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## OPINION ARTICLE

### One-Step surgical removal of a cutaneous melanoma: Current evidence<sup>☆</sup>



### Evidencia actual del tratamiento quirúrgico del melanoma cutáneo en un solo tiempo

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The management of cutaneous melanoma has changed radically in the last 30 years. While initial approaches involved wide excision with 5-cm margins and prophylactic radical lymph node dissection, now the tendency is to use increasingly conservative treatments based on the findings of multicenter clinical trials. New data continue to emerge that are driving changes at a dizzying speed.

The latest version of the National Comprehensive Cancer Network (NCCN) guidelines on the surgical treatment of melanoma recommends narrow excision with margins of 1–3 mm followed by a second surgical intervention to widen margins following histologic determination of Breslow thickness.<sup>1</sup> Wider margins in the initial procedure are advised against as they could alter local lymphatic drainage patterns and interfere with accurate sentinel lymph node (SLN) identification.

SLN biopsy has been considered a valuable staging tool in cutaneous melanoma for many years, as it provides prognostic information for patients with clinical stage I/II

disease (without clinical or radiographic evidence of lymph node involvement) and guides diagnostic and treatment decisions.<sup>2</sup>

One of the most important implications of SLN biopsy for melanoma management, based on findings from the first multicenter selective lymphadenectomy trial (MSLT I), was that immediate complete lymph node dissection (CLND) was recommended in patients with a positive SLN biopsy.<sup>3</sup> Nonetheless, the later DeCOG trial showed no significant survival advantage for CLND compared with observation only.<sup>4</sup> This lack of advantage was confirmed by the recently published findings from the second MSLT trial (MSLT-II) showing similar survival rates for patients with SLN positivity regardless of whether they underwent CLND or nodal basin ultrasound surveillance.<sup>5</sup>

The results of the above trials led some authors to recommend replacing CLND with nodal basin ultrasound surveillance.<sup>6</sup> The 2019 NCCN guidelines mention this as an option, that is, they say that a patient with positive SLN status can be observed by nodal basin ultrasound, without the need for CLND. These recommendations have led to a dramatic reduction in the performance of CLND among patients with a positive SLN biopsy at specialized melanoma centers.

Many authors are of the opinion that if SLN biopsy is no longer needed to determine whether or not CLND is

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indicated, then it should be purely considered a staging procedure and that its role in the management of melanoma needs to be rethought.<sup>7</sup> SLN biopsy is starting to lose its status as a standard procedure in melanoma, particularly outside the setting of clinical trials. There are numerous reasons for this, including false-positive and -negative rates, cost,<sup>8</sup> and the risk of morbidity (6% of patients develop lymphedema). SLN biopsy may still, however, continue to have a role in the selection of candidates for clinical trials evaluating adjuvant therapy with new biologic drugs.

This latest information should be clearly explained to patients in understandable language so that they can actively participate in decisions regarding their care. The NCCN guidelines have always referred to SLN biopsy as an option that should be discussed and considered; not just with members of multidisciplinary melanoma committees but also with patients. The latest NCCN guidelines also mention CLND as an option to be discussed with SLN-positive patients.

Equipped with clear information about their options, a considerable proportion of patients will probably choose the "interventional" route, that is, SLN biopsy, followed or not by CLND, and enrolment in a clinical trial investigating adjuvant therapy with biologics. Others will choose the "conservative" route, consisting of wide surgical excision (without SLN biopsy) and close nodal basin ultrasound surveillance.

Those who choose the first route probably consider that this is their best option, as by benefiting from the latest diagnostic and treatment methods, they will trust they are receiving the best possible care. The NCCN strongly encourages enrolment of melanoma patients in clinical trials as it considers this to be the best management option. In addition, clinical trials will obviously help advance existing diagnostic tools and treatments.

Patients who choose the more conservative route probably do so as they consider this to be the safest route, as they will not be exposed to the risks associated with SLN biopsy or CLND or new adjuvant drugs whose adverse effects and efficacy remain to be fully elucidated. Considering the latest findings that do not support the use of CLND in patients with positive SLN status, it is possible that we will see an increase in the percentage of melanoma patients who opt for wide excision and nodal basin ultrasound surveillance. The decision not to perform SLN biopsy can also be influenced by other factors, such as the patient's age and general health status, presence of the primary tumor in an area with multiple lymphatic drainage pathways, and a high risk of comorbidity (positive SLN in the parotid gland). It should also be noted that not all patients are referred to specialist centers equipped with multidisciplinary melanoma units. Many patients, whether for geographic or personal reasons, may decide not to travel to such centers, opting instead for a local or private hospital that may not have the latest technology or tools for the diagnosis and treatment of melanoma or that may not be participating in a clinical trial.

Patients who for whatever reason do not undergo SLN biopsy are candidates for 1-step melanoma surgery. The NCCN's recommendation for 2-step excision is based on the need to avoid disruption to lymphatic drainage patterns that could interfere with subsequent SLN identification. If, however, there are no plans to perform SLN biopsy, 1-step wide

excision is perfectly feasible, as it was before the advent of SLN biopsy.

