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Rapid Onset of Pruritus Relief With Upadacitinib Versus Dupilumab in Moderate-to-Severe Atopic Dermatitis: A Systematic Review of Early Outcome Trials

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Abstract

Choosing between targeted systemic biologics and oral small molecules for moderate-to-severe atopic dermatitis remains challenging, particularly with regard to early symptom control. This systematic review aimed to compare oral upadacitinib with subcutaneous dupilumab and placebo in phase III trials, focusing on early itch trajectories, skin clearance, and safety profiles.

A comprehensive systematic search was conducted across PubMed/MEDLINE, Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), Scopus, and Web of Science through October 2026. Prospective, double-blind, and open-label randomized controlled trials (RCTs) published between 2021 and 2026 and evaluating adult and adolescent populations receiving upadacitinib (15 mg or 30 mg) versus dupilumab or placebo were identified. Study quality and risk of bias were assessed using the Cochrane Risk of Bias 2 (RoB 2) tool.

Four publications reporting five pivotal phase III trials, comprising 4,177 patients, were included in the qualitative synthesis. Upadacitinib demonstrated significantly greater early itch reduction, evident as early as week 1, and higher week 16 Eczema Area and Severity Index 75 (EASI-75) and Eczema Area and Severity Index 90 (EASI-90) response rates than the comparators. Upadacitinib was generally well tolerated. Treatment-emergent adverse events (TEAEs) primarily included mild-to-moderate, dose-dependent acne, upper respiratory tract infections, and transient laboratory abnormalities. No cases meeting Hy's law criteria were reported. Serious adverse events and treatment discontinuations were low and comparable across treatment groups. Clinical and methodological heterogeneity precluded quantitative pooling through meta-analysis.

Although targeted systemic therapies demonstrate robust early efficacy, upadacitinib offers superior early itch reduction and higher short-term skin clearance rates than subcutaneous dupilumab. Oral upadacitinib represents a highly efficacious option for rapid symptom control; however, long-term pharmacovigilance and careful patient selection remain essential to minimize potential adverse events.

Categories: Internal Medicine, Allergy/Immunology, Dermatology
Keywords: atopic dermatitis, dupilumab, janus kinase inhibitors, pruritus, upadacitinib

Introduction And Background

Global epidemiological data confirm that atopic dermatitis remains a leading driver of chronic cutaneous morbidity, affecting over 171 million individuals worldwide [1]. This inflammatory condition triggers a debilitating clinical course in which persistent symptoms impair quality of life and productivity [2]. Beyond physical skin barrier damage, the disease burden induces significant psychological distress and emotional trauma linked to chronic inflammatory pathways [3]. Mechanistically, this process is driven by neuroimmune dysregulation, wherein triggers activate sensory nerve endings in the skin, transmitting intractable itch signals to the central nervous system and perpetuating inflammation [4].

Management of moderate-to-severe atopic dermatitis relies on targeted immunomodulatory agents [5]. As a standard biologic reference, dupilumab targets the interleukin-4 receptor alpha (IL-4Rα) chain, blocking IL-4 and IL-13 signaling pathways [5,6]. While clinical evaluations demonstrate robust long-term efficacy, biological inhibition typically exhibits a more gradual therapeutic onset in terms of clinical response [6]. Conversely, oral small-molecule therapies such as upadacitinib selectively inhibit intracellular Janus kinase 1 (JAK1), rapidly interrupting multiple pruritogenic cytokine networks, including IL-4, IL-13, IL-31, and thymic stromal lymphopoietin (TSLP), to confer a prompt therapeutic response within the initial days of

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administration [7]. Beyond atopic dermatitis, the therapeutic utility of JAK inhibition extends to a broader spectrum of chronic pruritic dermatoses driven by neuroimmune dysregulation and inflammatory cascades - including prurigo nodularis [8], chronic actinic dermatitis [9], primary cutaneous amyloidosis [10], and cutaneous T-cell lymphoma [11] - underscoring the central role of the JAK/signal transducer and activator of transcription (JAK/STAT) pathway in targeting recalcitrant itch across diverse skin pathologies.

Despite direct head-to-head trials comparing selective JAK inhibitors with biologics, current evidence prioritizes mid-term clearance milestones, leaving a knowledge gap regarding early symptom timelines. While upadacitinib demonstrates superior early clearance over dupilumab by week 1 [12], the granular day-by-day dynamics of rapid pruritus reduction remain uncharacterized. Because acute itch drives patient distress, evaluating early thresholds using patient-reported outcome measures (PROMs), such as the Peak Pruritus Numerical Rating Scale (PP-NRS), is vital. A reduction of 2-4 points is considered a clinically meaningful response [13].

Despite advanced clinical trials evaluating upadacitinib versus dupilumab, including landmark head-to-head evidence reported by Silverberg et al. (Level Up) [14], comprehensive syntheses focusing specifically on the ultra-rapid trajectory of early pruritus relief remain limited in current systematic evaluations [15,16]. To address this evidence gap, this systematic review synthesizes prospective randomized controlled trials (RCTs) published between 2021 and 2026, evaluating upadacitinib against dupilumab in patients with moderate-to-severe atopic dermatitis. By focusing on early temporal windows and standardized endpoints, such as PP-NRS, this study provides an updated, non-fragmented evaluation of rapid-onset efficacy.

Review

Methodology

Study Registration and Protocol

This systematic investigation was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) under registration number CRD420261549768 [17]. The methodology was developed to evaluate early-phase symptom control in cohorts of patients with moderate-to-severe atopic dermatitis undergoing targeted systemic biologic or small-molecule therapy.

