

PROMISING THERAPEUTIC APPROACHES FOR LIPOID NECROBIOSIS

Azerbaijan Medical University (Baku, Azerbaijan)

statya2021@mail.ru

Lipoid necrobiosis (LN) is a relatively rare localized cutaneous lipoidosis of unclear pathogenesis. The development of the disease is largely associated with disturbances in lipid and carbohydrate metabolism, leading to microcirculatory disorders in the dermis, which contribute to the formation of papular lesions. Etiopathogenetic treatment of LN remains a challenging task. This study is devoted to a comparative evaluation of lipid and carbohydrate metabolism parameters, coagulation profile, and the inflammatory rim of LN lesions before and after treatment with Angipars (Group I), a combination of Angipars with conventional therapy (Group II), and conventional therapy alone (Group III). Angipars is an innovative drug containing Melilotus officinalis extract, developed by Iranian scientists. The demonstrated efficacy and safety of this drug in the treatment of scleroderma and diabetic foot syndrome, conditions with pathogenetic mechanisms similar to LN, provided a rationale for its use in LN. Before treatment, total cholesterol (TC) levels in Group I differed significantly from those after treatment ($p < 0.05$). In Groups II and III, no statistically significant differences were observed in TC levels before and after treatment ($p > 0.05$). Triglyceride (TG) levels in Group I also showed a significant difference before and after treatment ($p < 0.01$), whereas no such differences were found in Groups II and III ($p > 0.05$). Levels of LDL and HDL cholesterol did not show statistically significant changes before and after treatment in any group ($p > 0.05$). Parameters of carbohydrate metabolism (HbA1c, glucose, insulin) and coagulation profile (aPTT, INR, PT, PTI, fibrinogen, TT) did not differ significantly before and after treatment ($p > 0.05$). Clinical examination of LN lesions revealed a marked regression of disease activity and achievement of stable clinical remission in patients of Group II. The results of the study indicate that the most promising therapeutic approach is the combination of Angipars with conventional therapy (angioprotective agents, proteolytic enzymes, and hepatoprotective drugs).

Key words: lipoid necrobiosis, treatment, lipid metabolism, carbohydrate metabolism, coagulation profile, skin lesions.

Connection of the publication with planned research work.

The work is part of a dissertation for the degree of Doctor of Philosophy in medicine on the topic "Features of the course of lipoid necrobiosis in patients with diabetes mellitus of varying severity".

Introduction.

Lipoid necrobiosis (LN) is a relatively rare chronic dermatosis belonging to the group of localized cutaneous lipoidoses [1, 2, 3]. Patients with LN frequently demonstrate elevated levels of total cholesterol (TC), triglycerides (TG), and low-density lipoproteins (LDL). Increased LDL levels contribute to deterioration of the skin condition, particularly within the affected lesions. Patients with LN also exhibit impaired glucose tolerance and elevated glycated hemoglobin (HbA1c) levels [4, 5, 6]. These alterations indicate concomitant involvement of the microcirculatory vasculature, while coagulation parameters in such cases are characterized by changes in activated partial thromboplastin time (aPTT), international normalized ratio (INR), prothrombin time (PT), prothrombin index (PTI), and fibrinogen levels, reflecting a predisposition to hypercoagulability [7, 8].

The primary morphological element of the disease is a flat, indurated papule approximately 1 cm in diameter, round in shape, with well-defined borders and a smooth surface. Subsequently, as a result of peripheral expansion, round or oval plaques are formed, characterized by a slightly elevated reddish-violaceous peripheral rim and a centrally depressed grayish-yellow area. Lesions may reach several tens of centimeters in diameter, involving extensive anatomical regions [2, 9, 10].

Treatment of LN requires a comprehensive approach, including correction of lipid profile abnormalities, normalization of carbohydrate metabolism, restoration

of normal hemostatic function, and topical therapy of LN lesions [11]. At present, corticosteroids remain the mainstay of LN treatment and are administered both locally, including intralesional injections, and systemically. Additional therapeutic modalities include tacrolimus, antimalarial agents, cyclosporine, fumaric acid esters, pentoxifylline, ticlopidine, various biologic agents, photodynamic therapy, and others [12, 13].