Noninvasive techniques such as dermoscopy or high-resolution ultrasound can help determine margin size for the excision of tumors with an unknown Breslow thickness. Clear correlations have been found between thickness and certain dermoscopic and histopathologic features. The irregular pigment network observed by dermoscopy, for example, corresponds to atypical melanocytic hyperplasia at the dermal-epidermal junction, which has been shown to be common in early-stage melanoma and much rarer in thicker melanomas because of the destruction of rete ridges. Blue-gray areas, in turn, reflect the presence of pigmented melanocytes or melanophages in the mid reticular dermis and are observed in melanomas that have reached this depth. Other dermoscopic findings observed in thicker tumors are radial streaming and an atypical vascular pattern.<sup>9</sup> Melanoma thickness measured by high-resolution ultrasound also correlates well with histologic Breslow thickness.<sup>10</sup> The availability of ultrasound in many dermatology departments has led to an increasing use of this tool for routine preoperative assessment. Integration of clinical characteristics (e.g., macules, papules, nodules, ulceration, > 4 colors) and dermoscopic and ultrasound findings can provide a highly accurate estimate of tumor thickness prior to surgery.

The recommended margin sizes for wide surgical excision of melanoma according to the NCCN are 0.5–1 cm for melanoma in situ, 1 cm for tumors with a Breslow thickness of 1 mm or less, 1–2 cm for tumors with a thickness of 1–2 mm, and 2 cm for tumors with a thickness of 2 mm or more. These sizes may be modified by individual anatomic or functional factors. The prospective multicenter prospective trials on which the NCCN recommendations are based recommend a Breslow thickness of 2 mm as the best cut-off for deciding whether to use an excision margin of 1 or 2 cm.<sup>11</sup> In the international prospective study conducted by the World Health Organization, patients with a Breslow thickness of less than 2 mm had similar survival rates regardless of the surgical margins used (1 cm or larger).<sup>12</sup> Studies conducted in Sweden<sup>13</sup> and France<sup>14</sup> have confirmed that excision with 1-cm margins does not affect survival in patients with melanomas with a Breslow thickness of less than 2 mm. In addition, a European multicenter trial found that excision with margins of over 2 cm did not provide any survival advantage to patients with a Breslow thickness of over 2 mm.<sup>15</sup>

Being able to distinguish between thin melanoma (Breslow thickness  $\leq 2$  mm) and intermediate-thickness melanomas ( $> 2$  mm) is very useful when planning 1-step melanoma surgery, as one of the limitations of dermoscopic and ultrasound evaluation is their limited ability to differentiate between melanoma in situ and thin melanoma.

Integration of clinical, dermoscopic, and ultrasound findings, however, provides a very accurate means of determining whether a melanoma has a thickness of more or less than 2 mm, guiding thus the decision on whether to use surgical margins of 1 or 2 cm, respectively.

Obviously, this preoperative estimate is not as accurate as postoperative histologic measurement and could give rise to the use of excessively large or small margins. In a recent study of 78 melanomas excised using 1-step

melanoma surgery guided by high-resolution ultrasound, 91% of margins were found to be adequate based on subsequent histologic evaluation of Breslow thickness. Just 2 of the 78 melanomas required a repeat intervention due to insufficient margins.<sup>16</sup>

Although the above approach would result in few cases with excessively large or small margins, it is worth analyzing the potential consequences. Excision using 1-cm margins of a melanoma subsequently staged as in situ in the histologic examination would result in an excessive margin of 0.5 cm. The aesthetic consequences would be a slightly longer scar than necessary, but this would be acceptable in most cases. Use of 2-cm margins to remove a melanoma subsequently found to have a Breslow thickness of less than 2 mm, by contrast, would result in an excessive margin of 1 cm. If the melanoma was located in a critical anatomic location, the resulting surgical defect might need complex reconstruction. In such cases, it might be more sensible to perform an excisional biopsy in the event of doubt.

Use of 1-cm margins to remove a melanoma with a Breslow thickness of over 2 mm in the histologic examination would be insufficient and would require a second intervention. This situation would be similar to standard 2-step surgery.

Although high diagnostic accuracy for melanoma has been observed among dermatologists,<sup>17</sup> 1-step surgery should be reserved for lesions with an unequivocal clinical and dermoscopic diagnosis to prevent benign lesions from being excised with excessively large margins.

It could be postulated that wide 1-step surgical removal of a melanoma would rule out the possibility of subsequent SLN biopsy, but findings have shown that wide local excision does not affect SLN identification.<sup>18</sup> The NCCN guidelines clearly state that even though its sensitivity might be affected, SLN biopsy is an option to consider after the repair of large defects using turnover flaps or grafts.

Although most lesions suspicious for melanoma can be easily biopsied by excision or saucerization, it is important to explain to the patient that 1-step surgery has the advantage of eliminating the need for a second procedure, saving the patient thus time, travel, and lost hours at work and reducing by half the risk of surgical complications and discomfort associated with local anesthesia and wound dressing.

One-step melanoma surgery also reduces costs, as there is no need for a second procedure or a second histologic study, which in any case, has a very low diagnostic yield, as additional findings are rarely observed.

A re-excision procedure to widen margins can also have a psychological impact on many patients who, despite having been previously informed, may think that something untoward was observed in the first operation that worsened their prognosis, calling for a second, more complex, operation.<sup>19</sup>

In conclusion, based on current evidence, 1-step melanoma surgery is a perfectly valid option for duly informed patients who opt for the more conservative approach of wide excision and close surveillance without the need for an SLN biopsy. Integration of clinical, dermoscopic, and/or ultrasound findings can be used to estimate tumor thickness (<2 vs. >2 mm) before the operation and decide whether to use 1-cm or 2-cm margins, respectively. This approach avoids the need for a second operation to

obtain wider margins in a high proportion of patients, bringing many benefits.

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