Study Criteria and Eligibility

The structural framework of this review adhered to the updated Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines [18]. To isolate highly reliable comparative evidence, the inclusion parameters were defined around a structured Population, Intervention, Comparator, and Outcomes (PICO) framework [19]:

Population (P): Clinical trial populations comprising adolescent and adult individuals (aged 12 years or older) diagnosed with moderate-to-severe atopic dermatitis according to standardized clinical criteria (e.g., Eczema Area and Severity Index (EASI) score ⩾ 16 [20], Investigator's Global Assessment (IGA) score ⩾ 3 [21], or affected body surface area (BSA) ⩾ 10%). Studies involving concomitant active systemic immunosuppressive therapies, primary cutaneous infections, or unrelated inflammatory skin conditions were excluded.

Intervention (I): Treatment arms assessing systemic monotherapy or background topical corticosteroid-combined therapy with oral upadacitinib at standard clinical dosages (15 mg or 30 mg once daily).

Comparator (C): Parallel active-comparator cohorts receiving subcutaneous dupilumab at standard dosing protocols (300 mg every two weeks following an initial loading dose), as well as direct placebo- or vehicle-controlled arms evaluated in early-phase comparative trials.

Outcomes (O): The primary endpoint focused on early pruritus dynamics, specifically the proportion of patients achieving a ⩾ 4-point improvement in the PP-NRS or Worst Pruritus Numerical Rating Scale (WP-NRS) [22] at early evaluation time points (specifically Days 1, 2, and 7 and Weeks 2-4), noting that both instruments share identical scoring mechanics, patient-reported methodology, and validated thresholds for clinical response. Secondary endpoints encompassed early lesion clearance (EASI-75 and EASI-90 achievement within two to four weeks) and treatment-emergent adverse events (TEAEs) leading to early discontinuation.

To maintain contemporary clinical relevance and reflect modern therapeutic standards in biologic and Janus kinase (JAK) inhibitor research, eligibility was restricted to prospective RCTs, including double-blind and open-label assessor-blinded designs, published between 2021 and 2026. Nonrandomized observational designs, retrospective chart reviews, single-arm open-label extensions without early baseline metrics, case series (n < 10), editorial commentaries, and conference abstracts lacking complete numerical trial datasets were excluded from the primary synthesis.

Information sources and search strategy

A comprehensive, systematic search was conducted across major biomedical bibliographicalic databases: Medical Literature Analysis and Retrieval System Online (MEDLINE via PubMed), Embase, the Cochrane Central Register of Controlled Trials (CENTRAL), Scopus, and Web of Science. Additionally, clinical trial registries (ClinicalTrials.gov and the European Union Clinical Trials Register) were examined to identify completed phase 3 studies with published early-outcome data.

The search strategy combined relevant Medical Subject Headings (MeSH), Emtree terms, and free-text synonyms using Boolean operators ("AND" and "OR"). The primary search string applied in PubMed/MEDLINE was structured as follows:

("Atopic Dermatitis"[Mesh] OR "atopic dermatitis"[Title/Abstract] OR "atopic eczema"[Title/Abstract]) AND ("Upadacitinib"[Mesh] OR "upadacitinib"[Title/Abstract] OR "JAK inhibitor"[Title/Abstract] OR "JAK-1 inhibitor"[Title/Abstract]) AND ("Dupilumab"[Mesh] OR "dupilumab"[Title/Abstract] OR "placebo"[Title/Abstract]) AND ("pruritus"[Title/Abstract] OR "itch"[Title/Abstract] OR "PP-NRS"[Title/Abstract] OR "early response"[Title/Abstract] OR "onset of action"[Title/Abstract]).

Additionally, clinical trial registries (ClinicalTrials.gov and the European Union Clinical Trials Register) were searched on October 24, 2026, using the term sequence "atopic dermatitis AND upadacitinib AND dupilumab" to identify completed phase 3 studies with published early-outcome data.

Filters were restricted to human clinical trials, English-language publications, and the 2021-2026 publication date range. Full-text accessibility was required to extract detailed day-by-day and week-by-week numerical pruritus metrics. A complete list of database-specific search strings and Boolean configurations is provided in Table *1*.

