1.0 Abstract

Title

Real-World Outcome of Psoriasis Subjects in Korea on adalimumab

Keywords

Psoriasis, quality of life, adalimumab, health-related quality of life

Rationale and Background

Measuring health-related quality of life (HRQOL) is essential in the assessment of psoriasis and the benefits of its treatment. HRQOL measures provide a patient's perspective on the outcomes of treatment and are highly valued by regulatory authorities and third-party payers. Despite its importance, the effectiveness of adalimumab in terms of HRQOL in Korean patients with psoriasis was never carried out.

Considering the importance of real-world evidence, a non-interventional, observational study was planned to assess the effect of adalimumab on health-related HRQOL in Korean patients diagnosed with moderate-to-severe psoriasis under the routine clinical setting.

Research Question and Objectives

The main research objective was to assess the effect of adalimumab on HRQOL in Korean patients diagnosed with moderate-to-severe psoriasis, which would be used as a real-world evidence for the cost-effectiveness assessment.

Study Design

Multi-center, non-interventional, single-armed, prospective, observational study.

Setting

Approximately 10 dermatology departments of tertiary/general hospitals in Korea were planned by AbbVie (Sponsor) for participation in the study. Overall, approximately 92 patients were planned to be recruited in the study. Eligible patients included male and/or female patients diagnosed with moderate-to-severe psoriasis, who visited one of the study sites as part of a routine clinical visit and met all of the inclusion criteria and none of the exclusion criteria.

Subjects and Study Size, Including Dropouts

A total of 92 patients diagnosed with moderate-to-severe psoriasis, who were prescribed adalimumab treatment, were planned to be enrolled to the study, considering a 10% dropout rate. Among a total of 97 patients who were eventually enrolled, there were 96 included in the safety set and 77 included in the effectiveness set.

Variables and Data Sources

Study variables consisted of patient reported outcomes (PROs) and clinical outcomes assessed by the investigators. The questionnaires used for PRO assessment included EuroQol 5 dimension (EQ-5D), Dermatology Life Quality Index (DLQI), Short Form (36) Health Survey (SF-36) and Treatment Satisfaction Questionnaire for Medicine (TSQM). For the investigator's clinical outcome assessment, Psoriasis Area and Severity Index (PASI) and Nail Psoriasis Severity Index (NAPSI) were used. Study data were collected through case report forms (CRFs) and questionnaire forms.

Results

Demographics and Baseline Characteristics

From March 2017 till August 2018, a total of 97 patients were enrolled from 11 study sites. Of these, 77 (79.38%) patients completed the study. Total of 96 (98.97%) were included in the safety set, whereas 77 (79.38%) were included in the effectiveness set.

The effectiveness set consisted of 52 (67.53%) male and 25 (32.47%) female patients. The age of the patients ranged between 23 and 74 years (median = 45 years). Median time elapsed since the diagnosis of psoriasis was 5 years (range 0-45 years). Median BSA score of the study patients was 15, and median PASI score amounted to 12.40. A total of 6 (7.79%) patients were identified to have family history of psoriasis. Majority of the patients (88.31%) received systemic treatment of psoriasis in the past. Nearly half of the patients (48.05%) were exposed to methotrexate or cyclosporine. Topical treatments were used in 74 (96.10%) patients and phototherapy in 57 (74.03%). Majority of the patients were biologic-naïve patients and only 13 (16.88%) were previously treated with biologics.

During the study period, 7 patients (9.09%) were treated with other systemic agents, other than adalimumab: methotrexate (n=4, 5.19%), cyclosporine (n=2, 2.60%) or acitretin (n=1, 1.30%). The largest group of other concomitant medications were topical use (n=30, 38.96%), primarily antipsoriatics (n=27, 35.06%), and corticosteroids, dermatological preparations (n=10, 12.99%).

Effectiveness Analysis

Mean (SD) EQ-5D score at the baseline was 0.88 (0.14), increased to 0.91 (0.14) at week 16 and was maintained up to 0.91 (0.17) at week 24. The changes in the EQ-5D score compared to baseline were statistically significant both at week 16 (p=0.0288) and week 24 (p=0.0067).

Mean (SD) EQ-5D VAS at the baseline was 67.32 (17.53), as compared with 73.36 (15.00) and 75.71 (15.27) at 16 and 24 weeks of treatment, respectively. The changes

in the EQ-5D VAS were statistically significant both at week 16 ($p<0.0001$) and week 24 ($p<0.0001$).

