Approach to Mycosis Fungoides in children: Consensus-based recommendations

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Background: Pediatric Mycosis fungoides (MF) management extrapolates from adult guidelines, despite differing clinical aspects. Recommendations are essential to address unique challenges in this distinct patient group.

Objective: This project aims to derive consensus recommendations for pediatric MF management.

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Methods: Experts from pediatric dermatology, general dermatology, dermatopathology, and pediatric hematology-oncology (N = 83) were invited to contribute to consensus recommendations. The process involved 3 electronic Delphi rounds, concluding with a final consensus meeting using a modified Nominal Group Technique for unresolved items.

Results: Consensus included more clinical severity measures than tumor-node-metastasis-blood staging: pruritus, functional or esthetic impairment (eg, palms, soles, genitalia), quality of life impact, and psychological aspects (eg, embarrassment, anxiety, depression), plus parental anxiety. Ten recommendations were made for managing early and advanced pediatric MF. Disagreement emerged in choosing therapies beyond stage I of the disease.

Discussion: This multinational initiative aimed to standardize optimal pediatric MF management and successfully generated consensus recommendations. Additional work is needed for structured, prospective protocols in advanced-stage pediatric MF.

Limitations: Lack of pediatric hematologists-oncologists and patients' representatives.

Conclusion: Documentation of extended clinical severity and outcome measures is recommended. Addressing the need for structured protocols in advanced-stage pediatric MF and implementing systematic, prospective data collection is crucial. (J Am Acad Dermatol 2024;91:1078-85.)

Key words: consensus; mycosis fungoides; pediatric; severity and outcome measures.

INTRODUCTION

Understanding of pediatric-onset Mycosis fungoides (MF) is limited, mainly due to its rare occurrence and the frequent delay in diagnosis.[1,2] Case series and retrospective studies have highlighted differences in MF epidemiology, clinical presentation, histopathology, and prognosis in children versus adults.[1,2]

CAPSULE SUMMARY

- Pediatric Mycosis fungoides management relies on adult guidelines, despite differing clinical aspects.
- Consensus expanded clinical severity measures beyond tumor-node-metastasis-blood staging to include pruritus, functional/esthetic impairment, quality of life impact, psychological aspects, and parental anxiety. Ten consensus-based treatment recommendations for early and advanced stages were established.

The World Health Organization-European Organization of Research and Treatment of Cancer guidelines cover adult MF classification, diagnosis, and management but lack specific protocols for children.[3] Children's unique needs and responses to management necessitate a specialized approach creating clinical guidelines for pediatric MF is challenging due to limited evidence, diagnostic criteria validity, and the absence of established core outcome sets. Guideline panels often refrain from making recommendations, instead gather primary data or rely on expert consensus.[4] Expert viewpoints have steered pediatric care, exemplified by publications on atopic dermatitis,[5] psoriasis,[6] and ichthyoses,[7] aiming to dispel uncertainties and enhance clinical care for young populations.

Consensus-based recommendations evolved to be valuable when evidence is scarce. We initiated a consensus project "AppRoach to Mycosis FUngoides in children" (ARMFUL) to develop recommendations with input from clinical experts caring for children with MF, utilizing an electronic Delphi (eDelphi),[8] and modified nominal group technique (mNGT) approach.[9] The Delphi method, described in 1963,[10] aims to generate expert consensus through serial questionnaires with rating scales to assess agreement.

This project was registered in the Core Outcome Measure for Effectiveness Trials database (www.comet-initiative.org) and supported by the Pediatric Dermatology Research Alliance 2020 Consensus Grant.

METHODS

The expert consensus was pursued using 3 separate rounds of a modified eDelphi exercise followed by a mNGT employed during final consensus meeting, led by a Focused Expert Committee of pediatric dermatologists (A.Z. and E.P.) and an expert in methodology (P.S.).

