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Bioakè Xerophy Repairing Anti-Scratching Cream in Patients Undergone to Radiotheraphy: Efficacy and Tolerability in Prevention Radiodermatitis

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Abstract

Radiation therapy (RT) is a widely and universally used treatment option for tumors of various organs. About 95% of patients receiving RT develop radiation side effects during or after treatment, affecting both the treatment outcomes and the patient's quality of life. This high frequency of adverse effects is due to the fact, that skin cells are among the rapidly renewing cell types. Some of these side effects, such as radiodermatitis (RD) and radiation recall dermatitis (RRD) – a phenomenon characterized by signs of acute dermatitis in previously irradiated skin areas following the administration of certain drugs – are commonly encountered in dermatological and oncological practice.

In oncology patients undergoing RT, the use of topical moisturizers is strongly recommended to reduce unwanted inflammatory skin reactions. Considering the mechanisms involved and the clinical characteristics of cancer patients, there is a need for continuous monitoring and optimization of the ideal topical product for the treatment of RD. An ideal product should have a minimal risk of adverse events, limited systemic absorption, and minimal drug interactions. It should also be effective in preventing local pain, with a carefully formulated composition, as some products can interfere with the effects of RT.

The purpose of this study was to evaluate the tolerability and effectiveness of Bioakè Xerophy repairing anti-scratching cream in patients with head and neck tumors undergoing radiotherapy and its impact in ameliorating the quality of life of the same patients.

The study included 60 adult patients of both sexes with solid tumors of the head and neck, who underwent radiotherapy as part of a radical program or postoperatively. The study (group 1; n=30) and control (group 2; n=30) groups were randomly formed. The groups were similar in terms of gender and age composition and tumor localization. Patients in group 1 used Bioakè Xerophy repairing anti-scratching cream daily throughout the entire course of radiation therapy and for two weeks after its completion. Patients in the control group were allowed to use any non-medicinal topical products available in pharmacies and retail stores, at their discretion.

The primary endpoint of the study was to assess product efficacy using the RTOG scale (Radiation Therapy Oncology Group / European Organization for Research and Treatment of Cancer; RTOG/EORTC). Secondary endpoints included the assessment of skin toxicity according to the CTCAE

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criteria system (Common Terminology Criteria for Adverse Events, version 4); evaluation of pain and itching at the RT site on a 10-point scale; and assessment of local status based on the criteria of "erythema", "folliculitis", "desquamation", "epilation", "dryness", "edema", "ulceration", "necrosis" and "hemorrhage." Quality of life was evaluated using the Dermatological Quality of Life Index (DQLI). Patient opinions about the cream were assessed using a Likert scale, and all adverse events were recorded.

The use of Bioakè Xerophy repairing anti-scratching cream in patients with head and neck tumors reduced the severity of toxic skin reactions associated with radiodermatitis during radiation therapy and facilitated the rapid restoration of skin barrier function after the completion of treatment.

Keywords: radiotherapy, radiation oncology, head and neck tumors, radiation dermatitis, radiation-induced skin toxicity, skin care, emollients

■ INTRODUCTION

Radiation-induced dermatitis (radiodermatitis, RD, radiation dermatitis, post-radiation dermatitis) refers to frequently occurring adverse reactions that develop in patients undergoing radiation therapy (RT) for cancer in various locations. RD occurs as a result of damage to the skin, its appendages, and underlying tissues caused by external radiation exposure. It has been shown that approximately 95% of patients receiving RT will eventually develop RD during or after treatment, directly impacting an individual's quality of life and treatment adherence. Thus, RD can significantly worsen the prognosis of clinical treatment outcomes [1–3].

■ PURPOSE

To determine the effectiveness and tolerability of Bioakè Xerophy repairing anti-scratching cream in the treatment and prevention of radiodermatitis in patients with head and neck tumors and its impact on quality of life of the patients.

■ MATERIALS AND METHODS

A prospective cohort observational study included 60 adult patients of both sexes with solid tumors of the head and neck who underwent radical or postoperative radiotherapy. The study (group 1; n=30) and control (group 2; n=30) groups were randomly formed. The groups were similar in terms of gender and age composition and tumor localization. The medians of the total radiation dose (70 Gy, min/max: 60/70) and single dose per fraction (1.8–2 Gy) were comparable in both groups. Almost all patients also received chemotherapy (Table 1).

The patients' condition was assessed at five time points: day 0 (T0 – the start of radiotherapy), and then every two weeks thereafter (T1, T2, T3, T4). Thus, the individual observation period for each patient was 56 days. Patients in group 1 used Bioakè Xerophy repairing anti-scratching cream daily from T0 throughout the entire course of RT and for two weeks following its completion until T4. The cream was applied to dry, clean skin twice a day, and additionally as needed. Patients were advised not to use soap in the area where the test substance was applied. Patients in the control group (group 2) were allowed to use any non-medicinal topical products available in retail pharmacies and stores, but the majority chose not to use any.

The authors developed strict inclusion and exclusion criteria for the study, according to which the material was collected for subsequent processing and analysis (Table 2).

