BACKGROUND

• Patient-reported outcome (PRO) measure used (eg, DLQI, Short-Form [SF]-36 Health Survey
• Definition of resolution of psoriasis (PASI, PGA)
• One reviewer performed level 1 screening on 328 titles and abstracts and level 2 screening on
• To summarize the incremental benefits in outcomes, such as HRQOL, associated with

RESULTS (continued)

Achieving Complete or Near-Complete Resolution is Associated With Significantly Greater Improvements in Patient-Reported Outcomes Compared with Lesser Response

• Edson-Heredia et al.10 examined whether greater improvements in PASI score were associated with larger changes in PRO and quality of life (QoL) values in patients with moderate to severe disease.

RESULTS

• A total of 14 articles were included in the literature review focusing on the added value of complete or near-complete resolution of psoriasis.
• The majority of studies were randomized controlled trials (n = 5) or pooled analyses or subanalyses of clinical trials (n = 5). The remainder of the studies were a mix of observational studies (n = 2), clinical reports (n = 1), and systematic reviews (n = 1).
• Most studies defined resolution of psoriasis based on the PASI (n = 10), whereas a smaller proportion used the PGA (n = 2) or both PASI and PGA (n = 2).
• No articles or conference abstracts were found for ustekinumab or secukinumab, which measured the added value of complete or near-complete resolution of psoriasis.
• The most commonly reported PRO instrument was the DLQI (n = 11). A few studies (n = 3) reported results of other instruments, including the psoriasis-specific Psoriasis Symptom Inventory (PSI) (n = 1), the Zung Self-Rating Depression Scale (ZDS) (n = 1), and an ich trial analog scale (VAS) (n = 1).
• The presented clinical studies and literature reviews (n = 10) focused on the association of scores (either observables or change) between the DLQI or PASI and PROs.

Objective Psoriasis Severity and Patient-Reported Outcomes

Correlation Between Psoriasis Activity and Severity Index and Patient-Reported Outcomes

• The correlation between PASI improvement and HRQOL improvement (ie, DLQI and depressive symptoms) has been reported in several studies.1• This relationship is similar for absolute scores in addition to change scores.
• In a systematic review of randomized controlled trials of biological agents for the treatment of psoriasis, a degree comparable to that of other major diseases such as cancer, arthritis, hypertension, heart disease, diabetes, and depression.1• Among studies of patients with psoriasis, no evidence of a correlation between the Psoriasis Area and Severity Index (PASI) and depression is presented in a recent study.1• The DLQI as a patient-administered, 10-question, validated dermatology-specific quality of life instrument that assesses the following domains: physical functioning and feeling daily activities, leisure, work, and personal relationships. The correlation between PASI and depressive symptoms has been less clear, ranging from a low correlation to a highly significant relationship. Overall, the disease and treatment has an effect in a patient's daily life.6 The absolute score for the disease and treatment has no effect. 5 It indicates a small effect. 6 To indicate a moderate effect, 10 indicates a very large effect. 2• A US phase II trial in the PASI-75 study is currently collecting the clinical standard of treatment effect in patients with psoriasis. 1• Outcomes for patients who achieve higher levels of resolution are linked to 90% or 100% PASI improvement (PASI 90 or PASI 100) are not fully characterized.

OBJECTIVE

• To summarize the incremental benefits in outcomes, such as HRQOL, associated with achieving complete or near-complete resolution of psoriasis, based on PASI 90 and/or PGA Global Assessment (PGA) score of 0, compared with lesser response.

METHODS

• A targeted literature search was conducted in the PubMed and Embase databases using a data set of 10 years (January 2005–May 2015) to identify clinical or observational studies or literature reviews on the relationship between complete or near-complete resolution of psoriasis in patients with moderate to severe disease.
• Complete or near-complete resolution was defined as either PASI 90 or PASI 100.
90%–96% or 100% improvement in PASI score (ie, PASI 90 or PASI 100) resulted in a complete or near-complete resolution. One reviewer performed level 1 screening on 328 titles and abstracts and level 2 screening on 92 full-text articles.

