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ORIGINAL ARTICLE

A method for determining resection margins in basal cell carcinoma of the skin

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ABSTRACT

Purpose of the study. To investigate the feasibility of applying a method of visual diagnosis of basal cell carcinoma (BCC) under ultraviolet (UV) light using Photoditazine for determining tumor margins in clinical practice.
Patients and Methods. The study was conducted at the Department of Reconstructive and Plastic Surgery and Oncology, National Medical Research Center for Oncology. Sixty patients (men and women) with cytologically verified stage I–II BCC were included. Among them, 30 patients (15 men and 15 women) presented with a superficial growth pattern, and 30 patients (15 men and 15 women) with a solid growth pattern. In all cases, Photoditazine gel-penetrant was applied topically to the tumor surface and the surrounding area (1.5–2 cm) for 30 minutes. The gel was then removed with a gauze swab moistened with distilled water. Under UV light in a dark room, a characteristic fuchsia fluorescence of the tumor and a pale or dark-red halo around the lesion were observed. This enabled assessment of the tumor spread into adjacent tissues that initially appeared visually unaffected.
Results. The study yielded the following findings: in 33 patients, the peritumoral area showed no fluorescence, whereas in 27 patients, zones of enhanced fluorescence ("hot spots") were detected around the tumor. These areas exhibited a round or irregular shape and were characterized by an intense dark-red fluorescence surrounding the tumor focus. Extensive "hot spots" indicated active adsorption of the photosensitizer in the area, which may result from altered hormonal and metabolic properties of the peritumoral skin. In cases where extensive peritumoral fluorescence was identified, the area should be included within the resection field as a potentially high-risk zone for subsequent recurrence.
Conclusion. The proposed method is simple to use, does not require expensive equipment or systemic administration of the photosensitizer, and therefore avoids patient inconvenience and precautionary restrictions. Detection of peritumoral fluorescence enables accurate determination of true tumor margins and facilitates subsequent surgical excision with an optimal margin from the visible edge of the lesion. These advantages support the recommendation of this method for broad implementation in routine practice of specialized medical institutions.

Keywords: basal cell carcinoma of the skin, photoditazine, recurrence, resection line, ultraviolet light

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Compliance with ethical standards: the study was carried out in compliance with the ethical principles outlined in the World Medical Association Declaration of Helsinki (1964, revised 2013). Ethical approval was obtained from the Ethics Council of the National Medical Research Center of Oncology (Protocol No. 29, dated 09/09/2022). Informed consent was obtained from all participants in the study

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ОРИГИНАЛЬНАЯ СТАТЬЯ

Метод определения границ резекции базальноклеточного рака кожи

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РЕЗЮМЕ

Цель исследования. Изучение возможности применения в клинической практике метода визуальной диагностики базальноклеточного рака кожи в ультрафиолетовом свете с использованием фотодитазина для определения границ распространения опухоли.

Пациенты и методы. Данное исследование проводилось на базе отделения реконструктивно-пластической хирургии и онкологии ФГБУ «Национальный медицинский исследовательский центр онкологии» Министерства здравоохранения Российской Федерации. В исследование были включены 60 мужчин и женщин с цитологически верифицированным базальноклеточным раком кожи I–II стадии, из них: 30 человек (15 мужчин и 15 женщин) с поверхностным типом роста опухоли, 30 человек (15 мужчин и 15 женщин) с солидным типом роста опухоли. Всем пациентам на поверхность опухоли и зону вокруг нее (1,5–2 см) наносился гель-пенетратор фотодитазин в виде аппликации на 30 мин., затем удалялся марлевой салфеткой, смоченной дистиллированной водой. Далее в темном помещении при помощи ультрафиолетового источника света отмечалось характерное свечение опухоли цвета фуксии и бледный или темно-красный ореол вокруг опухоли. Таким образом определялось распространение опухолевого процесса на окружающие, изначально визуально не измененные ткани.