The composition of the Bioakè Xerophy repairing anti-scratching cream moisturizing cream is presented in Table 3. The cream has been issued a declaration of compliance with the Technical Regulations of the Customs Union "On the Safety of Perfumery and Cosmetic Products" (TR CU 009/2011) by the Eurasian Economic Union. In EEC countries, the cream is also certified for conformity with the production requirements of ISO 22716:2007 (Certificate No. 18724). Fundamentally, the

Table 1
Characteristics of patients in the study and control groups

Age, average(min/max)	All, n=60	Group 1, n=30	Group 2, n=30
	56.6±8.9 (37/79)	57.4±10.1 (37/79)	55.8±7.5 (42/71)
Sex Male, No. (%) Female, No. (%)	 18 (30.0) 42 (70.0)	 13 (43.3) 17 (56.7)	 5 (16.7) 25 (83.3)
Family history, positive(%)	14 (23.3)	7 (23.3)	7 (23.3)
Smoker	31 (51.7%)	11 (36.7%)	20 (66.7%)
Tumor site: – oral cavity – oropharynx – hypopharynx – larynx – other	 9 12 15 15 9	 5 6 8 7 4	 4 6 7 8 5
Radiation therapy: – Primary treatment – Postoperative treatment – Total focal dose, Gy, median (min/max) – Dose/fraction, Gy	 34 26	 18 12 70 (60/70) 1.8–2	 16 14 70 (60/70) 1.8–2
Chemotherapy: – Neoadjuvant treatment – Chemoradiation treatment		 14 14	 13 16

composition is a hydrophilic barrier emollient with a high regenerative capacity. The formulation of the cream makes it suitable for use as a moisturizer for the care of dry and damaged skin on the face and body. The cream does not contain any substances that reduce the effectiveness of radiation therapy.

Table 2
Inclusion/exclusion criteria for/from the study

Inclusion criteria	Exclusion criteria
– compliant patients of both sexes – age between 18 and 70 years – patients who provided written consent to participate in the study – patients with solid tumors of the head and neck undergoing radiotherapy with a total dose 60–70 Gy – Concomitant chemotherapy allowed	– patients who have previously undergone radiation treatment – concomitant inflammatory skin diseases in the acute phase (e.g., atopic dermatitis, contact dermatitis, psoriasis, lichen planus, pityriasis versicolor) – collagenoses and vasculitis (e.g., vasculitis limited to the skin, scleroderma, dermatomyositis or lupus erythematosus) – chronic diseases that slow down reparative processes in the skin (e.g., diabetes mellitus, renal failure) – use of a tissue-equivalent bolus during radiation therapy – presence of skin rash or non-healing wounds in the radiation area – recent sun exposure – non-healing surgical sites – multiple neoplasms – known radiosensitivity syndromes (e.g., ataxia-telangiectasia) – known hypersensitivity to at least one of the components of the topical medications used – systemic or local use of steroids of any class (including inhaled or intranasal) within 15 days prior to inclusion in the study – phototherapy (PUVA, UVB) during the 4 weeks preceding study entry and/or planned to be administered during the study – pregnant or breastfeeding women – participation in another clinical trial (even as part of maintenance treatment), including trials involving drugs that cause skin toxicity

Table 3
Composition of moisturizing cream (Bioakè Xerophy repairing anti-scratching cream) used by patients in the study group

Composition of moisturizing cream	Aqua, Caprylic/capric triglyceride, Ethylhexyl stearate, Glycerin, Hydrogenated ethylhexyl olivate, Polyglyceryl- 6 behenate, Prunus amygdalus dulcis oil, Butyrospermum parkii butter, Panthenol, Ceramide NP, Glyceryl stearate, Tocopheryl acetate, Polyglyceryl- 6 stearate, Hydrogenated olive oil unsaponifiables, Calendula officinalis flower extract, Tocopherol, Allantoin, Cetearyl alcohol, Pentylene glycol, Butylene glycol, Caprylyl glycol, Xanthan gum, Sodium polyacrylate, Ascorbyl palmitate, Hydroxyphenyl propamidobenzoic acid, Phenethyl alcohol, Ethylhexylglycerin, Phenoxyethanol

The cosmetic product can be used to soothe, moisturize and protect irritated skin in different situation that involve a damage of the skin barrier, including allergic contact dermatitis, photodermatitis, radiodermatitis, and dermatitis that develops during chemotherapy in oncology patients. The active components of the cream help soothe irritation, promote skin regeneration, and reduce irritation, erythema, and itching.

The degree of acute skin toxicity (severity of RD manifestations) was assessed at each observation point according to the RTOG/EORTC scale (Radiation Therapy Oncology Group / European Organization for Research and Treatment of Cancer scale) [2, 20] (Table 4).

Local status over time was evaluated based on the severity of the main symptoms of RD: erythema (0–1–2–3), folliculitis (0 – none; 1–5 – 1; 5–10 – 2; >10 – 3), desquamation (0–1–2–3; compared to intact skin), epilation (0-1), dryness (0–1–2–3; compared to intact skin), swelling (0–1–2–3), ulceration, necrosis and hemorrhages (0–1). At each observation point, patients also completed the Dermatological Quality of Life Index (DQLI) questionnaire; the latest update of the validated Russian version was on February 19, 2019 [16]. The digital values of the DQLI reflect the degree of negative impact of the skin condition on the respondent's quality of life: the higher the index, the more the pathological process worsens the quality of life. For each question, there are four answer options, each scored from 0 to 3 points. The maximum possible score is 30, with the patient's quality of life being inversely proportional to the score. Interpretation of DIQL:

- 0–1 point – no impact on the patient's quality of life;
- 2–5 points – minor impact on the patient's life;
- 6–10 points – moderate impact on the patient's life;
- 11–20 points – very strong impact on the patient's life;
- 21–30 points – extremely strong impact on the patient's life [16].

