

INTRALESIONAL INJECTION OF FOTOLON FOR PHOTODYNAMIC THERAPY OF BASAL CELL CARCINOMA

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Abstract

The new method of photodynamic therapy for basal cell skin carcinoma with intralesional injection of photolon (at dose of 1.44-2.50 mg/cm³ of tumor volume 15 min before irradiation) was developed in the department of dermatology, venerology and dermatooncology in The State Budgetary Healthcare Institution of Moscow Area Moscovs regional research clinical institute n.a. M.F. Vladimirskiy. The efficacy of the developed method was evaluated in clinical studies in 30 patients comparing with the group of 32 patients who had conventional PDT with typical intravenous injection of photolon (at dose of 2.0–2.5 mg/kg of body weight 3 h before irradiation). The characteristics of irradiation were the same both in the study and in the control groups: power density of 0.31-0.47 W/cm², light dose of 300 J/cm². Compared PDT regimens had similar efficiency. As a result of the performed treatment complete tumor regression was achieved in 93.3% patients with intralesional injection of photolon and in 90.6% patients with intravenous injection. The rate of patients with 2-year recurrence-free survival after intralesional injection of photolon accounted for 96.7%; after intravenous injection – 93.8%. However, the developed method demonstrated superior safety comparing with intravenous injection of photolon: such as there was no need for light regimen after intralesional injection of photolon, there were no cases of skin phototoxicity (12.5% for intravenous injection), no increasing of transaminases (37.5% for intravenous injection).

Keywords: photodynamic therapy, oncology, dermatology, basal cell carcinoma of skin, photosensitizer, photolon, chlorine e₆.

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Introduction

The share of malignant skin neoplasms in the pattern of cancer morbidity in Russia is around 12%; they take the 2nd or 3rd place in incidence after lung-, stomach- and breast cancer. The most widespread among them is basal-cellular skin cancer (BCSC) – a neoplasm with locally invasive growth and rare metastasing. The share of BCSC in the general pattern of skin tumors reaches 90% [1]. Depending on applied therapy methods, the incidence of primary BCSC relapses reaches 42,9%, and the incidence of relapsing BCSC – 80,0 % [2]. Frequent relapsing and predominant localization on the head and neck skin determines the important practical value of this neoplasm treatment development and improvement of its methods.

Over recent years, the researchers often pay attention to application of physical methods of BCSC treatment [3–5]. Starting from 1992, in Russia, they use the photodynamic therapy method (PDT) for treatment of malignant skin neoplasms; it is based on ability of certain chemical substances (photosensitizers) to accumulate in the neoplasm tissue and to cause photochemical reactions under the influence of light with a certain wavelength, which leads to destruction of tumor cells [6, 7].

In recent years, cellular and tissue targets of PDT, as well as its mechanisms of action, have been the subjects of many experimental researches [8–10]. Different methods of endovenous-, intra-focal- and contact use of photosensitizers in experimental [11–13] and clinical studies [14–20] are under development.

The PDT effectiveness during BCSC treatment depends on the neoplastic process stage, photosensitizer chemical structure and dose, and parameters of tumor irradiation. The studies of recent years demonstrate a possibility of successful use of PDT for treatment of different skin tumors [21–23] and tumors with other localization [24–30].

There is available information on successful intra-focal administration of hematoporphyrin and photoditazin derivative – a chlorine series preparation. In our research, we studied PDT efficiency during intra-focal administration of another chlorine e_6 – based preparation – photolon.

The previously conducted experimental studies [9, 10] created basic prerequisites for the development of photolon clinical application regimen and treatment regimen for patients with BCSC.

Materials and methods

The study is based on the cases of 62 patients with BCSC of stage T1-3NOMO, undergoing medical treatment at the Department of Dermatovenereology and Dermatooncology of the State-Financed Health Care Institution of the Moscow Region “Moscow Regional Scientific-Research Clinical Institute named after M.F. Vladimirovskiy”. The patients underwent PDT with intra-focal (30 patients) and endovenous (32 patients) administration of photolon preparation (Republican Unitary Enterprise “Belmedpreparaty”, Republic of Belarus).

