

Leukotriene Receptor Antagonists for the Treatment of Atopic Dermatitis: A Systematic Review and Meta-analysis

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Atopic dermatitis is a chronic skin condition with no cure. Current conventional treatments can have many side effects or are expensive. Emerging evidence suggests leukotriene receptor antagonists could serve as a corticosteroid-sparing option. This meta-analysis examined 26 studies on the efficacy of leukotriene receptor antagonists for treating atopic dermatitis across 742 participants. There were non-significant reductions in atopic dermatitis severity overall. However, in subgroup analyses montelukast significantly reduced Severity Scoring of Atopic Dermatitis scores in adult populations (SMD = -0.94, 95% CI -1.35 to -0.54, $p < 0.0001$) and also when compared with conventional treatment rather than placebo (SMD = -0.84, 95% CI -1.21 to -0.47, $p < 0.0001$). Studies excluded from the statistical analysis generally showed a positive trend favouring montelukast, even if results were not statistically significant. Montelukast shows potential as an adjunct therapy in atopic dermatitis, particularly in adults, but its efficacy is inconsistent. While it may help with pruritus, it should not replace standard treatments. Future research should focus on standardized assessments and personalized approaches to clarify its role in atopic dermatitis management.

Key words: atopic dermatitis; leukotriene receptor antagonists; montelukast.

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Atopic dermatitis (AD) or eczema is a chronic inflammatory skin disease characterized by intense itching, dry skin, and recurrent eczematous lesions. It commonly occurs during early childhood but can affect individuals of any age group. AD is part of the “atopic triad” along with asthma and allergic rhinitis and is often associated with an overactive immune response to environmental allergens and frequently found present together in the same individual (1). The pathophysiology of AD is multifactorial and may involve a combination of genetic predisposition, immune system dysfunction, environmental triggers, and skin barrier defects (2).

SIGNIFICANCE

Our study found that montelukast (a type of medication used for asthma) can be beneficial for patients with eczema as an additional therapy alongside standard therapy like antihistamines, especially in adult patients who have other allergies along with eczema.

There is currently no cure for atopic dermatitis. However, several treatments are used to control it. Conventional treatments for AD primarily include topical therapies such as corticosteroids and calcineurin inhibitors along with emollients and moisturizers. In severe cases, systemic treatments like oral corticosteroids, cyclosporine, or methotrexate may be used (3).

Conventional treatments, namely topical steroids, can have side effects, including skin thinning and adrenal suppression with prolonged use. Systemic immunosuppressive drugs such as cyclosporine carry risks of kidney toxicity and increased infection rates. Biologics and JAK inhibitors, while effective, are costly and may not be suitable for all patients (3).

Leukotriene receptor antagonists (LTRAs), such as montelukast, inhibit leukotrienes (LTs) – inflammatory mediators derived from arachidonic acid – thereby reducing inflammation and allergic responses in conditions like asthma and allergic rhinitis (4). Elevated levels of LTs and proteinoids in chronic inflammatory diseases such as AD indicate their potential role in its pathogenesis (5). Specifically, LTB₄ is involved in recruiting neutrophils and Th2 cells related to acute inflammation, while CysLTs contribute to chronic features such as collagen deposition and skin thickening (4). LTs may also increase vascular permeability and promote eosinophil recruitment, further exacerbating skin inflammation (5). Studies have shown that mean urinary LTE₄ levels are abnormally elevated and increase consistently with the severity of AD (8). Montelukast was found to be prescribed for off-label use in allergic diseases such as AD (7). In a prescription event monitoring study, some general practitioners reported improvements with montelukast treatment in patients who had a history of longstanding eczema or urticaria (8). While LTRAs are primarily used for asthma, emerging evidence suggests they may also help alleviate AD symptoms, especially in patients with concurrent atopic conditions, although their specific efficacy for AD is still under evaluation (5).

If proven effective and safe, LTRAs could serve as a corticosteroid-sparing option for eczema. Additionally, they may be more cost-effective and accessible compared with newer treatment modalities.

We performed a systematic review to evaluate the safety and efficacy of LTRAs as a potential therapeutic option for atopic dermatitis. Secondary objectives included exploring changes in biological markers associated with AD in patients taking LTRAs and assessing changes in quality of life.

METHODS AND METHODS

This systematic review and meta-analysis were carried out as per the PRISMA Guidelines 2020 (9). Prior to the stage of data extraction, a protocol was registered on PROSPERO (registration number: CRD42024507184).

Literature search

A systematic search was performed in 5 electronic databases: PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), Google Scholar, ScienceDirect, and Scopus. Our search included studies published from database inception till May 2024. A search on ClinicalTrials.gov was done to identify any additional studies. Reference lists of the included studies were also manually searched. A general overview of the studies is given in Table SI.

The search was conducted using specific search strings taken from the review question, which were modified according to the specifics of the search engine of each database. The exact strategies used are given in Table SII.

Study selection

Studies that met the following criteria were included in the review:

Inclusion criteria:

1. Studies using montelukast or other LTRAs to treat AD.
2. Studies involving patients of any age, ethnicity or gender, and having varying severity of AD.
3. Randomized controlled trials (RCTs), case series, cohort, quasi-experimental, and case-control studies.

We excluded studies that did not report an analysable outcome, case reports, and articles for which full texts were unavailable despite contacting the authors.

According to the criteria, articles were screened independently by 3 authors (WNM, HZR, and OMA). Disagreements were resolved through discussion and if continued discourse occurred, a senior researcher (SFM) was involved to reach a consensus on the final decision for inclusion.

