation period, the following parameters were assessed: general condition of the animals, behavior and motor activity, presence of convulsions, coordination of movement, muscle tone, reaction to external stimuli, respiratory status, heart rate, condition of fur and skin, condition of mucous membranes, tail position, food and water consumption, weight changes, other clinical signs indicative of toxic effects

The time of intoxication development and any potential fatalities were also specifically recorded.

All animals were maintained under standard vivarium conditions throughout the experiment, with full access to feed and water.

Results of the research: within the framework of a study conducted using a full-thickness excision wound model on albino rats, the regenerative activity of the Goose fat + Aloe + Betamethasone combination was evaluated. The wound healing process was assessed by measuring the wound surface area at different time points (Table 1). In the control group, regeneration progressed significantly slower. On day 6, 78.33% of the wound surface area remained, and by day 13, this figure had decreased to 13.28%. However, by day 19, complete wound closure had still not been achieved.

Table 1

Results of the evaluation of the regenerative activity of Goose fat + Extract Aloe + Betamethasone (M±SD; n=5; p<0.05; *p<0.001)**

Groups	Wound Surface Area (mm²) – Day 13
Control	10.99 ± 2.54
Ointment (Goose fat + Extract Aloe + Betamethasone)	2.72*** ± 1.82
Ointment containing Methyluracil and Chloramphenicol	6,98* ± 5.66

Note: *** — *Statistically significant difference compared to the control group at p < 0.001.*

In the group treated with Goose fat + Extract Aloe + Betamethasone, the regeneration process in laboratory animals progressed much more rapidly. By day 6, the wound surface area had decreased to 65.38%, and by day 13, it was reduced to 3.74%. Complete wound closure was observed on day 14. This finding indicates that the given formulation possesses a clearly pronounced regenerative activity.

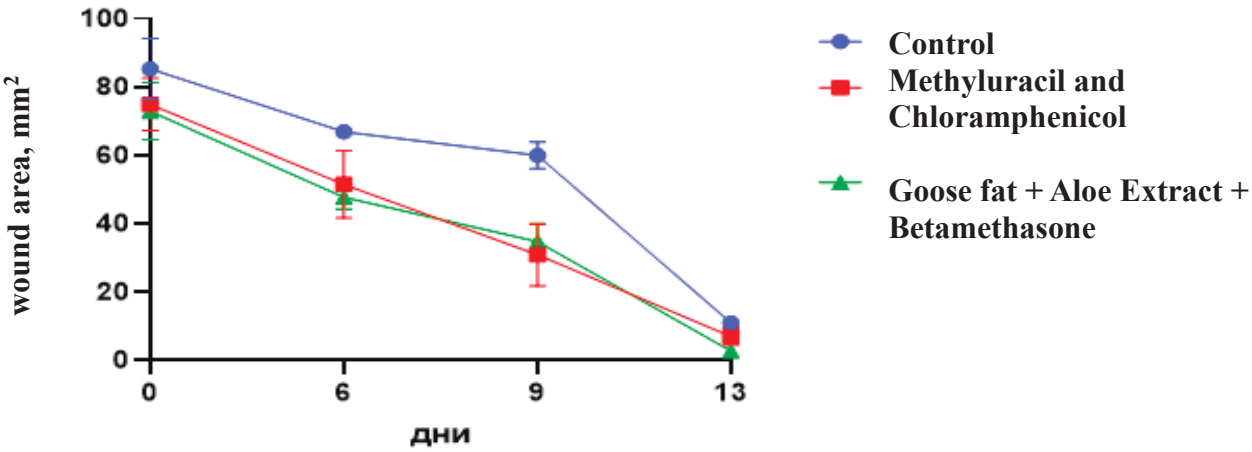

Fig. 1. Changes in wound surface area — results of the evaluation of regenerative activity of the Goose fat + Extract Aloe + Betamethasone formulation (p < 0.001, M±SD; n = 5; p = 0.05)

days

The comparator group treated with Methyluracil and Chloramphenicol ointment demonstrated high effectiveness in wound healing. Methyluracil and Chloramphenicol contains chloramphenicol (an antibiotic) and methyluracil (an immunostimulant), which contribute to its broad-spectrum antimicrobial effect and stimulation of tissue regeneration. This ointment is widely used in the treatment of purulent wounds, trophic ulcers, burns, and other skin injuries.

