

Approach to the Assessment and Management of Adult Patients With Atopic Dermatitis: A Consensus Document.

Section V: Consensus Statements on the Assessment and Management of Adult Patients With Moderate-to-Severe Atopic Dermatitis

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Abstract

This document is a concise, current, and practical guide for dermatologists and other health care providers managing adult patients with moderate-to-severe atopic dermatitis (AD). The recommendations made here are based on a consensus of specialists with extensive experience managing patients with AD. Topics reviewed in this publication include AD pathophysiology, assessment, comorbidities, and treatment options.

Keywords

atopic dermatitis, adult atopic dermatitis, consensus statement, management

This document is intended to serve as a concise, current, and practical guide for dermatologists and other health care providers managing adult patients with moderate-to-severe atopic dermatitis (AD). The recommendations made here reflect the expert clinical opinions of specialists with extensive experience managing patients with AD and reflect the 4 topics reviewed in this publication. A summary of the statements and results is provided in Table 1.

Methods

A full description of methods appears in the Introduction to this document. Following a structured literature search and content development, the expert panel of 17 Canadian dermatologists and allergists discussed and voted on 15 initial consensus statements. Statements were reviewed, discussed, and amended as needed. Voting on consensus statements was captured anonymously on a 5-point Likert scale, with responses ranging from *strongly agree* to *strongly disagree*. Voting occurred using a modified Delphi consensus technique with a prespecified cutoff agreement of 75% *agree* or *strongly agree*. A final result of 11 consensus statements was captured by the expert panel. The voting results for all statements failing to achieve consensus are captured in Supplementary Table S1.

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Table 1. Final Consensus Statements and Voting Results.^a

Section	Consensus Statements Voting Result (Strongly Agree/Agree/Neither Agree Nor Disagree/Disagree/Strongly Disagree)
Section I: Pathophysiology	1. AD is a chronic, relapsing, and remitting inflammatory skin disease associated with significant reduction in quality of life. Voting Result: 9, 8, 0, 0, 0 2. The pathophysiology of AD is complex and includes genetics, immune dysregulation, inflammation, epithelial barrier disruption, environmental triggers, perturbations in the microbiome, and pruritus. Voting Result: 14, 2, 1, 0, 0
Section II: Assessment	3. EASI and SCORAD are validated tools for clinical trials but impractical and not validated for routine use in a clinic setting. This group recommends the use of PGA and BSA in the clinic. Based on physician tools, moderate-to-severe disease can be defined by a PGA ≥ 3 or a BSA score of $\geq 10\%$. Recurrence or persistence of disease and disease location (eg, face, hands, genitals) should be considered when determining moderate-to-severe disease. Voting Result: 8, 7, 1, 0, 0 4. Patient-reported outcomes are helpful in assessing patient well-being, evaluating disease severity, and treatment efficacy not captured by PGA or BSA, including pruritus and sleep disturbance. Moderate-to-severe disease can be defined by a POEM score ≥ 8, a DLQI score ≥ 10, or a pruritus NRS ≥ 4. Voting Result: 11, 5, 1, 0, 0
Section III: Comorbidities	5. Atopic comorbidities include asthma, allergic rhinitis, food allergy, and ocular disorders. Depression and anxiety are also more prevalent in patients with AD. Health care providers should be aware of these comorbidities and refer appropriately. Voting Result: 13, 4, 0, 0, 0
Section IV: Treatment Options	6. The objectives of therapy are to reduce skin inflammation and pruritus, restore skin barrier function, and improve quality of life. Voting Result: 8, 6, 2, 1, 0 7. Moisturizers, topical corticosteroids, and topical calcineurin inhibitors have been shown to significantly reduce signs and symptoms of AD and are first-line therapy. Voting Result: 11, 6, 0, 0, 0 8. UVB phototherapy may be beneficial for patients with moderate-to-severe AD, where accessible. Voting Result: 6, 8, 1, 1, 1 9. Systemic therapies that are indicated for the treatment of moderate-to-severe AD should be used for patients who fail first-line therapy. Currently, in many countries, dupilumab is the only systemic therapy indicated for the long-term treatment of moderate-to-severe AD. Voting Result: 8, 7, 2, 0, 0 10. When medications indicated for the treatment of AD are not available, conventional systemic therapies may be used off-label. MTX may be considered for stable moderate-to-severe disease. Short-term CsA may be considered for rapid control in patients who experience acute flares or have unstable disease. Voting Result: 7, 9, 0, 1, 0 11. Consider systemic corticosteroids only in short courses as rescue therapy. Voting Result: 4, 13, 0, 0, 0

