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Looking Beyond the Skin: Examining the Patient and Clinician Reported Outcomes and Effects of Acne Vulgaris and Sarecycline Treatment

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Assessing the Impact of Acne and Its Treatment on Disease Burden and Quality of Life

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It is well established that acne vulgaris (AV) is associated with high patient burden and an associated adverse impact on quality of life (QoL), and it is also recommended that patient-reported outcome measures (PROs) be employed for assessment of health-related QoL in both clinical studies and routine practice. Quality of life assessment is frequently included in registration studies of new acne treatments, but less often in real-world studies. Thus, there is an important unmet need to address the burden of acne and the effects of treatment in the real-world using well-designed PROs.

The Patient-reported Outcomes for Sarecycline Effectiveness and Safety (PROSES) study was a real-world, single-arm, prospective cohort study that included 300 patients with moderate-to-severe non-nodular acne patients >9 years who were prescribed sarecycline in real-world community practices in the United States. Two measures were employed to assess the burden of acne at baseline and treatment effects. The first was the Acne Symptom and Impact Scale (ASIS), a validated 17-item PRO measure, with 9 items assessing signs and 8 items assessing impacts of AV designed for use in both adolescents and adults.[1,2] The second PRO was the Expert Panel Questionnaire (EPQ). It was developed using a modified Delphi approach that involved 8 dermatologists with expertise in treating acne, including pediatric and skin of color focused expertise, one dermatologist /clinical psychologist, and one dermatologist/ psychiatrist. This 11-item PRO aimed to address how acne impacts the patient's emotional functioning, social functioning, and activities of daily living.[3]

Results from PROSES indicated a high disease burden. Baseline results for the ASIS indicated that patients experienced moderate AV disease burden in the signs, symptoms, and impact domains as well as the emotional impact subdomain. At baseline, results obtained with the EPQ indicated that patients had moderate-to-severe anger; worries about AV worsening; and adverse impacts on both social media activity and real-life plans. Most patients also made efforts to hide their acne. ASIS mean scores significantly decreased at week 12 for signs, impact, emotional impact, and social impact. There were also significant reductions from baseline on the EPQ in the proportion of patients who felt angry, worried about AV worsening, had thoughts or worries about AV, altered their activity on social media, felt that AV had an impact on real-life plans, felt picked on/judged due to AV, or were concerned about their ability to reach future goals due to AV. These results for impacts of AV were associated with a significant increase from baseline in the percentage of patients reporting clear/almost clear on the Investigator's Global Assessment of Activity Severity.

The baseline data from the two PROSES papers provide very detailed information about the impacts of AV in both pediatric and adult patients. They also demonstrate that both ASIS and EPQ responses were significantly improved by the inclusion of oral sarecycline in the AV treatment regimen in routine clinical practice. These results are an important addition to those from controlled clinical trials. This is important since the effect of treatment for a disease on QoL evaluated in a clinical trial may differ substantially from those of the same intervention employed in routine clinical practice.[4] There are also well-described limitations of the single-arm design used in the PROSES studies that should be acknowledged. In such a study, responses could result from the efficacy of the treatment under evaluation, a placebo effect in patients receiving an ineffective intervention, or improvement that is spontaneous or perhaps predicted by the natural history of the disease.[5] Such concerns are, of course, ameliorated by prior demonstration of the efficacy of sarecycline on facial AV in controlled clinical trials. In addition, results from the phase 3 clinical program for sarecycline showed that it had significant positive effects on patients' symptoms, emotions, and functioning as measured by the Skindex-16, a PRO developed for use across dermatologic diseases.

In conclusion, the results from ASIS and EPQ provide new and important information about the impacts of facial AV in a wide range of patients assessed in the real world. They also support the view that sarecycline is effective in routine clinical practice and substantially decreases the burden of AV in both children and adults.

DISCLOSURE

Neal Bhatia MD has served as an advisor, consultant, and investigator for Almirall.

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