Database	Search strategy/syntax	Filters/limits	Search date
PubMed / MEDLINE	("Atopic Dermatitis"[Mesh] OR "atopic dermatitis"[Title/Abstract] OR "atopic eczema"[Title/Abstract]) AND ("Upadacitinib"[Mesh] OR "upadacitinib"[Title/Abstract] OR "JAK inhibitor"[Title/Abstract] OR "JAK-1 inhibitor"[Title/Abstract]) AND ("Dupilumab"[Mesh] OR "dupilumab"[Title/Abstract] OR "placebo"[Title/Abstract]) AND ("pruritus"[Title/Abstract] OR "itch"[Title/Abstract] OR "PP-NRS"[Title/Abstract] OR "early response"[Title/Abstract] OR "onset of action"[Title/Abstract])	Humans, Clinical Trial, Randomized Controlled Trial, English, Publication date: 2021-2026	October 2026
CENTRAL	(#1 MeSH descriptor: [Dermatitis, Atopic] explode all trees OR "atopic dermatitis":ti,ab,kw OR "atopic eczema":ti,ab,kw) AND (#2 MeSH descriptor: [Upadacitinib] explode all trees OR "upadacitinib":ti,ab,kw OR "JAK inhibitor":ti,ab,kw) AND (#3 "dupilumab":ti,ab,kw OR "placebo":ti,ab,kw) AND (#4 "pruritus":ti,ab,kw OR "itch":ti,ab,kw OR "early response":ti,ab,kw)	Trials, English, Publication date: 2021-2026	October 2026
Embase	('atopic dermatitis'/exp OR 'atopic dermatitis':ti,ab OR 'atopic eczema':ti,ab) AND ('upadacitinib'/exp OR 'upadacitinib':ti,ab OR 'janus kinase 1 inhibitor':ti,ab) AND ('dupilumab'/exp OR 'dupilumab':ti,ab OR 'placebo':ti,ab) AND ('pruritus'/exp OR 'pruritus':ti,ab OR 'itch':ti,ab)	Human, Randomized Controlled Trial, English, 2021-2026	October 2026
Scopus	TITLE-ABS-KEY (“atopic dermatitis" OR "atopic eczema”) AND ("upadacitinib" OR "JAK inhibitor") AND ("dupilumab" OR "placebo") AND ("pruritus" OR "itch" OR "early response"))	Article, Article in Press, English, 2021-2026	October 2026
Web of Science	TS=("atopic dermatitis" OR "atopic eczema") AND ("upadacitinib" OR "JAK inhibitor") AND ("dupilumab" OR "placebo") AND ("pruritus" OR "itch" OR "early response"))	Clinical Trials, English, Publication Years: 2021-2026	October 2026

TABLE 1: Detailed database-specific search strategies and query strings.

Database-specific search strategies include controlled vocabularies, field tags, Boolean operators, and applied filters used to identify eligible studies published between 2021 and 2026.

CENTRAL, Cochrane Central Register of Controlled Trials; Embase, Excerpta Medica Database; MeSH, Medical Subject Headings; MEDLINE, Medical Literature Analysis and Retrieval System Online

Study selection and data extraction

Two independent reviewers screened titles and abstracts retrieved from the electronic database search according to the predefined PICO eligibility criteria. Full-text articles of potentially eligible studies were subsequently retrieved and independently assessed for final inclusion. Any disagreements between reviewers regarding study eligibility were resolved through consensus or consultation with a third independent investigator. Data extraction was performed independently using a standardized data abstraction matrix designed to record primary study characteristics, baseline participant demographics, upadacitinib and dupilumab or placebo intervention regimens, primary efficacy outcomes (early itch dynamics, including improvement of ⩾4 points in the PP-NRS or WP-NRS), secondary skin clearance parameters (EASI-75 and EASI-90 achievement), and TEAEs. Missing data were analyzed as reported without imputation, and no automation tools were used during the screening phase.

Risk-of-bias assessment

Methodological quality and vulnerability to systematic errors across all included RCTs were independently evaluated using the Cochrane Risk of Bias 2 (RoB 2) tool [23]. Evaluations were conducted at the outcome level, specifically differentiating primary objective clinical endpoints (such as EASI-75 and EASI-90 skin clearance rates) from secondary subjective patient-reported outcomes (including Worst Pruritus Numerical Rating Scale improvements). Objective outcomes generally maintained a lower RoB regarding measurement, whereas open-label design components in comparative studies were carefully appraised for performance and detection biases, with risks mitigated through independent and blinded efficacy assessors. Five analytical domains were examined: the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Discrepancies between evaluators were resolved through joint re-examination of trial protocols and consensus. RoB summary plots were generated using the robvis web application [24].

Data synthesis

Clinical and statistical comparability across included RCTs was systematically assessed prior to quantitative synthesis. Although random-effects pooling and restricted subgroup meta-analyses (e.g., separate quantitative pooling of head-to-head trials vs. placebo-controlled cohorts) were explicitly evaluated, a formal meta-analysis was omitted due to insurmountable clinical and methodological intransitivity across trial designs. Specifically, pooling data across fundamentally disparate treatment paradigms, such as direct active-comparator head-to-head trials vs. placebo-controlled cohorts with background topical corticosteroid therapy, violates standard meta-analytic assumptions. Furthermore, even within the head-to-head subgroup, substantial methodological heterogeneity existed between trials (e.g., double-blind fixed-dose monotherapy in Heads Up [25] vs. open-label response-driven dose escalation with concomitant topical corticosteroids in Level Up [14]), and early pruritus evaluation time points varied significantly (ranging from day-two spot assessments to weekly PP-NRS averages). To prevent methodologically flawed or statistically distorted pooled estimates, data were synthesized narratively in accordance with the Synthesis Without Meta-analysis (SWiM) reporting guidelines [26]. Consequently, a structured qualitative synthesis was executed to characterize early symptom trajectories.

Results

Study Selection and Screening Flow

The comprehensive electronic database searches yielded 154 records, supplemented by 30 records identified through clinical trial registries, totaling 184 initial records. Following the removal of 42 duplicate citations, 142 unique titles and abstracts were independently screened based on the predefined eligibility criteria. A total of 106 records were excluded during primary screening due to non-relevance or non-peer-reviewed editorial commentaries.

Thirty-six full-text manuscripts were retrieved and evaluated for final inclusion. Of these, 32 reports were excluded for failing to meet strict PICO eligibility parameters: 14 evaluated off-target systemic or topical agents, eight lacked early-phase numerical pruritus assessment metrics (PP-NRS or WP-NRS), six represented long-term open-label extension sub-analyses without baseline early outcome data, and four were conference abstracts lacking complete numerical trial datasets. Ultimately, four primary publications reporting on five pivotal phase III RCTs met all selection requirements and were included in the qualitative synthesis (Figure *1*) [14,25,27,28].