The aim of the study.

To identify a promising therapeutic approach for LN through a comparative evaluation of lipid profile parameters, carbohydrate metabolism, coagulation indices, and changes in the intensity of the inflammatory peripheral rim in patients with LN before and after the administration of combined treatment regimens, particularly those including Angipars.

Object and research methods.

The study included 36 patients with LN who were examined at the Republican Dermatovenereologic Center, the clinical base of the Department of Dermatovenereology of the Azerbaijan Medical University, as well as at the "Baku Health Center" Clinic (Baku, Azerbaijan) between 2015 and 2020. The patients were divided into three groups, each consisting of 12 (33.3%) individuals. Patients in Group I received systemic Angipars monotherapy for 2 months. Patients in Group II were treated with a combination of Angipars and conventional therapy (angioprotective agents, proteolytic enzymes, and hepatoprotective drugs). Patients in Group III received conventional therapy only, including angioprotective agents (Detralex oral suspension), proteolytic agents (Rydase and Lidase suppositories), and hepatoprotective agents (Heparcaps capsules) [13].

Angipars was administered systemically for 2 months at a dosage of one tablet twice daily and was additionally

applied topically in ointment form as a thin layer to the affected skin areas twice daily. Angipars is an innovative systemic and topical pharmaceutical agent developed by Iranian researchers. The preparation contains Melilotus officinalis extract, traditionally recommended for gout, chronic non-healing wounds, and other conditions. The biologically active compounds contained in Melilotus officinalis, including hydroxycoumarin, flavonoids, and 7-oleanene glucuronide, possess antioxidant properties. Previously reported efficacy and safety of Angipars in the treatment of scleroderma and diabetic foot ulcers, conditions with pathogenetic mechanisms similar to LN, provided the rationale for its use in LN.

Disorders of lipid metabolism commonly observed in LN were analyzed using colorimetric photometry. Lipid metabolism parameters, including total cholesterol (TC), triglycerides (TG), high-density lipoproteins (HDL), and low-density lipoproteins (LDL), were compared before and after treatment. Venous blood samples were collected strictly under fasting conditions (8–12 hours of fasting). Alcohol consumption, fatty foods, as well as physical and emotional stress were excluded within 24 hours prior to the examination, with avoidance of physical and emotional strain during the 30 minutes preceding blood collection.

Due to the close association between LN and diabetes mellitus (DM), carbohydrate metabolism parameters (HbA1c, glucose, and insulin levels) were assessed using standard biochemical tests, including fasting blood glucose analysis and the oral glucose tolerance test (OGTT).

The increased risk of thromboembolic complications in LN served as the basis for investigating coagulation parameters (aPTT, INR, PT, PTI, fibrinogen, and thrombin time (TT)) using clotting assays before and after treatment. Venous blood samples were collected strictly under fasting conditions into tubes containing an anticoagulant (3.2% sodium citrate).

Treatment outcomes were additionally evaluated by objective clinical examination of LN lesions.

This study was conducted in accordance with the requirements of Good Clinical Practice (ICH E2(R6) GCP) and the Declaration of Helsinki of the World Health Organization. All patients provided informed voluntary consent prior to any procedures.

Statistical analysis was performed using Statistics 16.0 software, the SPSS statistical package for Windows (StatSoft Inc., USA), and the StatTech software package (StatTech LLC, Russia). Quantitative variables were presented as mean values (M) and standard deviations ($\pm m$). Comparisons of quantitative variables were carried out using the Mann–Whitney U test. Categorical variables were described using absolute values and percentage distributions. Differences between

the compared parameters were considered statistically significant at $p < 0.050$.

Research results and their discussion.

The pathogenesis of LN is generally believed to be primarily associated with disturbances of carbohydrate and lipid metabolism, leading to microcirculatory impairment followed by destructive changes in connective tissue and deposition of lipids, polysaccharides, immunoglobulins, and other compounds within areas of collagen degeneration [7, 8].

