DOI: 10.20514/2226-6704-2021-12-2-85-92 УДК 24.02.

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ВОЗМОЖНОСТИ ОБСЛЕДОВАНИЯ ПАЦИЕНТОВ С ПОДОЗРИТЕЛЬНЫМИ НА МЕЛАНОМУ НОВООБРАЗОВАНИЯМИ КОЖИ, ВПЕРВЫЕ ВЫЯВЛЕННЫМИ В ПЕРВИЧНОМ ЗВЕНЕ ЗДРАВООХРАНЕНИЯ

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The Principles of Examination of Patients with Detected Melanoma Suspected Skin Neoplasm in the Primary Health Care Stage

Резюме

В настоящее время в структуре смертности населения в Российской Федерации и ряда других странах онкологические заболевания занимают ведущие позиции среди других причин. Меланома кожи является одной из наиболее агрессивных злокачественных опухолей, с быстрым прогрессированием, нередко приводящим к летальному исходу в достаточно короткие сроки. Раннее выявление и рационально организованная маршрутизация пациентов с первично выявленной меланомой кожи в первичном звене здравоохранения направлена на снижение заболеваемости и смертности от злокачественных заболеваний, улучшение качества жизни пациентов. Результаты исследований предполагают, что увеличение заболеваемости меланомой кожи обусловлено как гипердиагностикой, так и настороженностью врачей и населения по отношению к пигментным новообразованиям кожи. В статье обсуждаются факторы риска развития меланомы кожи. Уделяется внимание современным клиническим методам прогнозирования течения меланомы кожи, поскольку данное заболевание является потенциально обратимым. Рассматриваются компьютерные методы скрининга и диагностики меланомы кожи, применимые в условиях первичного звена здравоохранения. Отдельный раздел посвящён дерматоскопии или эпилюминесцентной микроскопии, которая относится к исследованию пигментных поражений кожи с использованием поверхностной микроскопии. Представлен перечень исследований при подозрении на злокачественное новообразование кожи/меланому кожи у пациента, обратившегося за медицинской помощью в лечебно-профилактическое учреждение. Обсуждается значимость критериев алгоритма ABCDE, алгоритма «Арджензиано» в исследовании пигментных поражений кожи с дальнейшим анализом результатов искусственным интеллектом для принятия решения.

Ключевые слова: *злокачественное новообразование, меланома, дерматоскопия, первичное звено здравоохранения*

Конфликт интересов

Авторы заявляют, что данная работа, её тема, предмет и содержание не затрагивают конкурирующих интересов

Источники финансирования

Авторы заявляют об отсутствии финансирования при проведении исследования

Статья получена 12.08.2021 г.

Принята к публикации 29.11.2021 г.

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Для цитирования: Ларина В.Н., Гайдина Т.А., Дворников А.С. и др. ВОЗМОЖНОСТИ ОБСЛЕДОВАНИЯ ПАЦИЕНТОВ С ПОДОЗРИТЕЛЬНЫМИ НА МЕЛАНОМУ НОВООБРАЗОВАНИЯМИ КОЖИ, ВПЕРВЫЕ ВЫЯВЛЕННЫМИ В ПЕРВИЧНОМ ЗВЕНЕ ЗДРАВООХРАНЕНИЯ. Архивъ внутренней медицины. 2022; 12(2): 85-92. DOI: 10.20514/2226-6704-2021-12-2-85-92

Abstract

Currently, in the structure of mortality in the Russian Federation and a number of other countries, oncological diseases occupy a leading position among other causes. Melanoma of the skin is one of the most aggressive malignant tumors, with rapid progression, often leading to death in a fairly short time. Early detection and rationally organized refferral of patients with diagnosed skin melanoma in primary health care settings is aimed at reducing morbidity and mortality from malignant diseases, and improving the quality of life of patients. Research results suggest that the increased incidence of skin melanoma is due to both overdiagnosis. and an increase in the alertness of doctors and the population in relation to pigmented skin formations. The article discusses the proven risk factors for the development of skin melanoma, since this disease is potentially reversible. Attention is paid to modern clinical methods for predicting the course of skin melanoma. The review article examines computer-based methods for screening and diagnosing skin melanoma, applicable in primary health care settings. A separate section is devoted to dermatoscopy or epiluminescence microscopy, which refers to the study of pigmented skin lesions using surface microscopy. A list of studies is presented in case of suspicion of a malignant neoplasm of the skin / melanoma of the skin in a patient who sought medical help at a medical and prophylactic institution. The significance of the criteria of the ABCDE algorithm, the "Argenziano" algorithm in the study of pigmented skin lesions with further analysis of the results by artificial intelligence for decision-making is discussed.