Data extraction

Data from eligible studies were extracted independently by 3 authors (WNM, AN, and SFM). A standardized data extraction sheet developed for the study was used. It included the following information: first author, study designs, year of publication, eligibility criteria, participants demographics, interventions, controls used, concomitant therapy, general outcomes, safety outcomes, efficacy results measured either subjectively or by AD severity scoring systems, biological markers measured, effects on quality of life (QoL), and other relevant information. Data from the figure in the study done by Nettis et al. (10) were extracted using WebPlotDigitizer software (Version 5.2; <https://automeris.io/>). Any disagreement was resolved through discussion among the authors to reach a consensus.

Quality assessment

Quality assessment was conducted independently by 3 authors (WNM, OMA, SFM). Quality of RCTs was assessed using the Cochrane Risk of Bias Tool (RoB-2) (11). The quality of the observational studies was evaluated using JBI critical appraisal checklists (12), with each study design having its own checklist. Each question in the checklist was assigned 1 point and percentages-based scores were calculated based on total points received by the study, scores > 70 indicating high quality, 50–70 indicating medium quality, and < 50 indicating low quality. Any disagreements were resolved through discussion to reach a consensus.

Statistical analysis

We used R version 4.4.1 (R Foundation for Statistical Computing, Vienna, Austria), along with RStudio as an integrated development environment (Posit Team, 2024, Posit Software, PBC, Boston, MA), to analyse continuous variables for our study (13). The meta-analysis results were presented as standardized mean differences (SMD) with 95% confidence intervals (CI), and we applied a random-effects model using the inverse variance method for this analysis. Statistical heterogeneity was evaluated using the I-square (I^2) statistic, with I^2 values > 60% indicating substantial heterogeneity, between 30% and 60% indicating moderate heterogeneity, and < 30% indicating low heterogeneity (14).

Only RCT studies that were graded as low risk of bias or having some concerns were included due to the greater quality of evidence and larger sample sizes. Non-RCT studies, those with a high risk of bias, or studies with incomplete data were excluded from the statistical analysis. Comparison of studies was performed by pooling together all studies as well as stratifying studies based on the type of severity score used. Subgroup analyses based on scoring systems, age group, and comparator

used were conducted to explore variations among studies.

As a form of sensitivity analysis, both random-effects and fixed-effects models were used in the meta-analysis. However, the fixed-effects model was not preferred due to high heterogeneity and methodological differences across studies.

RESULTS

A total of 796 articles were identified during the preliminary search; 26 articles (8, 10, 15–38) of varying study designs were included in the final qualitative analysis (**Fig. 1**). The studies included a total of 742 participants with sample size ranging from 2 to 91 patients and ages ranging from 1–70 years. Most studies included both male and female participants except 2 studies: 1 that recruited only male subjects (10), and 1 with only female participants (15). The studies were conducted in 16 different countries. The dosages for montelukast used were either 4–5 mg for paediatric subjects or 10 mg for adults, while the dosage for zafirlukast was 20 mg in all subjects.

Outcomes were assessed using various measures across studies. Some utilized official severity scores such as SCORAD (Severity Scoring of Atopic Dermatitis), SASSAD (six area, six sign atopic dermatitis), EASI (Eczema Area and Severity Index), IGA (Investigator's Global Assessment), ADASI (Atopic Dermatitis Area and Severity Index), or self-made scales while others relied on subjective metrics such as body surface area. Additionally, certain studies measured alternative parameters such as urinary LTE4 levels or flare diameters. Quality of life outcomes were also considered in some studies, using tools such as the CDLQI (Children's Dermatology Life Quality Index) or DLQI (Dermatology Life Quality Index). Study characteristics are recorded in **Table I**.

Quality assessment

Sixteen studies were evaluated using RoB-2 (<https://methods.cochrane.org/bias/resources/rob-2-revised-cochrane-risk-bias-tool-randomized-trials>): 9 parallel and 7 crossover RCTs. Among these, 3 showed low concern, 8 had some concern, and 5 were rated high concern (**Fig. 2**).