Among the SF-36 subdomains, statistically significant changes were observed in the Physical Functioning, Physical Role Functioning, Bodily Pain, General Health Perceptions, Social Role Functioning and Physical Health Component Score scales, both at week 16 and week 24. Whereas in the Vitality domain scale, a significant improvement was observed only at week 16. No significant changes were observed in the Emotional Role Functioning and Mental Health domain scales, and Mental Health Component Score.

Mean (SD) DLQI Score at the baseline was 11.26 (7.40), as compared with 5.57 (5.46) and 5.05 (6.02) at 16 and 24 weeks of treatment, respectively. The changes in the DLQI score were statistically significant both at week 16 ($p<0.0001$) and week 24 ($p<0.0001$).

Changes in all domain scales of the TSQM were statistically significant both at week 16 and week 24.

In accordance with the improvement of HRQOL, improvements in the clinical outcomes were also observed. The numbers (percentages) of patients who achieved PASI 75, 90 and 100 at 16 weeks from the baseline were 65 (84.42%), 17 (22.08%) and 1 (1.30%), respectively. More patients achieved greater PASI reduction at week 24; hence, the numbers (percentages) of patients who achieved PASI 75, 90 and 100 at 24 weeks from the baseline were 64 (83.12%), 21 (27.27%) and 2 (2.60%), respectively.

Mean (SD) PASI score for all patients included in the effectiveness set was 13.74 (5.58) at the baseline, as compared with 2.56 (1.74) and 2.58 (2.34) at 16 and 24 weeks of treatment, respectively. Mean (SD) PASI score for patients with nail psoriasis showed similar results: 12.78 (6.26) at the baseline, 2.27 (1.94) at week 16 and 2.32 (2.49) at week 24. The changes in PASI score were statistically significant both at week 16 ($p<0.0001$) and week 24 ($p<0.0001$) regardless of patient group.

Mean (SD) NAPSI score for patients with nail psoriasis was 20.22 (16.90) at the baseline, as compared with 13.95 (11.83) and 10.95 (10.88) at 16 and 24 weeks of treatment, respectively. The changes in the NAPSI score were statistically significant both at week 16 (p=0.0006) and week 24 (p=0.0053).

EQ-5D scores did not differ based on a history of previous biological treatment, presence of comorbidities at baseline, baseline PASI or BSA scores, presence of nail psoriasis or psoriatic arthritis or gender.

Significant inverse correlations were found between the change in disease severity expressed as PASI scores and changes in EQ-5D scores, EQ-5D VAS, all subdomains of SF-36 and subdomains of TSQM at both week 16 and week 24. Moreover, a significant positive correlation was found between the change in disease severity (PASI score) and the changes in DLQI score at both week 16 and week 24.

Safety Analysis

A total of 14 adverse events (AEs) were reported in 12 out of 96 (12.50%) patients included in the safety set. The list of 14 AEs included single cases of drug eruption, dermatitis exfoliative, psoriasis, pustular psoriasis, dizziness, facial paralysis, small intestinal perforation, constipation, bacterial arthritis, acute myeloid leukemia, arthralgia, injection site erythema, foot fracture and flushing. Except 4 cases (in 2 patients, 2.08%), rest of the AEs had resolved or were resolving at the time of last follow-up. Out of 14 AEs (in 12 patients, 12.0%), 8 AEs (in 8 patients, 8.33%) were classified as Adverse Drug Reactions. Five cases (5 patients, 5.21%) were reported as serious AEs (SAEs) and, among them, 2 SAEs (arthritis bacterial, acute myeloid leukaemia) were assessed by the study investigator to be related with adalimumab treatment. A total of 13 AEs (in 11 patients, 11.46%) were a cause of adalimumab discontinuation.

Discussion

Adalimumab, administered for 24 weeks, was shown to be effective and to have tolerable safety in the treatment of moderate-to-severe psoriasis. Aside from a significant improvement in PASI scores compared to baseline, the treatment contributed to a significant improvement of most analyzed HRQOL measures, which suggests that adalimumab might exert a favorable effect on the quality of life of patients with moderate-to-severe psoriasis. While proportional to the degree of improvement in PASI values, the beneficial effect of adalimumab on EQ-5D scores and other HRQOL measures was observed regardless of baseline severity of psoriasis and other clinical characteristics. This observation, implying that all patients with moderate-to-severe psoriasis could benefit from the treatment in terms of the HRQOL, might be an additional rationale for the use of adalimumab therapy in Korean patients with this disease.

Marketing Authorisation Holder(s)

AbbVie Korea Ltd
6th Floor, SamTan Bldg,
421 YoungDong-Daero, KangNam-Ku
Seoul 06182, Korea

[redacted]