The obtained data were analyzed using the Statistical Package for Social Sciences (SPSS) for Windows, version 22.0. Categorical data are presented as numbers and percentages, while numerical data are presented as mean and standard deviation. The chi-square (χ^2) test was used to compare categorical variables between groups, and the Mann – Whitney U test was employed to compare numerical data without a normal distribution between groups. Differences with a p-value of less than 0.05 ($p<0.05$) were considered statistically significant.

Table 4
RTOG assessment criteria for acute radiation reactions (RD severity), taken from [20]

G0	No visible change to the skin
G1	Perifollicular, mild erythema, epilation, dry desquamation, decreased sweating
G2	Painful or bright erythema, patchy, moist desquamation, moderate swelling
G3	Confluent moist desquamation outside skin folds, swelling of the skin with the formation of eczematous wells
G4	Ulceration, hemorrhages, necrosis

RESULTS AND DISCUSSION

Radiation dermatitis (RD) is characterized by the development of symptoms such as pain, ulceration, swelling, itching, burning, and both physical and psychological discomfort. Opportunistic infections may sometimes occur during or after radiation therapy (RT) [6-9]. The concomitant use of systemic drugs, such as platinum-based regimens, cetuximab, and 5-fluorouracil, which are prescribed to a significant proportion of patients undergoing RT, can exacerbate the severity of RD [2, 11].

Early skin reactions to radiation typically occur within the first 1-4 weeks after the start of treatment and can persist for 2–4 weeks following its completion. These reactions are clinically identified and graded according to severity, ranging from erythema and dry desquamation to wet desquamation, and in more severe cases, erosion and ulceration. Generally, patients do not experience discomfort during the initial 2 weeks of treatment with daily fractionated doses of 1.8 to 2.0 Gy. Transient erythema may appear within 24 hours of starting treatment and becomes noticeably localized to the treatment area after 2–3 weeks. The skin may turn red, become hot to the touch, and a rash may develop. In such cases, patients often describe their skin as sensitive and tight.

Hyperpigmentation typically occurs 2–4 weeks after the start of treatment. With a cumulative dose reaching 20 Gy, patients may experience dryness, itching, peeling of the skin, or dry desquamation [12, 14]. This results from decreased ability of the basal layer to replace the superficial layers, significant epidermal desquamation, and reduced functioning of the sweat and sebaceous glands. At doses of 30–40 Gy, extracapillary cell damage can occur, leading to increased capillary blood flow, hyperemia, and edema. In severe cases, epilation and moist desquamation can occur at doses of 45 to 60 Gy. Moist desquamation exposes the basement membrane and dermis, resulting in a moist, painful, and red area with oozing of serous fluid and possible light or heavy crusting [14].

In this study, the severity of skin reactions in response to RT increased in both groups towards the end of the radiation treatment course. However, peak RTOG values in the study and control groups occurred at different points: T2 and T3, respectively (Fig. 1). This likely indicates the preventive potential of the cream used by patients in group 1, reflecting its protective properties. Although the RTOG curves for both groups were similar, the average values at points T2, T3, and T4 showed a significant difference in favor of patients in group 1 (Table 5).

The authors attribute the reduced side effects of RT in respondents who used the cream to its soothing, moisturizing and protecting effects. The average peak values in the study group were

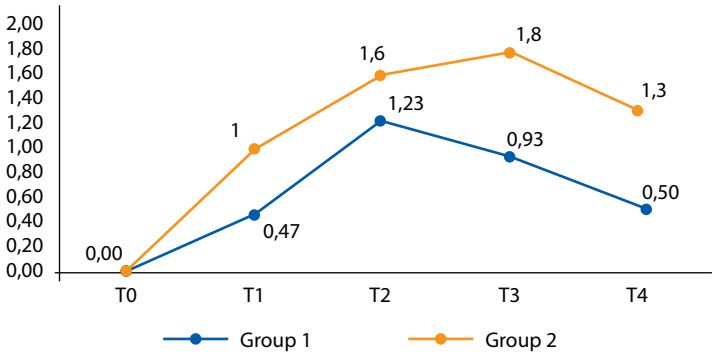

Fig. 1. RTOG curve for study and control groups during follow-up

Table 5
RTOG scores in the study and control groups throughout observation period

Score	T0		T1**		T2*		T3***		T4***	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
0	30 (100)	30 (100)	16 (53.3)	4 (13.3)	1 (3.3)	–	8 (26.7)	2 (6.7)	19 (63.3)	4 (13.3)
1	–	–	14 (46.7)	22 (73.3)	21 (70)	12 (40)	16 (53.3)	5 (16.7)	7 (23.3)	13 (43.3)
2	–	–	–	4 (13.3)	8 (26.7)	18 (60)	6 (20)	21 (70)	4 (13.3)	13 (43.3)
3	–	–	–	–	–	–	–	1 (3.3)	–	–
4	–	–	–	–	–	–	–	1 (3.3)	–	–

Notes: * p<0.05; ** p<0.01; *** p<0.001.

significantly lower (1.23/1.8), with restoration of function and damaged skin structures observed by the end of the RT course at point T3 (0.93/1.8). Two weeks after the end of RT, daily use of the cream led to almost complete resolution of all RD manifestations (0.5). In contrast, in the control group, the average RTOG value at point T4 was comparable to the peak RTOG value at point T2 (1.3/1.23), which may indicate pronounced reparative and restorative properties of the cream.