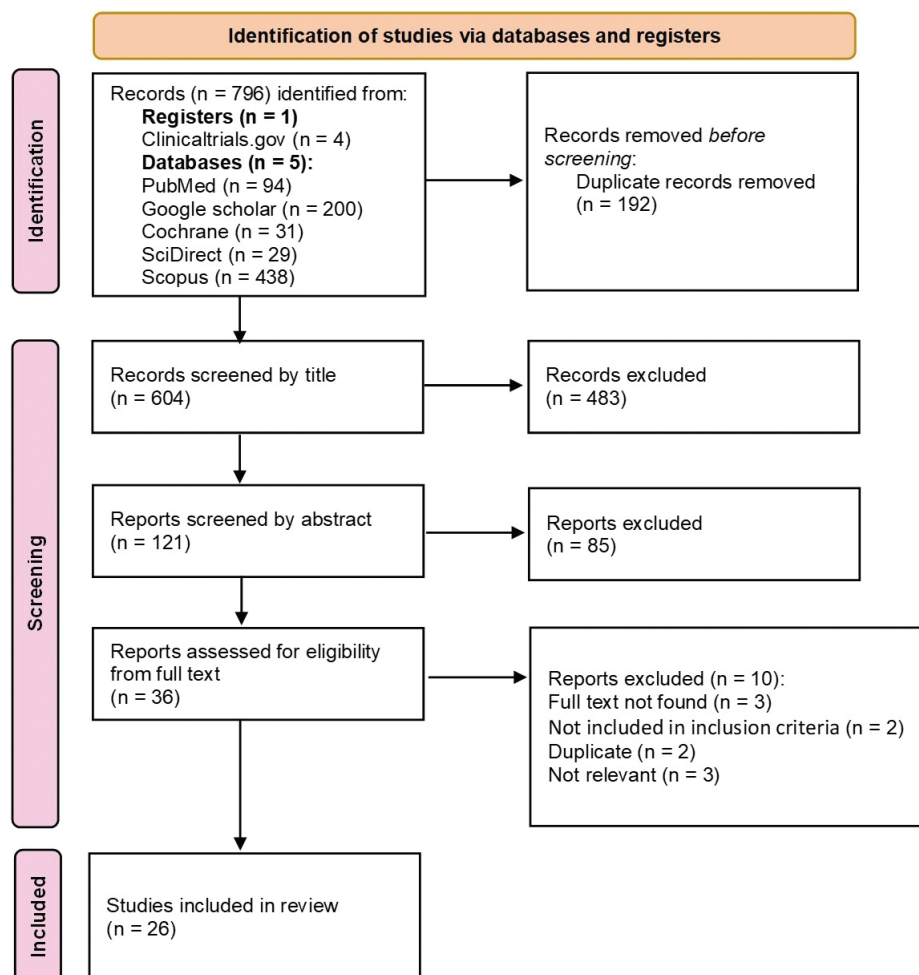


Fig 1. PRISMA flowchart.

Table I. Study characteristics

Author, country, year, (reference no.)	Study design	Initial Sample Size	Dropout rate (%)	Male/female (M/F)	Age range	Study duration	Eligibility criteria	Treatment	Comparator	Concomitant therapy	Outcomes assessed
Angelova-Fischer et al., Bulgaria, 2005 (15)	Case series	2	0%	0/2	32 and 19	24 weeks	Patients diagnosed with AD	10 mg of montelukast sodium OD	None	Emollient	• SCORAD scores and subjective observations • SCORAD index • Eosinophil levels • Serum IgE
Broshtilova et al., Bulgaria, 2010 (16)	Case series	3	0%	1/2	19–32	6 months	Patients diagnosed with AD	10 mg of montelukast OD	none	Emollients	• SCORAD • Eosinophilic CATIONIC PROTEIN (ECP) • Eosinophilic protein X (EPX)
Capella et al., Italy, 2001 (17)	Randomized, single-blind, parallel-group study	32	0%	18/14	18+	6 weeks	Patient with moderate-to-severe eczema with SCORAD ≥ 30	10 mg of montelukast OD, oral placebo tablet thrice daily, and topical placebo gel twice daily	Cetirizine and clarithromycin, topical corticosteroids and hydrating preparations	Inhaled or intranasal medications, or eye drops, for cases with coexisting allergic asthma, rhinitis, or keratoconjunctivitis	• SCORAD • Eosinophilic CATIONIC PROTEIN (ECP) • Eosinophilic protein X (EPX)
Carucci et al., USA, 1998 (18)	Case series	4	0%	3/1	41–61	Not given	Patients diagnosed with AD	20 mg of zafirlukast orally twice per day	None	Antihistamines and topical steroids, prednisone, as required	Percentage of body surface area
Craig et al., USA, 2002 (19)	Randomized, double-blind, placebo-controlled, parallel study	60	Not stated	Not given	Not given	8 weeks	Patients diagnosed with moderate to severe AD	10 mg of montelukast OD	Placebo	Daily use of a lubricant and hydroxyzine	• SCORAD, • Global assessment • Daily diary • Rash severity scoring • SCORAD scores
Ehlayel et al., Qatar, 2007 (20)	Randomized, double-blind, placebo-controlled, crossover study	25	0	13/12	2–16	12 weeks	Patients diagnosed with moderate to severe AD according to Hanifin and Rajka's criteria, who may also have allergic rhinitis and/or asthma, and who have not responded to conventional therapy	5 mg of montelukast	Placebo	Nasal medications for allergic rhinitis and inhaled asthma medications were allowed if the dosage remained unchanged, as were antihistamines and topical steroids	• SCORAD (objective + subjective assessment of severity of AD) • Blood tests were performed for CBC and blood chemistry • SASSAD • Topical corticosteroid usage was recorded using a 5-point scale
Nettis et al., Italy, 2002 (10)	Randomized, double-blind, placebo-controlled, parallel study	20	0%	20/0	18–28	6 weeks	Patients with severe AD with a mean SCORAD index of > 40	10 mg of montelukast OD	Placebo	Emollients	• SCORAD • Global assessment • Daily diary • Rash severity scoring • SCORAD scores
Friedmann et al., UK 2007 (21)	Randomized, double-blind, placebo-controlled, parallel study	60	10%	20/40	16–60	10 weeks	Patients with moderate AD diagnosed according to Hanifin and Rajka criteria, having a SASSAD score between 12 and 50 at visits 1 and 2	10 mg of montelukast OD	Placebo	Emollients, antihistamines and corticosteroids provided that the use of these had been stable over the preceding month	• SASSAD • Topical corticosteroid usage was recorded using a 5-point scale
Friedmann et al., UK, 2001 (22)	Quasi-experimental study	11	0%	Not given	Not given	2 weeks	Patients diagnosed with AD	10 mg of montelukast OD	none	None	• SASSAD • Leukotriene C4/D4 levels • SCORAD index • CDLQI
Goh et al., Australia, 2016 (23)	Randomized, parallel group, open label trial	62	Not stated	Not given	6–16	8 weeks	Children diagnosed with AD	Montelukast with topical therapy	Topical therapy	not mentioned	

(Continued)

