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Management of severe dysplastic nevus (high-grade dysplasia): Italian recommendations for good clinical practice

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Abstract

"Dysplastic nevus" (DN) is a histopathological term used to describe nevi with cytological atypia and architectural disorder. With the 2018 World Health Organization (WHO) classification, the grading system for atypia/dysplasia was simplified into two categories: low-grade dysplasia and high-grade dysplasia (severely atypical dysplastic nevus [SDN]); this classification is currently in use, and its criteria are applied by pathologists for the diagnosis of DN. Actually, there are currently no definitive guidelines for managing patients with DN. This lack of clear direction has historically led many specialists, both dermatologists and others, to perform or request a further widening of a lesion diagnosed as an SDN, even when it has already been completely excised, effectively treating it as a melanoma *in situ* (MIS). This tendency leads to a significant increase in the number of surgical procedures, consequently lengthening dermatological surgery waiting lists. Therefore, reducing the number of inappropriate widenings would have a strong impact on shortening these waiting lists, in addition to the physical and psychological impact a second procedure has on the individual patient. Moreover, the management of histologically severe DN has alternatives to widening because dermatologists can opt for observation (digital monitoring). The Italian National Center for Clinical Governance and Healthcare Excellence (CNCG) of the *Istituto Superiore di Sanità* (ISS) identified the scientific Italian Association of Hospital Dermatologists (ADOI) as the lead organization for the recommendations for good clinical practice on the management of SDN. Further, twelve scientific societies were involved. A systematic literature search was conducted on the following databases: Cochrane Library, MEDLINE, and Embase up to November 27, 2024. Only two retrospective, monocentric observational studies were considered eligible for the study, because they had outcome data for both re-excised and observed patients with the specific histological diagnosis of severe atypia and negative margins, and one relevant systematic review. A GRADE-based assessment was conducted using a narrative summary of findings. The quality of evidence was rated as very low, based on the results from the two non-randomized studies: 0 events among 213 observed patients and 0 events among 101 re-excised patients (total n=314). The available data suggest that observation alone may be a safe alternative to re-excision. The omission of re-excision for DN with negative margins does not appear to increase the subsequent risk of melanoma. The Expert Panel unanimously judged the desirable effect of re-excision in reducing melanoma occurrence to be negligible when compared to observation alone. After collegial discussion, the Expert Panel's judgment on the question, "In patients with a histological diagnosis of a completely excised high-grade DN (with negative margins), is re-excision of the surgical site more effective than clinical follow-up alone in reducing the risk of a recurrent nevus or melanoma?" was "probably not". The panel suggests that, in the absence of clear scientific evidence, further enlargement/radicalization of a high-grade DN, when

it has already been completely removed by elliptical excision, does not appear to be necessary. Furthermore, since it is well known that the differential diagnosis between high-grade DN and early melanoma is complex and difficult even for experienced pathologists, in controversial cases, the Expert Panel suggests, for a definitive decision, referring to a clinicopathological correlation to be assessed on a case-by-case basis.

Introduction

"Dysplastic nevus" (DN) is a histopathological term used to describe nevi with cytological atypia and architectural disorder. With the 2018 World Health Organization (WHO) classification, the grading system for atypia/dysplasia was simplified into two categories: low-grade dysplasia and high-grade dysplasia (severely atypical dysplastic nevus [SDN]); this classification is currently in use, and its criteria are applied by pathologists for the diagnosis of DN.[1] However, despite attempts to establish guidelines defining these histopathological criteria,[2-7] various studies show low reproducibility in grading DN even among expert pathologists and dermatopathologists, particularly in differentiating SDN from melanoma in the radial growth phase.[7,8] It must be underlined that incomplete excision or partial biopsy of the lesion should be avoided, and the lesion must be completely excised, because incomplete sampling carries the risk of missing melanoma associated with an SDN.[9]

