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Retrospective multicenter study on severely dysplastic melanocytic nevi: evaluating the need for re-excision and the risk of recurrence or progression

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Abstract

Severely dysplastic melanocytic nevi (SMD) are histologically challenging lesions with no consensus on optimal management. While complete excision is widely recommended, the necessity of additional re-excision remains debated. This retrospective, multicenter observational cohort study evaluated the risk of recurrence and disease progression in patients with SMD by comparing those who underwent a single complete excision to those who underwent a secondary widening procedure with 5 mm margins.

A total of 226 patients (230 SMD lesions) were included, with diagnoses based on the 2018 World Health Organization (WHO) criteria. Among them, 13.5% underwent re-excision despite clear margins, while 86.5% were followed clinically. Over a minimum 5-year follow-up period, no patient in either group experienced recurrence at the excision site or progression to melanoma.

These findings suggest that complete excision with clear margins is sufficient for managing SMD, with no added benefit from routine re-excision. Avoiding unnecessary surgical procedures could reduce patient anxiety, healthcare costs, and surgical morbidity. Given the lack of standardized guidelines, further prospective studies are needed to refine clinical decision-making for SMD management.

Introduction

In 1978, Clark *et al*. introduced the concept of the dysplastic nevus (DN), describing a cutaneous lesion as having atypical melanocytic hyperplasia, melanocytic cytologic atypia, mesenchymal changes in the papillary dermis, and a lymphocytic infiltrate.[1]

Since then, the term DN has increasingly become part of common practice, and several histopathological criteria have been proposed for its definition until, in 1992, the World Health Organization (WHO) introduced its criteria for the diagnosis of DN for the first time, derived from a consensus of pathologists, which organized and standardized the various definitions and classifications proposed up to that point.[2,3] However, the WHO criteria for the diagnosis of DN did not consider cytologic atypia, which many pathologists regarded as a fundamental criterion. For this reason, the WHO updated its histopathological criteria in 2018, including cytologic atypia and introducing guidelines for grading the degree of dysplasia.[4] Prior to this, cellular atypia was assessed using the criteria proposed by Duke University, which classified atypia into three different grades: mild, moderate, and severe.[5] With the 2018 WHO classification, the grading system was simplified into two categories: low-grade dysplasia and high-grade dysplasia.[4] This classification is currently in use, and its criteria are applied by pathologists for the diagnosis of DN. Additionally, in 1992, the National Institutes of Health in the United States issued a consensus statement recommending that the term “dysplastic nevus” be replaced with “atypical nevus”

(AN) which, along with the term “melanocytic dysplasia” (MD), is now one of the most commonly used and correct terms.[6]

The MD are a subset of melanocytic nevi that are clinically atypical and characterized histologically by architectural disorder and cytological atypia.[4] “Architectural disorder” refers to deviations from the typical junctional nevus pattern, where uniform nests of melanocytes are present at the tips of rete ridges across the lesion, and is also associated with an increased lesion size compared to common acquired nevi. Cytological atypia is marked by enlarged nuclei, which may exhibit varying degrees of irregularity, chromatin clumping, hyperchromatism, and variably prominent nucleoli. Mitoses within intraepidermal melanocytes are rare; however, their presence indicates severe cytological atypia and raises the differential diagnosis of melanoma *in situ*.[4] Like other nevi, dysplastic nevi are immunolabeled with melanocytic markers such as S100 protein, Melan-A, MITF, tyrosinase, and SOX10. HMB45 staining is particularly useful, as it can reveal stratification indicative of maturation or senescence, with staining typically limited to superficial cells. The Ki-67 proliferation index in dermal hotspots is generally less than 5%.[4] The 2018 WHO diagnostic criteria are summarized in Table 1.