Skin inflammation (dermatitis) is almost always accompanied by subjective symptoms such as itching, pain, and burning [17–19]. In our study, the pruritogenic potential of radiation dermatitis (RD) in patients from both the study and control groups did not show significant differences. The intensity of itching increased in all patients to maximum values at points T1–T2 and then rapidly decreased to near absence by the end of RT (T3) (Fig. 2).

It should be noted that in more than half of the cases, itching did not develop at all. This may be due to inadequate self-assessment by patients, who often had difficulty determining whether they were more bothered by itching, burning, or painful sensations in the affected area (Table 6).

Since the quantitative values of the RTOG scale in both groups did not exceed G2 limits, no severe manifestations of radiation dermatitis (RD), such as ulceration, necrosis, or hemorrhage, were recorded at any of the control points (T0–T4) (Table 5).

The vascular reactions of the dermal structures in dermatitis of various etiologies are typically assessed by criteria such as «erythema» and «edema.» Lower values for the «erythema» criterion were reliably observed in the study group throughout most of the observation period (T1, T3, T4). Edema developed more rapidly in the control group, with digital indicators at points T1 and T2 being significantly higher – by 3 and 2 times, respectively – compared to the study group (Table 5, Fig. 3).

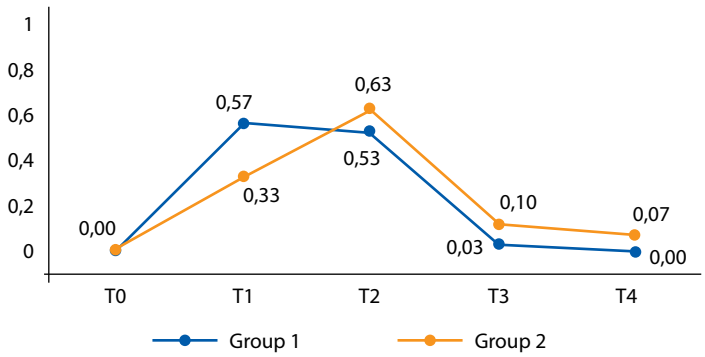

Fig. 2. Curve of itching assessment in the study and control groups over time

Table 6
Assessment of itching in the study and control groups throughout observation period

Score	T0		T1		T2		T3		T4	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
0	30 (100)	30 (100)	16 (53.3)	20 (66.7)	15 (50)	13 (43.3)	29 (96.7)	27 (90)	30 (100)	28 (93.3)
1	–	–	11 (36.7)	10 (33.3)	14 (46.7)	15 (50)	1 (3.3)	3 (10)	–	2 (6.7)
2	–	–	3 (10)	–	1 (3.3)	2 (6.7)	–	–	–	–
3	–	–	–	–	–	–	–	–	–	–
4	–	–	–	–	–	–	–	–	–	–

The involvement of the follicular apparatus was minimal in both groups, with folliculitis developing infrequently even in the control group. A reliable difference in folliculitis was observed only at point T3. There were no consistent reliable differences between the groups due to the generally low values of this criterion at any of the control points (Table 6, Fig. 3).

Desquamation peaked at point T3. Excessive desquamation and dryness indicate a disruption in the skin barrier function, including defects in the stratum corneum of the epidermis and its lamellar structure [21–23]. By point T4, 90% of patients in the study group showed complete restoration of this indicator, whereas nearly 60% of patients in the control group had not restored skin barrier function. Dryness, a key indicator of skin barrier failure, was significantly lower in the study group compared to the control group throughout RT and upon its completion (T1–T4) (Table 7, Fig. 3).

Table 7
Dynamic assessment of local status according to the criteria "erythema", "folliculitis", "dry peeling", "epilation", "dryness", "edema", "ulceration/necrosis/hemorrhage" in the study and control groups

Score	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Erythema										
	T0		T1**		T2		T3***		T4***	
0	30 (100)	30 (100)	16 (53.3)	5 (16.7)	1 (3.3)	1 (3.3)	10 (33.3)	2 (6.7)	20 (66.7)	5 (16.7)
1	–	–	14 (46.7)	21 (70)	20 (66.7)	14 (46.7)	15 (50)	4 (13.3)	7 (23.3)	13 (43.3)
2	–	–	–	4 (13.3)	8 (26.7)	12 (40)	5 (16.7)	21 (70)	3 (10)	11 (36.7)
3	–	–	–	–	1 (3.3)	3 (10)	–	3 (10)	–	1 (3.3)
4	–	–	–	–	–	–	–	–	–	–
Folliculitis										
	T0		T1		T2		T3**		T4	
0	30 (100)	30 (100)	28 (93.3)	29 (96.7)	26 (86.7)	26 (86.7)	30 (100)	22 (73.3)	–	–
1	–	–	2 (6.7)	1 (3.3)	4 (13.3)	4 (13.3)	–	5 (16.7)	–	–
2	–	–	–	–	–	–	–	3 (10)	–	–
3	–	–	–	–	–	–	–	–	–	–
4	–	–	–	–	–	–	–	–	–	–
Dry desquamation										
	T0		T1		T2*		T3		T4**	
0	30 (100)	30 (100)	30 (100)	26 (86.7)	14 (46.7)	15 (50)	20 (66.7)	13 (43.3)	26 (86.7)	13 (43.3)
1	–	–	–	4 (13.3)	6 (20)	14 (46.7)	6 (20)	5 (16.7)	3 (10)	14 (46.7)
2	–	–	–	–	–	1 (3.3)	4 (13.3)	11 (36.7)	1 (3.3)	2 (6.7)
3	–	–	–	–	–	–	–	1 (3.3)	–	1 (3.3)
4	–	–	–	–	–	–	–	–	–	–