The Melanocytic Pathology Assessment Tool and Hierarchy for Diagnosis (MPATH-Dx) is a diagnostic classification system developed to standardize the evaluation of melanocytic lesions, which was revised in 2023 (MPATH-Dx v2.0) to enhance diagnostic consistency among pathologists.[5] While this revision represents a significant improvement in standardization, it also continues to group SDN within the same risk category (Class II) as melanoma *in situ* (MIS), thereby recommending the same treatment approach: "re-excision with margins <1 cm", when margins are considered positive and the lesion adequately sampled.[5,6,10,11]

As a result, there are currently no definitive guidelines for managing patients with DN. This lack of clear direction has historically led many specialists, both dermatologists and others, to perform or request a further widening of a lesion diagnosed as an SDN, even when it has already been completely excised and effectively treated as a MIS.

This tendency leads to a significant increase in the number of surgical procedures, consequently lengthening dermatological surgery waiting lists. Therefore, reducing the number of inappropriate widenings would have a strong impact on shortening these waiting lists, in addition to the physical and psychological impact a second procedure has on the individual patient.

Moreover, the management of histologically severe DN has alternatives to widening because dermatologists can opt for observation (digital monitoring).[12]

In fact, a recent survey promoted by the Italian Association of Hospital Dermatologists (ADOI; *Associazione Dermatologi-Venereologi Ospedalieri Italiani e della sanità pubblica*) among 190 Italian dermatologists concerning the management of DN in Italy reported that for DN with SDN and clear margins, 64.2% preferred observation, while 35.8% performed re-excision (19.5% with 1-4 mm and 16.3% with 5-10 mm margins). When margins were involved in SDN, 54.7% chose re-excision with 1-4 mm and 41.6% with 5-10 mm margins; only 3.2% opted for follow-up.[13] Similar results have also been reported in Australia, Canada, the United States, and Spain.[9,14-16]

The Italian National Center for Clinical Governance and Healthcare Excellence (CNCG) of the *Istituto Superiore di Sanità* (ISS) identified the scientific society ADOI as the lead organization of Recommendations for Good Clinical Practice (RBPCA) on the management of SDN. Further, twelve scientific societies were involved (Table 1). Aim of this recommendation was to determine whether in patients with a histological diagnosis of a completely excised high-grade DN (with negative margins), is re-excision of the surgical site more effective than clinical follow-up alone in reducing the risk of a recurrent nevus or melanoma, without compromising quality of life and while containing the risk of surgical complications (*e.g.*, infections, scars). The target users of the guideline are all doctors who may perform the excision of a DN, particularly dermatologists, dermatosurgeons, and plastic surgeons. The viewpoints and preferences of the target population were gathered through the participation of a representative of the Melanoma Day Association in the RBPCA Working Group.

Materials and Methods

The Expert Panel (SDN-RBPCA Working Group; Table 1) was established as a multidisciplinary and multi-professional group, composed of content experts, such as medical specialists (dermatologist, oncologist, anatomical pathologist, forensic physician, plastic surgeon), and patient/caregiver representatives.

The Panel discussed and approved the clinical question, formulated according to the Population-Intervention-Comparison-Outcome (PICO) model (Table 2) with the support of the Working Group's methodologists.

The voted question read: "In patients with a histological diagnosis of a completely excised high-grade DN (with negative margins), is re-excision of the surgical site more effective than clinical follow-up alone in reducing the risk of a recurrent nevus or melanoma, without compromising quality of life and while containing the risk of surgical complications (*e.g.*, infections, scars)?".

Based on the clinical question and the pre-defined selection criteria, a systematic literature search was conducted on the following databases: Cochrane Library, MEDLINE, and Embase up to November 27, 2024, to identify systematic reviews, RCTs, and observational studies on the efficacy and safety of re-excision *vs.* observation for the management of high-grade DN (histological diagnosis). Specific search strategies were developed for each database, using MESH terms and free-text terms. The key words included "dysplastic/atypical nevus/mole" or "nevi", "melanocytic lesion" or "melanocytic skin lesion", "pigmented lesion" or "pigmented skin lesion", "excision" or "excisions" or "reexcision" or "re-excision", "melanoma", "recurrent nevus", and "follow-up".

