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Comparing 1.5% Ruxolitinib Cream and Other Therapies for Pediatric Patients With Atopic Dermatitis: A Systematic Literature Review and Network Meta-Analysis

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Introduction

- Atopic dermatitis (AD) is a chronic, recurring, inflammatory skin disease.[1,2] Affecting 13%–16% of children,[3] AD impacts the quality of life (QoL) of patients and caregivers alike.[4-7]
- 1.5% ruxolitinib cream is a topically administered selective Janus kinase (JAK)1/JAK2 inhibitor that provides anti-inflammatory and anti-pruritic effects when applied on areas affected by AD.
- The efficacy and safety of 1.5% ruxolitinib cream in patients ≥2 to <12 years of age were studied in TRuE-AD3 (NCT04921969), a phase 3, double-blind, randomized controlled trial (RCT).[8]
  - Patients were required to have mild to moderate AD (Investigator's Global Assessment [IGA] score of 2–3) for ≥3 months and body surface area involvement of 3%–20%. Patients received either 0.75% ruxolitinib cream, 1.5% ruxolitinib cream, or a vehicle cream over an 8-week vehicle-controlled period.
  - 1.5% ruxolitinib cream was safe and well-tolerated in patients, and it demonstrated statistically significant and clinically meaningful improvements in disease control, intensity of itch, and patient and caregiver QoL.
- 1.5% ruxolitinib cream is currently approved in Canada for the treatment of mild to moderate AD in adult and pediatric patients ≥2 years of age whose disease is not adequately controlled with conventional topical prescription therapies (topical corticosteroids [TCS] and topical calcineurin inhibitors [TCI]) or when those therapies are not advisable.[9]

Objective

- There are no head-to-head phase 3 clinical trials comparing 1.5% ruxolitinib cream with active treatments for pediatric patients with AD; thus, we assessed the efficacy and safety of 1.5% ruxolitinib cream vs relevant comparators in the treatment of mild to moderate AD among patients 2–11 years of age through a network meta-analysis (NMA).

Methods

Systematic Literature Review

- A systematic literature review (SLR) was conducted to identify phase 3 or 4 RCTs in pediatric patients (2–11 years of age) with AD evaluating 1.5% ruxolitinib cream and other treatments available in Canada including topical phosphodiesterase-4 (PDE-4) inhibitors, topical aryl hydrocarbon receptor (AhR) modulators, TCI, TCS, conventional systemic non-biologic immunosuppressants, and systemic biologics.

Feasibility Assessment

- NMA feasibility was assessed by qualitatively examining network connectivity and cross-trial differences in study design, patient populations, and outcome characteristics.

Network Meta-Analysis

- The choice of outcomes for NMAs was informed by data availability and relevance for Canadian payers and included:
  - IGA treatment success (IGA-TS): IGA score of 0 (clear) or 1 (almost clear) with a ≥2-point improvement from baseline
  - Eczema Area and Severity Index-75 (EASI-75): ≥75% improvement in EASI score from baseline
  - Itch Numerical Rating Scale 4 (Itch NRS4): ≥4-point reduction in Itch NRS from baseline
  - Treatment-emergent adverse events (TEAEs): proportion of patients experiencing any TEAE during the primary study period
- Fixed-effect Bayesian NMAs were conducted for all outcomes of interest.
- Sensitivity analyses were conducted to include dupilumab and improve alignment of outcome assessment timepoints.

Results

Systematic Literature Review

- 21 unique RCTs were identified evaluating the following 10 interventions: ruxolitinib cream, crisaborole ointment, roflumilast cream, tapinarof cream, pimecrolimus cream, tacrolimus ointment, hydrocortisone acetate, cyclosporine, methotrexate, and dupilumab.

Feasibility Assessment

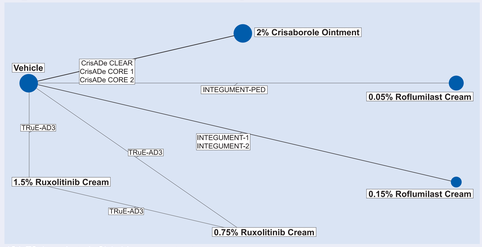
- 4 RCTs were excluded from the feasibility assessment due to appreciable differences with TRuE-AD3, including baseline disease severity and pre-study treatment.
- The remaining 17 RCTs were generally aligned in study design characteristics, clinical trial populations, and outcome definitions. Notable differences included the following:
  - Prior TCS response, higher baseline disease severity, and comparison with placebo + TCS (as opposed to vehicle only) for 1 dupilumab study.
  - Primary outcome assessment timepoint (eg, 4 weeks for crisaborole ointment and roflumilast cream RCTs vs 8 weeks for ruxolitinib cream RCT [TRuE-AD3]).
- Vehicle was identified as the common comparator across all clinical trials (apart from the dupilumab study noted above). Vehicles were considered equivalent because they were consistently described as emollients or included emollients as ingredients.
- An NMA was deemed feasible to compare the outcomes of IGA-TS, EASI-75, Itch NRS4, and any TEAE across clinical trials. A total of 13 clinical trials contributed to ≥1 of these networks. IGA-TS had a unique network, as did any TEAE, whereas EASI-75 and Itch NRS4 shared the same network of clinical trials.

