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3. სტატიის შესახებ გამოყენებული: საქართველოს წიგნი და ამ შეთავაზები ქართული ენაზე; გამოცემული ხელმძღვანელი საქართველოს პრეზიდენტს უწოდებთ საქართველოს პრეზიდენტი მისი შეფასების ან ქართული ნაწარმოები (ქრონიკული წარწერა).

4. სტატიის თან უფრო ახლავდელ ტიპის ხელმოწერი უნდა იწოდება 1/3 გვრითი ხელმოწერი, რომელიც შეიძლება საქართველოს პრეზიდენტი მისი შეფასების ან ქართული ნაწარმოები (ქრონიკული წარწერა).

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7. სტატიის თოვლის სიმბოლო უნდა იწოდეს 1/3 გვრითი ხელმოწერი.

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9. სტატიის თოვლის სიმბოლო უნდა იწოდეს 1/3 გვრითი ხელმოწერი. ზესახლის თოვლის სიმბოლო უნდა იწოდეს 1/3 გვრითი ხელმოწერი.

10. სტატიის თოვლის სიმბოლო უნდა იწოდეს 1/3 გვრითი ხელმოწერი. ზესახლის თოვლის სიმბო�ო უნდა იწოდეს 1/3 გვრითი ხელმოწერი.

11. სტატიის თოვლის სიმბოლო უნდა იწოდეს 1/3 გვრითი ხელმოწერი. ჰქონდეს გამორჩეული ქართული ენაზე.

12. სტატიის თოვლის სიმბოლო უნდა იწოდეს 1/3 გვრითი ხელმოწერი. მისი შეფასები საქართველოს პრეზიდენტი გამოყენებული იყო სხვა უფრო მდგომარეობა.

გაშნილია პერიოდის განსაზღვრელი შეხედულებები.
The methodology is applicable in up to 80% of cases, excluding only some rare findings such as: amelanotic cutaneous melanomas, cutaneous melanomas with regression zones or those with localization in the neck and head. However, after careful individual assessment and a subsequent selected approach, even these exceptions could be included in the innovative algorithm for one step surgical removal of cutaneous melanomas.

The resulting problems of not resolving these two dilemmas could lead to:
1) Generation of skin cancer (but not only), through the availability of nitrosamines in drugs.
2) Unnecessary and stressful /surgeries for the patients- 2 in number, which not infrequently lead to complication of their status (due to delay of histopathological analysis/ desire for optimisation of melanoma surgical treatment guidelines)
3) And subsequently, the diseases generated by them- treatment of skin cancer through the drugs public, clarifying it, studying it in detail and definitively stopping it.

At present, there is an alarming and unexplained tendency worldwide: 1) Potential acquired mutations, caused in all probability by contact with known exogenous mutagens- the nitrosamines in most commonly prescribed drugs, are allowed to occur.
2) And subsequently, the diseases generated by them- treated (at a later stage) by multiple surgical interventions and unjustifiably expensive targeted therapy; 3) Mutagens - such as nitrosamines for example, to be in a permissive or possibly permissive availability regime. Moreover, this permissible availability turns out to be ubiquitous and affects the most common medicines worldwide: metformin, ranitidine, propranolol, rifampicin, irbesartan, olmesartan, valsartan, telmisartan, eprosartan, losartan, ACE inhibitors, thiazide diuretics, etc.

In certain geographical regions, there is almost no patient taking this type of medication who has not had at least one tumour detected.

These significant correlations (nitrosamines/cancer) are labeled by the regulatory institutions as possible, probable, or not currently relevant. But in spite of “this inconclusiveness”, the drugs, containing nitrosamines, are withdrawn from the pharmaceutical market: quickly and quietly, despite the fact that “they did not pose a threat”.

The FDA was the only organization and the most important regulatory body worldwide, which lifted the veil from this ominous picture back in 2018: nitrosamines in blood medicines and cancer risk. Unfortunately, at the moment, the problems with this issue are proving to be more than the solutions, and at the same time it remains completely unclear who is to blame for this "sporadic contamination": the packaging of the drug, the humidity in the rooms where the preparations are stored or the synthesis process itself - the explanations are divergent, the responsibility is blurred.