The records obtained from the bibliographic search were selected based on their title and abstract. The full text of potentially relevant articles was retrieved, and their eligibility was assessed based on the inclusion and exclusion criteria reported in Figure 1.

For the melanoma outcome, a GRADE summary table or "summary of findings tables" was created to evaluate the quality of the evidence. This was the only outcome investigated in the studies (an outcome considered critical by the panel).

Results

Based on the pre-defined PICO criteria, as shown in the PRISMA diagram (Figure 1), only two retrospective, monocentric observational studies were considered eligible for the study[8,17] because they had outcome data for both re-excised and observed patients with the specific histological diagnosis of severe atypia and negative margins, and a relevant systematic review.[18] This review was used only as a source for references because it was not updated with the most recent literature and had broader objectives and inclusion criteria than the clinical question of this investigation.[18] All other studies were not considered due to the exclusion criteria defined in the PICO (mild and/or moderate atypia; positive margins; studies without relevant outcome data for either the observed or re-excised groups).[19-36]

The study by Engeln *et al.* (2017)[8] included a population with a median age of 41.3 years, while Fleming *et al.* (2020)[17] did not define the inclusion age of patients but reported a median age of 64 years for study participants; both studies included a total number of 451 patients with SDN (Figure 2). The primary outcome reported in both studies was the occurrence of melanoma. Fleming *et al.* additionally reported the presence of residual nevus, which differs slightly from the "recurrent nevus" outcome defined in the PICO framework. Both studies reported baseline characteristics related to melanoma history, but it was not possible to perform a subgroup analysis for the data and outcomes of interest, nor was it possible to conduct stratified analyses for follow-up (for details please refer to Table 3).[8,17]

Among patients managed with observation, no cases of melanoma were reported at the original site of the DN: 0 cases among 187 patients with negative margins in Engeln *et al.* and 0 cases among 26 patients with negative margins in Fleming *et al*. Based on the unanimous opinion of the Expert Panel, and as reported in the study, the single case of MIS described by Fleming *et al.* was considered a recurrence of a pre-existing melanoma, rather than a new primary melanoma, and was therefore excluded from the analysis.[17]

Among patients with negative margins who underwent re-excision of dysplastic nevi, no cases of melanoma were observed in either study: none among the 82 patients reported by Engeln *et al.* or the 19 patients reported by Fleming *et al*. In these cases, as well, based on unanimous agreement of the Expert Panel, the melanoma cases reported in the studies (1 case in 82 patients in Engeln *et al.*; and 1 case in 19 patients in Fleming *et al.*, diagnosed as early-stage cutaneous melanoma one month after initial biopsy) were considered questionable. Concerns were raised regarding both the original diagnosis of DN and the excision technique used (which was not clearly specified – *e.g.*, shave *vs.* elliptical excision). As such, these two cases were excluded from the final analysis. These cases, as also partially acknowledged by the study authors, were considered more likely to represent *residual melanomas* (*i.e.*, initially undiagnosed melanomas) rather than new melanoma occurrences.

Therefore, the final analysis considered 0 melanoma events among 101 patients who underwent re-excision and 0 events among 213 patients managed with observation/follow-up (Figure 2).[8,17] The risk of bias was evaluated as shown in Table 4.

A GRADE-based assessment was conducted using a narrative summary of findings. The quality of evidence was rated as very low (Tables 5 and 6), based on the results from the two non-randomized studies: 0 events among 213 observed patients and 0 events among 101 re-excised patients (total n=314).

As also discussed in the included studies,[8,17] the available data suggest that observation alone may be a safe alternative to re-excision. The omission of re-excision for DN with negative margins does not appear to increase the subsequent risk of melanoma. The Expert Panel unanimously judged the desirable effect of re-excision in reducing melanoma occurrence to be negligible when compared to observation alone.