Abbreviations: AD, atopic dermatitis; BSA, body surface area; CsA, cyclosporine A; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; MTX, methotrexate; NRS, Numerical Rating Scale; PGA, Physician Global Assessment; POEM, Patient Oriented Eczema Measure; SCORAD, SCORing Atopic Dermatitis; UVB, ultraviolet B.

^aVoting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.

Pathophysiology

- AD is a chronic, relapsing, and remitting inflammatory skin disease associated with significant reduction in quality of life.**

Consensus: 100% (Voting Result*: 9, 8, 0, 0, 0)

*Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.

This panel agreed on the importance of highlighting the chronic inflammatory nature of AD, despite the often episodic presentation, as a counselling point for patients seeking

management of their disease. In addition, the significant impact on quality of life and daily activities was seen as important in highlighting the need to improved care and management.

Patients should understand that their disease is caused by aberrant inflammation and should be advised of the ongoing need for therapy, including maintenance therapy, in minimizing disease activity and preventing flares.

2. The pathophysiology of AD is complex and includes genetics, immune dysregulation, inflammation, epithelial barrier disruption, environmental triggers, perturbations in the microbiome, and pruritus.

Consensus: 94% (Voting Result: 14, 2, 1, 0, 0)*

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

There are many overlapping factors contributing to the pathophysiology of AD in adults. While no one genetic or environmental trigger is responsible for development of disease in an individual, it is important to communicate the overarching role of immune dysregulation and skin barrier dysfunction affecting disease pathogenesis at multiple stages along the pathway.

Patient counselling should highlight the importance of minimizing skin inflammation and maintaining or restoring skin barrier function to positively affect the skin microbiome, reduce the effect of environmental or allergic triggers on the skin, and reduce pruritus, which may further exacerbate disease.

Assessment

3. Eczema Area and Severity Index (EASI) and SCORing Atopic Dermatitis (SCORAD) are validated tools for clinical trials but impractical and not validated for routine use in a clinic setting. This group recommends the use of Physician Global Assessment (PGA) and body surface area (BSA) in the clinic. Based on physician tools, moderate-to-severe disease can be defined by a PGA ≥ 3 or a BSA score of $\geq 10\%$. Recurrence or persistence of disease and disease location (eg, face, hands, genitals) should be considered when determining moderate-to-severe disease.

Consensus: 94% (Voting Result: 8, 7, 1, 0, 0)*

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

No single assessment tool sufficiently captures the overall severity and impact of AD, and there is significant variability with respect to the validity and clinical utility of the available assessment tools. PGA and BSA effectively capture the primary objective measures of disease impact: lesion severity and extent.

In addition, clinical judgement is necessary to form an overall assessment of disease severity. Importantly, disease recurrence, flares, and persistence are important considerations in the overall impact of disease on patients with AD. In addition, involvement of functionally important or highly visible areas, including face, hands, or genitals, significantly affects quality of life and daily activities.

4. Patient-reported outcomes are helpful in assessing patient well-being, evaluating disease severity, and treatment efficacy not captured by PGA or BSA, including pruritus and sleep disturbance. Moderate-to-severe disease can be defined by a Patient Oriented Eczema Measure (POEM) score ≥ 8 , a Dermatology Life Quality Index (DLQI) score ≥ 10 , or a pruritus Numerical Rating Scale (NRS) ≥ 4 .