Key words: *malignant tumors, melanoma, skin, dermatoscopy, primary health care settings*

Conflict of interests

The authors declare no conflict of interests

Sources of funding

The authors declare no funding for this study

Article received on 12.08.2021

Accepted for publication on 29.11.2021

For citation: Larina V.N., Gaydina T.A., Dvornikov A.S. et al. The Principles of Examination of Patients with Detected Melanoma Suspected Skin Neoplasm in the Primary Health Care Stage. The Russian Archives of Internal Medicine. 2022; 12(2): 85-92. DOI: 10.20514/2226-6704-2021-12-2-85-92

ABCDE — **a**symmetry of tumor, irregular **b**orders, irregular **c**oloration, **d**iameter 6 mm or more and morphological changes, i.e. **e**nlargement, CDKN2A — cyclin-dependent kinase inhibitor 2A, CI — confidence interval, CNN — convolutional neural network, CPRs — Complex Regional Pain Syndrome, MN — melanocytic nevus, OR — odds ratio, SM — skin melanoma

In recent decades, the incidence of skin melanoma (SM) in most developed countries has been steadily increasing, much faster than other types of cancer [1, 2]. According to statistics, in 2018 in the Russian Federation (RF), the skin was the leading localization in cancer morbidity for both men and women (12.6% — without melanoma; 14.4% — with melanoma) [3]. At the end of 2019, in local cancer institutions in the Russian Federation, the skin remained the leading localization in the incidence of malignant neoplasms for both men and women (without melanoma — 13.1%, with melanoma — 15.0%) [4].

From 2008 to 2018, mortality due to SM in men and women in our country increased by 11.19% [3]. The increase in the incidence of melanoma is due to both overdiagnosis and the vigilance of medical personnel and the general population in regard to pigmented skin neoplasms.

The life expectancy of patients with SM depends primarily on the stage of the tumor process when the treatment was started; disappointing statistics in the Russian Federation suggest the underdevelopment of early diagnosis of SM. Despite the increase in the rate of active detection of patients with SM in the Russian Federation in 2017, only one in three patients was actively detected. In 2016–2017, the neglect rate in regard to SM remained at 19.0%, which is unacceptably high in case of visually localized tumors [5].

An increase in the incidence of melanoma by 4–6% per year in elderly patients with fair skin has been reported in many countries, including Australia, the United States and most parts of Europe [6–8]. At the same time, there is a significant increase in the overall five-year survival of patients with SM, which is largely associated with early diagnosis and detection of tumors at initial stages [9]. The prognosis for some patients with melanoma may be favorable. However, the disease has a significant impact on the quality of life [10] and health care costs [11].

SM is a potentially preventable tumor because it has proven risk factors for its development. The most significant risk factor for SM is skin exposure to ultraviolet radiation [12]. Other risk factors include sunburn in childhood, Fitzpatrick skin phototypes I and II, CDKN2A genetic mutation, ten or more dysplastic nevi or more than 100 multiple melanocytic skin nevi, history of SM, familial melanoma [13, 14].

Early detection, well-organized routing of initially identified patients with SM and timely treatment significantly improve the prognosis. The diagnosis of SM in primary health care is difficult because physicians are not sufficiently qualified to conduct a differential assessment of the nature of pigmented skin lesions [15]. Considering the current situation, physicians of outpatient departments have to improve their skills in diagnosing SM [16].

Diagnosis of Skin Melanoma

To differentiate SM from benign pigmented skin lesions, a number of clinical prediction methods (CPRs — Complex Regional Pain Syndrome) and computer diagnostic methods have been developed.

The UK National Institute of Clinical Medicine (NICE) does not recommend the routine use of computer-assisted diagnostic tools in the initial assessment of skin lesions. However, it recommends a seven-step diagnostic algorithm in primary care for the diagnosis of SM. During the diagnosis of SM by dermatologists, some CPRs clinical prediction methods have demonstrated high sensitivity and specificity [9].

When examining a skin neoplasm, dermatologists most often use an ABCDE algorithm, which evaluates the following criteria: **a**symmetry of tumor, irregular **b**orders, irregular **c**oloration, **d**iameter 6 mm or more and morphological changes, i.e. **e**nlargement. If two criteria are met, the sensitivity and specificity of the ABCDE algorithm is 89.3% and 65.3%; if three criteria are met — 65.5% and 81% [9].