Network Meta-Analysis

IGA-TS

- 7 clinical trials were included in the IGA-TS network.
- 1.5% ruxolitinib cream was the highest-ranked treatment and was superior to all other treatments except 0.15% roflumilast cream, where it was numerically favored.

Figure 1. Network Connectivity for IGA-TS Outcome



IGA-TS, Investigator's Global Assessment treatment success.

Figure 2. NMA Results for IGA-TS Outcome

1.5% Ruxolitinib Cream	0.75% Ruxolitinib Cream	0.15% Roflumilast Cream	0.05% Roflumilast Cream	2% Crisaborole Ointment	Vehicle
2.25 (1.38–3.70)					
2.49 (0.77–8.30)	1.11 (0.34–3.64)				
3.86 (1.49–11.32)	1.71 (0.66–4.98)	1.56 (0.64–4.06)			
6.16 (2.60–16.81)	2.73 (1.15–7.38)	2.47 (1.13–6.06)	1.59 (0.92–2.85)		
11.16 (4.96–29.34)	4.95 (2.20–12.89)	4.49 (2.17–10.52)	2.89 (1.82–4.82)	1.82 (1.37–2.43)	

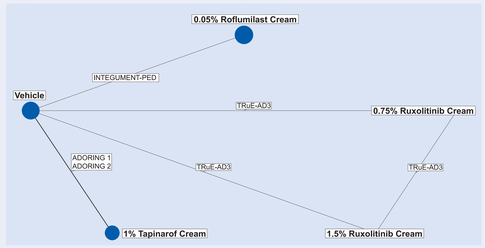
Results are presented as odds ratio and associated 95% credible interval. Superior results are depicted by green shading. 0.15% roflumilast cream was evaluated in patients ≥6 years of age, and 0.05% roflumilast cream was evaluated in patients <6 years of age. IGA-TS, Investigator's Global Assessment treatment success; NMA, network meta-analysis.

Network Meta-Analysis

EASI-75

- 4 clinical trials were included in the EASI-75 network.
- 1.5% ruxolitinib cream was the highest-ranked treatment and was superior to all other treatments.

Figure 3. Network Connectivity for EASI-75 Outcome



EASI-75, ≥75% improvement in Eczema Area and Severity Index score from baseline.

Figure 4. NMA Results for EASI-75 Outcome

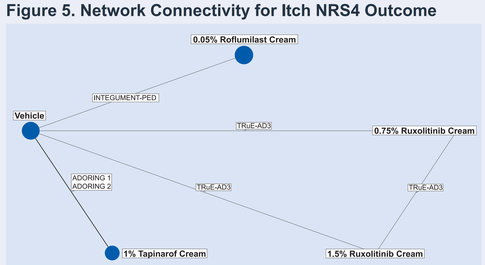
1.5% Ruxolitinib Cream	0.75% Ruxolitinib Cream	1% Tapinarof Cream	0.05% Roflumilast Cream	Vehicle
1.93 (1.18–3.20)				
2.46 (1.03–6.27)	1.27 (0.54–3.18)			
4.57 (2.00–11.30)	2.36 (1.04–5.75)	1.85 (1.03–3.36)		
11.64 (5.61–26.84)	6.02 (2.92–12.52)	4.74 (3.04–7.47)	2.56 (1.75–3.77)	

Results are presented as odds ratio and associated 95% credible interval. Superior results are depicted by green shading. 0.05% roflumilast cream was evaluated in patients <6 years of age. EASI-75, ≥75% improvement in Eczema Area and Severity Index score from baseline; NMA, network meta-analysis.

Itch NRS4

- 4 clinical trials were included in the Itch NRS4 network.
- 1.5% ruxolitinib cream was numerically favored over 0.75% ruxolitinib cream and vehicle, and it was similar but not numerically favored compared with 0.05% roflumilast cream and 1% tapinarof cream.

Figure 5. Network Connectivity for Itch NRS4 Outcome



Itch NRS4, ≥4-point reduction in Itch Numerical Rating Scale from baseline.

Figure 6. NMA Results for Itch NRS4 Outcome

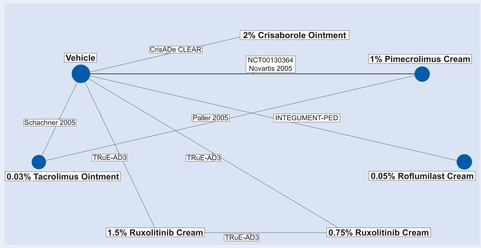
1% Tapinarof Cream	0.05% Roflumilast Cream	1.5% Ruxolitinib Cream	0.75% Ruxolitinib Cream	Vehicle
1.19 (0.61–2.39)				
1.61 (0.59–4.23)	1.34 (0.50–3.49)			
2.06 (0.75–5.38)	1.71 (0.64–4.47)	1.28 (0.68–2.43)		
2.97 (1.82–4.97)	2.49 (1.58–3.97)	1.86 (0.81–4.48)	1.45 (0.64–3.45)	

Results are presented as odds ratio and associated 95% credible interval. Superior results are depicted by green shading. 0.05% roflumilast cream was evaluated in patients <6 years of age. Itch NRS4, ≥4-point reduction in Itch Numerical Rating Scale from baseline, NMA, network meta-analysis.