Abbreviations used:

ARMFUL:	AppRoach to Mycosis FUngoides in children
eDelphi:	electronic Delphi
MF:	Mycosis fungoides
mNGT:	modified nominal group technique

Problem identification

A literature search established a scarce evidence base for MF management in children; most publications were limited to case reports/series or retrospective studies for early-stage MF.[1,2] Given limited evidence in clinical areas, we identified the need for expert consensus, drawing on clinical experience and literature for adults and children, to formulate consensus recommendations for optimal pediatric MF management. In this study we adopted the recommendations and checklists for selecting domains and items in the eDelphi consensus exercise.[11]

Expert identification and recruitment

Participants from 4 stakeholder groups, pediatric dermatologists, general dermatologists, pathologists, and pediatric hematologist-oncologists, were invited to participate. Participation was voluntary with no monetary incentive. Eligible invited participants were authors on pediatric MF publications, identified by a literature search from the years 2015 to 2020 utilizing PubMed (www.PubMed.org) MeSH terms from January 1st 2015 to February 5th 2020 for publications with available abstract text. Search terms included "mycosis fungoides" or "cutaneous T-cell lymphoma" or "CTCL" and "infant or child or adolescent" and search results were filtered using age filters inherent in the PubMed portal "Child: birth-18 years" and included affiliation as "dermatology", "pathology", "hematology", or "hematology", or "oncology". Inviting recent pediatric MF authors as experts ensured that the panel benefited from their deep understanding of evolving knowledge, enhancing the credibility, and relevance of consensus recommendations.

Eighty-three potential eDelphi participants from 35 countries were identified and invited to participate in the eDelphi exercise: 14 pediatric dermatologists, 48 general dermatologists, 17 dermatopathologists, and 4 hemato-oncologists.

eDelphi questionnaires

Participants provided anonymous individual responses devoid of group dynamics such as direct confrontation, dominance, and group think.[12] Following each round of questioning, information regarding the group responses was returned to individual participants for use in the following round. Participants could compare the group response to their individual response, considering this information when given the option to keep or change prior opinions. This process is referred to as controlled opinion feedback.[8] Following the literature review and extrapolation from adult guidelines, the committee developed a list of domains and domain items. The statements focused on epidemiology, diagnostic criteria, treatment strategies, and prognostic factors related to MF. Stages IA, IB, and IIA were considered early-stage disease and stages IIB to IVB were considered advanced-stage disease.[13]

Items were presented to the panelists for voting using a 9-point Likert scale. Consensus for inclusion of an item was defined as 70% or more of respondents scoring item importance as ≥7 AND 15% or less scoring the item importance as ≤3. Items that gained scores ≥7 by ≤70% of respondents AND scored as ≥3 by ≥15% were defined as items in disagreement (dissensus). Items that scored outside the ranges of consensus or lack of consensus were considered inconclusive. An anonymous electronic questionnaire was distributed using Alchemer online for a total of 3 rounds, using a modification of the Dillman Total Design Method (in which nonresponders are followed up) to optimize response rate.[14] The committee reviewed responses after each round and analyzed the proportion of responses and any open-ended comments.

After each round, a summary of the responses was reported to participants in the subsequent Delphi round. Items with inconclusive responses on a prior round and consensus items, in which additional input from participants was deemed necessary, were included in the subsequent round. Participants could decide to keep their original answers or change opinions in the next round, considering feedback and the summarized group response to the questions.

Final expert consensus meeting

Participants who completed all 3 rounds of the eDelphi process were invited to participate in a final expert consensus meeting, which was conducted in a hybrid format to accommodate both in-person and remote participation due to COVID-19-related travel constraints affecting the participating experts. We used a modified (hybrid format) nominal group technique (mNGT), which involved silent generation, round robin idea sharing, moderated group discussion (clarification), and private ranking (voting). Its flexibility made it a useful methodology

to elicit consensus, especially since the evidence was scarce.

The session was moderated by an independent nonvoting expert (P.S.) to ensure that the discussions and decision-making process were not dominated by individual participants. For the private/silent idea generation phase, participants were provided with a packet which included the eDelphi questionnaire results, unresolved issues, and relevant literature. At the final stage of the modified NGT each statement was reviewed and modified until no attendee disagreed.

RESULTS

Literature search on pediatric MF publications between 2015 and 2020 identified 83 eligible participants from the 4 stakeholder groups, pediatric dermatologists, general dermatologists, pathologists, and pediatric hematologist-oncologists; all were invited to participate. Of these, 39 consented to participate in the study (Table I) and comprised the expert panel. Three-quarters of the panelists had more than 20 years of experience, while ~ 10% of the panelists had less than 10 years of experience. The median number of children with MF managed by the panelists was 24. Two-thirds of the panelists manage patients with MF in a specialized cutaneous lymphoma clinic. The participation rate of the members of the expert panel was 95%, 95%, 86%, and 57% for round 1, round 2, round 3, and mNGT, respectively.

Following the literature review and extrapolation from adult guidelines, the committee developed a list of domains and domain items in various aspects of the disease, including diagnosis, management, and outcomes (Fig 1).