Table I (Continued). Study characteristics

Author, country, year, (reference no.)	Study design	Initial Sample Size	Male/female (M/F)	Age range	Study duration	Eligibility criteria	Treatment	Comparator	Concomitant therapy	Outcomes assessed
Hon et al., Hong Kong, 2005 (8)	Case series	7	4/3	3–16	3 months	Patients diagnosed with AD according to Hanifin and Rajka's criteria with SCORAD greater than 15	Ages < 12 years: 5 mg montelukast Ages > 12 years: 10 mg montelukast	None	Each subject remained on same type of oral antihistamine or topical corticosteroid throughout the study	SCORAD scores
Ibrahim et al., Egypt, 2014 (24)	Case-controlled study	32	16/16	8 adults 24 children	2 weeks	Patients with AD diagnosed according to Hanifin and Rajka criteria	4 mg of montelukast OD	none	none	• SCORAD scores • IgE • Eosinophil count • Genotyping for FLG gene
Jamalyan et al., Armenia, 2024 (25)	Randomized, double-blind, placebo-controlled, parallel study	91	Not given	21–37	12 weeks	Patients with a chronic AD diagnosis (at least 3 years) and a minimum of: an EASI score of 16, AD involving 10% of body surface area (BSA), an IGA score of 3 at, an average pruritus NRS score of 3, and an inadequate response to antihistamine therapy	5 mg of desloratadine and 10 mg of montelukast OD	Desloratadine	Topical corticosteroid (Elocon) twice daily, emollient, a probiotic, thrice per day	• SCORAD, GISS, EASI, PPNRS • DLQI • Skin functional assessment • outcomes- corneometry, pH and transepidermal water loss
Jeon et al., South Korea, 2016 (26)	Randomized, double-blind, placebo-controlled, crossover study	54	21/22	2–6	20 weeks	Children with moderate to severe atopic dermatitis diagnosed according to Hanifin and Rajka's criteria with a SCORAD greater than 15	Ages < 6 years: 4 mg montelukast Ages ≥ 6 years: 5 mg montelukast	Placebo	0.1% hydrocortisone lotion twice daily and emollients (3–4 times a day)	• SCORAD scores • Urinary LTE4 • EDN
Kägi et al., Switzerland, 2001 (27)	Case series	4	Not given	Not given	2 weeks	Patients with facial AD refractory to conventional treatment with topical steroids	10 mg of montelukast OD	none	Emollients	Subjective opinion
Lee et al., South Korea, 2007 (28)	Quasi-experimental study	10	8/2	8–36	8 Weeks	Patients with severe AD diagnosed according to Hanifin and Rajka criteria	10 mg of montelukast OD	None	Not mentioned	• SCORAD index
Lehtimäki et al., Finland, 2009 (29)	Randomized, double-blind, placebo-controlled, crossover study	49	12/33	18–40	6 weeks	Patients with a wheal diameter ≥ 4 mm on skin-prick tests for both birch and timothy pollen, experiencing allergic symptoms in both upper and lower airways during pollen season, and with at least one other type of allergy	10 mg of montelukast OD	Placebo	Short-acting antihistamine capsules and a short-acting inhaled beta 2 agonist were allowed as needed	• Primary outcome was assessment of 12 allergic symptoms, recorded on a 0 to 3 scale via questionnaire • Secondary outcomes included levels of lower-airway inflammation and the use of rescue medication
Melamed et al., USA, 2017 (30)	Randomized, double-blind, placebo-controlled, parallel study	20	11/9	1–8	9 weeks	Patients with a positive reactivity to food (indicated by skin or RAST test) with 10–25% body area affected by AD	Ages 2–5 years: 4 mg montelukast Ages 6–8 years: 5 mg montelukast	Placebo	A 1% hydrocortisone cream, and cetirizine HCl (Zyrtec) liquid was used when symptoms became severe	• Investigators' Global Assessment (IGA) • Severity scores • Percentage of body area affected

(Continued)

Table 1 (Continued). Study characteristics

Author, country, year, (reference no.)	Study design	Initial Sample Size	Dropout rate (%)	Male/ female (M/F)	Age range	Study duration	Eligibility criteria	Treatment	Comparator	Concomitant therapy	Outcomes assessed
Pei et al., Hong Kong, 2001 (31)	Randomized, double-blind, placebo-controlled, crossover study	15	26.66%	4/7	6–16	12 weeks	Patients diagnosed with chronic moderate-to-severe AD according to Hanifin and Rajka's criteria and resistant to conventional treatment	Montelukast	Placebo	70% light liquid paraffin as soap substitute, emollient, and 0.05% clobetasone butyrate cream	• Six signs of AD: erythema, oedema, oozing/crusting; excretion; lichenification, dryness • Subjective QoL • An extent of disease score involving percentage of body surface area involved SCORAD (subjective and objective observations)
Rahman et al., Bangladesh, 2006 (32)	Randomized, parallel group, open label trial	31	0%	17/14	≥ 6	4 weeks	Patients diagnosed with AD according to Hanifin and Rajka's criteria, with at least 1 year of intermittent or persistent symptoms of AD and a SCORAD ≥ 30	Ages 6–14 years: 5 mg montelukast once daily Ages > 14 years: 10 mg montelukast once daily	Antihistamines and topical hydrocortisone	None	
Sekerel et al., Turkey, 2003 (33)	Randomized, double-blind, placebo-controlled, crossover study	31	3.20%	20/10	6–15	3 weeks	Patients with ECARs and LCARs to Dermatophagoides pteronyssinus, and a value of pre-bronchodilator FEV1 greater than 70% of the predicted value	Montelukast 5mg/day for 2 days	Placebo	Not mentioned	Mean of longest diameter and longest perpendicular of the induration response
Silverberg et al., USA, 2004 (34)	Case series	7	0%	Not given	4–65	4 weeks	Patients with severe AD affecting more than 90% of body surface area	5 mg of montelukast OD 15-year-olds received 10 mg of montelukast OD Adults received 20 mg of zafirlukast twice daily	None	One 8-year-old girl hydroxyzine nightly. All patients continued their use of topical steroid with a potency class of 2–3	Observation of dermatitis on body surface area
Veien et al. Denmark, 2005 (35)	Randomized, double-blind, placebo-controlled, crossover study	59	20.30%	16/43	16–70	6 weeks	Moderate to severe AD diagnosed according to Hanifin and Rajka's criteria with involvement of 5–35% of the body surface and a minimum score of 4.5 based on Rajka and Langeland's grading system	10 mg montelukast	Placebo	Emollient	Modified EASI score as well as a pruritus score
Xabilullayevna et al., Uzbekistan, 2021 (36)	Randomized, parallel group, open label trial	40	Not stated	20/20	2–12	4 weeks	Patients diagnosed with AD	Ages 2–5 years: 4 mg montelukast Ages 6–12 years: 5 mg montelukast	Montelukast vs Singulon	None	• 4-point scales used to evaluate and tolerance efficacy of drug • Urinary LTE4, eosinophil %, IgE, PEFR1
Yanase et al., USA, 2001 (37)	Randomized, double-blind, placebo-controlled, crossover study	8	0%	Not given	≥ 18	5 weeks	Patients with persistent AD diagnosed according to Hanifin and Rajka criteria	10 mg of montelukast OD	Placebo	Emollients, antihistamines, and weak topical steroids when necessary	ADASI score assessing erythema, papulation, excretion, lichenification, scaling/dryness, and erosion/oozing
Zabawski et al., USA, 1999 (38)	Case series	5	0%	1/4	8–45	10 days–4 weeks	Patients diagnosed with AD	10 mg zafirlukast twice daily for 8 year olds, 20 mg twice daily for other patients	None	Corticosteroids or emollients were used as needed	Objective and subjective observations for improvement of disease