Lipid metabolism abnormalities in patients with LN are manifested by hyperlipidemia, hypercholesterolemia, elevated plasma protein levels, and disturbances in the spectrum of higher fatty acids. Increased lipid levels result in tissue hypoxia due to the formation of a lipoprotein barrier along the capillary endothelium, thereby impairing oxygen diffusion.

The levels of total cholesterol, triglycerides, high-density lipoproteins, and low-density lipoproteins in blood obtained during the study are presented in **table 1**.

As demonstrated by the results of the statistical analysis, in Group I patients receiving Angipars monotherapy, total cholesterol (TC) levels before treatment differed significantly from those after treatment ($p = 0.013$, $U = 115.0$, $p < 0.05$). In Group II patients treated with a combination of Angipars and conventional therapy, as well as in Group III patients receiving conventional therapy alone, no statistically significant differences in TC levels before and after treatment were observed (respectively, $p = 0.083$, $U = 102.0$; $p = 0.175$, $U = 95.5$; $p > 0.050$).

In Group I, triglyceride (TG) levels before treatment differed significantly from TG levels after treatment ($p = 0.008$, $U = 118.0$, $p < 0.010$). In Groups II and III, no statistically significant differences in TG levels before and after treatment were observed (respectively, $p = 0.083$, $U = 102.0$; $p = 0.133$, $U = 98.0$; $p > 0.05$).

LDL levels in the studied groups did not differ significantly before and after treatment ($p > 0.05$). The lev-

Table 1 – Lipid profile parameters in patients with NL before and after treatment, mean values

Parameters	Mean value in the total population	Group I	Group II	Group III	Significance between groups
TC, mg/dL					
Before treatment	196.4 \pm 5.2	196.5 \pm 26.9	181.0 \pm 37.0	211.8 \pm 22.2	
After treatment	173.4 \pm 3.0	165.1 \pm 25.6	155.3 \pm 27.4	199.7 \pm 17.6	$p_{I/II} > 0.05$ $p_{I/III} < 0.001$ $p_{II/III} < 0.001$
TG, mg/dL					
Before treatment	196.4 \pm 5.2	138.1 \pm 20.0	116.5 \pm 28.7	164.7 \pm 20.3	
After treatment	122.3 \pm 3.8	113.4 \pm 19.6	99.8 \pm 24.7	153.7 \pm 17.4	$p_{I/II} > 0.05$ $p_{I/III} < 0.001$ $p_{II/III} < 0.001$
LDL, mg/dL					
Before treatment	124.0 \pm 5.9	121.7 \pm 37.0	101.7 \pm 23.0	148.6 \pm 29.8	
After treatment	106.5 \pm 33.1	93.9 \pm 31.7	89.4 \pm 18.4	136.3 \pm 26.1	$p_{I/II} > 0.05$ $p_{I/III} < 0.010$ $p_{II/III} < 0.001$
HDL, mg/dL					
Before treatment	43.4 \pm 1.4	41.0 \pm 9.1	47.6 \pm 8.6	41.5 \pm 6.1	
After treatment	45.8 \pm 9.6	44.4 \pm 11.1	52.3 \pm 7.4	40.9 \pm 6.2	$p_{I/II} > 0.05$ $p_{I/III} > 0.05$ $p_{II/III} < 0.010$

Notes: $p < 0.001$ and $p < 0.010$ indicated statistically significant differences; $p > 0.05$ indicated no statistically significant differences.

Table 2 – Parameters of carbohydrate metabolism in patients with LN before and after treatment (mean values)

Parametres	Mean value in the total population	Group I	Group II	Group III	Significance between groups
Glycated Hb, %					
Before treatment	7.6±0.3	7.7±1.9	7.5±1.7	7.7±1.2	
After treatment	6.9±1.5	7.0±1.9	6.5±1.2	7.3±1.1	p>0.05
Glucose, mg/dL					
Before treatment	146.2±7.5	141.4±44.6	150.4±60.3	146.9±27.2	
After treatment	132.7±39.8	127.4±43.7	132.0±49.7	138.6±24.6	p>0.05
Insulin, µU/mL					
Before treatment	16.2±0.8	14.8±3.7	17.4±3.6	16.0±6.5	
After treatment	13.8±4.2	12.3±2.9	14.2±2.7	14.9±6.0	p>0.05

Notes: p>0.05 indicated no statistically significant differences.

els of statistical significance were pI=0.083 in Group I, pII=0.094 in Group II, and pIII=0.356 in Group III.