Skin neoplasms may have their own unique elements. However, there are common features that are typical for a particular neoplasm, so illustrations can be used in primary care as one of the clinical prediction methods. CPRs can be used alone for clinical (i.e. naked eye examination) examination of a skin lesion, or in combination with dermoscopy.

Dermoscopy

Dermoscopy, or epiluminescence microscopy, refers to the examination of pigmented skin lesions using surface microscopy [17]. The use of dermoscopy, primarily by dermatologists, improves the accuracy of diagnosis compared to naked eye examination, since it allows visualization of specific features that are not visible to the naked eye [18]. In their work, Kittler H. et al. (2002) demonstrated a higher diagnostic accuracy of dermoscopy than when no dermoscopy is used to detect SM (OR 4.0 [95% CI 3.0–5.1] vs OR 2.7 [95% CI 1.9–3.4]; p = 0.001) [19].

However, the effectiveness of dermoscopy depends on the clinical experience and professionalism of the specialist. Dermatologists with extensive experience and training in dermoscopy have higher rates of detecting SM than inexperienced dermatologists or primary care physicians [20]. According to D. Piccolo et al. (2002), the sensitivity of diagnosing SM via dermoscopy was higher for an experienced dermatologist (92%) and lower — for an inexperienced dermatologist (69%); specificity was also higher for the experienced (99%) than the inexperienced professional (94%). The authors cited an interesting fact that computer analysis showed more false results (26%) than an experienced (0.6%) and inexperienced (5.5%) dermatologist [21].

Software for computer analysis of malignancy of skin neoplasms is being improved. This is critical during a pandemic when patients want to get a "second opinion" remotely.

In recent years, new methods for assessing the pigmentation of skin neoplasms and detecting melanoma have emerged, including spectrophotometric intracutaneous analysis, or SIAscopy, optical coherence tomography, confocal microscopy, multiphoton tomography, electrical impedance spectroscopy etc.; all these methods should be more actively implemented in general clinical practice [22].

Primary care physicians often deal with skin lesions with suspicions of malignancy; they are difficult to differentiate from true malignant neoplasms when the patient should be immediately referred to a specialist for verification of diagnosis and treatment. At the same time, a primary care physician should be informed about benign skin neoplasms that can be observed when working in an outpatient department [15].

In the Russian Federation, particularly the Moscow Healthcare Department, one of the priorities in recent years has been delivering preventive medical care to the public, including early diagnosis of oncological diseases and timely start of treatment. New algorithms and educational projects for the early diagnosis of malignant neoplasms and routing of patients with suspected or newly diagnosed cancer are being developed and implemented. One of the regulations governing the organization of oncological medical care in the Moscow Healthcare Department is the order of the Moscow City Healthcare Department No. 16 of January 15, 2020 "On the Provision of Medical Care in the Field of Oncology in Medical Organizations of the State Healthcare System of the City of Moscow" [17].

This order approved a list of examinations for patients with complaints or signs typical for an oncological disease, as well as the timing of examination and the timing consulting oncologist when the preliminary diagnosis of a malignant neoplasm is confirmed (3 and 5 days, respectively). One of the sections of this order includes a list of complaints/signs of skin malignant neoplasm/melanoma and a list of examinations for suspected skin malignant neoplasm/melanoma.

The list of complaints/signs of skin malignant neoplasm/skin melanoma requiring further examination of patients is given below:

1. Pigmented lesion with rapid growth.
2. Pigmented lesion with changing configuration of its boundaries.
3. Pigmented lesion with different coloration.
4. Itching in the area of pigmented lesion.
5. Burning sensation in the area of pigmented lesion.
6. Indolent skin ulcer.
7. Painful and bleeding ulcers, induration, crusts on the skin surface (especially on the scalp, neck).
8. Induration of skin area.
9. Red border around any mass lesion.

If the patient has any complaint, they should be examined according to the list given in Table 1.

To meet the requirements of this order and improve the quality of medical care for the early diagnosis and

Table 1. Checklist for suspected skin malignancy / skin melanoma

N	Investigation	Importance	Additional condition
1.	Clinical blood test	Yes, if it was not performed during the last 14 days	No
2.	Activated partial thromboplastin time	Yes	No
3.	Prothrombin (thromboplastin) time	Yes	No
4.	Antibodies to the Hepatitis C virus in blood	Yes	No
5.	Hepatitis B virus antigen (HBsAg) in blood, qualitative study	Yes	No
6.	Antibodies to the Treponema pallidum in blood test	Yes	No
7.	Human immunodeficiency virus test	Yes	No
8.	Consultation with an oncologist	Yes	No

treatment of oncological diseases, the Personal Assistant project was implemented in the work of primary health care facilities in Moscow [23]. This project is intended to provide consultative and logistical assistance to patients from the moment of suspicion of a malignant neoplasm and examination to confirm the diagnosis to registration with an oncologist for regular medical check-ups and treatment.