Epilation										
	T0		**T1**		**T2**		**T3**		**T4**	
0	30 (100)	30 (100)	30 (100)	26 (86.7)	27 (90)	25 (83.3)	24 (80)	22 (73.3)	23 (76.7)	16 (53.3)
1	–	–	–	4 (13.3)	3 (10)	5 (16.7)	6 (20)	8 (26.7)	7 (23.3)	14 (46.7)
2	–	–	–	–	–	–	–	–	–	–
3	–	–	–	–	–	–	–	–	–	–
4	–	–	–	–	–	–	–	–	–	–
Dryness										
	T0		**T1***		**T2****		**T3****		**T4****	
0	30 (100)	30 (100)	29 (96.7)	22 (73.3)	20 (66.7)	10 (33.3)	20 (66.7)	8 (26.7)	26 (86.7)	11 (36.7)
1	–	–	1 (3.3)	8 (26.7)	9 (30)	8 (26.7)	7 (23.3)	7 (23.3)	2 (6.7)	9 (30)
2	–	–	–	–	1 (3.3)	12 (40)	1 (3.3)	6 (20)	2 (6.7)	8 (26.7)
3	–	–	–	–	–	–	2 (6.7)	9 (30)	–	2 (6.7)
4	–	–	–	–	–	–	–	–	–	–
Edema										
	T0		**T1***		**T2****		**T3**		**T4**	
0	30 (100)	30 (100)	25 (83.3)	15 (50)	18 (60)	9 (30)	20 (66.7)	15 (50)	25 (83.3)	22 (73.3)
1	–	–	5 (16.7)	11 (36.7)	12 (40)	13 (43.3)	6 (20)	9 (30)	4 (13.3)	7 (23.3)
2	–	–	–	4 (13.3)	–	8 (26.7)	4 (13.3)	6 (20)	1 (3.3)	1 (3.3)
3	–	–	–	–	–	–	–	–	–	–
4	–	–	–	–	–	–	–	–	–	–
Ulceration/necrosis/hemorrhage										
	T0		**T1**		**T2**		**T3**		**T4**	
0	30 (100)	30 (100)	30 (100)	30 (100)	30 (100)	30 (100)	30 (100)	29 (96.7)	30 (100)	30 (100)
1	–	–	–	–	–	–	–	1 (3.3)	–	–
2	–	–	–	–	–	–	–	–	–	–
3	–	–	–	–	–	–	–	–	–	–
4	–	–	–	–	–	–	–	–	–	–

Notes: *p<0,05; ** p<0,01; *** p<0,001.

As a rule, the manifestations of radiation dermatitis (RD) typically resolve over time. However, they can significantly impact the patient's quality of life, limit the duration of treatment and the total radiation dose, and directly affect the effectiveness of the therapy [4, 10]. In our observation, we did not find significant changes in the Dermatological Quality of Life Index (DQLI) scores (Table 8, Fig. 4). We do not believe that radiation therapy (RT) has no effect on the quality of life of our patients. The extremely low DQLI values are likely due to two main factors. First, since patients were hospitalized throughout the entire RT period, their responses to questions about interpersonal relationships, daily life, and social activities were negatively skewed. Second, patients had difficulty distinguishing and accurately assessing their subjective symptoms, often confusing "itching" with "pain", "burning" or "discomfort".

Table 8
Assessment of quality of life in the study and control groups over time

	T0	**T1**	**T2**	**T3***	**T4**
Group 1	0	0,57±0,62	0,67±0,80	0,13±0,43	0,03±0,18
Group 2	0	0,47±0,57	1,0±0,91	0,5±0,93	0,17±0,75

Note: * p<0,05.