Discussion

After collegial discussion, the Expert Panel judgment to the question, “in patients with a histological diagnosis of a completely excised high-grade DN (with negative margins), is re-excision of the surgical site more effective than clinical follow-up alone in reducing the risk of a recurrent nevus or melanoma?”, was “probably not”. “The panel suggests that, in the absence of clear scientific

evidence, further enlargement/radicalization of a high-grade DN, when it has already been completely removed by elliptical excision, does not appear to be necessary".

Furthermore, since it is well known that the differential diagnosis between high-grade DN and early melanoma is complex and difficult even for experienced pathologists, in controversial cases, the Expert Panel suggests, for a definitive decision, referring to a clinicopathological correlation to be assessed on a case-by-case basis.

The quality of evidence was rated as very low because it was based on the results from only two non-randomized studies.

Concerning the MPATH-Dx recommendations for Class II lesions of "re-excision with margins <1 cm", when margins are considered positive and the lesion adequately sampled, although this recommendation is well-supported by established evidence and clinical guidelines for MIS, it is necessary for incompletely excised SDN (positive margins), but its application to completely excised SDN (negative margins) lacks robust supporting data.[5,6]

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

A 2015 survey of Canadian dermatologists on the management of DN found that 65.4% of dermatologists always re-excise an SDN 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.[16] A similar survey among Australian dermatologists in 2017 disclosed that 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.[15] In a 2018 survey of pigmented lesion clinic directors in the United States, all participants agreed on the necessity of achieving complete excision of SDN and requiring an additional procedure; however, recommendations for clinical margins varied widely.[9] Another survey conducted in 2023 among Spanish dermatologists concerning cases of SDN 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. In cases where the SDN 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.[14]

Shortly after completing this RBPCA, Ariasi *et al.* published an Italian retrospective, multicenter observational cohort study that evaluated the risk of recurrence and disease progression in patients

with SDN by comparing those who underwent a single complete excision to those who underwent a secondary widening procedure with 5 mm margins.[11] A total of 226 patients (230 SDN lesions) were included, with diagnoses based on the 2018 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 also suggest that complete excision with clear margins is sufficient for managing SDN, with no added benefit from routine re-excision.[11]

The aim of this recommendation for good clinical practice is to provide dermatologists and other specialists with clear guidance on how to manage patients who have had a skin lesion histologically diagnosed as an SDN that has been completely removed. This recommendation applies to all patients who have had a skin lesion histologically diagnosed as an SDN removed, regardless of the patient's age, gender, or general clinical condition.

This recommendation will benefit patients who have undergone SDN removal in several ways:

- It helps avoid unnecessary repeat excisions, thereby reducing indirect costs for the patient.
- It minimizes psychological distress and anxiety associated with a second procedure when it is not needed.
- It contributes to improved cosmetic outcomes by preventing additional surgical intervention.

Moreover, it will also benefit the healthcare system by lowering overall costs and helping to reduce waiting lists.

Conclusions

This RBPCA demonstrates that complete excision of SDN is sufficient and does not require a secondary widening procedure. In controversial cases, for a definitive decision, the Expert Panel suggests referring to a clinicopathological correlation to be assessed on a case-by-case basis.

This approach leads to a reduction in health care use, cost, and morbidity without compromising patient safety. In the absence of clear – or otherwise scarce and very low-quality – scientific evidence, the recommendation against re-excision is also supported by the advantages in terms of reducing potential adverse effects, lowering costs for both patients and the National Health System, and, not least, reducing waiting lists.

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ADMINISTRATIVE OFFICE		
Name	Affiliation	
Doris Franco	Administrative Manager - ADOI	

Table 2. The PICO model.