Consensus: 94% (Voting Result: 11, 5, 1, 0, 0)*

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

All patients should be assessed, whether formally or informally, for pruritus and sleep disturbance, as these are important quality-of-life indicators not captured by objective assessments. POEM is the best-validated formal assessment of patient-reported outcomes, can be easily implemented in clinic, and captures both of these important quality-of-life measures. As an alternative, DLQI and/or pruritus NRS are practical for clinical use, but it should be noted that neither captures sleep as an outcome measure.

Comorbidities

5. Atopic comorbidities include asthma, allergic rhinitis, food allergy, and ocular disorders. Depression and anxiety are also more prevalent in patients with AD. Health care providers should be aware of these comorbidities and refer appropriately.

Consensus: 100% (Voting Result: 13, 4, 0, 0, 0)*

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

Assessment for atopic comorbidities should be considered when appropriate, including careful assessment of asthma as well as inhalant allergy testing in patients with relevant history. Routine food allergen testing is unnecessary in patients with no history of immediate-type symptoms.

Ocular disorders, including atopic keratoconjunctivitis, should be recognized as common comorbidities in patients with AD. Health care providers should be aware of these conditions and manage or refer appropriately.

Formal screening for depression and anxiety should be considered when appropriate.

Treatment Options

6. The objectives of therapy are to reduce skin inflammation and pruritus, restore skin barrier function, and improve quality of life.

Consensus: 82% (Voting Result*: 8, 6, 2, 1, 0)

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

The panel agreed that given the complex pathophysiology of disease and impact on patient quality of life, therapies should be aimed at improving the disease characteristics listed above. This includes basic care such as emollients, skin hydration with baths, and irritant avoidance, as well as both broad and targeted therapies.

7. Moisturizers, topical corticosteroids, and topical calcineurin inhibitors have been shown to significantly reduce signs and symptoms of AD and are first-line therapy.

Consensus: 100% (Voting Result*: 11, 6, 0, 0, 0)

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

Patients should be counselled that, due to the chronic nature of their disease, ongoing basic care, including moisturizers, is important for disease control and prevention of flares even in the absence of active disease.

Topical corticosteroids (TCS) should be used first line and medication choice should consider potency, formulation, patient age, and treatment area, with avoidance of potent TCS on areas such as the face, neck, skin folds, or genitals.

Topical calcineurin inhibitors (TCI) should be used in patients with inadequate response to TCS and in those with frequent disease relapse. Patients should be counselled that despite the black box warning, the risk of lymphoma associated with TCI use is not supported by clinical data.

The phosphodiesterase E4 inhibitor crisaborole has recently been approved in some countries for the treatment of AD and can also be used to control the disease.

8. Ultraviolet B (UVB) phototherapy may be beneficial for patients with moderate-to-severe AD, where accessible.

Consensus: 82% (Voting Result*: 6, 8, 1, 1, 1)

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

Phototherapy is relatively safe, can be an effective therapeutic option with a demonstrated steroid-sparing effect, and can be used in combination with topical therapies and basic care. Availability of and accessibility to phototherapy varies regionally but should be considered where available.

9. Systemic therapies that are indicated for the treatment of moderate-to-severe AD should be used for patients who fail first-line therapy. Currently, in many countries, dupilumab is the only systemic therapy indicated for the long-term treatment of moderate-to-severe AD.

Consensus: 88% (Voting Result*: 8, 7, 2, 0, 0)

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

Systemic therapies should be considered for patients who fail first-line topical therapies or for whom first-line therapies are not appropriate. Treatment failure may be considered as inadequate response after 8 weeks of at least moderate-potency topical therapy (TCS/TCI) or disease flare within 1 week of treatment discontinuation.

In many countries, dupilumab is currently the only systemic therapy indicated for the long-term treatment of AD, as other therapies are limited by toxicity.

10. When medications indicated for the treatment of AD are not available, conventional systemic therapies may be used off-label. Methotrexate (MTX) may be considered for stable moderate-to-severe disease. Short-term cyclosporine A (CsA) may be considered for rapid control in patients who experience acute flares or have unstable disease.

