

One Step Surgery for Cutaneous Melanoma: “We Cannot Solve Our Problems with the Same Thinking We Used When We Created Them?”

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Abstract

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One step melanoma surgery is, in fact, an innovative combined method for diagnosis and treatment of cutaneous melanoma (at the same time). The methodology allows an accurate assessment of the actual status of the affected patients by 1) clinical status, dermatoscopy, high-frequent ultrasonography (HFUS) of the pigmented lesion (eventually in combination with normal lymph nodes ultrasonography), followed by a single surgical intervention. Within this intervention, the primary tumour is removed with the appropriate surgical field, with or without parallel detection and draining lymph node biopsy (depending on the established tumour thickness). Removal of the lymph node may, in turn, be associated with or without locoregional lymphadenectomy, which is determined by its macroscopic appearance, established intraoperatively or after the histopathological evaluation. The methodology is sparing, innovative, easy to apply, tested in its functionality and logically justified. For an unknown reason, this methodology is not applicable in melanoma treatment's guidelines in Europe and America. In Bulgaria and France, however, there are centres and hospitals that apply the technique mentioned above with enormous results, in particular in Bulgaria, the methodology is getting more and more improved to the current moment. Based on the above, as well as on the scant experience, we may share the opinion that the current melanoma treatment's guidelines need major corrections in their recommendations, which are not optimal for patients due to the following facts: (1) the adverse effects on patients as a result of the necessity of at least 2 surgical interventions; (2) the frequent occurrence of changes in the lymph flow after the primary excision; (3) the frequent non-obtaining of the suggested in the guidelines terms for re-excisions with or without sentinel lymph node removal; and (4) the creation of additional financial difficulties for the patients in the framework of two unneeded hospitalizations.

Introduction

One step melanoma surgery is not implicated as an idea yet, and not even as a possible opportunity for an eventual recent realisation or as a postulate in the recommendations of the American / European guidelines for melanoma's treatment [1]. A little more encouraging is probably the situation with the European guideline for the diagnosis and treatment of melanoma, even though this approach is not even mentioned as an opportunity. This should be interpreted at least as critical.

This "hot topic", however, has been already mentioned in some current publications in the world's

literature, but remains without an adequate or logical answer at the moment, unfortunately [1]? A solution of problems within a one-step model (a model with some advantages or advantages regarding at least the patients) appears to be considerably better as an option for clinical behaviour, especially if this model is compared to the actual one. The multistep model finds "the silent disapproval of the audience", but only few dare to rise against it loudly. In our previous manuscript, we tried to give a precise and accurate explanation of the problematic or "hot spots" (in the AJCC's recommendations), which is "widely accepted" for unknown reasons, and they should not be even debated [1]? Or at least not in public debate [1].

Interestingly, the ultrasound measurement of

tumour thickness is also not incorporated (in AJCC's / European recommendations for the treatment of melanoma as a way of facilitating the diagnostic approach, and hence a kind of opportunity for a more gentle clinical behaviour towards the patients themselves (regarding the number of surgical interventions). Namely this approach of a kind of "wrong" or "unconscionable" for patients as well as the health system of clinical behaviour, should be at least sharply criticised due to the following two points:

1) the adverse effects on the patients themselves due to the necessity of at least two surgical interventions, as well as;

2) the creation of additional financial difficulties within the two hospitalisations.

Thus, (in the current model of clinical behavior in patients with melanoma), prerequisites for increasing the number of visits to the clinician as well as the number of hospitalization are created indirectly (maybe also regarding the number of postoperative complications), and last but not least to create conditions for unnecessary high pays by the cashier to the appropriate treatment facilities as a second surgical intervention, for example. Or, in other words, isn't it a matter of forming a kind of cartel (highlight a question)?

"The cartel by definition is a form of monopoly unification or consent to maintain market shares of independent producers and to determine the quantity and price of the production offered in the industry. The cartel is one of the most serious violations of the rules of effective market competition. Its primary objective is to raise prices by reducing or eliminating the competition, which directly damages the consumers of goods and services. Cartels also harm the economy as a whole by removing of the enterprises' stimuli for innovations and optimisations of their productivity."