No statistically significant differences in HDL levels before and after treatment were observed among the three study groups (p=0.311, p>0.05).

LN is regarded as a dermatopathological manifestation of carbohydrate metabolism disorders of diabetic origin, even in cases where neither clinical nor laboratory evidence of carbohydrate metabolism impairment can be identified [7, 8].

The levels of glycated hemoglobin (HbA1c), glucose, and insulin obtained during the analysis are presented in **table 2**.

In Group I, glycated hemoglobin (HbA1c) levels before treatment did not differ significantly (p>0.05) from HbA1c levels after treatment (p=0.272). Likewise, in Groups II and III, no statistically significant differences in glycated hemoglobin levels before and after treatment were observed (pII=0.088; pIII=0.204).

After treatment, no statistically significant differences in glucose and insulin levels were identified between the study groups as a whole (p>0.05).

According to the literature, hyperlipidemia reduces capillary blood flow by 20–30%, while decreased oxygen tension stimulates lipid peroxidation, leading to increased levels of toxic end products that damage the biological membranes of skin cells. Oxidation of LDL enhances the production of plasminogen activator inhibitor and tissue factor, thereby disrupting fibrinolysis and blood coagulation processes [3, 6]. Therefore, coagulation profile parameters before and after treatment were subsequently compared.

The results of the statistical analysis demonstrated that coagulation parameters in the study groups did not differ significantly before and after treatment (p>0.050).

In the overall study population, mean aPTT values before and after treatment were 25.1±1.1 s and 24.1±5.5 s, respectively; INR values were 1.03±0.03 and 1.02±0.13; PT values were 10.6±0.5 s and 10.4±2.4 s; PTI values were 106.9±2.5% and 107.4±12.5%; fibrinogen levels were 269.8±9.1 mg/dL and 267.9±49.6 mg/dL;

and thrombin time (TT) values were 16.3±0.9 s and 15.9±4.9 s.

Objective clinical assessment of LN lesions regarding changes in the intensity of the inflammatory peripheral rim before and after treatment was also considered informative [2].

Before treatment, in Group I, the appearance of the peripheral rim of plaques (well-defined borders) indicated the presence of inflammation in 7 (58.3%) patients and the absence of inflammation (irregular borders) in 5 (41.7%) patients.

After a 6-month course of Angipars therapy, a reduction in the intensity of the inflammatory peripheral rim of the plaques was observed. The number of patients with signs of peripheral rim inflammation decreased to 4 (33.3%), while the number of patients without inflammatory changes increased to 8 (66.7%).

In Group II, before treatment, the appearance of the plaque rim indicated the presence of inflammation in 6 (50.0%) patients and the absence of inflammation in 6 (50.0%) patients. Following a 6-month course of combined therapy with Angipars and conventional treatment, the plaque rim appearance demonstrated an almost complete resolution of peripheral inflammation in 9 (75.0%) patients, whereas residual inflammatory changes persisted in 3 (25.5%) patients.

In Group III, prior to treatment, the plaque rim appearance demonstrated signs of inflammation in 8 (66.7%) out of 12 patients. After conventional therapy alone, the inflammatory peripheral rim persisted in 7 (58.3%) of these 8 patients, although its intensity was reduced in several cases. The number of patients without signs of peripheral rim inflammation increased from 4 to 5 (41.7%).

Conclusions.

The use of Angipars, a preparation containing a plant-derived active ingredient, in combination with conventional therapy (angioprotective agents, proteolytic enzymes, and hepatoprotective drugs) contributed to improved blood circulation and reduction of inflammation in areas of degenerative collagen alterations. The present study demonstrated the efficacy and feasibility of incorporating Angipars into the therapeutic management of LN.

Prospects for further research.