All the 19 domains reached consensus for inclusion in the recommendations for pediatric MF (Fig 2). Sixty-two of 76 domain items related to diagnostic clinical and laboratory evaluations reached consensus for inclusion in diagnosis of pediatric MF (Supplementary Table II, available via Mendeley at https://data.mendeley.com/datasets/nm2xxy794p/1). Beyond tumor-node-metastasis-blood staging, additional clinical measures were rated as important for documenting MF severity in children. These include the presence or absence of pruritus, functional or esthetic impairment due to involvement of palms, soles, and genitalia, quality of life impact as well as presence or absence of psychological impact (embarrassment, anxiety, or depression) along with parental anxiety (Fig 3). Disagreement or inconclusive results remained in 14 (18%) domain items regarding clinical or laboratory evaluation in pediatric MF (Supplementary Table III, available via Mendeley at https://data.mendeley.com/datasets/nm2xxy794p/1).

Table I. Invited and consented eligible participants

	Invited	Consented (%)
Pediatric dermatologists	14	10 (71)
General dermatologists	48	26 (54)
Dermato-pathologists	17	3 (18)
Pediatric hemato-oncologists	4	0 (0)
Total	83	39 (47)

Consensus on management and assessing outcomes included established measures such as complete remission, relapse, and progressive skin disease. In addition, consensus added other pediatric specific outcomes such as a decrease in the surface area of affected skin, symptom-free partial response, time to the next relapse, and partial functional or esthetic response (Supplementary Table IV, available via Mendeley at https://data.mendeley.com/datasets/nm2xxy794p/1). Divergent opinions primarily surfaced in selecting therapeutic approaches beyond stage I of the disease, even though there was nearly unanimous agreement on incorporating this domain into the consensus-based recommendations. The complete list of items that achieved consensus, disagreement, or gained inconclusive scores is summarized in the Supplementary Tables IV and V, available via Mendeley at https://data.mendeley.com/datasets/nm2xxy794p/1, respectively.

During round 2 participants were asked: "How many children with MF Stage III or IV have you seen in the last 3 years?" and "Do you feel sufficiently comfortable to manage children with MF stage III or IV?" Seven out of 9 experts (78%) who saw 5-10 children with stage III or IV in the past 3 years felt comfortable managing them, compared to only 2/23 (9%) of those seeing less than 5 patients (chi-square P value = .0005). There were no statistically significant differences between experience of participants and their preferences for proposed setting choices for management of children with advanced MF: self-management, referral to a multidisciplinary team, and/or referral to a pediatric hematologist-oncologist and/or dermatology specialist in adult MF (Supplementary Table VI, available via Mendeley at https://data.mendeley.com/datasets/nm2xxy794p/1).

Potential occurrence of opposing groups of experts with respective intragroup consensus was excluded by absence of bimodal distributions and visually inspected histograms of expected probability assessments for all statements.