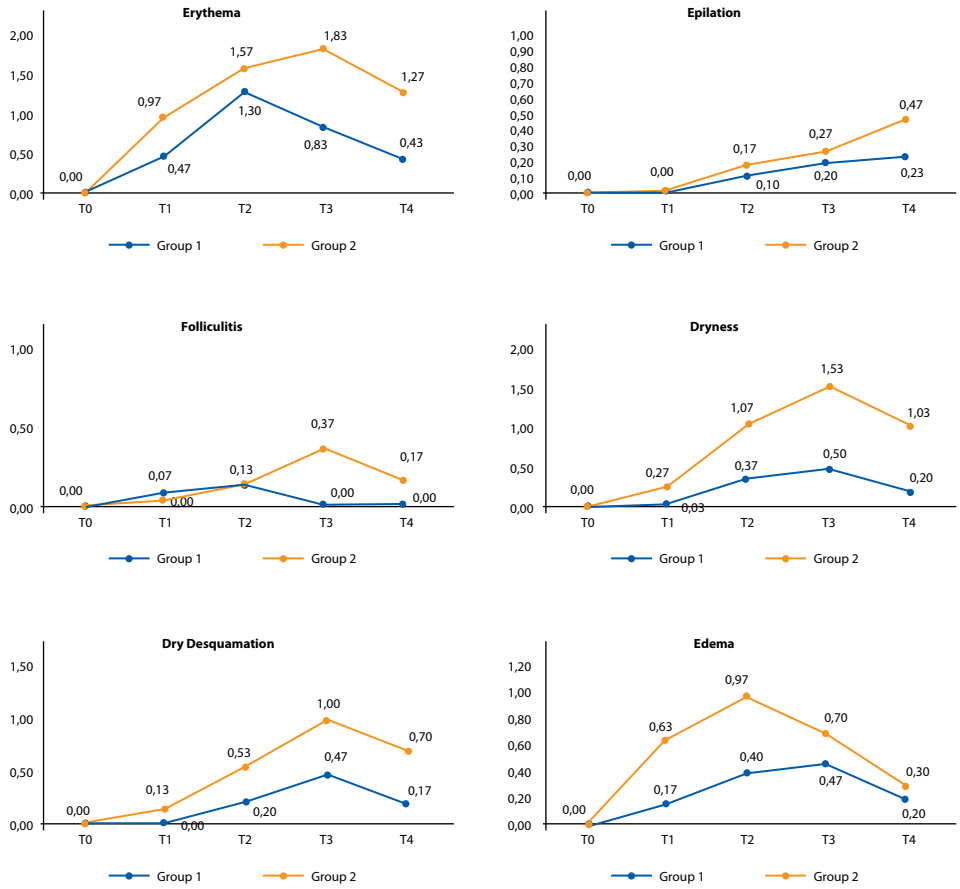

Fig. 3. Scores throughout observation period of the criteria "erythema", "folliculitis", "dry peeling", "epilation", "dryness", "edema", "ulceration/necrosis/hemorrhage" in the study and control groups

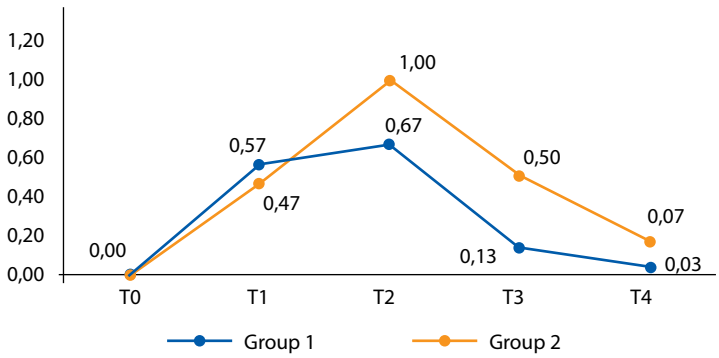

Fig. 4. Dynamics of the "Quality of Life" score in the study and control groups throughout observation

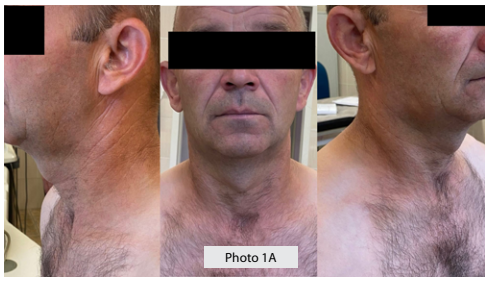

Фото 1A.
Точка 0, RTOG 0
Пациент У, группа 1 (исследуемая), 48 лет
Диагноз: Рак боковой стенки ротоглотки, корня языка справа с МТС в л/у шеи справа
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 1A.
Point 0, RTOG 0
Patient U, group 1 (study), 48 y.o.
Diagnosis: Cancer of the lateral wall of the oropharynx, root of the tongue on the right with MTS in the lymph nodes of the neck on the right
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность	Indicator	Intensity
RTOG	0	RTOG	0
Зуд	0	Pruritus	0
Эритема	0	Erythema	0
Фолликулит	0	Folliculitis	0
Шелушение	0	Desquamation	0
Отек	0	Edema	0
Ульцерация	0	Ulceration	0

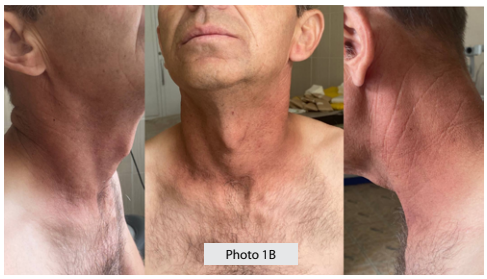

Фото 1B.
Точка 1, RTOG 1
Пациент У, группа 1 (исследуемая), 48 лет
Диагноз: Рак боковой стенки ротоглотки, корня языка справа с МТС в л/у шеи справа
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 1B.
Point 1, RTOG 1
Patient U, group 1 (study), 48 y.o.
Diagnosis: Cancer of the lateral wall of the oropharynx, root of the tongue on the right with MTS in the lymph nodes of the neck on the right
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность	Indicator	Intensity
RTOG	1	RTOG	1
Зуд	1	Pruritus	1
Эритема	1	Erythema	1
Фолликулит	0	Folliculitis	0
Шелушение	0	Desquamation	0
Отек	0	Edema	0
Ульцерация	0	Ulceration	0

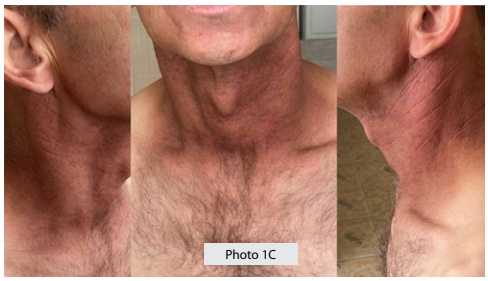

Фото 1C.
Точка 2, RTOG 1
Пациент У, группа 1 (исследуемая), 48 лет
Диагноз: Рак боковой стенки ротоглотки, корня языка справа с МТС в л/у шеи справа
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 1C.
Point 2, RTOG 1
Patient U, group 1 (study), 48 y.o.
Diagnosis: Cancer of the lateral wall of the oropharynx, root of the tongue on the right with MTS in the lymph nodes of the neck on the
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность	Indicator	Intensity
RTOG	1	RTOG	1
Зуд	1	Pruritus	1
Эритема	1	Erythema	1
Фолликулит	1	Folliculitis	0
Шелушение	0	Desquamation	0
Отек	0	Edema	0
Ульцерация	0	Ulceration	0

