APPLICATION OF REAL-WORLD EFFECTIVENESS OUTCOMES OF UPADACITINIB FOR ATOPIC DERMATITIS TO MINIMAL DISEASE ACTIVITY CRITERIA: A RETROSPECTIVE MULTICENTER ANALYSIS OF 1 YEAR DATA

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Conflicts of Interest

Dr. Vimal H. Prajapati has been an advisor, consultant, and/or speaker for AbbVie, Actelion, Amgen, Apogee Therapeutics, Aralez, Arcutis, Aspen, Bausch Health/Valeant, BioScript Solutions, Boehringer Ingelheim, Bristol Myers Squibb, Canadian Psoriasis Network, Celgene, Cipher, Concert, CorEvitas, Eczema Society of Canada, Eli Lilly, Galderma, GlaxoSmithKline, Homeocan, Incyte, Janssen, LEO Pharma, Medexus, Novartis, Pediapharm, Pfizer, Sanofi Genzyme, Sun Pharma, Tribute, and UCB; investigator for AbbVie, AnaptysBio, Arcutis, Arena, Asana, Bausch Health/Valeant, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Concert, CorEvitas, Dermavant, Dermira, Eli Lilly, Galderma, Incyte, Janssen, LEO Pharma, Nektar Therapeutics, Nimbus Lakshmi, Novartis, Pfizer, Regeneron, RAPT Therapeutics, Reistone, Sanofi Genzyme, Sun Pharma, Takeda, and UCB; received grants from AbbVie, Bausch Health, Janssen, LEO Pharma, Novartis, and Sanofi Genzyme.

Introduction

- Randomized controlled trials have demonstrated the efficacy and safety of upadacitinib in moderate-to-severe atopic dermatitis (AD).[1,2]

- However, real-world evidence on treatment outcomes and achievement of minimal disease activity (MDA) with upadacitinib remains limited.

- This retrospective, multicenter study evaluates upadacitinib use in patients with AD according to MDA criteria.

1. Katoh N, Ohya Y, Murota H, et al. Safety and Efficacy of Upadacitinib for Atopic Dermatitis in Japan: 2-Year Interim Results from the Phase 3 Rising Up Study. *Dermatol Ther (Heidelb)*. 2023;13(1):221-234. doi:10.1007/s13555-022-00842-7
2. Simpson EL, Papp KA, Blauvelt A, et al. Efficacy and Safety of Upadacitinib in Patients With Moderate to Severe Atopic Dermatitis: Analysis of Follow-up Data From the Measure Up 1 and Measure Up 2 Randomized Clinical Trials. *JAMA Dermatol*. 2022;158(4):404-413. Doi:10.1001/jamadermatol.2022.0029

Methods

- Our retrospective multicenter study included adult and adolescent patients with AD from three Canadian institutions who were initiated on upadacitinib treatment.
- All patients who initiated upadacitinib prior to July 1, 2025, were included.
- Both patient-reported and physician-assessed clinical adverse events (AEs) were recorded at each follow-up; laboratory-related AEs were also monitored.
- Reasons for treatment discontinuation and estimated time until treatment discontinuation were recorded by physicians at each follow-up.

Methods

- The primary outcome was achievement of optimal targets at week 52±6 as per the **MDA criteria**, which included achievement of 1 clinician-reported outcome (CRO) and 1 patient-reported outcome (PRO)

MDA Criteria:

1. **CRO**
    1. Eczema Area and Severity Index (EASI) improvement of ≥ 90% (EASI90), **or**
    2. EASI ≤ 3, **or**
    3. Investigator's Global Assessment (IGA) 0/1 ***and*** Body Surface Area (BSA) ≤ 2%
2. **PRO**
    1. Worst Pruritus Numeric Rating Scale (WP-NRS) 0/1, **or**
    2. Dermatology Life Quality Index (DLQI) 0/1

Results | Demographics/Characteristics

- This analysis included a total of 192 patients
  - Mean age: 44.6 years (range: 12-79) years
  - Gender: 94 (49%) being male