This fuzzy liability does not affect the manufacturers and distributors of the preparations/nitrosamines themselves in the manner required by law for this (mis)act.

The Bulgarian Society of Dermatological Surgery remains to be the only organization worldwide that for the 5th consecutive year continues to seek solutions to the above-mentioned problems by:

1) Officialising all cases of skin tumors (but not only) occurring after intake of nitrosamine-contaminated drugs, 2) also officialising a significant number of cases of patients with cutaneous melanomas treated by the one-stage surgical removal method within one surgical session (OSMS).

The main priorities of the organization remain: 1) the complete elimination of nitrosamines from drugs worldwide, 2) the optimization of melanoma surgical treatment guidelines with the goal of treatment within 1 surgical session: for thin melanomas, dysplastic nevi and melanoma in situ, a surgical margin of safety of 1 cm in all directions and without detection and removal of the draining sentinel lymph node. Whereas for medium and thick melanomas, the focus should be directed to the following recommendation: 2 cm surgical margin of safety plus detection and removal of the draining lymph node within one surgical session.

The indication for the surgical removal of these lesions should be made on the basis of radically different criteria from those used to date by the AJCC/EJC, namely: based on 1) clinical presentation/ clinical morphology, 2) dermatoscopic finding, and if there is a melanoma suspected lesion with possible tumour thickness greater than 1 mm , 3) ultrasonographic measurement for preoperative determination of tumor thickness should be additionally performed.

The methodology is applicable in up to 80% of cases, excluding only some rare findings such as: amelanotic cutaneous melanomas, cutaneous melanomas with regression zones or those with localization in the neck and head. However, after careful individual assessment and a subsequent selected approach, even these exceptions could be included in the innovative algorithm for one step surgical removal of cutaneous melanomas.

The resulting problems of not resolving these two dilemmas could lead to:

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second opinion/ delay regarding the timeframe for the second surgical intervention/ uncertainty regarding the resection lines within the first intervention/ failure to respect the recommended surgical security resection margins already within the first surgical session, etc.).

3) Huge additional costs to health care systems on the order of probably/roughly calculated about $50 billion per year.

Resolution of these two dilemmas would likely result in a dramatic drop in cancer incidence worldwide and a significant improvement in the effectiveness/efficiency of surgical treatment for cutaneous melanoma.

Key words. Nitrosamines, metformin, irbesartan, telmisartan, eprosartan, Lisinopril, ranitidine, one step melanoma surgery, dermatologic surgery.

Report.

For the fifth year in a row, the Bulgarian Society for Dermatologic Surgery (BULSDS) hosted a very dynamic forum, in which the Bulgarian specialists/young scientists alongside colleagues from countries all over the world joined hands together to discuss the current hot topics in the dermatologic oncology/ surgery field. The national conference has established itself over the years as a place in which different approaches and unconventional thinking are always welcomed.

This year the congress was held again in the capital city of Sofia, Bulgaria on the 11th of March 2023. Many experts have presented their field of interest with interesting observations and engaging presentations.

The main focus at the 5th national congress this year was put on skin cancer in general in connection to external mutagens or the so-called nitrosamines and possible treatment options within the surgical therapy of cutaneous melanoma. The subject of discussion was not only rare dermatoses, but also innovations in the field of dermatosurgery and skin cancer prevention.

Since acquired mutations are the main cause for over 80% of all skin cancer incidents, identifying and eliminating these causes should be of primary importance [1].

In 2018 a serious step forward was taken by the Food and Drug Administration (FDA) with revealing the truth about the nitrosamine contamination within the antihypertensive drug – valsartan [2].

The dermatologists, who were keeping an eye on the situation, quickly started their own investigations and soon established a link between the possible contamination and the subsequent development of melanoma [3-5] or melanoma in combination with other types of tumors [6].

The BULSDS remains the only organization that over the years has been actively involved in solving and publicly announcing this issue. This topic is one of the reasons many international experts – dermatologists, dermatopathologists and dermatosurgeons from all over the world are willing to engage in the conference and give their expert opinion on the matter.