There is no consensus regarding the treatment of MD, nor do the guidelines provide clear recommendations. On one hand, it is now well-known that MD is not considered a precursor to melanoma; on the other hand, the presence of MD is known to be associated with an increased general risk for melanoma, particularly if the patient has multiple DN.[7,8] MD are often removed because they are part of the differential diagnosis with melanoma due to their clinical and dermoscopic overlapping features. DN may be both clinically and histologically “simulators” of melanoma.[9] Substantial evidence indicates that low and mildly or moderately MD are not definitive precursors to melanoma and do not necessitate re-excision following complete excision.[9] Severely dysplastic melanocytic nevi (SMD) should be fully excised due to significant histopathologic overlap with melanoma, which increases the potential for diagnostic error.[7] There is no consensus on the management of SMD with negative biopsy margins, with approaches varying from active surveillance to re-excision using different surgical margins.[10] This recommendation arises from the diagnostic uncertainty rather than definitive proof that these nevi act as melanoma precursors.

The lack of clear guidelines on the management of SMD leads some centers to adopt precautionary practices, treating DN similarly to melanoma *in situ*.[11] This approach involves excision followed by a wider resection with margins up to 5-10 mm. This approach leads to a significant increase in costs for the healthcare system, the patient, or insurance companies, as well as further prolonging waiting lists.

Additionally, it exposes the patient to complications from a second surgical procedure without clear evidence of the actual necessity for such treatment.

The study aims to evaluate the risk of recurrence and/or disease progression in patients treated for SMD by comparing those who underwent a single surgical procedure in which the SMD was completely excised with varying margins to those who, after complete excision, underwent a secondary procedure with 5 mm margins.

Materials and Methods

The study was approved by the Ethics Committee "Lombardia 6" and assigned protocol number 6398. It is a retrospective, multicenter observational cohort study, non-sponsored and non-profit, promoted by the Association of Italian Hospital Dermatologists (ADOI).

The Pathology Department records from "ASST-Spedali Civili" of Brescia, "Azienda Ospedaliera Carlo Poma" of Mantova, "Ospedale di Circolo e Fondazione Macchi" of Varese, "Ospedale Maurizio Bufalini" of Cesena, "Ente Ospedaliero Ospedali Galliera" of Genova, and "Istituto Dermatologico San Gallicano" of Roma were analyzed. Patients with a histological diagnosis of SMD were extracted for the period from June 1, 2018, to May 31, 2019. The diagnosis of SMD was made according to the criteria of the 2018 WHO classification.

The data collected and analyzed included the anatomical site of SMD excision, the date of dysplasia removal, the patient's sex and age, any concurrent diagnosis of melanoma and/or other SMD during their lifetime, the histological lesion size, the lesion-free margins at the first excision, whether or not a second wider excision was performed after the complete removal of the SMD, the date of re-excision, additional pathology comments, the presence and location of any subsequent melanomas, and any local recurrence and/or disease progression (defined as the development of locoregional or distant metastases) during the follow-up period. If patients had more than one SMD that met the criteria for our study, each was evaluated as a separate entity and followed over time. The decision to perform a second widening procedure was made independently by the dermatologist in charge of the patient's care.

The necessary data were extracted from the records or information systems of the hospitals participating in the study. If one or more data points were missing, the patient was contacted directly to obtain the information. A clinical history of at least 5 years of follow-up since the diagnosis of SMD and histopathological evaluation according to the 2018 WHO classification were essential inclusion criteria for patient selection.

To reduce potential confounding factors, it was decided to exclude from the study patients with a diagnosis of SMD and a concomitant history of melanoma of stage IB or higher, according to the 8th AJCC melanoma classification,[12] in order to avoid misattribution of disease progression.

The statistical analysis was performed using SPSS software (version 29.02; IBM SPSS, Armonk, NY, USA). Continuous variables were tested using the Kolmogorov-Smirnov and Shapiro-Wilk tests to assess their approximation to a normal Gaussian distribution. The statistical investigation began with a descriptive analysis of the variables, including the calculation of means and standard deviations for continuous variables and percentages for categorical variables. This was followed by a non-parametric inferential analysis with the appropriate test, namely the Mann-Whitney U test for independent samples. The Pearson's chi-square test and Fisher's exact test were used to assess associations through contingency tables; for tables larger than 2x2 matrices, standard residuals were evaluated. All results were tested at a 5% significance level.

