D atópica

Dra. Esther Serra Baldrich

Jefe de Unidad de inmunología cutánea. Servicio de Dermatología. Hospital Quirón Salud. Barcelona
Upadacitinib Improved Patient-Reported Pruritus in Moderate-to-Severe Atopic Dermatitis: Results From a Phase 2b Randomized, Placebo-Controlled Trial

Chih-Ho Hong, MD; Tianhuang Wu, PhD; Brian Calimlim, DRPH, MS; Henrique D Teixeira, PhD, MBA; Marjolein de Bruin-Weller, MD, PhD

University of British Columbia, Department of Dermatology and Skin Science and Pro biopsy Medical Research, Surrey, BC, Canada; AbbVie, Inc, North Chicago, IL, USA; University Medical Center Utrecht, The Netherlands.

Presented at the 6th Skin Inflammation & Psoriasis International Network Congress • Paris, France • 25 – 27 April 2019

INTRODUCTION

Atopic dermatitis (AD) is a common, chronic, inflammatory skin disease, characterized by pruritus, lesions, and plaques, and is associated with considerable morbidity that affects up to 50% of children and 20% of adults worldwide.

The American Academy of Dermatology treatment guidelines recommend systemic immunomodulatory agents for patients with moderate to severe disease for whom topically applied corticosteroids provide insufficient control.

Objectives: To evaluate the efficacy and safety of upadacitinib (a Janus kinase (JAK) inhibitor) in the treatment of AD.

METHODS

Concurrent, double-blind, placebo-controlled, randomized Phase 2a study with active comparator. Patients were randomized 2:1 to receive upadacitinib 30 mg or placebo once daily for 12 weeks. The primary endpoint was the change in Investigator’s Global Assessment (IGA) score from baseline to Week 12.

RESULTS

At baseline, patients had a mean age of 42.7 years, 58.5% were male, and 50% had a concomitant diagnosis of asthma. The mean baseline IGA score was 4.6 at baseline. The proportion of patients with an IGA score of 0 or 1 at Week 12 was significantly higher in the upadacitinib group compared to placebo (85.0% vs 32.4%, difference of 52.6%, 95% CI 41.0% to 64.1%, p = 0.001). No serious adverse events were reported. The most common adverse events were upper respiratory tract infections and nasopharyngitis.

CONCLUSIONS

Upadacitinib 30 mg once daily for 12 weeks was well tolerated and demonstrated significant improvements in disease severity and pruritus at all time points compared to placebo. These findings support the further evaluation of upadacitinib in the treatment of AD.

REFERENCES


Background: In Atopic Dermatitis (AD), the Harmonizing Outcome Measures for Eczema (HOME) initiative has selected the Eczema Area and Severity Index (EASI) as the core instrument for assessing the clinical findings, and the Patient Oriented Eczema Measure (POEM) as the most appropriate tool for evaluating patient-reported symptoms. In adult patients with AD, the Dermatology Life Quality Index (DLQI) and the Quality of Life Index for Atopic Dermatitis (QoLIAD) have shown test-retest reliability, internal consistency, and construct validity. They have the potential for being recommended as QoL instruments in adult patients with AD, but validation studies are missing. In the QoLIAD banding has not been established.

Objective: To find which score (DLQI, POEM, and QoLIAD) is better for assessing QoL affection in adult patients with AD through correlation with EASI, and to determine QoLIAD banding for mild, moderate, and severe QoL affection in AD.

Methods: Patients >18-years-old with AD that agreed to fill the DLQI, POEM, and QoLIAD questionnaires; and to undergo a physical examination which was classified according to the EASI. Age, gender, profession, personal or familiar atopic history, AD evolution, previous and current treatments were registered.

The POEM score was the only following a normal distribution, for that reason we estimated the Pearson Correlation Coefficient for determining its correlation with EASI. The Spearman Correlation Coefficient was estimated for correlating DLQI and QoLIAD with EASI as they did not follow a normal distribution. We adjusted three robust simple linear regression models, in order to quantify the association between EASI and DLQI, POEM, and QoLIAD. A p-value lower than 0.05 was considered as statistical significant.
Results: A total of 72 patients were registered. 55% were women and 45% were men. As it is shown in Table 1, with the correlation coefficient there is a linear relation within the three scores and the EASI.

<table>
<thead>
<tr>
<th></th>
<th>CORRELATION COEFFICIENT</th>
<th>REGRESSION COEFFICIENT</th>
<th>P-VALUE</th>
<th>PSEUDO R²</th>
<th>FORMULA</th>
</tr>
</thead>
<tbody>
<tr>
<td>POEM</td>
<td>0.4444</td>
<td>0.234</td>
<td>0.0000</td>
<td>0.1106</td>
<td>POEM=9.9+0.234(EASI)</td>
</tr>
<tr>
<td>DLQI</td>
<td>0.4915</td>
<td>0.219</td>
<td>0.0000</td>
<td>0.1492</td>
<td>DLQI=7.48+0.219(EASI)</td>
</tr>
<tr>
<td>QoLIAD</td>
<td>0.4307</td>
<td>0.252</td>
<td>0.003</td>
<td>0.0951</td>
<td>QoLIAD=5.89+0.252(EASI)</td>
</tr>
</tbody>
</table>

Table 1

According to the Pseudo-R² value the DLQI has the strongest correlation with EASI. Using the obtained value in the regression coefficient we developed three formulas that are able to estimate POEM, DLQI, and QoLIAD. by using the EASI. With the QoLIAD’s formula we established banding for this instrument as shown in Table 2.

Conclusion: In the era where QoL instruments are being more frequently used in AD. The DLQI stands as the most suitable instrument. Dermatologists are more familiarized with it and is more practical in the day-to-day practice.

References:
TREATMENT OUTCOMES AND GOALS IN ATOPIC DERMATITIS”

Esther Serra Baldrich.
Sant Pau Hospital. Barcelona
FOCUS SESSION 7
TREATMENT OUTCOMES AND GOALS IN ATOPIC DERMATITIS”. E Serra Baldrich

• The decision to start systemic medication should include assessment of severity and quality of life while considering the 

Personnal attitudes toward syst therapis

Individual’s general health status

Psychologic needs
• For an **instrument** to be **useful** to the general dermatologist, it should have demonstrated

1. validity in clinical practice  
2. require minimal training,  
3. be time-efficient, and  
4. seamlessly integrate into day-to-day practice.

To be “adequate” for use in clinical practice, a severity score should not take longer than 3 minutes.
A systematic review of randomized controlled trials (RCT) performed in 2016 demonstrated that the most commonly used severity measures were

• SCORAD (signs + symptoms)

• Visual Analogue Scale (VAS)-pruritus (symptoms)

• IGA (signs)

• and EASI (signs)
TO TAKE HOME EASY TOOLS

• APP SCORAD-EASI
• VAS scales /SLEEP
• DLQI only changes Tx
• POEM (PRO) and PO-Scorad