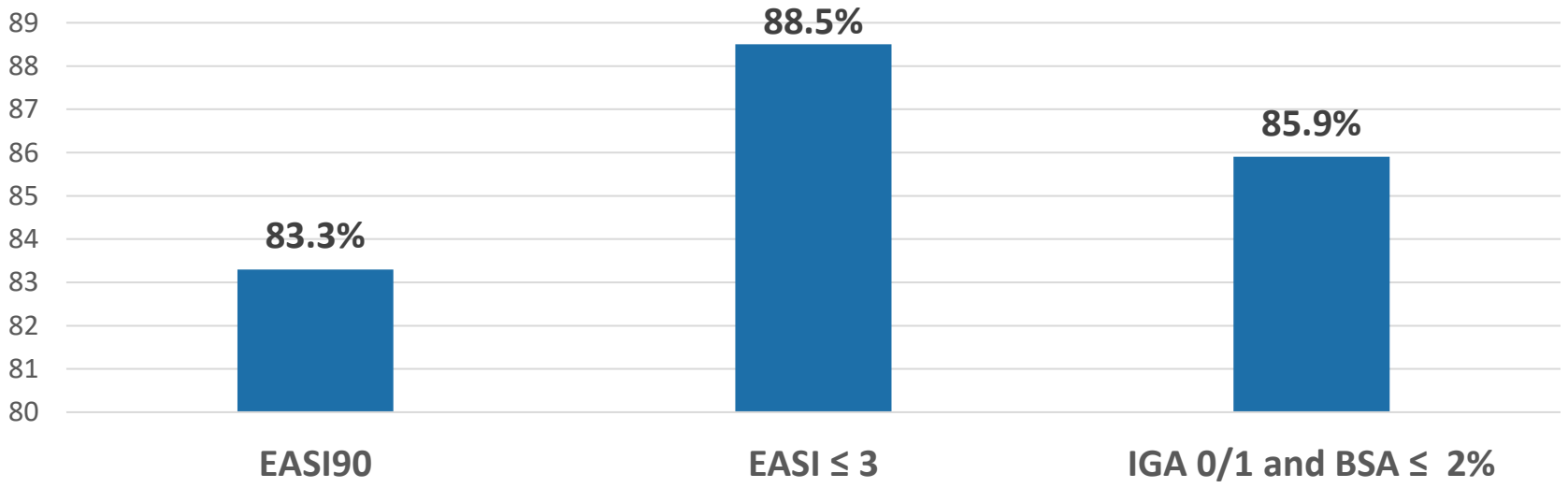
- Common prior systemic therapies included:
  - Cyclosporine (43.2%, 83/192)
  - Prednisone (29.2%, 56/192)
  - Methotrexate (26.6%, 51/192)

- At baseline:
  - IGA scores were 3 (moderate) in 66.7% (128/192) and 4 (severe) in 17.2% (33/192) of patients.
  - Mean (± SD) EASI score was 14.3 ± 8.7
  - Mean (± SD) BSA was 15.1% ± 12.1%

Results | Effectiveness (Continued)

Week 52 ± 6 Outcomes

Effectiveness metrics	n/N (%)
EASI90	160/192 (83.3%)
EASI ≤ 3	170/192 (88.5%)
IGA 0/1 and BSA ≤ 2%	165/192 (85.9%)



Results | Effectiveness (Continued)

Week 52 ± 6 Outcomes

- **CRO**
  - ≥ 1 CRO achieved: 89.6% (172/192)
  - All 3 CROs achieved (EASI90, EASI ≤ 3, IGA 0/1 + BSA ≤ 2%): 80.2% (154/192)