Results

From the data analysis conducted through electronic records, 243 patients with a diagnosis of SMD were identified. Following a review of clinical histories, 16 patients were excluded due to a diagnosis of melanoma, either preceding or subsequent to the diagnosis of SMD, with a stage greater than IA. Additionally, 1 patient was excluded due to a follow-up period of less than 5 years, as the patient passed away from cardiovascular complications shortly after the SMD diagnosis.

A total of 226 patients were included in the study, accounting for 230 SMD lesions. Among these, 2 patients had two lesions each, diagnosed as SMD that met the study's inclusion criteria, and 1 patient had three lesions meeting the criteria.

The examined population, whose characteristics are summarized in Table 2, consisted of 101 women (44.7%) and 125 men (55.3%) with a mean age of 51.97 years (SD 15.24; range 16-84). The location of the lesions was found to be in the head and neck region in one case (0.4%), the upper limbs in 24 cases (10.4%), the trunk in 180 cases (78.3%), and the lower limbs in 25 cases (10.9%). The mean size of the studied SMD lesions, measured as the maximum diameter, was 5.83 mm (SD 2.41; range 2-25 mm).

All analyzed lesions were completely excised through excisional biopsy (negative margins). In 31 (13.5%) cases, a second widening procedure with 5 mm margins was performed, while the remaining 199 (86.5%) underwent clinical follow-up only. Regarding the histological margins in the population that did not undergo a widening procedure, the margins were measured in 32 cases, with a mean of 1.95 mm (SD 0.72; range 0.7-4.1 mm). In the remaining 167 patients, the margins were reported as "negative" but

were not measured. For the 31 lesions that underwent widening, the mean margin at the first excision was 1.7 mm (SD 0.7; range 0.6-4 mm); only in one case were the margins reported as "negative" but not measured in this population.

No patient, either among those who underwent a single excision with clear margins or among those who underwent a second widening procedure after complete excision, experienced recurrence at the excision site or disease progression, defined as the development of locoregional or distant melanoma metastases, during the follow-up period, which mean was 67.7 months (SD 4.97; range 60.1-78). Specifically, the means and the respective 95% exact confidence intervals for the two groups were 65.03±1.7 for the single excision group and 68.15±0.69 for the group who underwent a second widening procedure after complete excision.

The personal clinical history of each patient was evaluated, and in 31 patients (13.7%), a prior or subsequent diagnosis of Stage 0 or IA melanoma was observed. This percentage increased to 19.3% when considering the entire population diagnosed with SMD, including patients with all stages of melanoma.

No statistically significant correlations were observed between the variables age, sex, lesion size, margin at the first excision, and the patient's history of melanoma with the likelihood of influencing the clinician's decision to perform or not perform widening of the already completely excised SMD (p-value≥0.05).

Discussion

In 2015, a consensus promoted by the Pigmented Lesions Subcommittee (PLS) of the Melanoma Prevention Working Group addressed the management of mild and moderate MD, supporting the concept that if dysplasia is excised with clear histologic margins, no further excision is necessary. Additionally, clinical observation, rather than re-excision, may represent a safe option for mild and moderate MD with positive histologic margins, provided there is no clinically apparent residual pigmentation.[13] This concept was later supported by a subsequent multicenter retrospective cohort study conducted by the PLS.[14]

Regarding SMD, there is no consensus on its management. However, it is agreed that incomplete excision or partial biopsy of the lesion should be avoided, and the lesion must be completely excised.[15] This is because incomplete sampling carries the risk of missing melanoma associated with a severely dysplastic nevus.