The congress remains a place where ideas, criticisms, doubts, and unconventional thinking are welcomed regarding the currently unresolved problems concerning the pathogenesis and treatment of skin cancer and the possible connection to nitrosamines.

The conference was divided into several sessions in which esteemed scientists from all over the world presented different perspectives and opinions regarding the current hot topics in the dermatology field – melanoma surgery/personalized (one step) melanoma surgery, adverse drug reactions and rare skin diseases and syndromes.

The first morning session began with the presentation of the well-known and internationally recognized dermatologist/ dermatopathologist Prof Dr Michael Tronnier (Figure 1). He presented the current insides and updates concerning the diagnosis and management of atypical/dysplastic nevi which was well received by the audience and the other guest lecturers. The lecture demonstrated the need of precisely establishing the nevi's nature using clinical, dermatoscopic and histological methods and if necessary – their removal.

The session was continued with a video lecture about the controversies in the melanoma surgery by another esteemed guest scientist - Prof Dr Uwe Wollina. The lecture itself was a direct recognition of the one step melanoma surgery model as possible in certain patients. In summary, it was stated that the resection lines of the different dermatosurgical societies around the world may differ, but they do not exceed 0.5 cm within the first excision under the standard guidelines.

Dr Simona Kordeva and Dr Manojj Dhanarajan continued with interesting presentations about the Bulgarian experience with the one step melanoma surgical approach and the successful surgical removal of thin melanomas, melanoma in situ and dysplastic nevi with another surgical margin : 1 cm in all directions and without SLN biopsy [7-9]. The use of guidelines for innovative melanoma treatment (OSMS) practically saves the re-exision of the lesion which will later on result in less traumatic experience and financial burden for the patient [9-11]. These conclusions resulted in a major positive reaction from the auditory and will perhaps be even more applicable in the near future. Optimizing and updating the guidelines should be a priority regarding patient benefits.

OSMS can be used in the treatment of severe dysplastic nevi, melanoma in situ and thin melanomas – lesions that are not always clearly differentiated from each other but could be treated the same way – with a field of initial surgical safety of
1 cm in all directions within one surgical session [7,11,12]. Several case reports were presented with successful outcomes for each patient following the OSMS guidelines [8,9].

The session was followed by two case presentations from Prof Georgi Tchernev about the applicability of one step melanoma surgery for thick melanomas (Figure 2) [13,14].

Medium thick [15,16] and thick [13] melanomas – both were proven as possible candidates for the one step surgical approach with 2 cm and a sentinel lymph node removal within one surgical session [15,16].

Both the initial stages of medium thick and thick melanomas should be in the near future probably a top priority for every clinician [13,16]. OSMS is a personalized approach to surgical treatment which provides the patient with not only decreased risk of postoperative complications, but also reduces the psychological stress and financial burden [15].

This session was highly anticipated both by the young colleagues at the forum and the esteemed scientists in the field. Debates were carried out which resulted in different thoughts and observations. International specialists have thematized the OSMS approach several times, but it has never been fully addressed by the scientific community around the world [17]. But gradually, the veil is being lifted and more professionals are beginning to acknowledge the model.

In the second morning session another important topic was discussed with several original presentations about adverse drug reactions: nitrosamines, sartans and skin / other cancer development.

The first lecture was carried out by Assoc Prof Dr Kossara Drenovska about drug or paraneoplastic bullous disorders associated with anti-PD-1 and anti-PD-L1 therapy. It is not always clear whether it is a paraneoplastic bullous dermatosis within a melanoma recurrence or a drug-induced bullous dermatoses.

An important presentation by Prof Georgi Tchernev about sartans, nitrosamines and HCT as key factors for the development of lentigo maligna and dysplastic nevi was presented [18]. Both classes of medications have been reported as possibly contaminated [18-20]. It was stated that monotherapy with HCT is a separate risk for melanoma and non-melanoma skin cancers, so the question remained open: does the nitrosamine contamination in the given drug increase the risk for skin cancer development? [19,20]. Constructive debate about the pathogenetic form of the nitrosamine availability/contamination was started which resulted in all doubts being lost [21].