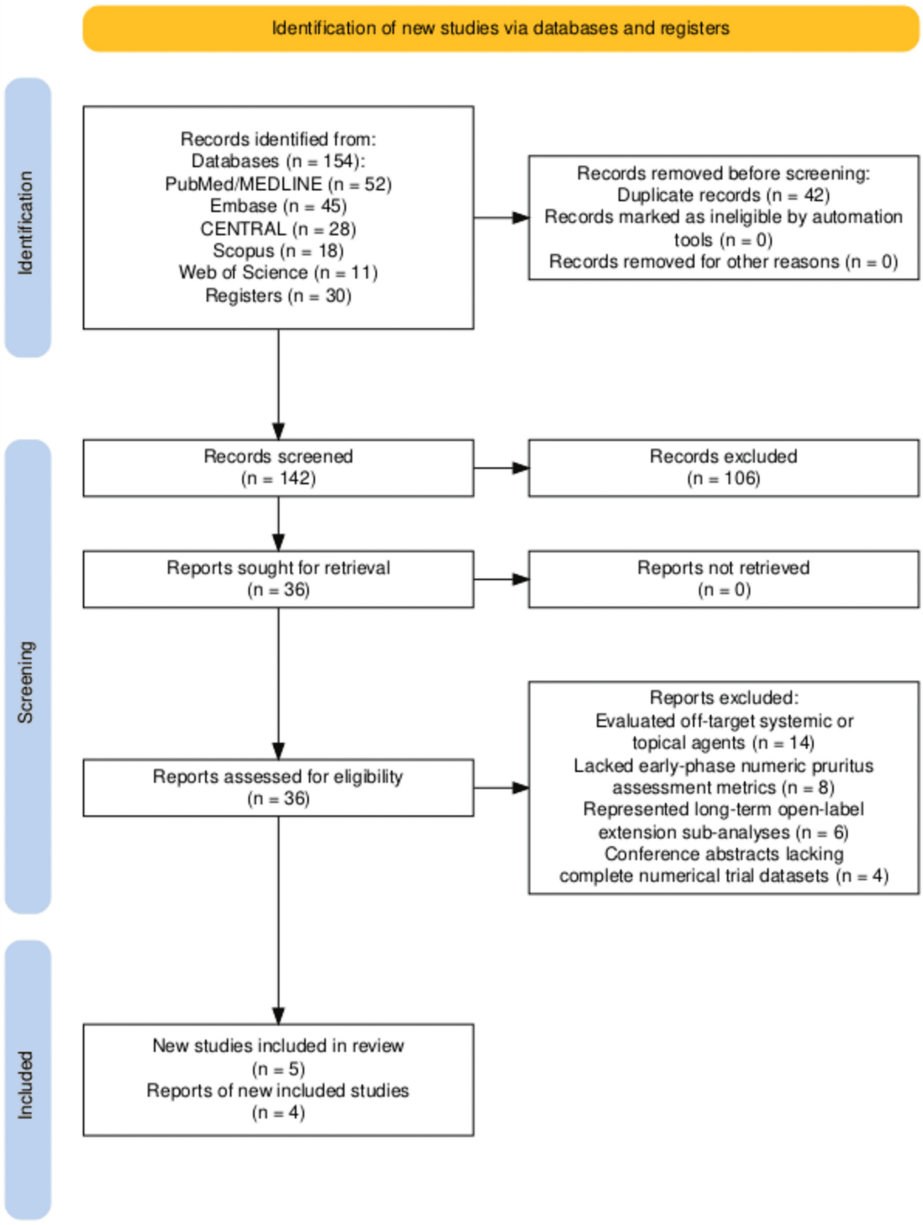


FIGURE 1: PRISMA 2020 flow diagram for the systematic review process.

PRISMA 2020 flow diagram detailing the identification, screening, eligibility, and inclusion phases of prospective randomized controlled trials (RCTs) evaluating upadacitinib vs. dupilumab in moderate-to-severe atopic dermatitis.

CENTRAL, Cochrane Central Register of Controlled Trials; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses

Methodological and population characteristics

Regarding the pre-specified early itch evaluation timeline (spanning days one, two, and seven, as well as weeks two through four), all included trials successfully captured and reported data within these targeted windows in alignment with our registered PROSPERO protocol, with no protocol deviations regarding temporal outcome extraction. Table *2* details the foundational study designs, sample sizes, target populations, and intervention protocols across the five phase III RCTs (encompassing four primary publication sets) [14,25,27,28]. The combined evidence base comprises a pooled cohort of 4,177 adolescent and adult patients with moderate-to-severe atopic dermatitis across multinational clinical centers. Trial designs encompass active-controlled direct comparisons evaluating upadacitinib vs. dupilumab (Heads Up and Level Up) [14,25], background topical corticosteroid combination regimens (AD Up) [27], and monotherapy placebo-controlled replicate trials (Measure Up 1 and Measure Up 2) [28]. Across all trials,

baseline disease severity was standardized using composite criteria (EASI ⩾ 16, validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) ⩾ 3 [21], and WP-NRS ⩾ 4). Treatment durations for primary double-blind evaluation phases spanned 16 to 24 weeks, evaluating daily oral upadacitinib dosages of 15 and 30 mg against standard biological dosing schedules or matching placebos.