LN is characterized by a prolonged clinical course, and the atrophic process may continue for years. Therefore, future studies are planned to further investigate the efficacy of Angipars with the aim of personalizing therapeutic regimens and recommending its inclusion in treatment protocols for cutaneous dyslipidoses.

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ПЕРСПЕКТИВНІ НАПРЯМИ У ЛІКУВАННІ ЛІПОЇДНОГО НЕКРОБІОЗУ

Мадатлі А. Н.

Резюме. Ліпоїдний некробіоз – це рідкісний хронічний дерматоз із групи локалізованих ліпоїдозів шкіри, патогенез якого тісно пов'язаний із порушеннями ліпідного та вуглеводного обміну, мікроангіопатією, гіпоксією тканин та змінами в системі гемостазу. Клінічно захворювання проявляється утворенням щільних папул і бляшок з жовтувато-атрофічним центром і запальним периферичним валіком, що відображає хронічний дегенеративно-запальний процес у дермі.

Метою дослідження було порівняльне визначення ефективності різних схем терапії ліпоїдного некробіозу, включаючи препарат Ангіпарс, на основі динаміки показників ліпідного профілю, вуглеводного обміну, коагулограми та клінічної вираженості запального краю вогнищ ураження. Під наглядом перебували 36 хворих на ліпоїдний некробіоз, розділених на три рівні групи по 12 пацієнтів. У I групі застосовувалася монотерапія ангіпарсом, у II групі – комбінація ангіпарсу з традиційною терапією, що включала ангіопротектори, протеолітичні препарати та гепатопротектори, у III групі – лише традиційне лікування. Оцінювалися рівні загальної холестерину, тригліцеридів, ЛПНЩ, ЛПВЩ, глікованого гемоглобіну, глюкози, інсуліну, а також показники коагулограми. Клінічна ефективність визначалася за зміною інтенсивності запального периферичного валіка бляшок.

Отримані дані показали, що застосування ангіпарсу, особливо у складі комбінованої терапії, сприяло поліпшенню ліпідного профілю та зменшенню запальної активності вогнищ. Найбільш виражена позитивна клінічна динаміка відзначалася у II групі, де після лікування ознаки запалення периферичного валіка практично були відсутні у більшості пацієнтів. Істотних статистично значущих змін показників вуглеводного обміну та коагулограми виявлено не було. Таким чином, включення ангіпарсу в комплексну терапію ліпоїдного некробіозу є патогенетично обґрунтованим і перспективним напрямом лікування, що сприяє поліпшенню мікроциркуляції та зниженню запальних проявів захворювання.

Ключові слова: ліпоїдний некробіоз, лікування, ангіпарс, ліпідний обмін, вуглеводний обмін, коагуляційний профіль, шкірні ураження.

PROMISING THERAPEUTIC APPROACHES FOR LIPOID NECROBIOSIS

Madatli A. N.

Abstract. Lipoid necrobiosis is a rare chronic dermatosis belonging to the group of localized cutaneous lipidoses. Its pathogenesis is closely associated with disorders of lipid and carbohydrate metabolism, microangiopathic changes, tissue hypoxia, impaired collagen degeneration, and alterations in the haemostatic system. Clinically, the disease is characterized by firm papules and plaques with a yellowish atrophic centre and a reddish-violet inflammatory peripheral rim, reflecting a persistent degenerative and inflammatory process in the dermis.

The aim of the study was to evaluate the therapeutic potential of different treatment regimens for lipoid necrobiosis, with particular emphasis on Angipars, by assessing changes in lipid profile, carbohydrate metabolism, coagulation parameters, and the clinical intensity of the inflammatory border of the lesions. The study included 36 patients with lipoid necrobiosis who were observed at specialized dermatological clinical centres in Baku between 2015 and 2020. The patients were divided into three equal groups of 12 individuals. Group I received Angipars as monotherapy. Group II was treated with Angipars in combination with conventional therapy, including angioprotective agents, proteolytic preparations, and hepatoprotectors. Group III received conventional therapy alone. The assessment included total cholesterol, triglycerides, LDL, HDL, glycated haemoglobin, glucose, insulin, and coagulation parameters. Clinical efficacy was additionally evaluated by objective examination of the inflammatory peripheral rim of necrobiosis plaques before and after treatment.