Результаты. В ходе исследования были получены следующие результаты: у 33 пациентов зона вокруг опухоли не демонстрировала никакого свечения, тогда как у 27 – наблюдались участки повышенной флуоресценции вокруг опухоли – так называемые «засветы». Эти области имели округлую или неправильную форму и характеризовались интенсивным темно-красным свечением, окружающем опухолевый очаг. Обширные «засветы» свидетельствуют об активной адсорбции фотосенсибилизатора в данной области, которая возникает вследствие изменения гормонально-метаболических свойств кожи вокруг опухоли. При выявлении обширного перитуморального «засвета» данную область следует включать в резецируемое поле как потенциально опасную зону в отношении последующего рецидивирования.

Заключение. Предлагаемый метод прост в использовании, не требует дорогостоящего оборудования и системного пути введения фотосенсибилизатора, что позволяет избежать ряда неудобств и соблюдения мер предосторожности пациентами. Перитуморальная флуоресценция позволяет определить истинные границы распространения опухолевого процесса и выполнить дальнейшее хирургическое иссечение с оптимальным отступом от видимого края опухолевого поражения. Все вышеперечисленные достоинства позволяют рекомендовать данный метод для широкого внедрения в рутинную практику специализированных лечебных учреждений.

Ключевые слова: базальноклеточный рак кожи, фотодитазин, рецидив, линия резекции, ультрафиолетовый свет

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Соблюдение этических стандартов: в работе соблюдались этические принципы, предъявляемые Хельсинкской декларацией Всемирной медицинской ассоциации (World Medical Association Declaration of Helsinki, 1964, ред. 2013). Исследование одобрено на заседании совета по этике при ФГБУ «Национальный медицинский исследовательский центр онкологии» Министерства здравоохранения Российской Федерации (выписка из протокола заседания № 29 от 09.09.2022 г.).
Информированное согласие получено от всех участников исследования

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BACKGROUND

Due to its high prevalence and increasing incidence, the timely and accurate diagnosis and treatment of basal cell carcinoma (BCC) of the skin remain a relevant focus of numerous studies and innovative developments. The tumor microenvironment plays a pivotal role in BCC carcinogenesis. It is becoming increasingly evident that the stromal microenvironment, in which neoplastic cells develop, exerts a profound influence on many stages of cancer progression [1]. Detection of tumor cells in the perifocal zone is possible only through histological examination of surgical specimens following excision. It is well established that the visually unchanged skin surrounding a neoplasm undergoes structural and biochemical alterations, thereby creating a so-called "tumor bed". In cases of incomplete excision, this area may become a source of continued tumor growth or recurrence.

One of the non-invasive treatment modalities for BCC is photodynamic therapy (PDT). Prior to the procedure, a photosensitizer (PS) is administered intravenously, which becomes selectively adsorbed in tumor cells (exposure time ~3 hours). Currently, second-generation photosensitizers are widely used; unlike those of the first generation, they are activated by light in the long-wavelength red region of the spectrum (λ = 650–680 nm). They penetrate deeper into tissues, accumulate more selectively in tumor cells, and are eliminated more rapidly from the body [2–4].

Several second-generation photosensitizers derived from chlorin e6 (such as Photoditazine) were developed between 1996 and 1998 by Prof. G. V. Ponomarev at the Institute of Biomedical Chemistry, Russian Academy of Sciences (RF Patent No. 2144538). Clinical trials of Photoditazine commenced in 1998 at the State Research Center of Laser Medicine. Among second-generation PSs, chlorin derivatives such as Radachlorin (Radapharma, Russia), Photoditazine (Veta-Grand LLC, Russia), Photolon (Belmedpreparaty, Belarus), and Foscan (Biolitec AG, Germany) are the most widely applied in clinical practice [4].

Photoditazine accumulates rapidly in tumor tissues, reaching maximum concentration within 1.5–2.5 hours [5]. It demonstrates high photodynamic activity and has several advantages compared to other chlorin e6 derivatives:

– a high selectivity index for tumor accumulation versus surrounding intact tissues (10, compared with 6 for Radachlorin and 4 for Photolon) [5–7];

– high quantum yield owing to its monomeric, hydrophilic, and homogeneous properties, ensuring strong phototoxicity [5];

– the ability to bind to tumor cell membranes [8];

– a lower therapeutic dose (0.3–1.5 mg/kg body weight) compared to Radachlorin (0.5–2.4 mg/kg) and Photolon (2.5–3.0 mg/kg).