Dr Simona Kordeva had an interesting presentation about the simultaneous development of cutaneous melanoma, Kaposi sarcoma and colon carcinoma after valsartan/ hydrochlorothiazide intake [22]. Several facts and controversies were questioned: possible carcinogenic effect of the active ingredient, of the additional substances available – nitrosamines or sporadic manifestations of three types of tumors within the therapy [22]. All of these questions were answered within the presentation which resulted in more clarity when addressing this major issue – nitrosamine contamination as a possible main triggering factor for skin and other cancers development. These answers led to the conclusion that nitrosamine contamination is “rather a reality than a myth” and their possible pathogenetic role for skin cancer development and progression needs to be further investigated [23,24].

Different independent case reports in the medical literature have been described stating that the commonly used angiotensin receptor blockers (ARBs) for the treatment of arterial hypertension are a definitive risk for cancer development [3,19,20,25-27]. After a careful analysis there was no doubt that a melanoma development after sartan intake is not an incidence but rather a strongly associated connection [3,19,20,25-27]. A nationwide study of 1.4 million valsartan (nitrosamine contaminated) users has reported an increased risk for melanoma [28] which led to this conclusion.

Dr Konstantin Stavrov presented three different clinical cases about problematic congenital nevi being disguised as melanoma imitators [29]. They could easily lead to devastating surgical interventions so that a histopathological examination might be important in order to prevent a misdiagnosis or unnecessary sentinel lymph node removal [29].

The following lecture was from Prof Georgi Tchernev about giant pretilial located melanoma with a focus on the clinician’s behavior as the main triggering factor [14]. In the presented case report the patient was misdiagnosed which later on resulted with an advanced pretilial melanoma lesion with multiple lung metastases [14]. An importance of the precise diagnosis was discussed [14].

The second morning session was put to an end with two presentations by Dr Manojj Dhanarajan about achromatous melanoma in the genital area [30] and the danger of dark genital spots – vaginal melanosis/leontinosis in the genital area [31]. A conclusion about the importance of an early diagnosis and histopathological evaluation after surgical excision of the lesion was ascertained in order to prevent a penectomy and partial penile amputation [30].

A heated debate about the choice of treatment for patients with vaginal melanosis and the potential risk of a possible
progression to melanoma lesion was started which resulted in different observations and opinions. Rare cases of vaginal melanosis/lentiginosis turned into melanomas over time have been reported [32]. While new therapeutic approaches may be on the horizon, for example, target therapy, a combination of chemo- and immunotherapy, the preferable treatment choice would be complete surgical removal of the lesion in terms of survival rate [32].

The third session was focused on nonmelanoma skin cancer, acne inversa and other dermatological conditions.

A breathtaking lecture by Prof Dr Ricardo Vieira revealed to the audience his unparalleled and invaluable experience in the surgical treatment of nail diseases. With his review on nail surgery, he presented not only great theoretical explanation but also different surgical approaches when commenting on the topic (Figure 3).

Other rare dermatoses discovered and published by Bulgarian dermatologists in the recent past were commented on and presented.

Dr Hailey Kirilova introduced the audience an extremely rare case of progressive cutaneous hemangiomatosis with ocular involvement, discovered and published in the recent past by the famous Bulgarian dermatologist Dr. Anastasia Chokoeva [35].

Dr Heily Kirilova also presented a unique case of Seneear Usher syndrome in a Bulgarian patient associated with a dissecting aneurysm of the aorta and sepsis, which resulted in a fatal outcome [36].

The first officially reported case of a Bulgarian patient with a comedogenic nevus in the neck area, treated successfully via surgery, was also presented by Dr Simona Kordeva [37]. Although benign in complicated cases the condition could cause discomfort and a surgical removal is recommended [37].