Consensus: 94% (Voting Result*: 7, 9, 0, 1, 0)

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

When indicated and approved therapies are not accessible or appropriate, conventional systemic therapies may be considered for specific patient groups. Amongst the off-label systemic immunosuppressants used to treat moderate-to-severe AD, MTX may be considered first-line for stable disease due to its safety and low cost. CsA may also be considered for rapid control but should not be used as a long-term therapy. CsA is approved for AD in some countries. Laboratory monitoring for these agents should be noted and assessed as required.

11. Consider systemic corticosteroids only in short courses as rescue therapy.

Consensus: 100% (Voting Result: 4, 13, 0, 0, 0)*

**Voting results reflect number of authors voting strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree, respectively.*

The use of systemic corticosteroids should be avoided in patients with AD. Systemic corticosteroids should be reserved for unusual circumstances such as severe flares before the introduction of another systemic therapy and should only be administered in short courses due to concerns with toxicity and long-term side effects. These medications should be tapered slowly so as to minimize disease flare upon discontinuation of therapy.

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Supplementary Table 1. Statements failing to achieve consensus.

Statement	Voting Result
The pathophysiology of AD involves immune dysregulation, epithelial barrier disruption, pruritus, environmental triggers, genetics and perturbations in the microbiome.	3,5,5,2,2
EASI and SCORAD are reliable, well-validated and appropriate tools for clinical trials, but impractical and not validated for routine use in a clinic setting. This group recommends the use of PGA and BSA in clinic. Based on investigator tools, moderate-to-severe disease can be defined by a PGA of 3 to 4 or a BSA score of $\geq 10\%$.	0,0,6,6,5
QoL assessments are helpful in assessing patient well-being and evaluating treatment efficacy not captured by PGA or BSA, including itch and sleep disturbance. Consider the use of POEM as it incorporates both of these important QoL measures. Based on PRO tools, moderate-to-severe disease can be defined by a POEM score ≥ 8 , or as an alternative consider a DLQI score ≥ 10 or a NRS score ≥ 4 to define moderate-to-severe disease.	1,3,6,5,2
Allergic airway disease is more common in patients with AD compared to the general population and often underdiagnosed in general. Careful history of wheezing should be taken.	0,1,6,5,5

Early recognition and appropriate management of ocular comorbidities are important to prevent long-term sequelae and disability. Consider managing patients with ocular symptoms in collaboration with an ophthalmologist.	0,3,6,4,3
Depression, anxiety and suicidality are more common in patients with AD compared to the general population. Physicians treating AD should consider screening for these conditions during assessment.	0,3,3,6,4
Atopic dermatitis often precedes the progression to asthma, allergic rhinitis, and food allergy, known as the atopic march. Prevention of atopic dermatitis can be achieved by early intervention to preserve and protect the skin barrier. Effective treatment of atopic dermatitis may prevent the atopic march.	2,7,3,1,4
The objective of therapy is to reduce skin inflammation and pruritus, restore skin barrier, and decrease frequency of skin infections.	0,2,3,4,8
Pruritus is an important symptom in AD that reduces quality of life. Moisturizers, topical glucocorticoids, topical calcineurin inhibitors, and phototherapy have been shown to significantly reduce pruritus in AD and should be used first-line.	2,7,3,2,2
When a conventional oral systemic therapy is being used, MTX should be considered as a 1st line conventional systemic for stable moderate-to-severe disease.	1,2,2,4,8

Consider systemic corticosteroids in short courses only as a bridge to steroid sparing immunosuppressants. Systemic corticosteroids should not be used as maintenance therapy.	2,5,3,2,5
Dupilumab is a systemic biologic therapy that should be considered for patients with moderate-to-severe AD who fail topical and/or phototherapy.	2,4,6,3,1

Voting results reflect number of authors voting Strongly Agree, Agree, Neither Agree nor Disagree, Disagree, or Strongly Disagree, respectively.

AD, atopic dermatitis; BSA, Body Surface Area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; MTX, methotrexate; NRS, Numerical Rating Scale; PGA, Physician Global Assessment; PRO, Patient-Reported Outcome; POEM, Patient Oriented Eczema Measure; SCORAD, SCORing Atopic Dermatitis.