AD: atopic dermatitis; OD: once daily; SCORAD: Severity Scoring of Atopic Dermatitis 1; IgE: immunoglobulin E; SASSAD: six area, six sign atopic dermatitis; CDLQI: Children's Dermatology Life Quality Index; FLG: flaggrin; EASI: Eczema Area and Severity Index; IGA: Investigator's Global Assessment; LTE4: leukotriene E4; EDN: eosinophil-derived neurotoxin; QoL: quality of life; ECAR: early cutaneous allergic response; LCAR: late cutaneous allergic response; FEV1: forced expiratory volume; PEFR1: peak expiratory flow rate; ADASI: Atopic Dermatitis Area and Severity Index.

	Randomisation process	Deviations from the intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	
	D1	D2	D3	D4	D5	Overall
Capella 2001	!	+	+	!	!	!
Craig 2002	!	-	-	!	-	-
Nettis 2002	!	+	+	+	!	!
Friedmann 2007	+	+	+	+	!	!
Goh 2016	!	!	-	+	!	-
Jamalyan 2024	+	+	+	+	+	+
Melamed 2017	!	+	+	+	-	-
Rahman 2006	!	+	+	+	!	!
Xabibullayeva 2021	+	+	-	+	!	-

+ Low risk
 ! Some concerns
 - High risk

	Randomisation process	Bias arising from period and carryover effects	Deviations from the intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported result	
	D1	D5	D2	D3	D4	D5	Overall
Ehlayel 2007	+	!	+	+	+	!	!
Jeon 2016	+	+	+	+	+	+	+
Lehtimäki 2009	!	!	+	+	+	!	!
Pei 2001	+	+	+	+	+	!	+
Sekerel 2003	!	!	+	+	+	!	!
Veien 2005	!	+	+	+	+	!	!
Yanase 2001	!	-	+	+	+	!	-

+ Low risk
 ! Some concerns
 - High risk

Fig. 2. Risk of bias summary. Review of authors' judgements on the level of risk of bias across each bias domain for parallel randomized controlled trials (RCTs) on right and crossover RCTs on the left. D = domain.

Ten studies were assessed using the JBI critical appraisal checklists (12). Among these studies, 5 were rated high quality, 1 medium, and 3 low (**Fig. 3**).

Meta analysis

Analysis was done only for studies using EASI and SCORAD due to insufficient data present for other severity scores or lack of appropriate comparability. A total of 7 groups using both scoring systems were analysed. In comparison with the control group ($n=191$), our meta-analysis showed a non-significant effect of montelukast in reducing severity scores in the intervention group ($n=183$; $SMD=-0.99$ at 95% CI -2.11 to 0.13 , $p=0.0828$, $I^2=94.4\%$) (**Fig. 4**).

Subgroup analyses

Subgroup analyses stratified studies by severity scoring (EASI or SCORAD), population (paediatric or adult), and control type (placebo or conventional treatment). Forest plots and details of each analysis are available in Figs S1–S6. While montelukast reduced severity scores in both EASI and SCORAD analyses, the results were not statistically significant. In the SCORAD paediatric vs adult analysis, reductions were observed in both groups, but significance was reached only in adults (intervention $n=54$; $SMD=-0.94$, 95% CI -1.35 to -0.54 , $p<0.0001$, $I^2=1.8\%$). Similarly, in the SCORAD analysis comparing placebo and conventional treatment controls (antihistamines and/or corticosteroids), reduc-



Fig. 3. Quality assessment graph showing authors' assessments, presented as percentages for all studies except randomized controlled trials (RCTs).

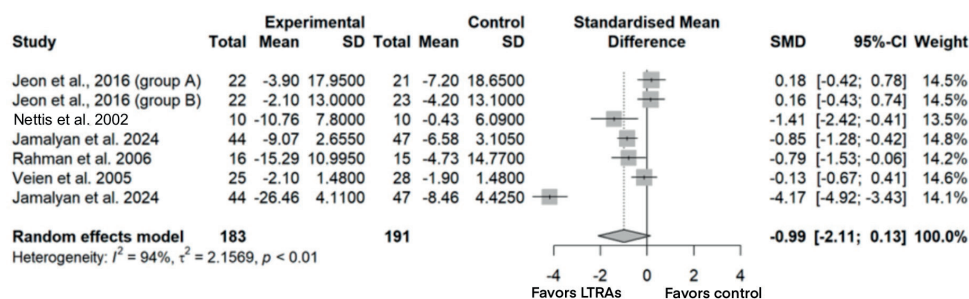


Fig. 4. Forest plot for meta-analysis of all studies. LTRAs = leukotriene receptor antagonists.

tions occurred in both subgroups, but significance was achieved only with conventional treatment (intervention $n=60$; SMD=-0.84, 95% CI -1.21 to -0.47, $p<0.0001$, $I^2=0\%$).