Study (author, year)	Study design	Sample size	Population	Technical arms	Intervention regimens	Sponsor	RoB
Blauvelt et al., 2021 [25]	Phase IIIb, multicenter, randomized, double-blind, double-dummy, active-controlled RCT	*N* = 673	Adults aged 18-75 years with moderate-to-severe atopic dermatitis (EASI ≥ 16, vIGA-AD ≥ 3, Worst Pruritus NRS ≥ 4)	Group 1: Upadacitinib; Group 2: Dupilumab	Group 1: Upadacitinib 30 mg oral extended-release tablet once daily through Week 24; Group 2: Dupilumab 300 mg subcutaneous injection every two weeks (following 600 mg loading dose) through Week 22	AbbVie	Low risk
Silverberg et al., 2025 [14]	Phase IIIb/IV, global, randomized, open-label, efficacy assessor-blinded, head-to-head multicenter trial	*N* = 920	Adolescents (≥ 12-17 years) and adults (18 to < 64 years) with moderate-to-severe atopic dermatitis (EASI ≥ 16, vIGA-AD ≥ 3, WP-NRS ≥ 4)	Group 1: Upadacitinib; Group 2: Dupilumab	Group 1: Upadacitinib 15 mg once daily (dose-escalated to 30 mg from weeks 4-16 based on clinical response); Group 2: Dupilumab administered subcutaneously as per its label for 16 weeks (period 1).	AbbVie	Low risk
Reich et al., 2021 (AD Up) [27]	Phase III, randomized, double-blind, placebo-controlled, multicenter trial	*N* = 901	Adolescents (≥ 12-17 years) and adults (18-75 years) with moderate-to-severe atopic dermatitis (EASI ≥ 16, vIGA-AD ≥ 3, Worst Pruritus NRS ≥ 4) under background topical corticosteroids (TCS)	Group 1: Upadacitinib 15 mg + TCS; Group 2: Upadacitinib 30 mg + TCS; Group 3: Placebo + TCS	Group 1: Upadacitinib 15 mg oral tablet once daily + TCS; Group 2: Upadacitinib 30 mg oral tablet once daily + TCS; Group 3: Matching placebo once daily + TCS through Week 16 (double-blind period).	AbbVie	Low risk
Guttman-Yassky et al., 2021 (Measure Up 1 and 2) [28]	Two replicate Phase III, multicenter, randomized, double-blind, placebo-controlled RCTs	*N* = 1,683 total (MU-1: *n* = 847; MU-2: *n* = 836)	Adolescents (12-17 years) and adults (18-75 years) with moderate-to-severe AD (EASI ≥ 16, vIGA-AD ≥ 3, BSA ≥ 10%, Worst Pruritus NRS ≥ 4)	Group 1: Upadacitinib 15 mg; Group 2: Upadacitinib 30 mg; Group 3: Placebo	Group 1: Upadacitinib 15 mg oral tablet once daily; Group 2: Upadacitinib 30 mg oral tablet once daily; Group 3: Matching oral placebo once daily for 16 weeks (double-blind period).	AbbVie	Low risk

TABLE 2: Main methodological characteristics and intervention regimens of the included clinical trials.

AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; MU-1, Measure Up 1; MU-2, Measure Up 2; NRS, Numerical Rating Scale; RCT, randomized controlled trial; RoB, risk of bias; TCS, topical corticosteroids; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numerical Rating Scale

RoB and quality assessment results

Evaluation using the Cochrane RoB 2 tool [23] demonstrated overall high methodological rigor and low vulnerability to systematic errors across the five included phase III RCTs (reported across four primary publication sets) [14,25,27,28]. Overall RoB was judged as low across all domain evaluations for primary objective efficacy endpoints (such as EASI-75 and EASI-90 achievement) and secondary symptom-control metrics.

Specifically, the pivotal double-blind protocols Blauvelt et al. (Heads Up) [25], Reich et al. (AD Up) [27], and Guttman-Yassky et al. (Measure Up 1 and Measure Up 2) [28] demonstrated a low RoB across all five analytical domains, supported by robust allocation concealment, double-dummy designs, and complete outcome data reporting. For Silverberg et al. (Level Up) [14], despite its open-label design implemented to

accommodate flexible dose-escalation algorithms, domain-specific evaluation yielded a low RoB because outcome assessment for primary and secondary efficacy endpoints was strictly blinded to independent adjudicators, and patient-reported pruritus metrics (WP-NRS) demonstrated high compliance without differential attrition.

Domain-specific assessments and overall RoB summaries are illustrated in Figure *2*. Overall, the included phase III RCTs demonstrated high internal methodological validity and low RoB across evaluated outcome domains, reflecting rigorous trial protocols, robust allocation concealment, low attrition rates, and consistent outcome measurement trajectories across cohorts.

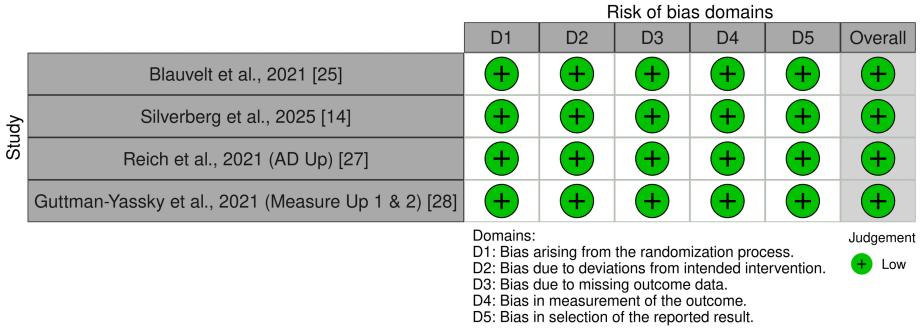


FIGURE 2: Risk of bias (RoB) traffic-light plot for included randomized controlled trials (RCTs).