The clinical efficacy of PDT using Photoditazine has been reported in several studies [9– 12]. Two methods of administration have been described: intravenous (RF Patent No. 2347567, RF Patent No. 2482893) and topical (RF Patent No. 2286780). Photoditazine (N-dimethylglucamine salt of chlorin e6) accumulates most intensively in proliferating areas. Its structural formula is provided in [13]. In the electronic absorption spectrum, Photoditazine exhibits five characteristic absorption bands with maxima at 400 ± 2 nm, 504 ± 2 nm, 534 ± 2 nm, 608 ± 2 nm, and 662 ± 2 nm (RF Patent No. 2448745, publ. 27.04.2012, A61B 5/06). The main absorption peak occurs at 402 nm, where energy requirements for excitation are threefold lower than in the 660-nm spectrum.

The intravenous route of administration poses certain limitations for patients: for two days post-infusion, they must observe precautionary measures avoid direct sunlight, preferably remain indoors until sunset, and wear UV-protective sunglasses.

The pharmaceutical company Veta-Grand manufactures Photoditazine as a 0.5 % topical gel-penetrant [4]. Registration certificate: No. FSR 2012/13043, dated 06/08/2017. Chemical name: N-dimethylglucamine salt of chlorin e6. Description: greenish polymer gel for topical use. Dosage form: 0.5 ml, 1.0 ml, or 2.0 ml of gel supplied in a 2.0 ml disposable injection syringe with a plastic cap in sterile packaging. Composition: 1 ml of gel contains 5 mg of the active substance (Photoditazine) and excipients (methylhydroxyethylcellulose ethers).

An alternative technique contact fluorescent biomicroscopy using acridine orange (concentration 1:5000) is described in RF Patent No. 23887376. This method requires specialized contact lenses (LK 25 × 0.75) and costly equipment (LUMAM–IZ), configured for detection in a broad spectral range (480–700 nm), which significantly limits its use in routine clinical practice. This technique identifies BCC tumor complexes by detecting clusters of intensely fluorescent cells against the background of green fluorescence of the intercellular matrix and collagen fibers, thereby enabling diagnosis of BCC.

Purpose of the study. To evaluate the feasibility of applying a method of visual diagnosis of basal cell carcinoma under ultraviolet light using Photoditazine for determining tumor margins in clinical practice.

PATIENTS AND METHODS

The study included 60 patients of both sexes: 30 men and 30 women with stage I–II basal cell carcinoma (BCC) of the skin. The diagnosis of BCC had been cytologically verified at the pre-hospital stage. The cohort comprised 15 patients with the nodular growth pattern and 15 with the superficial growth pattern, none of whom had received prior treatment. In all cases, Photoditazine gel-penetrant was applied topically as an occlusive dressing to the tumor surface and the visually unchanged skin surrounding the lesion, extending 1.5–2 cm from the tumor margin. The dosage was calculated as 1 ml of gel per 3–5 cm² of treated surface, with an exposure time of 30 minutes. Following application, the gel was removed from the tumor and adjacent skin with a gauze swab moistened with distilled water. In a darkened room, under directed ultraviolet (UV) light, characteristic fuchsia fluorescence of the carcinoma and a pale or dark-red halo surrounding the lesion were observed and documented by photographic registration.

The following results were obtained: in 33 patients (55 %), the peritumoral zone exhibited no fluorescence (Fig. 1), whereas in 27 patients (45 %), areas of increased peritumoral fluorescence so-called "hot spots" were detected (Fig. 2).