NARRATIVE SYNTHESIS

Severity and improvement of AD

A total of 26 studies were utilized in narrative synthesis across adult, paediatric, and mixed populations. The relevant findings of each study are presented in **Table II**. SCORAD, used in 13 studies (5 paediatric), was the most common tool for assessing pruritus, erythema, and other symptoms. SCORAD assessments included both objective measures, such as extent and intensity of lesions, and subjective measures such as patient discomfort.

A total of 18 studies favoured the use of LTRAs, while 8 studies did not show significant benefits. Even among the studies that did not find statistically significant results, most still reported some positive effects, such as reductions in AD severity. Of 20 longer duration studies (≥ 4 weeks), 8 studies (7 RCTs and 1 case series) did not find LTRAs to be significantly beneficial. Notably, the case series by Silverberg and Paller (34) found an initial temporary improvement in AD, after which symptoms reappeared. Most studies using zafirlukast showed improvement, while montelukast had inconsistent outcomes. Studies favouring montelukast were generally smaller, whereas those showing no significant benefit often had larger sample sizes. Six adult and 7 paediatric studies supported montelukast, while 2 in each group did not.

Overall, montelukast helped alleviate pruritus but had little effect on skin dryness, and showed a generally positive but mixed response across studies.

LTRAs vs placebo

Among 11 placebo-controlled RCTs, montelukast showed mixed effectiveness in reducing AD severity. Four studies reported significant improvements, particularly in pruritus, while the others found no significant differences compared with placebo. For example, Goh et al. (23) reported a 32% reduction in SCORAD scores with

montelukast vs 10% with placebo ($p=0.047$), indicating moderate benefit. Other studies noted no significant changes in secondary outcomes such as skin dryness, rescue medication use, or disease extent.

LTRAs vs conventional treatment

In 5 RCTs, montelukast significantly reduced AD severity, showing efficacy comparable to conventional treatments such as antihistamines and/or corticosteroids. Rahman et al. (32) found it as effective as topical steroids and antihistamines, especially for pruritus and erythema, while Capella et al. (17) reported significant improvements and score reductions that were similar to but had no advantage over conventional therapy. Notably, 2 studies found montelukast combined with antihistamines to be more effective than conventional treatment alone.

Biological markers associated with AD

Markers such as eosinophilic cationic protein (ECP), eosinophil protein X (EPX), immunoglobulin E (IgE), and urinary leukotriene E4 (LTE4) were evaluated. Montelukast significantly reduced serum ECP and EPX, and urinary LTE4s levels in some studies, suggesting modulation of eosinophil activity and inflammation, though others found no significant changes. Ibrahim et al. (24) detected the FLG mutation 2282del4 in all 20 AD patients, who showed significant reductions in eosinophil levels and improvements in SCORAD and IgE levels ($p<0.05$) after montelukast treatment. Several studies also found a decrease in cys-LT levels. These findings underscore the complexity of AD and the need for further research to clarify how montelukast influences specific biomarkers associated with the disease.

Quality of life (QoL)

QoL of patients with AD was reported only in some studies using patient-reported outcomes. In a paediatric study by Goh et al. (23), CDLQI was used to assess QoL, and reported a 50% improvement in the montelukast group compared with a 23% improvement in the control group. However, in the study performed by Pei et al.