• The majority of studies were randomized controlled trials (n = 5) or pooled analyses or subanalyses of clinical trials (n = 5). The remainder of the studies were a mix of observational studies (n = 2), clinical reports (n = 1), and systematic reviews (n = 1).
• Most studies defined resolution of psoriasis based on the PASI (n = 10), whereas a smaller proportion used the PGA (n = 2) or both PASI and PGA (n = 2).
• No articles or conference abstracts were found for ustekinumab or secukinumab, which measured the added value of complete or near-complete resolution of psoriasis.
• The most commonly reported PRO instrument was the DLQI (n = 11). A few studies (n = 3) reported results of other instruments, including the psoriasis-specific Psoriasis Symptom Inventory (PSI) (n = 1), the Zung Self-Rating Depression Scale (ZDS) (n = 1), and an ich trial analog scale (VAS) (n = 1).
• The presented clinical studies and literature reviews (n = 10) focused on the association of scores (either observables or change) between the DLQI or PASI and PROs.

- Patients with moderate to severe psoriasis
- Included both clinical (PASI) and PGA and HRQOL data
- Included treatments of interest, adalimumab, infliximab, ustekinumab, secukinumab, and brodalumab.
- The following were extracted from each selected article, where available:
  - Study design elements
  - Study type (ie, randomized controlled trial, observational study)
  - Treatment and duration treatment
  - Definition of resolution of psoriasis (PASI, PGA)
  - Patient-reported outcome (PRO) measure used (eg, DLQI, Short-form [SF] Health Survey [SF-36])
  - Relationship of complete or near-complete resolution and PROs, such as PASI 90 or PGA 100
  - Mean change in PRO by PASI level: PASI 100, PASI 90, PASI 75, PASI 50
  - Proportion of PRO responders by PGA response level
  - Mean change in PRO by PGA level

CONCLUSIONS

• This literature summary provides further evidence that achieving complete or near-complete resolution in psoriasis is associated with greater improvement in PROs. 2• Most studies assessing the relationship between improvements in psoriasis severity and PROs allowed the DLQI, which appears to capture significant incremental improvements in patients with psoriasis achieving complete or near-complete skin clearance. The relationship between depression, work productivity, and healthcare care resource utilization should be further assessed.

REFERENCES

4. Edson-Heredia E, Banerjee S, Zhu B, et al. A high level of clinical response is associated with improved patient-depressive symptoms) has been reported in several studies. 7–9 This relationship is similar for other major diseases such as cancer, arthritis, hypertension, heart disease, diabetes, and depression. 1

DISCUSSION

• Several analyses of clinical studies of adalimumab, infliximab, secukinumab, and brodalumab and combined treatments have indicated that achieving PASI 90, PASI 100, and a PGA score of 0 yields benefits as demonstrated by significant improvements in PROs (eg, DLQI score, measures of symptom severity compared with lower PGA or PGA score). 4• Most studies assessing the relationship between improvements in psoriasis severity and PROs allowed the DLQI, which appears to capture significant incremental improvements in patients with psoriasis achieving complete or near-complete skin clearance. The relationship between depression, work productivity, and healthcare care resource utilization should be further assessed.

• This literature summary provides further evidence that achieving complete or near-complete resolution in psoriasis is associated with greater improvement in PROs. 2

• According to previous studies, achieving complete or near-complete resolution in psoriasis would have a significant impact on HRQOL and other outcomes in patients with moderate to severe psoriasis. 2

• Achieving complete or near-complete resolution in psoriasis with adalimumab is associated with a decrease in depression symptoms over time compared with placebo. 11

• Edson-Heredia et al. 10 examined whether greater improvements in PASI score were associated with larger changes in PRO and quality of life (QoL) values in patients with moderate to severe disease.

• In a systematic review of randomized controlled trials of biological agents for the treatment of psoriasis, a degree comparable to that of other major diseases such as cancer, arthritis, hypertension, heart disease, diabetes, and depression. 1

• Among studies of patients with psoriasis, no evidence of a correlation between the Psoriasis Area and Severity Index (PASI) and depression is presented in a recent study. 1

• The DLQI as a patient-administered, 10-question, validated dermatology-specific quality of life instrument that assesses the following domains: physical functioning and feeling daily activities, leisure, work, and personal relationships. The correlation between PASI and depressive symptoms has been less clear, ranging from a low correlation to a highly significant relationship. Overall, the disease and treatment has an effect in a patient's daily life. 6

• The absolute score for the disease and treatment has no effect. 5 It indicates a small effect. 6 To indicate a moderate effect, 10 indicates a very large effect. 2

• A US phase II trial in the PASI-75 study is currently collecting the clinical standard of treatment effect in patients with psoriasis. 4

• Outcomes for patients who achieve higher levels of resolution are linked to 90% or 100% PASI improvement (PASI 90 or PASI 100) are not fully characterized.

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