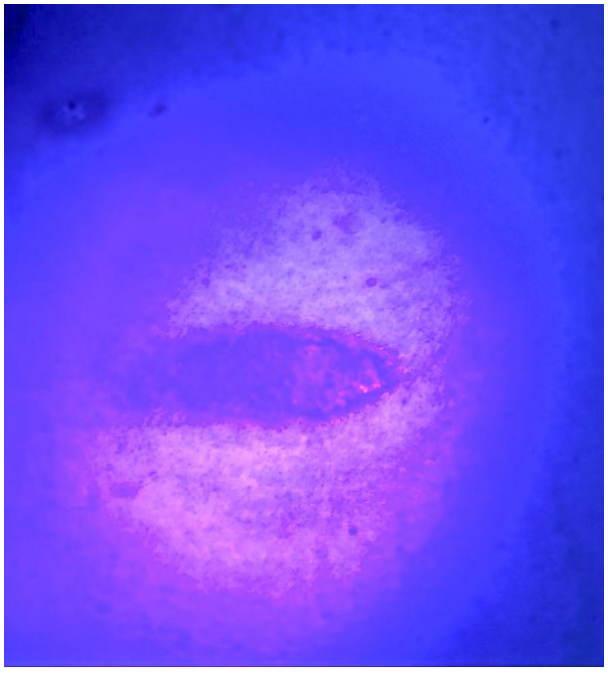

Fig. 1. Under directed ultraviolet light: skin of the lumbar region with a tumor lesion (basal cell carcinoma of the back, T1N0M0, stage I, clinical group 2). Photoditazine gel-penetrant was applied to the tumor surface and the peritumoral zone. No fluorescence of the perifocal area is observed

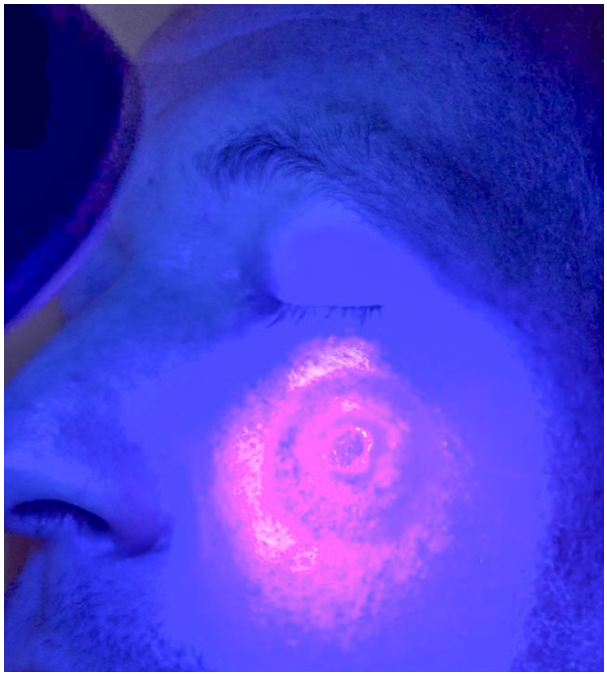

Fig. 2. Under directed ultraviolet light: skin of the left cheek with a tumor lesion (basal cell carcinoma of the left cheek, T1N0M0, stage I, clinical group 2). Photoditazine gel-penetrant was applied to the tumor surface and the peritumoral zone. An extensive round-shaped peritumoral "hot spots" is observed around the tumor

These regions displayed either round or irregular contours and were characterized by intense dark-red fluorescence encircling the tumor focus. In our view, such areas should be unconditionally included in the resection field, as they represent potentially hazardous zones with respect to local recurrence. Active adsorption of the photosensitizer in these regions indicates alterations in the hormonal and metabolic properties of the peritumoral skin, thereby signifying the formation of a tumor field.Additionally, growth factor content, receptor expression, and fibrinolytic system activity were analyzed in the surgical material obtained after tumor excision. Our previously published findings demonstrated that, despite the absence of tumor cells at the resection margin, elevated levels of VEGF-A, VEGF-C, TGF-β, and EGF [14], along with activation of the fibrinolytic system [15], contributed to continued malignant growth. This was confirmed by recurrence diagnosed 12–15 months postoperatively in three male patients with solid-type BCC who had exhibited the most extensive peritumoral "hot spots".

The total time required for the diagnostic procedure prior to surgery did not exceed 70 minutes. Indication for use of the proposed method: cytologically verified BCC.

STUDY RESULTS AND DISCUSSION

Among 60 patients, peritumoral "hot spots" were detected in 27 cases (45.0 %): in 24 patients (40.0 %) with solid-type tumor growth and in 3 patients (5.0 %) with superficial-type growth. For these patients, surgical excision was performed with a margin greater than 4 mm from the fluorescent zone. In cases with a pale peritumoral halo or without fluorescence, standard excision with a 4-mm margin from the visible tumor border was carried out. In all cases, histological analysis confirmed the radicality of surgery: the tumors were completely excised within healthy tissues, with no evidence of malignant growth at the resection margins.