Table II. Relevant findings

Author, country, year, (reference no.)	Results
Angelova-Fischer et al., Bulgaria, 2005 (15)	• SCORAD score decreased in both patients
Broshtilova et al., Bulgaria, 2010 (16)	• SCORAD reduction was observed in all patients
Capella et al., Italy, 2001 (17)	• Significant improvement in SCORAD score was observed in both the montelukast group and the conventional treatment group. There was no significant difference between the groups
Carucci et al., USA, 1998 (18)	• Decrease in the percentage body surface area in all cases
Craig et al., USA, 2002 (19)	• No statistical difference noted in AD between groups
Ehlayel et al., Qatar, 2007 (20)	• A positive trend indicated potential benefits of montelukast in the paediatric subset
Nettis et al., Italy, 2002 (10)	• Use of rescue medication was not significantly different between groups
Friedmann et al., UK, 2007 (21)	• There was no significant difference in AD severity scores between the 2 groups
Friedmann et al., UK, 2001 (22)	• Montelukast group showed a significant 20% reduction in disease activity, as measured by SCORAD values, compared with the placebo group
Goh et al., Australia, 2016 (23)	• Improvement in mean SASSAD score from baseline to the end of treatment was marginally superior in the placebo group
Hon et al., Hong Kong, 2005 (8)	• 7 out of 11 patients showed improvement and there was a median reduction of SASSAD from 11 to 9
Ibrahim et al., Egypt, 2014 (24)	• Montelukast group experienced a 32% reduction in objective SCORAD scores, compared with a 10% reduction in the comparator group ($p=0.047$)
Jamalyan et al., Armenia, 2024 (25)	• CDLQI scores improved by 50% in the treatment group vs 23% in the control group ($p=0.0846$)
Jeon et al., South Korea, 2016 (26)	• Montelukast led to a reduction of over 30% in total SCORAD scores in some children
Kägi et al., Switzerland, 2001 (27)	• Before treatment with montelukast, SCORAD score was 24.81 ± 1.99 while after montelukast treatment it was 1.56 ± 0.46 ($p<0.05$)
Lee et al., South Korea, 2007 (28)	• Significant improvements favouring montelukast were observed in the Extent and Severity of Eczema, GISS, EASI, PPNRS, DLQI, and Skin Functional Properties scales ($p > 0.05$)
Lehtimäki et al., Finland, 2009 (29)	• Montelukast was significantly more effective than antihistamine monotherapy
Melamed et al., USA, 2017 (30)	• There was no statistically significant difference in clinical improvement or biomarker levels between the montelukast and placebo groups
Pei et al., Hong Kong, 2001 (31)	• AD subsided in all patients
Rahman et al., Bangladesh, 2006 (32)	• Complete discontinuation of topical steroid therapy
Sekere et al., Turkey, 2003 (33)	• All components of SCORAD (extent, intensity, symptoms) decreased
Silverberg et al., USA, 2004 (34)	• Serological markers were significantly decreased
Veien et al., Denmark, 2005 (35)	• Montelukast was ineffective for treating non-airway allergic symptoms in individuals with atopic syndrome
Xabibullayevna et al., Uzbekistan, 2021 (36)	• There was no difference between montelukast and placebo treatments in the need for oral antihistamines
Yanase et al., USA, 2001 (37)	• Significant reduction in the pruritus score ($p=0.002$)
Zabawski et al., USA, 1999 (38)	• Trend toward decreased use of rescue medications (cetirizine: $p=0.056$; hydrocortisone cream: $p=0.056$)
	• Reduction in nerve growth factor levels
	• LTRAs, used as an adjunct treatment, exhibit an anti-inflammatory effect on AD
	• Net change in median severity scores was statistically significant during the drug and placebo phases for Group B, but not for Group A
	• Changes in the extent-of-disease score were not statistically significant for either group
	• The subjective patient-reported QoL score remained consistent across the study in both groups
	• Significant improvement in SCORAD scores ($p=0.003$) was observed in the montelukast group
	• Pruritus was the most alleviated symptom
	• No observed effect on skin dryness
	• Montelukast significantly improved allergen-induced cutaneous late-phase responses
	• No sustained benefit was observed for extensive AD
	• AD symptoms temporarily improved but returned after a while
	• No difference in efficacy amongst both groups
	• Both groups showed reduced allergy symptoms
	• There was a significant decrease in eosinophil levels
	• Serum IgE levels improved, indicating better treatment outcomes ($p<0.001$)
	• Significant difference in atopic dermatitis scores was observed between the placebo and active agent groups ($p=0.014$), with scores generally higher in the placebo group
	• No significant interaction was found between treatment order and outcome
	• Improvement was noted in descending order of severity for scaling/dryness ($p=0.003$), lichenification ($p=0.009$), induration ($p=0.016$), erythema ($p=0.024$), erosions ($p=0.027$), and excoriation ($p=0.062$)
	• Resolution of pruritus, secondary lichenification, and erythema of AD occurred in all patients

SCORAD: Severity Scoring of Atopic Dermatitis; AD: atopic dermatitis; SASSAD: six area, six sign atopic dermatitis; CDLQI: Children's Dermatology Life Quality Index; GISS: Global Individual Signs Score; EASI: Eczema Area and Severity Index; PPNRS: Peak Pruritus Numerical Rating Scale; DLQI: Dermatology Life Quality Index; LTRAs: leukotriene receptor antagonists; QoL: quality of life; IgE: immunoglobulin E.

(31), no significant difference in QoL scores was noted between montelukast and placebo.

Rescue medication

Most studies did not provide detailed information on rescue medication. Friedmann et al. (21) assessed the frequency of corticosteroid use but found no significant steroid-sparing effect, with similar use in both the montelukast and placebo groups. Lehtimäki et al. (29) and Ehlayel et al. (20) also reported no difference, while

Melamed (30) noted a trend towards reduced rescue medication use.

Emollient usage

Emollient use was not a primary focus in the studies reviewed but was included as part of treatment regimens alongside other therapies. While trials mentioned emollients, their impact on montelukast's efficacy or on reducing the need for treatments like corticosteroids was not directly assessed.

Adverse effects

Montelukast's adverse effects in AD treatment were generally mild and infrequent. Three studies reported notable effects: Friedmann et al. (21) observed septicaemia and dizziness, Sekerel and Akpinarli (33) found no difference between groups, and Jamalayan and Azaryan (25) noted mild effects (in 13.6% of patients) such as conjunctivitis and nasopharyngitis without discontinuation. Its safety profile was comparable to conventional treatments, with no significant long-term toxicity, though monitoring patients for potential reactions during treatment remains important.

DISCUSSION

This review synthesized data from 26 studies examining montelukast's efficacy in AD across adult, paediatric, and mixed populations. We observed that LTRAs show some improvement in AD, but the clinical significance is variable.

Our findings align with prior reviews by Chin et al. and Ferguson et al., showing montelukast's superiority to conventional treatments and a non-significant trend favouring it over placebo (39, 40). Unlike these reviews, our broader scope – 26 studies, compared with Ferguson et al.'s 5 and Chin et al.'s 11 studies – allowed for subgroup analyses by population and scoring systems, addressing heterogeneity. Our inclusion of all LTRAs, not just montelukast, further expanded the review.

Our subgroup analyses also reached statistical significance in 2 subgroups, providing additional insights beyond previous reviews. Overall, our results tend to be more favourable towards LTRAs than those reported by Chin et al. and Ferguson et al. (39, 40), likely due to our inclusion of a larger and more diverse set of studies.

Our meta-analysis yielded mixed results. Montelukast demonstrated no significant improvement in AD severity, whether evaluated using both EASI and SCORAD indices or each score separately. Our overall analysis showed a non-significant trend favouring montelukast, likely due to high heterogeneity ($I^2=94\%$) from variations in patient and control populations, scores used, and study quality. Subgroup analyses were conducted to address this and better understand montelukast's impact on AD.