Population (P)	Adult patients (including pregnant and breastfeeding women) and children who have had a skin lesion completely excised (negative margins) with a histological diagnosis of high-grade DN.
Stratification	By: adults (age >18 years) and children; risk factors for melanoma (childhood sunburns, family history, phototype, number of nevi, number of dysplastic nevi); presence/absence of patient follow-up.
Intervention (I)	Further widening/re-excision surgery of the lesion diagnosed as a high-grade DN, when it has already been completely excised.
Comparison (C)	No widening surgery, observation/watchful waiting/follow-up.
Outcomes (O)	Occurrence of recurrent nevus or melanoma, quality of life, surgical complications (infection, scarring).
Exclusion criteria	Low-grade DN.
Type of studies	High methodological quality systematic reviews (assessed with AMSTAR 2), of RCTs or observational studies. If multiple reviews exist for the same question, the most recent and highest quality are selected. In the absence of such reviews, RCTs or observational studies are selected.

DN, dysplastic nevus; RCT, randomized controlled trial.

Table 3. Characteristics of included studies.

Study author, year, country (study design)	**Participant characteristics**	**Re-excision**	**Observation**	**Follow-up duration**	**Methods-defined outcomes**
Engeln *et al.*, 2017,[8] United States (retrospective study)	451 participants with DN and severe atypia; Mean age: 43.3 years; Women: 53%; Subgroup with negative margins: 82	36.6%; 82 with free margins (free + free but close)	63.4%; 187 with free margins (free + free but close)	Median: 11.9 years (IQR 9.00-14.8)	Melanoma incidence
Fleming *et al.*, 2020,[17] United States (retrospective cohort study)	125 participants with DN and severe atypia; Median age: 64 years; Women: 3.2%; Subgroup with negative margins: 53	85 (68%); 19 with negative margins	40 (32%); 34 with negative margins (26 with follow-up >6 months)	Median: 7.5 years (range: 0.6-17.5)	Residual nevus incidence; melanoma incidence

DN, dysplastic nevus; IQR, interquartile range.

Table 4. Assessment of *bias* risk of selected studies.

Study	Bias due to confounding	Selection bias	Bias in classification of intervention	Bias due to deviation from intended intervention	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall Bias
Engeln *et al.*, 2017	Serious risk	Serious risk	Moderate risk	Low risk	Serious risk	Moderate risk	Low risk	Serious risk
Fleming *et al.*, 2020	Serious risk	Serious risk	Moderate risk	Low risk	Moderate risk	Serious risk	Low risk	Serious risk

Assessment done by Vuong *et al.*[18]

Table 5. Summary of judgments.

	Judgments
Desirable effects of re-excision	Irrelevant
Undesirable effects of re-excision	Irrelevant
Quality of evidence	Very low
Patient values and preferences regarding the considered outcomes	Probably no relevant uncertainty or variability
Balance of effects	Probably in favor of comparison
Acceptability of re-excision	Probably not

Table 6. Summary of findings.

Outcomes	Narrative		N. of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Observation	Re-excision			
Melanoma (free + free but close margins)	0/213	0/101	314 (two non-randomized studies)[8,17]	Very low	Outcome deemed "critical"

Figure 1. PRISMA diagram.