RoB assessment generated using the Cochrane RoB 2 tool via the robvis application. Domains: D1 (randomization process); D2 (deviations from intended interventions); D3 (missing outcome data); D4 (measurement of the outcome); D5 (selection of the reported result) [14,25,27,28].

Comparative monotherapy and efficacy outcomes

Comparative clinical efficacy across active-controlled and placebo-controlled trials demonstrated significant, dose-dependent superiority for upadacitinib monotherapy. In the head-to-head comparison conducted by Blauvelt et al. (Heads Up) [25], upadacitinib 30 mg daily achieved significantly higher week 16 EASI-75 response rates compared with dupilumab 300 mg every two weeks (72.4% vs. 62.6%; absolute risk difference, +9.8%; $P = 0.007$). Furthermore, upadacitinib exhibited a remarkably rapid onset of action regarding early itch relief, inducing a mean percent reduction in Worst Pruritus NRS at Week 1 of -32.0% vs. -8.9% for dupilumab (between-group difference, -23.1%; $P < 0.001$), a primary symptom response sustained through Week 16.

In the open-label, assessor-blinded trial by Silverberg et al. (Level Up) [14], simultaneous achievement of high-threshold skin clearance and strict itch resolution (EASI-90 plus WP-NRS 0/1) at Week 16 was attained by 19.9% of patients receiving upadacitinib (15 mg dose-escalated to 30 mg) vs. 8.9% of those on dupilumab (absolute risk difference, +11.0%; $P < 0.001$). Regarding early categorical response thresholds, the proportion of patients achieving a clinically meaningful early reduction in itch (ΔWP-NRS ⩾ 4 points) was significantly superior with upadacitinib as early as Day 2 (25.4% vs. 10.2%; absolute difference, +15.2%; $P < 0.001$), alongside significantly higher early skin clearance rates demonstrating superior EASI-75 achievement at Week 2 ($P < 0.001$).

In the replicate placebo-controlled trials by Guttman-Yassky et al. (Measure Up 1 and Measure Up 2) [28], monotherapy with both upadacitinib 15 mg and 30 mg met coprimary endpoints at Week 16 with high statistical significance ($P < 0.0001$). EASI-75 was achieved by 70% and 60% of patients on upadacitinib 15 mg, and 80% and 73% on upadacitinib 30 mg, compared with 16% and 13% in placebo arms across Measure Up 1 and Measure Up 2 [28], respectively. Corresponding vIGA-AD 0/1 clearance rates reached 48% and 39% (15 mg) and 62% and 52% (30 mg) vs. 8% and 5% with placebo ($P < 0.0001$). Rapid itch reduction (ΔWP-NRS ⩾ 4) was established within Week 1 across all active arms.

Synergistic combination and multimodal strategies

Evaluating targeted small-molecule therapy combined with topical agents, Reich et al. (AD Up) [27] demonstrated marked clinical enhancement when oral upadacitinib was administered alongside background topical corticosteroids. At Week 16, primary coprimary endpoint evaluations revealed EASI-75 achievement in 64.6% of patients receiving upadacitinib 15 mg plus topical corticosteroids and 77.1% receiving upadacitinib 30 mg plus topical corticosteroids, compared with 26.4% in the placebo plus topical corticosteroid group ($P < 0.001$).

Similarly, vIGA-AD 0/1 response rates reached 39.6% in the 15 mg combination arm and 58.6% in the 30 mg combination arm versus 10.9% in placebo controls ($P < 0.001$). Rapid pruritus control (ΔWP-NRS ⩾ 4) was consistently maintained from Week 1 through Week 16, establishing the strong additive value of combined systemic-topical regimens without compromising treatment adherence.

Safety profile and adverse events

Safety profiles evaluated across all five RCTs indicated that oral upadacitinib was generally well tolerated, with TEAEs predominantly comprising mild-to-moderate transient conditions. Across trials, the most frequently reported TEAEs in upadacitinib arms were dose-dependent acne (ranging from 7.0% to 16.1% on upadacitinib regimens vs. 1.5% to 7.4% on comparators), nasopharyngitis (6.0% to 12.7%), upper respiratory tract infections (9.0%-13.0%), and headache (5.0%-7.0%), as detailed in Table *3* [14,23,27,28]. Discontinuations specifically attributed to adverse events remained low and comparable, occurring in 2.9% versus 2.0% of patients in Heads Up (upadacitinib vs. dupilumab) [25], 2.0% versus 1.3% in Level Up [14], and remaining minimal or balanced across AD Up [27] and the Measure Up trials [28].