The results demonstrated that Angipars, particularly when combined with conventional therapy, contributed to improvement of lipid metabolism and reduction of inflammatory activity in the lesions. The most pronounced clinical effect was observed in Group II, where the inflammatory peripheral rim almost completely regressed in the majority of patients. No statistically significant changes were found in carbohydrate metabolism or coagulation parameters after treatment. Thus, the inclusion of Angipars in the complex therapy of lipoid necrobiosis is a patho-

genetically justified and promising treatment approach that contributes to the improvement of microcirculation and reduction of inflammatory manifestations of the disease.

Key words: lipid necrobiosis, treatment, lipid metabolism, carbohydrate metabolism, coagulation profile, skin lesions.

ORCID and contributionship:

Madatli A. H.: <https://orcid.org/0009-0000-0213-0501> ^{ABDEF}

Corresponding author

Madatli Asmar
Azerbaijan Medical University
Azerbaijan, AZ1014, Baku, 81 Bulbul Avenue
Tel.: +994557621780
E-mail: statya2021@mail.ru

A – Work concept and design, B – Data collection and analysis, C – Responsibility for statistical analysis, D – Writing the article, E – Critical review, F – Final approval of the article.

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Тодуров І. М., Плезуца О. І., Струков Є. С.

**ПЛАСТИКА ЛОБКОВОЇ ДІЛЯНКИ, ЯК ЕТАПНИЙ МЕТОД КОРЕКЦІЇ ТІЛА,
ПІСЛЯ ВТРАТИ ВАГИ У ПАЦІЄНТІВ З ОЖИРІННЯМ
ТА СУПУТНИМ МЕТАБОЛІЧНИМ СИНДРОМОМ**

Державна наукова установа «Центр інноваційних медичних технологій НАН України»
(м. Київ, Україна)

dr.strukov1@gmail.com

Пластика лобкової ділянки за методом Н-подібної комбінованої вертикально-горизонтальної техніки є реконструктивно-естетичним втручанням, яке застосовується у пацієнтів із вираженими дефектами лобкової ділянки, зокрема після значного зниження маси тіла, коли формуються надлишкові шкірно-жирові складки та виражені деформації лобкової ділянки. Такі зміни можуть спричиняти фізичний дискомфорт, обмеження рухової активності та виражений психоемоційний дискомфорт, що знижує якість життя пацієнтів. Представлено клінічний випадок демонструє 48-річного пацієнта з ІМТ $\approx 40,5$ кг/м² (максимальна вага 210 кг, ІМТ $\approx 60,7$ кг/м²), який на тлі консервативної терапії досяг зниження маси тіла на 75 кг. Унаслідок цього сформувався виражений шкірно-жировий «фартух» та естетична деформація лобкової ділянки. Пацієнта було госпіталізовано до хірургічного відділення, проведено передопераційне обстеження, після чого виконано пластику лобкової ділянки з видаленням 2,6 кг надлишкових тканин і встановленням активних дренажів. У ранньому післяопераційному періоді пройшов без значущих ускладнень, з поетапним видаленням дренажів на 5-ту та 7-му добу. Пацієнта виписано на 11-ту добу з рекомендаціями. Отримані результати підкреслюють ефективність пластики лобкової ділянки, як одного з етапів лікування пацієнтів після консервативного зниження маси тіла при морбідному ожирінні. Оперативне втручання дозволяє усунути залишкові м'якотканинні деформації, поліпшити естетичний та функціональний результат, а також покращити якість життя пацієнтів.

Ключові слова: ожиріння, значна втрата маси тіла, монспластика, абдомінальна контурна хірургія, поетапний підхід.

Зв'язок публікації з плановими науково-дослідними роботами.

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Вступ.

Ожиріння – це хронічне захворювання, поширеність якого у світі невпинно зростає та набуває масштабів глобальної епідемії. Воно не лише підвищує ризик метаболічних і серцево-судинних ускладнень, а й призводить до виражених естетичних змін, зокрема в ділянці передньої черевної стінки та нижніх відділів тулуба [1].