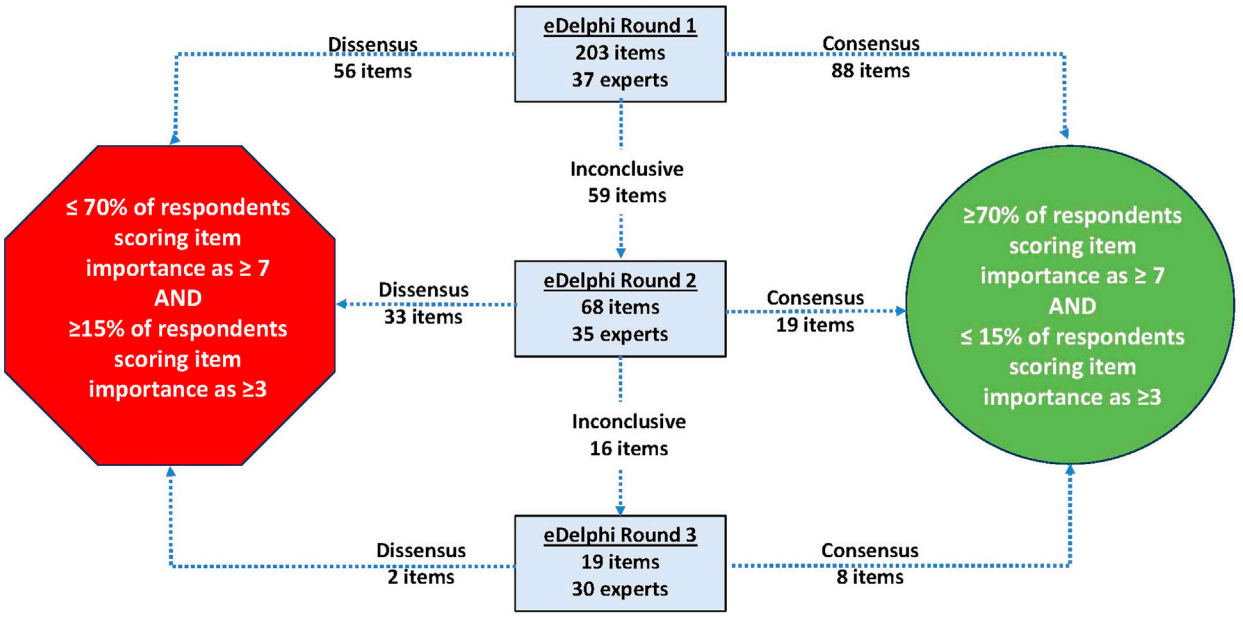

Fig 1. Flow-chart of three-round Delphi sequence.

The mNGT was employed during the final consensus meeting to reach a consensus on treatment of the various stages of pediatric MF. Seventeen participants attended the final consensus meeting. The following recommendations gained unequivocal consensus on therapeutic management of early-stage and advanced-stage pediatric MF:

1. Complete, sustained remission is a goal of therapy for early-stage disease.
2. The goal of therapy is control of signs and symptoms while minimizing the long-term negative effects of the therapy.
3. Treatment choices should consider the risk of progression of the disease.
4. There is limited evidence that current treatment options including maintenance therapy improve long-term prognosis of the disease.
5. Observation without active intervention is acceptable for selected cases of T1a and T2a stages of the disease.
6. Therapy is recommended for cases with large cell transformation, plaque stage, and disease acceleration.
7. Advanced stage disease is extremely rare in children and adolescents, and there are currently no recommended protocols on treatment.
8. Given its rarity of advanced stage disease in pediatric patients, an underlying disease (eg immunosuppression, human T-lymphotropic virus infection, etc.) should be considered.
9. Considering rarity and lack of evidence for any specific therapy advantage in pediatric MF, future protocols for treatment of advanced-stage MF should be extrapolated from data in adults MF.
10. Establishment of an international registry for advanced-stage pediatric disease is recommended.

DISCUSSION

The multinational ARMFUL study attempted to address all aspects of pediatric-onset MF from clinical presentation, clinical variants, and pathological diagnosis to stage-based therapeutic ladders and core outcome measures. The core outcome measures can serve as a backbone for data collection subsets in future prospective registries.

The consent rate for participation was surprisingly high among pediatric (71%) and adult (54%) dermatologists, compared to the expected <45% acceptance rate for specialists with a shared professional affiliation and a specific interest aligned with the study's goals.[15] Given that pediatric hemato-ocologists and dermato-pathologists do not usually manage the bulk of the pediatric MF in real-world clinical practice, the low participation rate from these stakeholder groups was expected. Despite challenges, Delphi experts remained engaged, evidenced by high response rates in each round, indicating the perceived value of the exercise.

Beyond the tumor-node-metastasis-blood and the European Organization of Research and Treatment of Cancer staging systems, commonly used in clinical practice as indices of severity, health-related quality