Study (author, year)	Follow-up	Evaluation metrics/Outcomes	Key findings	Documented adverse events	Withdrawals
Blauvelt et al., 2021 [25]	Follow-up: 24 weeks	EASI-75 at Week 16 (primary endpoint); EASI-90, EASI-100, Worst Pruritus NRS improvement (≥ 4 points), and safety parameters through Week 16 and Week 24	EASI-75 (Week 16, primary endpoint): Achieved by 72.4% of UPA-treated patients vs. 62.6% of DUPI-treated patients ($P = 0.007$); early itch reduction: UPA showed significantly greater improvement in Worst Pruritus NRS as early as Week 1 (-32.0% vs. -8.9%, $P < 0.001$); maintenance of efficacy: Improvements were maintained through Week 16	TEAEs: 72.8% (UPA) vs. 65.0% (DUPI); acne: 16.1% vs. 2.7%; conjunctivitis: 1.5% vs. 8.8%; serious infections: 1.1% vs. 0.6%; herpes zoster: 2.0% vs. 0.9%; hepatic disorders/transaminase elevations: 2.9% vs. 1.2%; anemia: 2.0% vs. 0.3%; neutropenia: 1.8% vs. 0.6%; CPK elevations: 6.7% vs. 3.0%; fatal events: 1 death due to influenza-associated bronchopneumonia (UPA group)	Discontinuation due to AEs occurred in 2.9% (10/342) of UPA patients and 2.0% (7/331) of DUPI patients.
Silverberg et al., 2025 [14]	Follow-up: 16 weeks (Period 1)	Simultaneous achievement of EASI-90 and WP-NRS 0/1 at Week 16 (primary endpoint); ranked secondary endpoints including individual EASI-90, WP-NRS 0/1, ΔWP-NRS ≥ four at early and final timepoints; and safety assessments through Week 16	Simultaneous EASI-90 and WP-NRS 0/1 (Week 16, primary endpoint): Achieved by 19.9% of UPA patients vs. 8.9% of DUPI patients ($P < 0.001$); early kinetic response: UPA demonstrated significantly higher response rates in ΔWP-NRS ≥ 4 as early as Day 2 ($P < 0.001$) compared with DUPI; efficacy velocity: EASI-75 achieved as early as Week 2 ($P < 0.001$) compared with DUPI	TEAEs: 65.3% (UPA) vs. 52.7% (DUPI); nasopharyngitis: 12.7% vs. 7.4%; acne: 12.0% vs. 1.5%; serious AEs: 0.9% vs. 0.9%; severe AEs: 3.5% vs. 2.6%; opportunistic infections: Eczema herpeticum on UPA ($n = 5$); higher herpes zoster rates on UPA (mostly mild/moderate, one disseminated case leading to discontinuation); lab alterations: Hepatic disorders, anemia, neutropenia, CPK elevations higher on UPA but transient without DILI	Discontinuations due to AEs occurred in 2.0% (9/458) of UPA patients and 1.3% (6/461) of DUPI patients. Overall study discontinuation rate was 6.5% (60/920).
Reich et al., 2021 (AD Up) [27]	Follow-up: 16 weeks (double-blind period)	Coprimary endpoints: EASI-75 and vIGA-AD 0/1 at Week 16. Key secondary endpoints: EASI-90, EASI-100, and Worst Pruritus NRS improvement (≥ 4 points) at early and final timepoints, alongside safety parameters	EASI-75 (Week 16): UPA 15 mg: 64.6%, UPA 30 mg: 77.1% vs. PBO: 26.4% ($P < 0.001$); vIGA-AD 0/1 (Week 16): UPA 15 mg: 39.6%, UPA 30 mg: 58.6% vs. PBO: 10.9% ($P < 0.001$); early onset: Rapid itch reduction (ΔWP-NRS ≥ 4) observed as early as Week 1 for UPA vs. PBO	TEAEs: Dose-related increases observed; most frequent TEAEs: Acne and upper respiratory tract infections; acne and oral herpes: Dose-dependent increases observed; serious infections and herpes zoster: Rates were low and balanced, and herpes zoster cases were nonserious and mild-to-moderate; laboratory changes: Included transient transaminase and CPK elevations without Hy's Law cases	Discontinuations due to adverse events and serious AEs were similar across treatment groups
Guttman-Yassky et al., 2021 (Measure	Follow-up: 16 weeks (double-	Coprimary endpoints: EASI-75 and vIGA-AD 0/1 at Week 16. Secondary endpoints: EASI-90,	EASI-75 (Week 16, MU-1/MU-2): UPA 15 mg: 70%/60%, UPA 30 mg: 80%/73% vs. PBO: 16%/13% ($P < 0.0001$); vIGA-AD 0/1 (Week 16): UPA 15 mg: 48%/39%, UPA 30 mg:	Overview: TEAEs were well tolerated overall; acne: 7%-13% on UPA 15 mg; 15%-17% on UPA 30 mg vs. 2% PBO; upper respiratory tract infection: 9%-13% vs. 4%-7%; nasopharyngitis: 6%-8% vs. 5%-6%; headache: 5%-7%	Discontinuations due to AEs were low and similar between UPA

Up 1 and 2) [28]	blind period)	EASI-100, itch reduction, and safety parameters	62%/52% vs. PBO: 8%/5% (P < 0.0001); early onset: Rapid itch and skin clearance superiority observed across all active arms vs. PBO	vs. 4%; CPK elevation (dose-dependent): 4%-6% vs. 2%-3%; serious AEs: Low and similar across arms	and placebo groups in both trials.

TABLE 3: Clinical outcomes, efficacy variables, and safety profiles of the analyzed studies.

Statistically significant difference (P < 0.05).

AD, atopic dermatitis; DUPI, dupilumab; AEs, adverse events; CPK, creatine phosphokinase; DILI, drug-induced liver injury; HZ, herpes zoster; EASI, Eczema Area and Severity Index; MU-1, Measure Up 1; MU-2, Measure Up 2; NRS, numerical rating scale; PBO, placebo; RCT, randomized controlled trial; TEAE, treatment-emergent adverse event; UPA, upadacitinib; vIGA-AD, validated Investigator's Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numerical Rating Scale

Serious adverse events and overall study discontinuation rates remained low and comparable between active treatment groups and control arms. Discontinuations specifically attributed to adverse events occurred in 2.9% versus 2.0% of patients in Heads Up (upadacitinib vs. dupilumab) [25], 2.0% versus 1.3% in Level Up [14], and were minimal across the AD Up [27] and Measure Up trials [28]. Opportunistic infections and laboratory monitoring identified low rates of non-disseminated herpes zoster and transient, asymptomatic creatine phosphokinase or transaminase elevations, without cases fulfilling Hy's Law criteria for drug-induced liver injury.