The "Melanocytic Pathology Assessment Tool and Hierarchy for Diagnosis" (MPATH-Dx), a diagnostic classification system developed to standardize the evaluation of melanocytic lesions, was revised in 2023 (MPATH-Dx v2.0) to enhance diagnostic consistency among pathologists.[16] While this revision

represents a significant improvement in standardization, it also continues to group SMD within the same risk category as melanoma *in situ* (MIS), thereby recommending the same treatment approach: "re-excision with margins <1cm".[16]

Although this recommendation is well-supported by established evidence and clinical guidelines for MIS, it is necessary for incompletely excised SMD (positive margins), but its application to completely excised SMD (negative margins) lacks robust supporting data.[9,17] Consequently, this approach may lead to unnecessary surgical interventions and induce substantial anxiety for both patients and clinicians.

The lack of clear guidelines on the management of SMD allows for various possible scenarios, ranging from observation of partially removed SMD to complete excision followed by a second intervention with margin widening from 2 to 10 mm.[11,15,18-21]

A 2015 survey of Canadian dermatologists on the management of MD revealed that 65.4% of dermatologists always re-excise an SMD when the pathology report states that margins are negative (19.1% do so frequently, 9.9% rarely, and only 2.5% never perform this practice).[21]

In a 2018 survey of pigmented lesion clinic (PLC) directors in the United States, all participants agreed on the necessity of achieving complete excision of SMD and requiring an additional procedure; however, recommendations for clinical margins varied widely.[15]

In a 2017 survey of Australian dermatologists, there was agreement on performing a second surgical procedure in cases of SMD diagnosed from an incomplete excision. However, there was no consensus on performing a wider excision if the dysplasia had already been removed with at least a 1 mm margin. In this scenario, 56% of Australian dermatologists considered a second procedure unnecessary, while 44% tended to perform a wider excision with 5 mm margins.[20]

In a 2023 survey of Spanish dermatologists in cases of SMD with involved margins, 1.2% of dermatologists report not performing radical excision and continuing with clinical follow-up alone, 53.5% perform a complete excision with margins of 1 to 4 mm, and 45.3% perform a second procedure with margins of 5 to 10 mm.[11] In cases where the SMD has been excised with clear margins, 68.6% of dermatologists report not performing any further procedures, while 12.8% perform a radical excision with margins of 1 to 4 mm, and 18.6% use margins of 5 to 10 mm.

As for the evidence in the literature, there are numerous studies on the outcomes of MD, but when focusing specifically on SMD, the body of literature becomes less extensive.

In 2017, Engeln *et al.* retrospectively analyzed 451 patients with a histologic diagnosis of SMD and at least 5 years of follow-up.[22] They compared the outcomes of patients who underwent re-excision with those who did not, following an initial diagnostic biopsy. This biopsy showed clear margins in 140 cases,

clear but close margins in 47 cases, involved margins in 40 cases, indeterminate margins in 3 cases, and margins not reported in 56 cases. In their study, they observed that only 2 cases of SMD, which were not completely excised at the initial biopsy, were later diagnosed with melanoma following re-excision. This population represented 0.4% of the total patients and 1.2% of those who underwent re-excision. Melanoma progression with metastasis was observed in 7 patients, all from the cohort with SMD that had not undergone re-excision. However, all 7 patients had a history of prior melanoma at another site, with an average Breslow thickness of 2.95 mm (range 0.9-9 mm), and the authors considered it almost certain that the disease progression was attributable to the prior melanoma and not the SMD. None of the 390 patients without a history of melanoma developed metastases during the observation period of the study, and only 37.7% of this group had undergone re-excision.