Any TEAE

- 7 clinical trials were included in the any TEAE network.
- 1.5% ruxolitinib cream was similar to all other treatments.

Figure 7. Network Connectivity for Any TEAE Outcome



TEAE, treatment-emergent adverse event.

Figure 8. NMA Results for Any TEAE Outcome

0.03% Tacrolimus Ointment	0.75% Ruxolitinib Cream	Vehicle	1% Pimecrolimus Cream	2% Crisaborole Ointment	1.5% Ruxolitinib Cream	0.05% Roflumilast Cream
0.88 (0.40–1.89)						
0.81 (0.56–1.18)	0.93 (0.47–1.85)					
0.75 (0.50–1.12)	0.86 (0.40–1.85)	0.93 (0.64–1.35)				
0.68 (0.34–1.37)	0.78 (0.32–1.92)	0.84 (0.47–1.52)	0.90 (0.45–1.82)			
0.53 (0.24–1.11)	0.60 (0.35–1.01)	0.65 (0.33–1.23)	0.70 (0.33–1.47)	0.78 (0.32–1.85)		
0.53 (0.31–0.90)	0.61 (0.28–1.35)	0.66 (0.44–0.96)	0.70 (0.41–1.20)	0.78 (0.38–1.56)	1.01 (0.47–2.22)	

Results are presented as odds ratio and associated 95% credible interval. Superior results are depicted by green shading. 0.05% roflumilast cream was evaluated in patients <6 years of age. NMA, network meta-analysis; TEAE, treatment-emergent adverse event.

Sensitivity Analyses

- 2 sensitivity analyses were conducted.
  - The first analysis assessed the impact of assuming placebo + TCS as equivalent to placebo (vehicle) alone to allow the inclusion of a dupilumab clinical trial.
  - The second analysis assessed the impact of aligning TRuE-AD3 outcome data with the primary timepoint of included crisaborole ointment and roflumilast cream clinical trials (week 4).
- Results for both sensitivity analyses aligned with the base case analysis, with 1.5% ruxolitinib cream being superior to most other treatments for IGA-TS and EASI-75 and similar compared with all other treatments for Itch NRS4 and any TEAE.
- Specifically, using week 4 TRuE-AD3 data to align with the primary timepoint of roflumilast and crisaborole clinical trials, we found that 1.5% ruxolitinib cream was superior to 2% crisaborole ointment (3.76 [1.61–9.68]) for IGA-TS and superior to 1% tapinarof cream (2.61 [1.05–7.14]) and 0.05% roflumilast cream (4.85 [2.06–12.76]) for EASI-75.

Strengths, Limitations, and Other Considerations

- Strengths include the following:
  - NMAs were based on a recent, comprehensive SLR identifying relevant clinical evidence in pediatric AD, with data quality ensured by the involvement of 2 independent researchers at each phase of the review.
  - The feasibility assessment thoroughly evaluated cross-trial differences and identified whether an NMA was appropriate.
  - SLR and NMAs were performed according to well-established methods from the National Institute for Health and Care Excellence.[10,11]
- Limitations include the following:
  - Age varied across included clinical trials, with several trials including patients <2 or >12 years of age and others not providing subgroup data for their 2- to 11-years-of-age population.
    - The proportion of patients 2–11 years of age was evaluated, and only clinical trials with an estimated >80% of the population to be in this age range were considered for NMAs.
  - The primary timepoint at which outcomes were assessed varied across clinical trials, from 4 to 26 weeks, which may bias results toward 1.5% ruxolitinib cream for clinical trials with a timepoint of assessment earlier than the week 8 timepoint in TRuE-AD3.
    - This was addressed in the sensitivity analysis using outcomes for the week 4 primary timepoint of clinical trials for crisaborole ointment and roflumilast cream, with results of this analysis being consistent with the base case.

Conclusions

- **Comparators in the NMAs included topical PDE-4 inhibitors (2% crisaborole ointment, 0.05% and 0.15% roflumilast cream), topical AhR modulators (1% tapinarof cream), and TCIs (0.03% tacrolimus ointment, 1% pimecrolimus cream).**
- **Sensitivity analyses demonstrated results consistent with the base case.**
- **Results of NMAs indicated that 1.5% ruxolitinib cream offers similar or better disease control (IGA-TS, EASI-75, and Itch NRS4) than that of available topical therapies for pediatric AD and similar safety (any TEAE).**

Disclosures

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