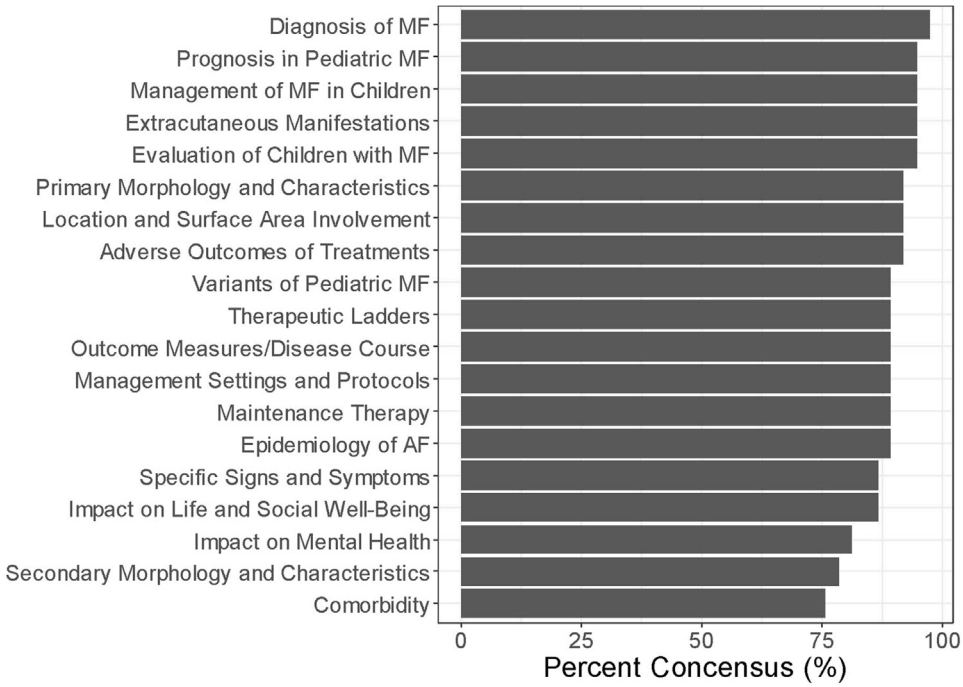

Fig 2. Consensus rates for inclusion of domains in consensus recommendations.

of life and modified Severity Weighted Assessment Tool are employed in research settings in adults,[16] but not in children with MF. Furthermore, these severity indices are insufficient, prompting a consensus for additional clinical measures deemed important in documenting MF severity in children. These include the presence or absence of pruritus, functional, or esthetic impairment due to involvement of palms, soles, and genitalia, as well as the psychological and quality of life impact, along with parental anxiety. These comprehensive measures aim to provide a better understanding of the disease's impact on affected children, encompassing not only physical manifestations but also the broader psychosocial and functional dimensions.

Despite frequent delays in diagnosis exceeding 3 years, pediatric MF generally follows an indolent course, with over 97% of patients diagnosed at stage 1A-2A.[1] Commonly used outcome measures, such as a 10-year disease-specific survival rate of 95%, complete response in 43%, and partial response in 35%, along with a low disease progression rate of 7.5% and a progression-free survival exceeding 73 months,[1,2] reflect a favorable prognosis. However, given the indolent nature of pediatric MF, these outcomes measures may be deemed insufficient for a pediatric patient, leading to a consensus for additional parameters in outcome documentation.

The decrease in the surface area of affected skin emerged as a prominent metric, demonstrating the tangible impact of therapeutic approaches. Additionally, symptom-free partial response and time to next relapse are important considerations, shedding light on the durability and sustainability of treatment effects. Understanding the duration of response may provide crucial information for tailoring treatment plans and managing long-term outcomes effectively. This temporal perspective is essential for clinicians aiming to optimize intervention strategies and minimize the risk of recurrent episodes. Moreover, beyond the physical manifestations of the disease, the impact on functional aspects and esthetic considerations may play a pivotal role in determining the overall well-being and quality of life for pediatric patients with MF.

Our consensus revealed overlap with the adult recommendations with respect to management of early stages diseases. There was no consensus regarding treatment of advanced stage MF in the pediatric population as even cutaneous lymphoma experts rarely encountered and managed children with advanced stages of disease. The absence of representation from pediatric hematology-oncology, a subspecialty that is most skilled to treat advanced stages of MF, meant that our panel was not ideally suited for statements on advanced stage disease, and