Compared to our study, Engeln *et al.* included patients with a history of melanoma, including those with advanced stages, who are undoubtedly at risk of developing metastases and may act as confounding factors. Moreover, unlike our study, where SMD are always completely excised as part of clinical practice, they included a large number of SMD with involved margins after the initial excision. Among this population, melanoma was diagnosed in 2 cases after re-excision. Although this finding is consistent with other studies, it underscores the necessity, as previously mentioned, of complete excision of SMD due to the risk of missing melanoma associated with a severely dysplastic nevus.[23-25]

Building on the study by Engeln *et al.*, where cases were collected between November 1994 and November 2004 and underwent histological review by two independent pathologists prior to the article's publication in February 2017, it is worth noting that the histopathological criteria used in that study were neither standardized nor explicitly defined. In contrast, our study relied on diagnoses made by expert dermatopathologists using the currently valid 2018 WHO criteria. These diagnoses were further supported by the latest immunohistochemical techniques routinely employed in clinical practice. To ensure our findings accurately reflect everyday clinical practice, we chose not to re-evaluate the slides of the included patients. Instead, we relied on the original diagnosis made by the first pathologist who assessed each case.

In the study by Soleymani *et al.*, a total of 426 biopsy-proven SMD who underwent conservative re-excision with 2- to 3-mm surgical margins were retrospectively evaluated.[18] This study investigates the outcomes of conservative surgical excision (2-3 mm margins) for SMD diagnosed *via* biopsy, including cases with both negative (clear) and positive (involved) histologic margins. The authors concluded by noting that no excision specimens resulted in upstaging of SMD to MIS or invasive melanoma, and no

subsequent local nevus recurrence or development of melanoma at the excision site was observed. However, the mean follow-up time of 28 months represents a limitation of this study.

In their 2013 study, Hocker *et al.* included 7 SMD excised with a margin of at least 0.2 mm that did not undergo re-excision, none of which developed invasive melanoma at the same site or metastasis from melanoma, with a mean follow-up of 17.4 years.[19]

In a retrospective observational cohort study, Fleming *et al.* evaluated 30 patients with excised SMD, 26 with negative margins, and 4 with positive margins, observed for a median of 7.5 years (range 0.6-17.5). No cases of invasive melanoma at the same site, metastasis, or melanoma-related deaths were reported. This study reports a case of local recurrence during follow-up, with upstaging to melanoma *in situ* (MIS) at the site of a previous excision with clear margins for severe dysplasia. This is the only study in the literature documenting a clinical recurrence of the disease with subsequent pathological reclassification to MIS. However, it is important to note that this study has significant limitations, as acknowledged by the authors themselves, including the lack of standardization of margins and biopsy techniques and the absence of several data points not retrievable in the retrospective analysis. Regarding the case of progression to MIS, no additional information is provided except for the histological margin of the initial excision, described as “narrow”. As with other studies in the literature, this case highlights the lack of updated, standardized, and explicitly defined histopathological criteria.

Semsarian *et al.*, in a recent article published in 2022, explore the challenges and controversies in diagnosing MIS and SMD.[26] The authors argue that the increase in reported cases of MIS and SMD may be partly due to overdiagnosis, potentially causing unnecessary anxiety, treatment, and healthcare costs. The authors propose rethinking diagnostic labels and thresholds to reduce overdiagnosis and its associated harms. They suggest these lesions might be better conceptualized as risk factors for melanoma rather than precursors.[26]

Our study corroborates findings reported in the literature, confirming that DM is a significant marker for melanoma risk. Among the examined population, 19.3% had a concomitant history of DN and cutaneous melanoma.

A key strength of this study is the uniform assessment of melanocytic lesions based on the 2018 WHO classification, ensuring consistency in diagnostic criteria. Additionally, this is the first study to include a homogeneous population in terms of biopsy technique, as only complete excisional biopsies were analyzed. This approach eliminates sampling errors and the potential for residual lesions, which are common limitations of partial or shave biopsies. By excluding these methods, the study provides more reliable histopathological data, reducing misclassification risks.

However, the study also has some limitations. As a retrospective study, it is subject to selection bias and relies on pre-existing medical records, which may introduce variability in data collection. Additionally, the sample size, although multicentric, may limit the generalizability of the findings. A larger cohort and prospective studies would be needed to further validate these results and provide stronger evidence for clinical decision-making.