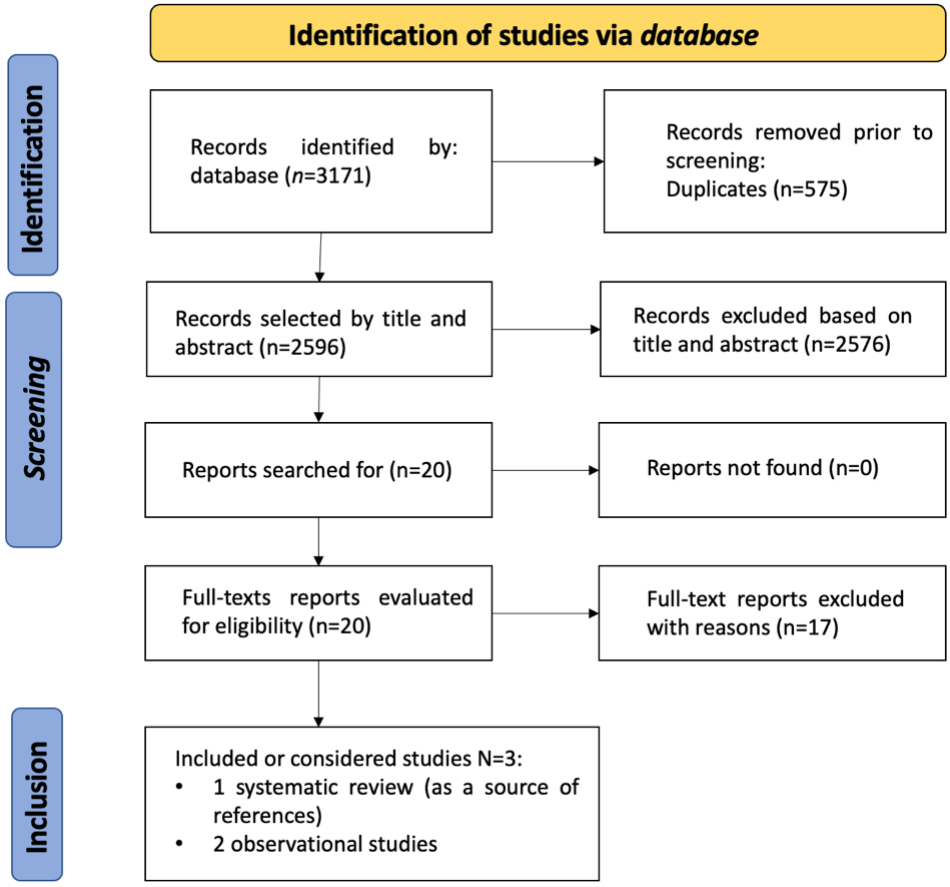
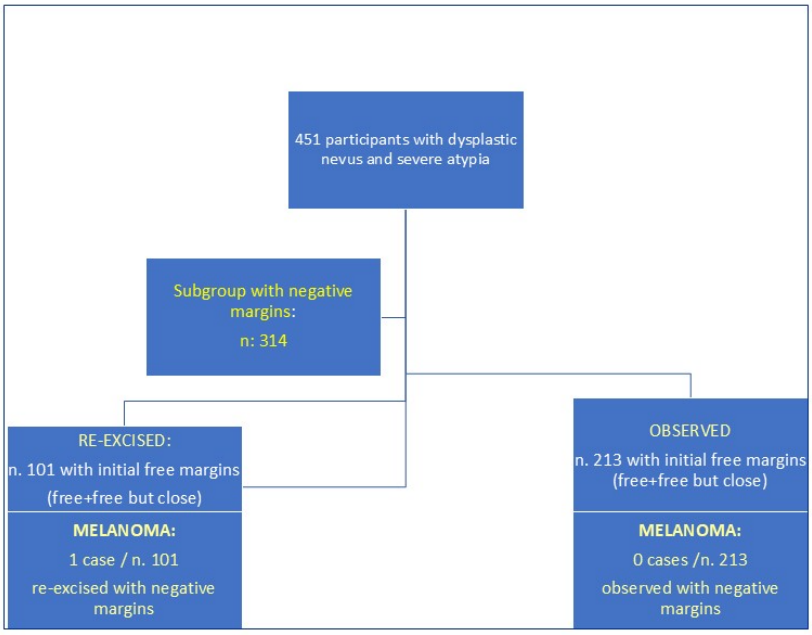


Figure 2. Patient flow diagram (outcome melanoma).



Based on the unanimous opinion of the Expert Panel, and as reported in the study, *the single case of melanoma in situ described by Fleming et al. was considered a recurrence of a pre-existing melanoma*, rather than a new primary melanoma, and was therefore excluded from the analysis