Effects of Ruxolitinib Cream in Patients With Atopic Dermatitis With Head and/or Neck Involvement

Eric L. Simpson, MD, MCR,1 Robert Blissettsonnette, MD, FRCP,2 Michael E. Kuligowski, MD, PhD, MBA,1 May E. Venturanza, MD,1 Kang Sun, PhD,1 Jonathan I. Silverberg, MD, PhD, MPH1

Introduction

Atopic dermatitis (AD) is a highly prevalent inflammatory skin disease that involves the head and/or neck.1–3 It is a chronic, relapsing condition of skin that can be exacerbated by numerous factors, including environmental triggers, dry skin, and stress.4–6 Treatment options for AD can be challenging, particularly for patients with involvement of the head and/or neck region, as this can lead to significant distress and discomfort.7–10

Objective

The objective of this study was to evaluate the efficacy and safety of ruxolitinib cream (1.5% and 0.75%) in patients with AD with head and/or neck (HN) involvement in comparison with vehicle, a 1% calcineurin inhibitor cream, and a 1% steroid cream. The primary endpoint was 3-point improvement in the Investigator’s Global Assessment of AD (IGA-TS) score from baseline at Week 8. Patients were randomized to receive 1.5% ruxolitinib cream, 0.75% ruxolitinib cream, vehicle, or 1% calcineurin inhibitor cream for 12 weeks. Safety and tolerability were also evaluated, including application site reactions and patient-reported symptom assessments.

Methods

Study Design and Patients

Patients were eligible if they had AD with HN involvement for at least 3 months, with a baseline HN Region score ≥2 and ≤25. Key exclusion criteria included unstable AD course, other types of inflammatory skin disease affecting the face, pregnancy or lactation, and history of serious adverse reactions to topical medications. Patients were randomized (2:2:1) to receive 1.5% ruxolitinib cream, 0.75% ruxolitinib cream, vehicle, or 1% calcineurin inhibitor cream for 12 weeks. The study was conducted at 41 centers in 7 countries in Europe and Canada.

Results

Efficacy

- IGA-TS (Figure 2) and itch numerical rating scale (NRS) (Figure 3) were achieved by significantly more patients with ruxolitinib cream compared with vehicle at Week 8 (P < 0.0001).
- There was a significant difference favoring ruxolitinib cream compared with vehicle in terms of PASI, EASI, and other subscales among patients with HN involvement.

Safety

No treatment-related serious adverse events were reported. The most common adverse events were local application site reactions, including erythema, irritation, and swelling. The incidence of application site reactions was significantly lower with ruxolitinib cream compared with vehicle (1.5% ruxolitinib cream, 0.75% ruxolitinib cream, vehicle, and 1% calcineurin inhibitor cream: 3.9%, 3.3%, 7.5%, and 22.4%, respectively).

Conclusions

- In patients with AD with HN involvement, ruxolitinib cream showed superior efficacy compared with vehicle.
- Ruxolitinib cream was well tolerated (ie, low rates of stinging/burning) in patients with HN involvement with a safety profile comparable to the overall population.

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References