If you changed any of the terms in the above-mentioned text, namely: "market shares" - with "medical services", "independent producers" -with "independent clinics", "offered production"- with "offered medical services", "damage to the consumers"- with "damage or disadvantages of the patients' health" or with "prerequisites for damage of the patients' health, ... or "strange complications?" Would that sound different? But at least, would that be somewhat logically justified or largely overlapping with the definition of a cartel? Parallels and equivalents should be sought precisely because optimization and perfection could be achieved only in this way. No matter if we talk about medicine or other activity. This erases the errors, and the corresponding system becomes more efficient. The lack of response from AJCC (as well as from the European guidelines for melanoma's treatment) to these pressing issues at the moment makes we think in two directions:

1) silence as the main sign of consent (with shared by us information); or

2) there is a real lack useful move and explanation - so it would be better to be silent (whatever we say - we will still be wrong, and a useful move will not be found).

Luckily or not, some clinics in Europe (in particular France and Bulgaria, and possibly other countries) increasingly ignore the AJCC's criteria, even the European Melanoma's Treatment Criteria. This, in turn, or at the expense of this, optimizes the clinical approach in certain patients' groups. And it also creates some advantages for them. It should not be forgotten that the guidelines are not obligatory, but only recommended (by presumption and by definition) [1]. Isn't it possible then these guidelines not to be strictly followed? Namely - by explaining their minuses (which are more than the pluses)? Within detailed discussions, even the patients are wondering how these guidelines support them or should we stick to them strictly? Informed consent of these patients for a certain divergent surgical intervention would be the best solution for the patient. And it works definitely!

One of the main arguments that should be highlighted and confirming the suggestion shared by us is that the measured ultrasound tumour thickness (with high sensitive ultrasounds HFUS) correlated in a very high percentage of cases with the established postoperative histopathological thickness of Breslow. A fact, which is confirmed in some studies recently [2-15]!

We should ask ourselves - what then stops the innovations and who does not know that the proposed changes for a new melanoma's clinical management guideline are beneficial? Furthermore, most of these benefits are directed only to the patients? Or that is precisely what prevents the progress and implication of these recommendations, ... maybe?

The European criteria for surgical treatment of melanoma from 2016 differ somewhat from those of the American Dermatologic Society (AJCC) as they are definitely more strict and clear to the surgeons, regarding the recommended surgical field: 5 mm for melanoma in situ, 1 cm for melanoma under 2 cm and 2 cm for melanomas over 2 mm. Unfortunately, they also do not answer the urgent questions about the performance of high sensitivity ultrasound examination before the surgery.

Despite this, isn't it necessary these criteria be transformed and to introduce a new, uniform approach to the diagnosis and treatment of cutaneous melanoma? Cheaper and more reliable? Through simplification and logic to optimisation and progress? Or some colleagues need too much this second hospitalization and excision with draining lymph node removal, amounting to about 12 000 dollars (based on nonofficial data, personal conversations, unclear with or without sentinel lymph node removal or partial or complete lymphadenectomy)? Or as they say: "It's

nothing personal, it's just business!"

Especially when it comes to patients requiring detection and removal of the corresponding draining lymph node: ...wouldn't be this the best option to maintain an intact and authentic draining lymph flow? Wouldn't this facilitate the approach in melanoma patient in general? The high-frequent ultrasonography in these cases would be a superb solution? As well as an unobstructed transition to one step melanoma surgery!

Naturally, the risks of wrongly measured (lesser or greater) tumour thickness should not be ignored. These are errors that should be "swallowed" in the first place, because: (1) when a larger tumour thickness is established with simultaneous removal of the sentinel lymph node within one operative session; (2)... the patient does not lose anything in practice? An additional operation is not necessary, but a kind of "over-security" is provided at the same time? And if the tumour thickness is wrongly established (smaller than the real one), a re-excision has to be done with or without draining lymph node (depending on the already established tumour thickness).

It is precisely the balance between these statements, criticisms; innovations, suggestions or ... whatever we call them has not been reached at the current moment. The quicker solution, or at least consensus achieving or balance on these key issues, I would even call them "destiny's questions", for someone, would lead to more adequate and effective treatment of patients with melanoma.

Solutions are often in front of us, and they just have to be accepted!

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