Discussion

Principal Findings

Therapeutic choices in moderate-to-severe atopic dermatitis are shifting as comparative clinical data evaluate traditional biologic references against rapid-onset small-molecule oral therapies [1,5]. When evaluation focuses on primary monotherapy and head-to-head protocols, the gathered evidence demonstrates distinct kinetic advantages regarding symptom control velocity [5,6]. While biological agents such as dupilumab provide established long-term efficacy through interleukin-4 and interleukin-13 inhibition, their therapeutic onset is typically more gradual [5,6]. In contrast, selective JAK1 inhibitors like upadacitinib confer a significantly prompt response, achieving measurable pruritus reduction within the initial days of administration [5,7].

The available prospective trials suggest remarkable clinical efficacy for upadacitinib across both active-comparator and placebo-controlled cohorts, though these findings must be interpreted in light of study dosing parameters and design methodologies [7,12]. In the direct head-to-head trial conducted by Blauvelt et al. (Heads Up) [25], upadacitinib demonstrated superior early itch reduction compared to subcutaneous dupilumab. This rapid pharmacodynamic response operates on a sound biological basis: while biological agents target extracellular receptor blockade, intracellular JAK1 inhibition modulates proximal signaling components across multiple pruritogenic cytokine pathways (such as those involving IL-4, IL-13, IL-31, and TSLP) [4,5], providing a plausible mechanistic framework for prompt symptom relief, though individual pathway contributions warrant further dedicated investigation. Furthermore, data from Silverberg et al. (Level Up) [14] and the replicate trials by Guttman-Yassky et al. (Measure Up 1 and 2) [28] reinforce consistent high-threshold skin clearance and rapid itch resolution across diverse patient populations.

Contextualizing With Existing Literature

When contextualizing these primary trial outcomes within broader secondary literature, data from recent network meta-analyses by Drucker et al. [15] and Chu et al. [16] confirm that targeted small-molecule oral regimens achieve prominent short-term clinical responses, though findings must be weighed against study heterogeneity. Our qualitative synthesis expands upon these quantitative models by focusing specifically on early kinetic benchmarks and comparative head-to-head protocols.

Clinical Implications and Safety Profile

From a safety and compliance perspective, systemic JAK inhibition presents an adverse event profile largely consistent with the data summarized in Table *3*, predominantly comprising mild-to-moderate transient events such as acne, upper respiratory symptoms, and reversible laboratory alterations without severe systemic complications. While therapeutic compliance remains manageable, these safety profiles are inherently bounded by the short-to-medium-term follow-up periods (16-24 weeks) of the included phase III trials [14,25,27,28], underscoring the necessity for extended long-term pharmacovigilance.

From a broader clinical standpoint beyond primary PICO criteria, updated international guidelines such as

those by Davis et al. [29] and the AAAAI/ACAAI joint task force [30] advocate for a nuanced integration of targeted oral therapies in moderate-to-severe cohorts, explicitly conditioning their positioning on individualized risk-benefit balances, baseline patient risk factors, and rigorous safety monitoring rather than unqualified endorsement. Limitations of this review include the restricted window of primary trial comparators and inherent variations in study designs, warranting sustained long-term pharmacovigilance.

Limitations

Several methodological limitations affect the generalizability of these findings. First, trial procedures exhibited notable clinical and methodological heterogeneity, encompassing variations in active comparators (head-to-head subcutaneous dupilumab versus placebo controls), background therapeutic protocols (monotherapy versus mandatory topical corticosteroid combination), and dosing schedules (fixed regimens versus response-driven dose escalation). Second, outcome assessment intervals for early pruritus dynamics varied across studies, ranging from spot evaluations on Day 2 to weekly numerical rating scale averages. Furthermore, inherent methodological boundaries of this review must be explicitly acknowledged: the literature search was intentionally restricted to peer-reviewed prospective RCTs published between 2021 and 2026, full-text availability was required for inclusion, the final qualitative synthesis relied on a focused pool of eligible trials (n = 4 publications evaluating five pivotal cohorts, N = 4,177 patients), and substantial clinical intransitivity precluded formal quantitative meta-analysis pooling or GRADE certainty scoring. Moreover, restrictive search filter parameters targeting specific pruritus terminology and dual-drug constraints in database strings may have theoretically limited broader sensitivity for auxiliary secondary disclosures. Finally, potential language restrictions limiting records strictly to studies published in English introduced a minor source of selection bias. Additionally, potential industry sponsorship influence across included trials [14,25,27,28] was mitigated by pre-registered protocols and independent statistical analyses.

Conclusions

While individual comparative trials demonstrate notable early symptom control and superior skin clearance advantages with targeted systemic therapy, available evidence confirms that upadacitinib confers significant kinetic advantages in early itch reduction and response rates compared to subcutaneous dupilumab. Systemic administration of oral upadacitinib regimens represents a highly efficacious therapeutic option that offers rapid symptom relief and robust lesion clearance in moderate-to-severe atopic dermatitis populations, while maintaining a manageable safety profile consistent with short-term trial data. Ultimately, balancing individual benefit-risk profiles regarding TEAEs and standardizing evaluation windows remain critical priorities to optimize clinical efficacy and healthcare value in dermatological practice.

Additional Information

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All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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