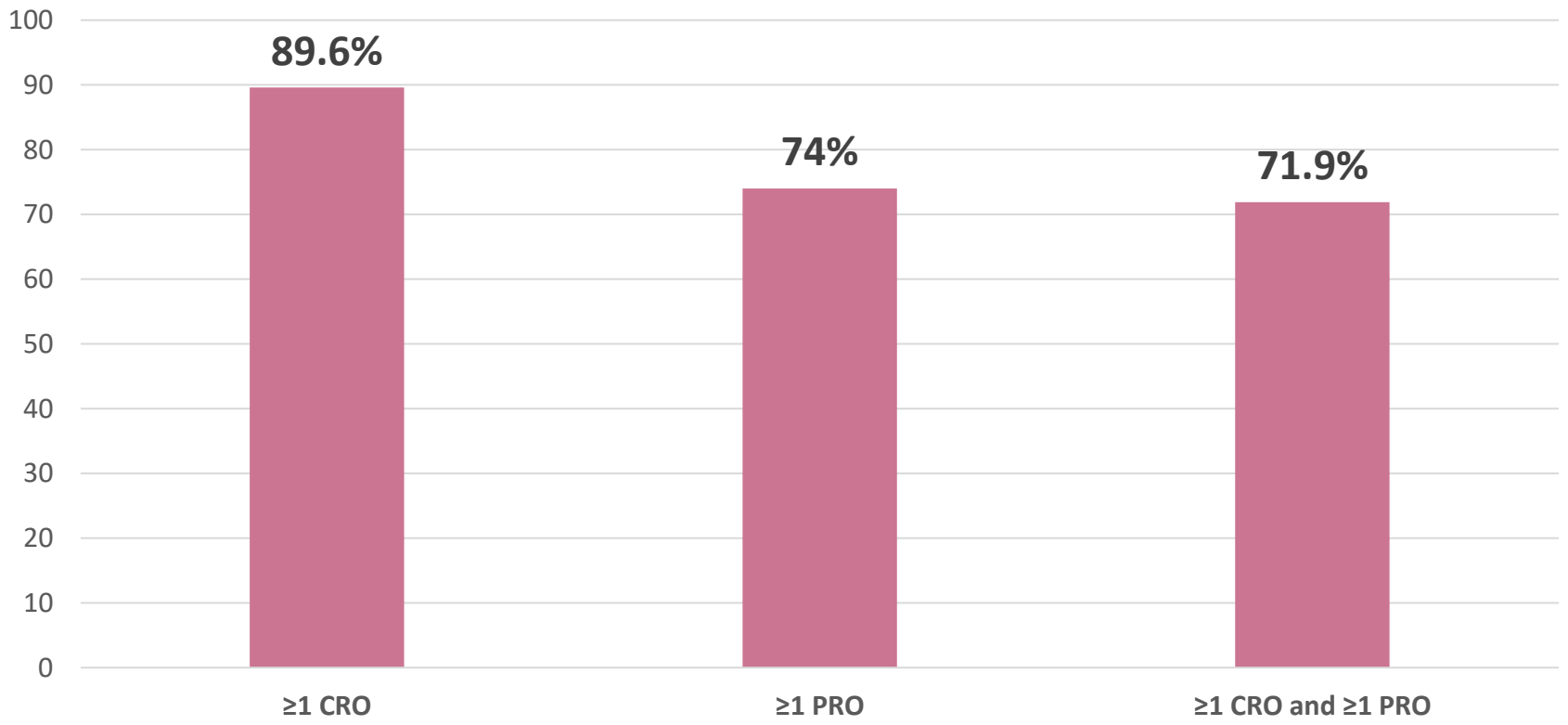
- **PRO***
  - ≥ 1 PRO achieved (WP-NRS 0/1 or DLQI 0/1): 74.0% (142/192)

- Overall MDA Achievement
  - 71.9% (138/192) of patients achieved Minimal Disease Activity (MDA) defined as ≥ 1 clinician-reported outcome (CRO) and ≥ 1 patient-reported outcome (PRO)

*WP-NRS was reported in n=52 patients due to limitations of real-world charting

Results | Effectiveness (Continued)

Week 52 ± 6 Outcomes



Results | Safety

- Up to 1 year, there were 86 patients (44.8%) who experienced at least one AE while on upadacitinib.
- The most common AEs included elevated creatine kinase (7.3%, 14/192), elevated triglycerides (5.2%, 10/192), and elevated liver enzymes (4.7%, 9/192).
- Three discontinuations (1.6%) were noted (HSV-1 [n=1], folliculitis [n=1], and respiratory failure [n=1]).

Results | Safety (Continued)

Adverse event	n/N (%)
Elevated CK	14/192 (7.3%)
Elevated triglycerides	10/192 (5.2%)
Elevated liver enzymes	9/192 (4.7%)
Hyperlipidemia	6/192 (3.1%)
Acne	6/192 (3.1%)
UTI	5/192 (2.6%)
Neutropenia	5/192 (2.6%)
HSV	4/192 (2.1%)
Thrombocytosis	4/192 (2.1%)
Hypercholesterolemia	4/192 (2.1%)

Conclusions

- Our 52-week multicenter real-world study demonstrated that 71.9% (138/192) of patients with AD achieved MDA, as defined by ≥ 1 CRO and ≥ 1 PRO.
- Nearly nine in ten patients (89.6%) achieved ≥ 1 CRO (EASI90, EASI ≤3, or IGA 0/1 with BSA ≤2%), and 80.2% (154/192) achieved all three clinician-reported endpoints.
- At one year, AEs were observed in 44.8% (86/192) of patients, most commonly elevated CK (7.3%), triglycerides (5.2%), and liver enzymes (4.7%). Discontinuation due to AEs occurred in only 1.6% (3/192).
- These findings support that upadacitinib demonstrates real-world effectiveness and favorable tolerability over 1 year, aligning with clinical trial efficacy and supporting its use as a targeted therapy for moderate-to-severe atopic dermatitis.