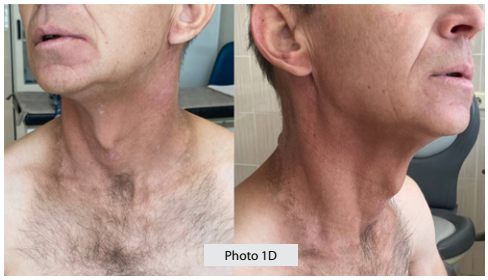

Фото 1D.
Точка 3, RTOG 1
Пациент У, группа 1 (исследуемая), 48 лет
Диагноз: Рак боковой стенки ротоглотки, корня языка справа с МТС в л/у шеи справа
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 1D.
Point 3, RTOG 1
Patient U, group 1 (study), 48 y.o.
Diagnosis: Cancer of the lateral wall of the oropharynx, root of the tongue on the right with MTS in the lymph nodes of the neck on the right
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность	Indicator	Intensity
RTOG	1	RTOG	1
Зуд	0	Pruritus	0
Эритема	0	Erythema	0
Фолликулит	0	Folliculitis	0
Шелушение	1	Desquamation	1
Отек	0	Edema	0
Ульцерация	0	Ulceration	0

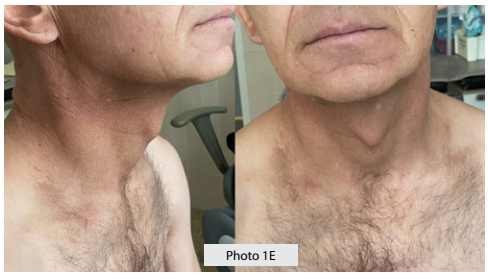

Фото 1E.
Точка 4, RTOG 0
Пациент У, группа 1 (исследуемая), 48 лет
Диагноз: Рак боковой стенки ротоглотки, корня языка справа с МТС в л/у шеи справа
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 1E.
Point 4, RTOG 0
Patient U, group 1 (study), 48 y.o.
Diagnosis: Cancer of the lateral wall of the oropharynx, root of the tongue on the right with MTS in the lymph nodes of the neck on the right
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность	Indicator	Intensity
RTOG	0	RTOG	0
Зуд	0	Pruritus	0
Эритема	0	Erythema	0
Фолликулит	0	Folliculitis	0
Шелушение	0	Desquamation	0
Отек	0	Edema	0
Ульцерация	0	Ulceration	0

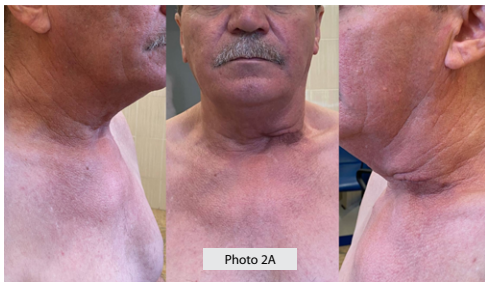

Фото 2А.
Точка 0, RTOG 0
Пациент А, группа 2 (контроль), 58 лет
Диагноз: МТС в л/у шеи из НПО (невыявленный первичный очаг)
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 2A.
Point 0, RTOG 0
Patient A, group 2 (control), 58 y.o.
Diagnosis: metastases to lymph nodes of the neck from unidentified primary tumor
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность
RTOG	0
Зуд	0
Эритема	0
Фолликулит	0
Шелушение	0
Отек	0
Улькерация	0

Indicator	Intensity
RTOG	0
Pruritus	0
Erythema	0
Folliculitis	0
Desquamation	0
Edema	0
Ulceration	0

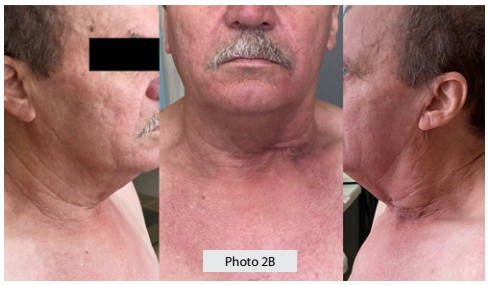

Фото 2В.
Точка 1, RTOG 1
Пациент А, группа 2 (контроль), 58 лет
Диагноз: МТС в л/у шеи из НПО (невыявленный первичный очаг)
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 2B.
Point 1, RTOG 1
Patient A, group 2 (control), 58 y.o.
Diagnosis: metastases to lymph nodes of the neck from unidentified primary tumor
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность
RTOG	1
Зуд	1
Эритема	1
Фолликулит	0
Шелушение	0
Отек	0
Улькерация	0

Indicator	Intensity
RTOG	1
Pruritus	1
Erythema	1
Folliculitis	0
Desquamation	0
Edema	0
Ulceration	0