All patients were diagnosed with BCSC on the basis of the results of morphological studies performed in the clinical laboratory and Department of Pathomorphology of Moscow Regional Institute named after M.F. Vladimirovskiy.

Depending on the method of photolon administration, there were two groups of patients. The 1st (main) group included 30 patients at the age from 36 to 75; they were administered photolon intra-focally. The 2nd (control group) included 32 patients at the age from 39 to 78 who were administered photolon intravenously.

The criteria for inclusion of the patients into the research included: presence of solitary and multiple focal points of BCSC of stage T1-3NOMO, tumors with “inconvenient” localizations (parotic-, periorbital areas, nose, etc.), patients’ refusal to undergo radiation- and surgical treatment. Both groups did not statistically differ from each other by the main clinical indices, histologic characteristics of BCSC, comorbidities. In both groups, the ulcerated- and nodular forms of neoplasms were prevailing. Most frequent types were the solid- and surface multicentric BCSC. The most frequent comorbidities were the diseases of the cardiovascular system (CVS), digestive tract, nervous system. In both groups, patients with neoplastic process prevalence rate T1-2 (90,3%) prevailed.

Laser irradiations were conducted with medical lasers for PDT: “LAMI” (662 nm) and “Lameda”

(666 nm). For the supply of light, use was made of flexible quartz single-fiber light guides with a lens disperser. Light energy was supplied perpendicularly to the neoplasm surface; it covered 0,5-1,0 cm of the surrounding healthy skin. The power density of the supplied laser radiation was 0,31-0,47 W/cm², the energy density – 300 J/cm². DI-6A power meter was used to measure the laser radiation power.

Photolon preparation is a complex of chlorine e₆ and its derivatives with polyvinyl pyrrolidone, with the peak absorption of 666 nm.

For intra-focal use, photolon was dissolved directly before administration in 20 ml of normal saline solution, stirred up and kept for 5 minutes for deposition of the foam. After the neoplasm surface treatment with 70% ethyl alcohol, the patients were administered photolon solution directly into the tumor 15 minutes before irradiation. The dose of the administered preparation was 1,44-2,50 mg/cm³.

For endovenous administration of the preparation, photolon was dissolved, directly before the infusion, in 40 ml of normal saline solution, stirred up and kept for 5 minutes for deposition of the foam. After that, the solution was put into a vial with 150 ml of normal saline solution and administered to the patient endovenously, dropwise, at the rate of 2,0-2,5 mg/kg of the patient's body weight, 3 hours before the radiation. The duration of the preparation infusion was minimum 30-40 min.

During intra-focal administration of photolon, compliance with the light regime was not required. During endovenous administration of photolon, all patients were advised to comply with the limited light regime throughout the treatment period. During the first 5 days after PDT, the patients stayed in wards protected from light. The patients were advised to wear sun glasses and lightproof clothes. Starting from the 6th day after PDT, the patients were allowed to expand their light regime.

In order to protect healthy skin tissues during PDT, these zones were screened with black paper. 1 hour prior to PDT, we conducted standard pre-medication with intramuscular injection of butorphanol in the volume of 1,0 ml.

During the treatment process, in order to prevent the patients from secondary infection development,

they took antibiotics; the focal areas of destruction were treated with 5%-solution of potassium permanganate 3-5 times a day. After the treatment, the patients were advised to take antioxidants.

The immediate-, short-term- and later results of PDT were compared with the method of photolon administration and evaluated in compliance with the WHO criteria (1996). After the treatment, the patients were examined daily during the first five days, then once a week, then once a month during three months, and finally – once every 6 months. The patients underwent a regular medical check-up during 2 years.