According to the results of the conducted study, the wound healing dynamics in the group treated with Methyluracil and Chloramphenicol are presented in figure 2.

Fig. 2. Visual assessment results of the regenerative activity of Goose fat + Extract Aloe + Betamethasone

By day 6, the wound area had reduced by up to 68.71%. This indicates Methyluracil and Chloramphenicol's ability to reduce inflammation and activate granulation processes even in the early stages of treatment.

On day 13, the wound area was significantly reduced, amounting to 9.31%, which suggests that the wound was nearing complete closure. This confirms the ointment's effectiveness in accelerating tissue regeneration.

Complete wound closure was recorded by day 15. This outcome supports the conclusion that Methyluracil and Chloramphenicol is a reliable agent for the effective short-term treatment of wounds of moderate severity.

The ointment base of Methyluracil and Chloramphenicol ensures deep penetration of its active ingredients into the damaged tissues, facilitating effective concentrations at the site of inflammation. Its regenerative properties, in addition to its antibacterial effects, enhance its overall therapeutic value.

Comparative analysis results demonstrated that wound healing progressed more rapidly in the group treated with Goose fat + Extract Aloe + Betamethasone. Complete closure was achieved by day 14, whereas the group treated with the ointment containing methyluracil and chloramphenicol achieved similar results only by day 15. In contrast, wound healing in the control group was significantly slower, with no complete closure observed.

These results confirm that the goose fat formulation enriched with Betamethasone possesses high regenerative efficacy as a topical agent.

The findings of the study clearly show that the Goose fat + Extract Aloe + Betamethasone formulation exhibits remarkable regenerative activity in wound healing. This unique topical combination significantly accelerated the healing process, with full wound closure observed by day 14 in treated animals.

Goose fat has traditionally been used in folk medicine as an anti-inflammatory and emollient agent. It nourishes the skin, enhances its elasticity, and promotes the formation of new cells.

Aloe possesses strong regenerative, anti-inflammatory, and antibacterial properties. It accelerates skin repair, reduces pain, and helps prevent infections.

Betamethasone, due to its glucocorticoid content (e.g., betamethasone), exhibits potent anti-inflammatory and anti-allergic effects, helping to optimize the healing process by reducing the inflammatory response.

Although the comparison ointment containing methyluracil and chloramphenicol (commonly known as Methyluracil and Chloramphenicol) also accelerated the wound healing process, its effectiveness was observed to be slightly lower than that of the Goose fat + Extract Aloe + Betamethasone modification. Complete wound closure in the methyluracil and chloramphenicol group was recorded by day 15, which is one day later than the group treated with the novel formulation.

The obtained results confirm that the Goose fat + Extract Aloe + Betamethasone formulation is a highly effective, promising topical therapeutic agent for wound healing. This combination may offer significant advantages, particularly in cases where rapid and effective wound closure is required. These findings serve as a foundation for the development of new and effective therapeutic strategies aimed at restoring damaged skin.

Conclusions: The results of the conducted study demonstrated that the Goose fat + Extract Aloe + Betamethasone formulation possesses clearly expressed regenerative activity. By day 13, the wound surface area in the treated group had significantly decreased to 3.74%, with complete closure observed by day 14. This indicates that the formulation strongly stimulates tissue regeneration and is capable of accelerating the wound healing process.

The regenerative efficacy of Goose fat + Extract Aloe + Betamethasone was found to be superior compared to the standard ointment containing methyluracil and chloramphenicol. While the standard ointment achieved complete wound closure by day 15, the Goose fat + Extract Aloe + Betamethasone formulation provided full closure one day earlier, on day 14. Thus, the combination of goose fat and aloe with Betamethasone can be scientifically recommended as a highly effective topical agent with enhanced regenerative potential.

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