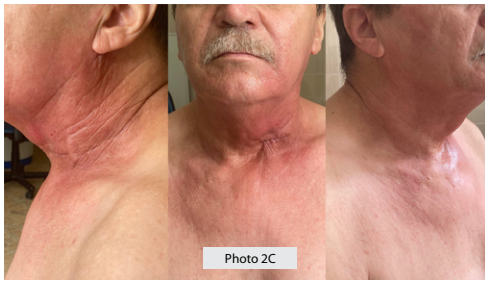

Фото 2С.
Точка 2, RTOG 2
Пациент А, группа 2 (контроль), 58 лет
Диагноз: МТС в л/у шеи из НПО (невыявленный первичный очаг)
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 2C.
Point 2, RTOG 2
Patient A, group 2 (control), 58 y.o.
Diagnosis: metastases to lymph nodes of the neck from unidentified primary tumor
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность
RTOG	2
Зуд	1
Эритема	2
Фолликулит	0
Шелушение	0
Отек	1
Улькерация	0

Indicator	Intensity
RTOG	2
Pruritus	1
Erythema	2
Folliculitis	0
Desquamation	0
Edema	1
Ulceration	0

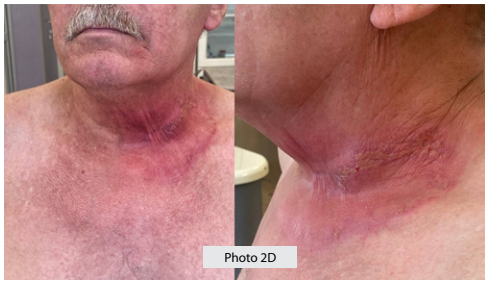

Фото 2D.
Точка 3, RTOG 4
Пациент А, группа 2 (контроль), 58 лет
Диагноз: МТС в л/у шеи из НПО (невыявленный первичный очаг)
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 2D.
Point 3, RTOG 4
Patient A, group 2 (control), 58 y.o.
Diagnosis: metastases to lymph nodes of the neck from unidentified primary tumor
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность
RTOG	4
Зуд	1
Эритема	3
Фолликулит	0
Шелушение	1
Отек	2
Улькерация	1

Indicator	Intensity
RTOG	4
Pruritus	1
Erythema	3
Folliculitis	0
Desquamation	1
Edema	2
Ulceration	1

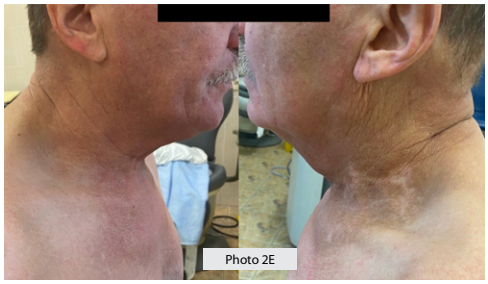

Фото 2Е.
Точка 4, RTOG 1
Пациент А, группа 2 (контроль), 58 лет
Диагноз: МТС в л/у шеи из НПО (невыявленный первичный очаг)
Зона облучения: лицевой череп и шея, СОД (суммарная очаговая доза) 70 Гр

Photo 2E.
Point 4, RTOG 1
Patient A, group 2 (control), 58 y.o.
Diagnosis: metastases to lymph nodes of the neck from unidentified primary tumor
Irradiation zone: facial skull and neck, TFD (Total Focal Dose) 70 Gy

Показатель	Интенсивность
RTOG	1
Зуд	0
Эритема	1
Фолликулит	0
Шелушение	1
Отек	1
Улькерация	0

Indicator	Intensity
RTOG	1
Pruritus	0
Erythema	1
Folliculitis	0
Desquamation	1
Edema	1
Ulceration	0

НА ПЕРВУЮ | НА СЛЕДУЮЩУЮ | НА ПРЕДЫДУЩУЮ | К СОДЕРЖАНИЮ

Photos 1 (A, B, C, D, E) and 2 (A, B, C, D, E) illustrate the clinical observations throughout this period for both the study and control groups. Patients in the study group rated the moisturizing and soothing effects of the test cream highly, with scores of 4.8 and 4.4, respectively, on a 5-point scale. They were satisfied with the cream's application and absorption and reported no complaints about its color or texture. During the study, no adverse reactions, including toxic responses, were recorded that could be attributed to contact allergy to the cream.

■ CONCLUSIONS

The use of Bioakè Xerophy repairing anti-scratching cream in patients with head and neck tumors significantly reduces the severity of toxic skin reactions associated with radiodermatitis during radiation therapy and ensures rapid restoration of the skin's barrier function after treatment:

1. RTOG Values: The RTOG scores in the study group were significantly lower than those in the control group.
2. Edema and Erythema: These primary manifestations of dermal inflammation developed significantly more frequently and rapidly in the control group compared to the study group.
3. Dryness and Desquamation: Indicators of impaired skin barrier function and epidermal failure (epidermitis) were minimal in the study group. Unlike the control group, where only partial restoration of skin barrier function was observed 2 weeks after the end of radiation therapy, patients using Bioakè Xerophy repairing anti-scratching cream achieved nearly complete restoration.
4. Patients in the study group highly rated the moisturizing and soothing effects of Bioakè Xerophy repairing anti-scratching cream, noting its ease of application and good absorption.
5. Furthermore, absence of notable side effects attests to Bioakè Xerophy repairing anti-scratching cream 's high degree of safety and tolerability, and it may inspire future research into the cream's potential as a useful therapy to promote skin wellness and the quality of life of oncological patients.
6. Further studies are recommended to make Bioakè Xerophy repairing anti-scratching cream standardized and to assess the effects of its dosage, duration and the repetition of treatments.
7. The inability to accurately assess the status of skin by biopsy was one of the limitations of this study.

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