Results and discussion

In the process of PDT, we observed signs of a photochemical reaction, progressing in the tumor, which later caused the tumor destruction. The subjective evidence of the photochemical reaction included sensations of pain of different intensity, heat and tingling, which could remain during a few days after PDT and, in individual cases, required administration of analgesics. The intensity of these sensations depended on the density of the supplied light energy, the size of the tumor and the depth of its invasion. In case of neoplasm was localized in the head, a facial edema was observed, sometimes with transition onto the neck, which subsided in 2-4 days without treatment. Patients endured the treatment easily. After 3-5 days, on the place of the neoplasm, a necrotic eschar was formed, which sloughed by itself on the 20-30th day, or, in case of a generalized process (T2-3N0M0), – in 1,5-2,0 months. After the necrotic eschar rejection, a pale pink scar was formed on the place of the tumor destruction; it was soft and non-glomerate with the surrounding tissues.

Short-term results of BCSC PDT with intra-focal administration of photolon solution are presented in Table 1.

Short-term results of BCSC PDT with intravenous administration of photolon solution are presented in Table 2.

As a result of the conducted therapy, full regression of BCSC in the case of photolon intra-focal administration was achieved in 28 (93,3%) patients, in the case of endovenous administration – in 29 (90,6%) patients.

Table 1.
Immediate results of PDT for skin BCC with intralesional injection of photolon

Clinical type of skin BCC	Number of patients/number of tumors	Tumor regression	
		Complete	Partial
Superficial	7/9	7	-
Ulcerative	10/10	9	1
Nodular	12/13	12	-
Morpheaform	1/1	-	1
Total	30/33	28	2

Table 2.
Immediate results of PDT for skin BCC with intravenous injection of photolon

Clinical type of skin BCC	Number of patients/number of tumors	Tumor regression	
		Complete	Partial
Superficial	6/7	6	-
Ulcerative	11/12	10	1
Nodular	13/13	12	1
Morpheaform	2/2	1	1
Total	32/34	29	3

Afterhistory results of BCSC PDT with different methods of photolon administration are shown in the Fig.

The share of patients with a 2-year relapse-free period in the group treated with the intra-focal photolon administration method was 96,7%; in the group with endovenous administration – 93,8%.

During the evaluation of the treatment effectiveness, esthetic results were also taken into account, as BCSC was often localized in the area of the head and neck (79% of patients). After intra-focal use of photolon, healing was quicker; an eschar was formed on the treated place, it sloughed by itself on the 20-30th day, and, in case of a generalized process,

– in 1,5-2,0 months. After PDT with endovenous administration of photolon, the eschar stayed for 2-2,5 months; the resulting soft scars were non-glomerate with the surrounding tissue and satisfactory from the esthetic point of view. Good cosmetic results of PDT are related to the minimum damage of collagen fibers, which creates optimal conditions for healing of the defects. For this reason, in many cases after PDT, there occurs “an effect of complete regeneration of tissues” regardless of the way of the preparation administration.

Thus, the conducted research did not reveal differences in immediate and remote effectiveness of BCSC PDT with intra-focal and endovenous

administration of photolon. However, during PDT with local administration of photolon, there were a number of observed considerable advantages in the treatment safety. So, the main side effects of PDT with endovenous administration of photolon are determined by skin phototoxicity related to the accumulation of the photosensitizer in the patient's skin, which requires compliance with the light regime. All patients undergoing PDT with endovenous administration of photolon are advised to comply with the strict light regime throughout the treatment period. Due to noncompliance with the light regime, 4 (12,5%) patients observed a photocontact dermatitis of open skin areas. In 12 (37,5%) patients, doctors observed an increase in blood transaminase. During PDT, 5 (15,6%) patients (with hypertensive disease) noted an increase in arterial pressure (after conducting of antihypertensive therapy the pressure was normalized); 2 (6,2%) patients had subfebrile temperature during 2 days after the treatment. During local use of the preparation, compliance with the light regime was not required and the above described side effects were not registered.

Conclusion

The authors developed the PDT method for treatment of patients with BCSC of T1-3N0M0 stage, presupposing intra-focal administration of photolon, the active substance of which is chlorine e_6 .