Conclusions

Our study demonstrates that complete excision of SMD is sufficient and does not require a secondary widening procedure. This approach leads to a reduction in health care use, cost, and morbidity without compromising patient safety.

Additionally, there is no evidence in the literature demonstrating that excision with wide margins provides a survival benefit or improves disease-free survival compared to the more conservative approach of complete excision with clear margins.

It would be advisable to develop specific guidelines for the management of SMD to support decision-making in clinical practice.

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Table 1. Diagnostic criteria for dysplastic nevus and nuclear features in the varying grade of dysplasia, adapted from: *D.E. Elder, D. Massi, R.A. Scolyer (4th Ed), WHO Classification of Skin Tumours, 11th Volume, International Agency for Research on Cancer (2018).*

Diagnostic Critiria for melanocitic dysplasia

- **Width >4mm in fixed sections (>5mm clinically)**
- **Presence of architectural disorder, which requires both of the following:**
  - irregular (i.e. horizontally oriented, bridging adjacent rete, and/or varying in shape and size) and/or discohesive nests of intraepidermal melanocytes
  - increased density of non-nested junctional melanocytes (e.g. more melanocytes than keratinocytes in an area > 1mm²)
- **Presence of cytological atypia, which is graded on the basis of the highest degree of cytological atypia present in more than a few melanocytes**

2018 WHO Classification	Former grade	Nuclear size vs resting basal cells	Chromatin	Variation in nuclear size and shape	nucleoli
Not a dysplastic naevus	0 (Mild dysplasia)	1x	May be hyperchromatic	Minimal	Small or absent
Low grade dysplasia	1 (Moderate dysplasia)	1-1.5x	Hyperchromatic or dispersed chromatin	Prominent in a small minority of cells (random atypia)	Small or absent
High grade dysplasia	2 (Severe dysplasia)	≥ 1-5x	Hyperchromatic, coarse granular chromatin, or peripheral condensation	Prominent in a larger minority of cells	Prominent often lavender

* Architectural features are required for the diagnosis of dysplasia and also contribute to grade; attributes that indicate a diagnosis of high grade (severe) dysplasia, even when cytological atypia is low grade, include pagetoid scatter above the basal layer (but to a lesser degree than in melanoma, usually not above the middle third, and local, le contained within an area <0.5mm²), focal continuous basal proliferation, and intraepidermal mitoses (any dermal mitosis or anything more than a rare mitosis should raise concern for melanoma).

Table 2. Study cohort clinical and histopathologic characteristics and outcomes.

Characteristics and outcomes	Values
Sex **Age**	55.3% male, 44.7% female Mean 51.97 (range 16–84; SD 15.24)
Location, n (%)	Head and neck 1 (0.4%) Upper extremities: 24 (10.4%) Trunk 180 (78.3%) Lower extremities 25 (10.9%)
Lesion maximum diameter in mm	Mean: 5.83 mm (range 2-25 mm; SD 2.41)
Histopathologic margin analysis of initial biopsy, n (%)	Negative/complete excised: 230 (100%)
Surgical excision margin, n (%)	▪ not measured but free 168 (73%) • <1-mm margin: 4 (1.7%) • 1-2.9 mm margin: 54 (23.5%) • ≥3-mm margin: 4 (1.7%)
Lesions undergoing widening after complete excision, n (%)	31 (13.5%)
Lesions undergoing clinical follow-up only after complete excision, n (%)	199 (86.5%)
Histopathologic persistence of melanocytic dysplasia or upgrading of diagnosis in patients undergoing re-excision	None
Length of follow up (months)	Mean: 67.7 (range: 60.1-78; SD 4.97)
Local recurrence **Progression of disease**	None None
History of melanoma	31 patients (13.7%) with prior history of, or subsequent development of, MIS or stage IA melanoma at last follow up