The EASI subgroup showed a trend favouring montelukast, though it was not statistically significant. This was likely due to the presence of only 2 studies and high heterogeneity ($I^2=99\%$), reducing statistical power. The lower-quality study by Veien et al. (35) showed minimal effect, while Jamalayan and Azaryan's more recent, higher-quality study (25), with a longer duration and larger sample size, showed stronger results. However, this may be due to the fact that montelukast was used in combination with antihistamines. Results were significant under the fixed-effects model but not the random-effects model, reflecting substantial study variability.

In the SCORAD subgroup, montelukast showed some benefits but lacked statistical significance. The placebo-controlled, high-quality, long-duration paediatric study by Jeon et al. (26) found no benefit, possibly due to greater power and crossover effects. In contrast, the lower-quality paediatric study by Rahman et al. (32) and Jamalayan and Azaryan's high-quality study (25) favoured montelukast but used conventional treatment as a comparator. Results were significant under the fixed-effects model but not the random-effects model, similar to the EASI group analysis. The observed heterogeneity across populations, study designs, comparators, and quality likely contributed to the lack of statistical significance.

In both the pediatric and placebo subgroups of studies using SCORAD, no statistical significance was found under either the fixed or random-effects model, likely due to the same reasons as the overall SCORAD subgroup.

In the adult subgroup of studies using SCORAD, montelukast significantly improved SCORAD scores, supported by Jamalayan and Azaryan's high-quality study (25) using adjunct therapy and Nettis et al. 2002's standalone treatment study. Low heterogeneity ($I^2=2\%$) strengthens these results. These findings suggest montelukast may be effective for adults, particularly with combination therapy, though further studies are needed.

In the conventional treatment subgroup using SCORAD, statistically significant results favouring montelukast were observed, with low heterogeneity ($I^2=0\%$) reinforcing the findings. The high-quality study by Jamalayan and Azaryan (25) focused on adults, while the study by Rahman et al. (32) of moderate quality examined paediatric patients, suggesting montelukast may have comparable efficacy across age groups as opposed to the findings in the paediatric subgroup.

The disparity between the placebo and conventional treatment subgroups could be explained by the difference in population size, as the conventional subgroup has a higher sample size ($n=122$) compared with placebo ($n=108$). There was no difference in the number of high-quality studies or between the number of paediatric studies between the 2 groups. Another possible confounding factor could be that Jamalayan and Azaryan's study (25) utilized montelukast along with antihistamines vs antihistamines, and the use of montelukast as an adjunct treatment could have tipped the results in favour of montelukast.

Montelukast was generally well tolerated, with mild side effects reported and no neuropsychiatric events noted in the reviewed studies. The 2007 study by Friedmann et al. (21) noted septicaemia, but it is unlikely to be related to montelukast. Its safety profile is comparable to conventional AD treatments, making it a potential option for patients who cannot use standard therapies. Most studies lacked details on coexisting atopic conditions; however, Lehtimäki et al. (29) evaluated its effectiveness in individuals with comorbid allergic disorders and

found it to be ineffective in managing non-airway-related allergies in patients with atopic syndrome.

While montelukast may benefit select adult populations, particularly as an adjunct treatment, its efficacy remains inconsistent, and more effective treatments are available. Genetic factors such as the FLG mutation were linked to improved SCORAD and IgE levels, suggesting that biomarker-driven approaches could identify patients who may benefit most from montelukast. Montelukast is not recommended for AD in current guidelines, its use for this condition remains primarily off-label, and further research is needed to clarify its role.

Limitations

A key limitation was the lack of standardized scoring systems for assessing AD severity, complicating comparisons and hindering unified data analysis. High heterogeneity further challenged meta-analyses. Additionally, some studies lacked numerical data, with Nettis et al. 2002's study requiring estimations via tools like WebPlotDigitizer, introducing potential error.

Most studies were underpowered with small sample sizes, risking type II errors or overestimating benefits due to statistical bias. Furthermore, the focus was primarily on montelukast, with limited data on other LTRAs like zafirlukast. Disease severity also varied, with most studies involving moderate cases and fewer examining severe or mild AD. Diagnostic criteria for AD differed across studies, with some studies lacking detail. However, all studies used for statistical analysis employed valid diagnostic methods such as Hanifin and Rajka criteria or severity scores above particular cut-off values.

Concomitant therapies, including antihistamines, topical corticosteroids, and antibiotics, were common. For instance, the study by Capella et al. (21) included antibiotics, which are not standard AD treatments. Additionally, the lack of clarity on rescue medication use complicated the evaluation of montelukast's standalone efficacy in the narrative synthesis. However, in all studies included in the statistical analysis, concomitant therapies were either prohibited or administered at standardized doses uniformly across both experimental and control groups. Despite limitations, our analysis yielded some statistically significant results, providing valuable insights into montelukast's effects in patients with AD.

Future directions

Future research should prioritize larger, long-term, multi-centre trials with standardized assessment tools to enhance comparability and consistency. Exploring biomarker-driven approaches could identify subgroups likely to benefit, while studies on combination therapies may reveal montelukast's potential to enhance conventional treatments. Paediatric-focused research is especially important, given montelukast's suitability as an oral treatment for

children and its demonstrated efficacy in adults, suggesting potential benefits in younger populations.

CONCLUSION

Montelukast shows promise, particularly in adult populations and as an adjunct to conventional treatments, but its effectiveness in AD is variable. While it offers modest benefits, especially in relieving pruritus, its overall efficacy remains inconsistent. Given its favourable safety profile, montelukast may be a useful adjunct therapy, particularly for patients with comorbid asthma. However, it should not replace standard treatments in comprehensive AD management. Future research should focus on standardizing assessments and developing patient-specific approaches to better define montelukast's role in AD treatment.

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