The last surgical session started with the lecture of one of the enigmatic surgeons/dermatologic surgeon Prof Dr Ilia Lozev presenting his experience and observations in the surgical field. He introduced a giant advanced SCC of the scalp with cranial bone invasion, treated successfully via surgery and rotation advancement flaps, which was published again in JEADV [38]. The Department of Dermatosurgery of Medical Institute of the Ministry of Interior and the surgical interventions carried out so far for these types of tumors and others with similar localization were determined as exceptional not only for Bulgaria! (Figure 4).

The session was continued with a lecture from Prof Dr Giovanni Damiani about hidradenitis suppurativa. His presentation “from genetics to epigenetics and back to therapy” was well received from the auditory despite the complexity of the subject. He introduced a new insights and breakthroughs regarding the genetics of this disease.

Following the subject, the next presentation was from Dr Chisti Biji about an early surgical approach in acne inversa/hidradenitis suppurativa as the best treatment option for the condition [33]. In world literature different approaches are described as successful and durable but only with a temporary improvement [33]. The case report showed the audience that recurrent mild to moderate HS (Hurly stage 1&2) can be successfully managed by serial excisions under local anesthesia [33].

The session resumed with the Bulgarian experience and, in particular, with a case report from the Medical Institute of the Ministry of Interior, regarding the treatment of hidradenitis suppurativa, with Dr Simona Kordeva presenting an expert opinion which was published not long ago in JEADV [34]. It was stated that the surgical approach in patients with advanced (Hurley 3) acne inversa should be acknowledged with a more priority than the systemic therapy with adalimumab [34].

Dr Jose Carlos Cardoso once again impressed the audience with a precise and methodologically perfectly delivered lecture on basal cell carcinoma emphasizing the different clinicopathological features according to the underlying risk factors (Figure 5).

Dr Simona Kordeva continued the session with another interesting presentation about adverse drug events. She presented data from her publications for the first time in the world literature published cases of keratinocyte tumors developed after oral intake of potentially nitrosamine-contaminated sartans in combination with hydrochlorothiazide [39,40]. Two new cases of keratoacanthoma and squamous cell carcinoma development...
after intake of nitrosamine-contaminated irbesartan and hydrochlorothiazide was presented [39,40], resulting in a serious dose of silence among the audience! The new concept of skin cancer pathogenesis enhanced by nitrosamines did not find any contradictions among the young audience and the scientists representing the global dermatological community.

Figure 5. Dr Jose Carlos Cardoso from Portugal with one of the best congress lectures about the BCC and the different clinicopathological features according to the underlying risk factors.

Figure 6. Final common photo after the last congress session, 5th congress of the Bulgarian Society for Dermatologic Surgery, 11 march, 2023, Sofia, Hotel Marinela. A.

There were also lectures by young doctors, which concerned the surgical treatment of medium and high-risk basal cell carcinomas of the face; rare lymphomas of the skin, mimicking long-standing atheromas; atheromas with atypical localization and difficult differential diagnosis or cutaneous lymphomas with systemic involvement. Dr Chloe Kam alongside Dr Christi Biji presented the auditory four new cases about high and intermediate risk BCCs of the face and neck areas [41,42]. Dr Irina Todorov presented an interesting case of extraarticular lipoma of the knee.

Assoc Prof Dr Julian Ananiev had a lecture about a slowly progressive B-cell lymphoma-like lesion of the back [43]. The session was then put to an end with two presentations by Dr Tania Popova about the treatment of lymphomas with different drugs on the market. Dr Popova’s lectures emphasized the leading role of the interdisciplinary collaboration with oncohematology in order to achieve more reliable final results in the patient’s treatment.

The annual national conference has established itself over the years as a place, in which the Bulgarian specialists/young scientists alongside international colleagues from all over the world gather together to discuss and debate the current topics in the dermatology field (Figure 6). Alternative ideas and unconventional thinking seem to have become an unwritten concept of the forum. For another year, the conference presented the latest achievements in the dermatology and dermatosurgical fields. This year the forum was extremely successful with international recognition from scientists from all around the world. Therefore, the BULSDS invites you to next year’s annual national conference which will take place again in Sofia, 16 March 2024, Hotel Marinela, in which brand new ideas, observations and methods will be waiting to be presented.

REFERENCES