The comparative study shows that the developed method, in terms of its effectiveness for patients with BCSC, is comparable to traditional endovenous administration of photolon, and, in terms of its safety, demonstrates even better results in the studied groups.

The authors have made a conclusion that PDT with endovenous administration of the photosensitizer is an inexpensive and effective method of BCSC treatment. It is characterized by a good cosmetic result, does not require strict compliance with the light regime and has no side effects and complications. It can be used without taking into account age-related limitations and presence of comorbidities. This is a method of choice for patients with a heavy somatic pathology and patients of the senior age group; it can be used repeatedly in case of the disease relapse, and is recommended for application at outpatient departments.

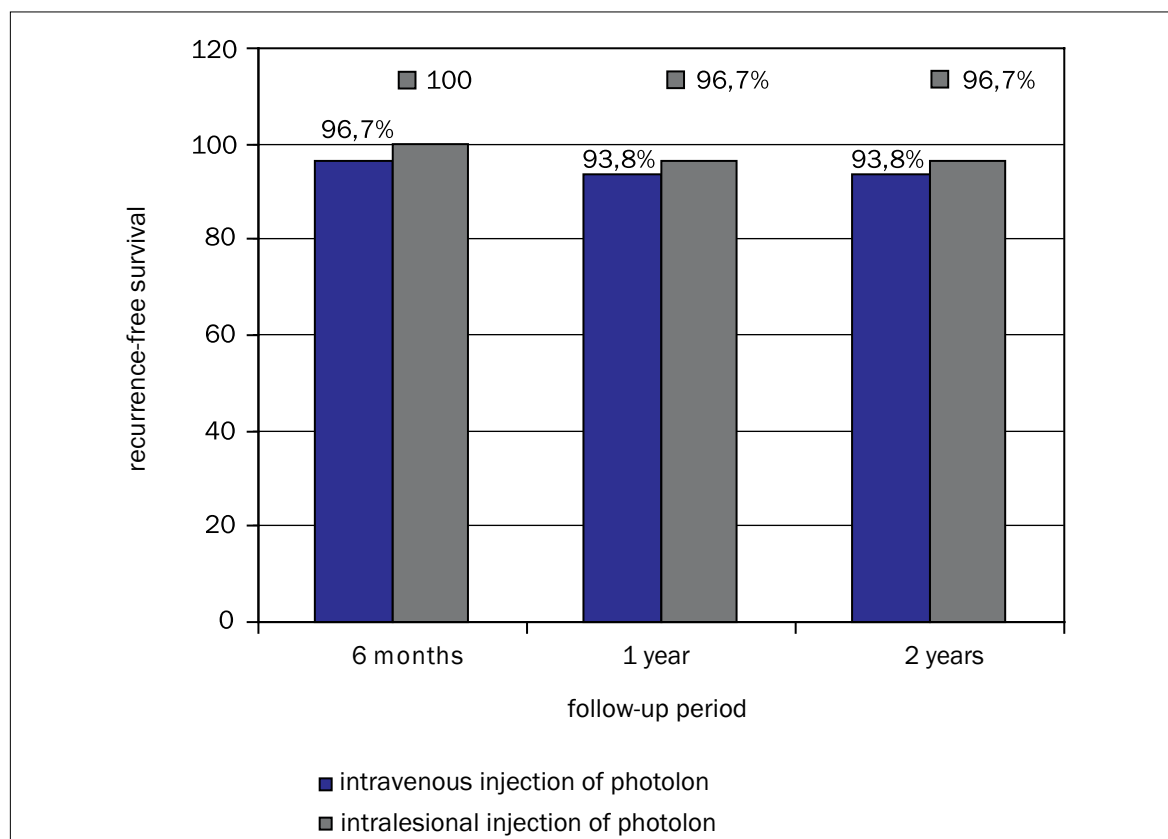


Fig. Recurrence-free survival of patients after PDT with photolon

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