At present, for the early diagnosis of SM, primary care physicians of the Moscow Healthcare Department can use clinical research methods (naked eye) and improvised low-magnification optical systems (loupes). The latter were approved in the mandatory list of devices for primary care physicians and have been widely used only in the last five years with the addition of general practitioners to the staff of local clinics. In recent years, general practitioners have also been using dermoscopes in their routine practice. An illustrative example is dermoscopy performed by a primary care physician/general practitioner in the case of suspicious skin neoplasms as part of a comprehensive examination of patients in "Zdorovaya Moskva" pavilions.

Despite that recently, at the primary care stage in Russian health care, special attention has been paid to the early diagnosis of malignant skin neoplasms, the incidence of neglected SM remains high [5].

This is primarily due to primary care physicians not being sufficiently skilled in the field of skin neoplasms. Insufficient time devoted to oncodermatology during the initial training and postgraduate education of primary care physicians/general practitioners, little experience in working with SM patients — all this affects the timely verification of malignant skin tumors [24].

Diagnosis of Skin Neoplasms Using the Example of Examination of a Patient in Primary Health Care

Below is an example of patient examination, which indicates the possibility of timely diagnosis of skin neoplasms in primary health care with subsequent routing to provide immediate specialized treatment.

During examination in the course of periodic medical check-up at a Moscow clinic, a mass lesion was revealed on the skin of the back of patient N., 7 mm in diameter, with a round shape, distinct boundaries, light brown in color, with slight polychromy, an uneven surface, rising above the surface of unchanged skin.

Consultation was conducted with an associate professor of the Department of Outpatient Therapy of the Medical Faculty of the N.I. Pirogov Russian National Research Medical University. During the visit, a macro photo of the skin neoplasm was taken (Fig. 1, A), as well as a dermoscopic micro photo (Fig. 1, B) using a Handyscope optical device with 20x magnification (FotoFinder; Germany) connected to a smartphone with the Handyscope3 mobile application. Artificial intelligence in this application is a convolutional neural network (CNN), which is trained based on more than 100,000 micro photos of skin neoplasms with a histologically confirmed diagnosis; it is the optimal option for screening diagnostics in primary health care [25]. CNN is able to develop its own decision-making algorithms during image analysis and demonstrates better specificity and sensitivity compared to dermatologists with initial (up to 2 years) and intermediate (up to 5 years) experience in dermoscopic evaluation [25]. Handyscope is a convenient portable device that allows to not only take high-quality images of skin neoplasms and analyze them with CNN, but also e-mail them through the Handyscope3 application for prompt discussion of a clinical case with competent subject matter experts, which is critical for primary care physicians and the development of telemedicine in general.

In patient N., computer analysis by CNN in the Handyscope3 mobile application showed a high risk of neoplasm malignancy (red zone 0.93) (Fig. 1, C). The patient was referred to an oncologist to determine further treatment tactics.

Amid the ongoing Covid-19 pandemic, the option to take a photo of a skin melanocytic nevus (SMN) with the subsequent entry of macro and dermoscopic micro photos into an electronic patient record for further analysis and remote consultation is especially relevant. Our foreign colleagues widely use the opportunities for teledermoscopic consultations. In a pilot study, Zink A. et al.

Figure 1. *A — macro view of a neoplasm on the back skin*
B — dermatoscopic micrograph of a neoplasm on the back skin
C — assessment of a dermatoscopic micrograph of the neoplasm by artificial intelligence

compared the accuracy of the results of teledermoscopic consultations with subsequent SMN histology. Macro and dermoscopic micro photos of SMNs were taken by five medical residents in 26 patients using a mobile phone and a Handyscope optical system, and the images were analyzed by an experienced dermatologist. As a result of remote teleconsultation, it was decided to excise and histologically examine 23% of SMNs from those examined. There was a 92.3% match of diagnoses made remotely using macro photos and dermoscopic microimages with histological examination. It is important that macro photos and dermoscopic microimages of SMNs can be taken not only by subject matter experts but also by primary care physicians. And the analysis of the obtained images can be used both for screening for SM and for remote consultations on further tactics of patient management. Mobile teledermoscopy may be an alternative to a clinical examination by a subject matter expert [26].