Example of clinical use of the proposed method can be illustrated by the following case records.

Example No. 1. Patient I., female, 71 years old. History: a flat pink spot appeared 3 years ago, periodically covered with a crust, slowly increased in size, treated with Akriderm – without improvement. Local status: on the skin of the left lumbar region – a flat pink lesion measuring 0.6 × 1.3 cm in diameter, without ulceration. Dermatoscopy with HEINE DELTA 20 revealed arborizing vessels (presumably basal cell carcinoma). After cytological examination, the result was obtained – a few groups of basal cell carcinoma on the background of basal cell hyperplasia with proliferation, with polymorphism of some cells, hyperkeratosis. Photoditazine gel-penetrant was applied to the lesion and peritumoral zone, then examined under directed ultraviolet light. No peritumoral fluorescence was observed. The tumor was surgically excised according to clinical guidelines with a 4-mm margin from the visible edge. The skin-fat flap with the tumor, 1.4 × 2.1 cm, was sent for histological examination. Final histology: superficial basal cell carcinoma without ulceration, without vascular or perineural invasion, with focal lymphocytic peritumoral infiltration, maximum horizontal spread 9.5 mm, thickness 0.3 mm. No tumor cells detected at the resection margins, pT1. Result: the patient was followed for 1 year and 3 months without signs of recurrence.

Example No. 2. Patient M., male, 55 years old. History: according to the patient, a "pimple" appeared 1.5 years ago, self-treated with celandine, followed by ulcer formation and gradual growth. Local status: on the skin of the left cheek – a pink lesion measuring 0.8 cm in diameter, irregular in shape, with central ulceration and pearly rolled borders. Dermatoscopy with HEINE DELTA 20 revealed an ulcerated defect with elevated rolled edges and arborizing vessels (presumably basal cell carcinoma). Cytological examination confirmed basal cell carcinoma. Photoditazine gel-penetrant was applied to the lesion and peritumoral zone, then examined under directed ultraviolet light. An extensive round peritumoral “hot spot” was detected around the tumor. The lesion was surgically excised with a 7-mm margin from the visible edge, taking into account the fluorescence zone. The excised skin-fat flap, 1.5 cm in diameter, was sent for histological examination. Flap plasty was performed to close the defect. Final histology: basal cell carcinoma, nodular form, solid variant. Clark level IV invasion. Tumor thickness – 2 mm. The tumor was excised within healthy tissues,

pT1. Result: the patient was followed for 1 year and 2 months without signs of recurrence.

Among patients with solid-type tumor growth, three male patients developed recurrence within 12–15 months after treatment. All had shown extensive peritumoral "hot spots". In our previously published studies, metabolic changes in the peritumoral zone of these patients were described [14]. In particular, elevated concentrations of VEGF-A and VEGF-C were found both in tumor tissue and in the peritumoral zone, as well as in conditionally healthy skin, preceding the development of recurrence. Thus, these indicators are prognostically significant markers of recurrence risk (RF Patent No. 2823211 C1, 07/22/2024).

In addition, in patients with nodular BCC who subsequently developed recurrences, activation of the fibrinolytic system was observed both in the tumor and in the peritumoral zone [15]. This combination of changes reflected metabolic disturbances characteristic of an extended tumor field and created prerequisites for local recurrence. The obtained data emphasize the importance of a comprehensive assessment of not only morphological but also molecular and biological features of the tumor and surrounding tissues for predicting disease progression.

CONCLUSION

Thus, the results obtained indicate that determining the true boundaries of tumor cell spread by the method of photosensitization has significant advantages over known diagnostic approaches for BCC. Its application allows: 1. to determine the boundaries of tumor spread with maximum accuracy; 2. to perform the study without systemic administration of the drug; 3. to carry out subsequent surgical excision with an optimal margin.

It is recommended to implement the use of the photosensitization method into routine practice, as it does not require expensive specialized equipment, is effective, and is simple to perform.

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