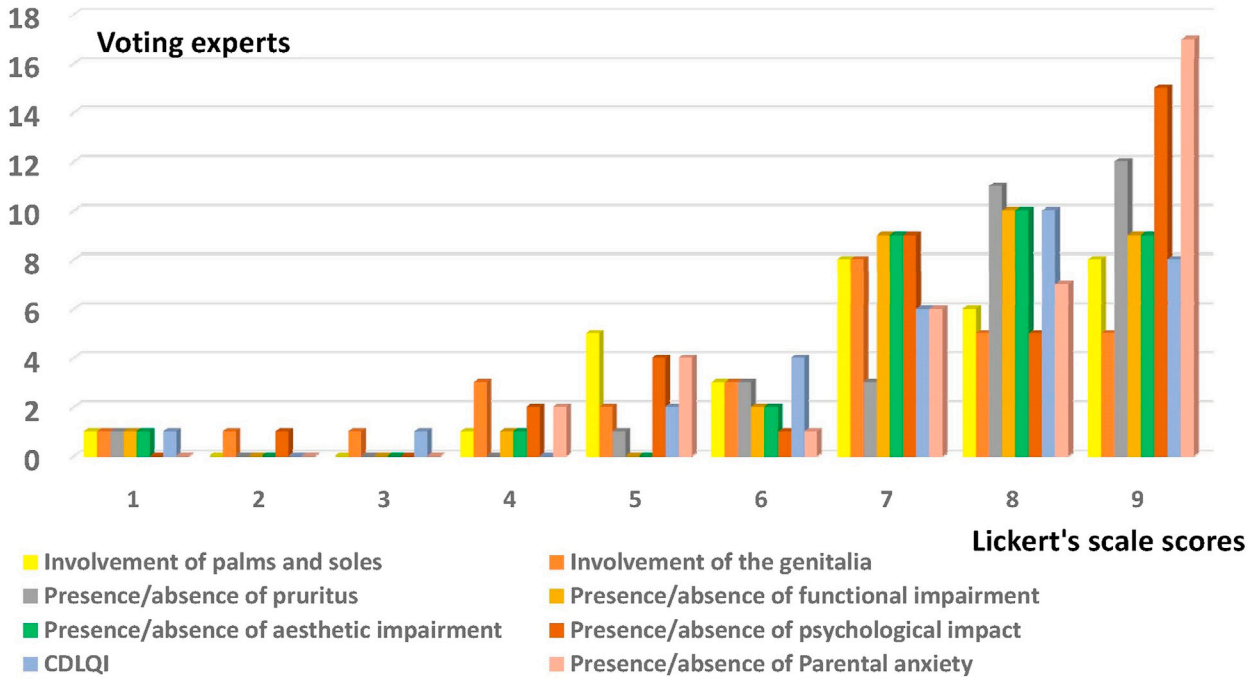

Fig 3. Voting scores on 9-point Likert's scale for inclusion of documentation of additional disease severity measures in consensus recommendations (1 = strongly disagree, 9 = strongly agree).

particularly BMT. However, early-stage disease is mostly managed by people represented in our panel, and we feel our consensus recommendations are relevant in early MF.

Inclusion of patients' representative stakeholder group could enhance the reflection of various clinical severity and outcome measures. However, due to their potentially limited contribution to issues of diagnostic evaluation or management, similar consensus initiatives on atopic dermatitis,[5] psoriasis,[6] and ichthyoses[7] did not include patients' representatives.

Extensive consideration was given to the formulation of statements; however, feedback responses revealed a divergence in the interpretation of certain items. This issue was subsequently addressed in subsequent rounds and during the final consensus meeting.

Despite its limitations, the ARMFUL study generated international consensus statements regarding pediatric MF. Input from patient support organizations and practical utility may guide further recommendations. There is still an unmet need for development and implementation of structured protocols for management of advanced-stage pediatric MF and systematic, prospective data collection for pediatric MF. These consensus results can serve as a foundation for future work on: (1) priorities in future research; (2) development of core outcomes for use in future clinical trials; (3) developing international clinical practice guidelines; and (4) establishing variables within an international registry to prospectively capture key clinical aspects of this disorder.

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Conflicts of interest

None disclosed.

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JAAD Game changer

JAAD Game Changers: Clinical and dermoscopic features of atypical Spitz tumors: A multicenter, retrospective, case-control study

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Original Article Information: Moscarella E, Lallas A, Kyrgidis A, et al. Clinical and dermoscopic features of atypical Spitz tumors: a multicenter, retrospective, case-control study. *J Am Acad Dermatol*. 2015;73(5):777-784. https://doi.org/10.1016/j.jaad.2015.08.018

How did this article change the practice of dermatology?

- This multicenter, retrospective, case-control study, analyzed the clinical and dermoscopic characteristics of 55 atypical Spitz tumors and 110 Spitz nevi that were excised and diagnosed.
- Atypical Spitz tumors presented as either a pigmented nodule or plaque with a multicomponent or unspecific pattern dermoscopically, or in approximately 16% of the cases as a nonpigmented nodule with a typical Spitzoid pattern with dotted vessels and white lines on dermoscopy. Detection of a pigmented typical Spitzoid pattern (starburst pattern) is highly suggestive of Spitz nevi.
- The presence of a starburst pattern on dermoscopy almost invariably corresponds to Spitz nevi and therefore monitoring such a lesion seems a safe management strategy. In contrast, surgical excision might represent the best choice for hypopigmented and amelanotic nodules dermoscopically displaying dotted vessels and white lines, because these findings characterize almost 20% of atypical Spitz tumors.

Conflicts of interest: None disclosed.

Note: A Game Changer is a short narrative stating how an article that originally appeared in *JAAD* changed the game of dermatology. The Game Changer author is not the author of the original article.

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