Undoubtedly, entering macro photos and dermoscopic microimages of SMNs into an electronic patient record for subsequent computer analysis by CNN and/or for remote telemedicine consultations can be a good instrument for early diagnosis of SM by primary care physicians.

Prospects for Improving the Diagnosis of Skin Melanoma in Primary Health Care

Particular attention should be paid to improving the equipment of primary care physicians' offices with dermoscopes and guidance materials (illustrations of skin neoplasms, clinical guidelines, clinical prediction methods) [27].

Optimization of the routing of patients with suspected malignant neoplasms, including SM, has a significant impact on the timely establishment of diagnosis, speeds up diagnosis, improves its accuracy and enables to start treatment earlier [23].

If SM is suspected, primary care physicians often refer patients to a dermatologist and not an oncologist in order to determine further tactics for examining the patient, which delays diagnosis and treatment. Referral for a biopsy only after consultation with an oncologist and the inability to take a biopsy from a patient with suspected SM directly at the district cancer detecting center at the patient's place of residence also delay diagnosis and are often the key challenges. Using the example of delivering cancer care at the Moscow Healthcare Department under the new Moscow Standard for the provision of cancer care, such challenges can be resolved by setting up multidisciplinary cancer centers with a full range of clinical capabilities. These centers enable the diagnosis, surgical treatment, medication therapy and regular medical check-up of patients with oncological diseases. Each center receives patients from one or two administrative districts of Moscow. In this way, all stages of specialized care are carried out within one medical facility [23].

Overdiagnosis of SM is an equally important problem [28]. On the one hand, referral of a patient with any skin neoplasm for consultation with an oncologist with further biopsy to confirm the diagnosis will not be helpful. On the other hand, it requires additional resources of the cancer department and leads to emotional stress in case of a wrong diagnosis of skin cancer and referral to an oncologist, as well as in the case of an unjustified biopsy. Therefore, training primary care physicians in the field of dermatooncology and equipping the workplace with modern diagnostic instruments is justified and necessary.

Using computer information systems in routine practice could significantly improve the diagnosis of SM. For example, the presence of a dermoscopy report in the patient's electronic record with the option to enter data in accordance with the criteria of various algorithms (ABCDE, Argenziano 7-point checklist, etc.) with further analysis by artificial intelligence, obtaining a result and making a decision.

The option to take photos of skin neoplasms with their transfer to an electronic record will allow to visually assess changes in the skin neoplasms. If dermoscopy is not accompanied by photographic evidence, i.e. dermoscopic images — and this is precisely the state of affairs in Russian primary health care — then, when observing a patient over time, it is difficult to compare the results of the current and previous dermoscopy examinations, especially if they are carried out by different specialists. This is also because there is no standardized protocol for recording the detected dermoscopic signs using a certain sequence and unified terminology for their description, depending on the particular dermoscopic algorithm used [23, 28].

An image (photo) of a skin neoplasm in the patient's electronic record will also allow remote diagnosis and double-checking by experts or a computer similar to the "artificial intelligence" of the X-ray department of the Moscow Healthcare Department [29–31].

The use of SM clinical prediction methods in actual clinical practice by primary care physicians requires additional time during examination, which is currently not provided for these procedures and, according to the standard, averages 15–18 minutes [32].

Conclusion

Today, more and more attention is paid to the problem of early diagnosis of malignant skin neoplasms. New clinical prediction methods are being developed, and the existing ones are being improved. Workplaces are beginning to be equipped with new diagnostic instruments; new innovative methods for diagnosing SM are being applied, such as "smartphone optical systems", etc. [33–39]. However, there are several issues that have not been fully resolved, such as the competence of primary care physicians in the field of dermatooncology, the full equipment of workplaces with diagnostic instruments and guidance material and the improvement of routing patients with suspected skin malignancy and additional time for diagnostic procedures. Solving these issues will reduce not only the frequency of underdiagnosis of SM but also its overdiagnosis, which leads to unjustified biopsies, surgical interventions that affect the quality of life of patients, as well as additional financial costs. A well-functioning system of providing medical care to patients with suspected skin cancer will enable the timely verification of the diagnosis of SM, the placement of such individuals under care, their monitoring and treatment and extending the life expectancy and improving the quality of life of such patients.

Вклад авторов

Все авторы внесли существенный вклад в подготовку работы, прочли и одобрили финальную версию статьи перед публикацией

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