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Real-World Outcomes of Adalimumab Treatment for Moderate and Severe Psoriasis in Korean Patients (RAPSODI Study)

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Background: Psoriasis imposes a significant treatment burden on patients, particularly impacting well-being and quality of life (QoL). The psychosocial impact of psoriasis treatments remains unexplored in most patient populations.
Objective: To assess the impact of adalimumab on health-related QoL (HRQoL) in Korean patients with psoriasis.
Methods: This 24-week, multicenter, observational study, assessed HRQoL in Korean patients treated with adalimumab in a real-world setting. Patient-reported outcomes (PROs) including European Quality of Life-5 Dimension scale (EQ-5D), EQ-5D VAS, SF-36, and DLQI were evaluated at week 16 and 24, versus baseline. Patient satisfaction was assessed using TSQM.
Results: Among 97 enrolled patients, 77 were assessed for treatment effectiveness. Most patients were male (52, 67.5%) and mean age was 45.4 years. Median baseline body surface area and Psoriasis Area and Severity Index (PASI) scores were 15.00 (range 4.00~80.00) and 12.40 (range 2.70~39.40), respectively. Statistically significant improvements in all PROs were observed between baseline and week 24. Mean EQ-5D score improved from 0.88 (standard deviation [SD], 0.14) at baseline to 0.91 (SD, 0.17) at week 24 (p=0.0067). The number of patients with changes in PASI 75, 90, or 100 from baseline to week 16 and 24 were 65 (84.4%), 17 (22.1%), and 1 (1.3%); and 64 (83.1%), 21 (27.3%), and 2 (2.6%), respectively. Overall treatment satisfaction was reported, including effectiveness and convenience. No unexpected safety findings were noted.
Conclusion: Adalimumab improved QoL and was well-tolerated in Korean patients with moderate to severe psoriasis, as demonstrated in a real-world setting. Clinical trial registration number (clinicaltrials.gov: NCT03099083).

Keywords: Adalimumab, Health-related quality of life, Psoriasis

INTRODUCTION

Psoriasis is a chronic, incurable, immune-mediated disease, predominantly manifesting as a skin disorder, owing to the rapid turnover of epidermal cells[1]. It is now recognized as a multisystem inflammatory disease, since most patients experience symptoms in organs in addition to the skin[1,2]. Psoriasis is one of the leading skin conditions that contributes to significant loss in disability-adjusted life years, due to its strong association with comorbidities such as cardiovascular disease,

psoriatic arthritis, metabolic disorders, and mental illnesses[3,4]. Despite significant efforts directed towards improving diagnosis and treatment, psoriasis incidence continues to rise, with the 2016 World Health Organization global report on psoriasis estimating a worldwide disease prevalence ranging from 0.09% to 11.43%[5]. Psoriasis also considerably impacts patient quality of life (QoL), with a majority of patients experiencing a negative effect on their regular activities[6].

Disease severity is a key clinical feature guiding treatment of choice in patients with psoriasis[7]. In routine clinical practice, psoriasis disease severity is classified by physicians as mild, moderate or severe, based on clinical assessments such as affected body surface area (BSA), or Psoriasis Area and Severity Index (PASI). However, these measurements may fail to provide an accurate estimation of the disease, particularly in cases with a lower extent of skin involvement (BSA <10%)[8]. A consensus statement by the American Academy of Dermatology noted that disease severity in psoriasis should be qualitatively categorized, based on disease activity, resistance to previous treatment, and psychosocial factors[9]. The patient's perspective is, therefore, key to guiding psoriasis treatment and is important in measuring clinical outcomes[10].

The psoriasis incidence rate of 0.45% in Korea, is considerably high[11]. However, the impact of psoriasis on the QoL among Korean patients is not very well understood. A noninterventional, observational study, "Real-World Outcome of Psoriasis Subjects in Korea on Adalimumab (RAPSODI)," was conducted to assess the effect of the anti–tumor necrosis factor (TNF)-α adalimumab[12], on health-related quality of life (HRQoL), in Korean patients diagnosed with moderate to severe psoriasis.

MATERIALS AND METHODS

Study design, setting and participants

RAPSODI (NCT03099083) was a prospective, multicenter, noninterventional, single-arm, observational study, that recruited Korean patients aged ≥19 years, who had been diagnosed with moderate to severe psoriasis. Patients who had been prescribed adalimumab treatment for their psoriasis and had regularly visited any of the selected dermatology departments, were eligible for enrollment. Pregnant or lactating patients, or those patients intending to become pregnant during the 24-week study period were excluded. Participation in any other psoriasis-related clinical trial at the time of enrollment, at baseline, or during the study period would exclude a patient from the study. Patients who were considered by the investigator to be unable to accurately complete the study questionnaires were also excluded.

Data collection tools

Participants enrolled in the study were required to complete patient-reported outcome (PRO) questionnaires at baseline and at investigator-scheduled routine clinical practice visits scheduled near to week 16 and week 24 of adalimumab treatment (Supplementary Table 1). Patient HRQoL was assessed based on the following instruments: the European Quality of Life-5 Dimension scale (EQ-5D), the 36-Item Short-Form survey (SF-36; 0~100 scale with higher scores indicating better health), and the Dermatology Life Quality Index (DLQI; 0~30 scale with 0 corresponding to no impact on QoL). The EQ-5D, consisting of five dimensions of HRQoL (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), was recorded at three response levels ('no problems', 'some problems', and 'extreme problems') and index scores were calculated. In addition, EQ-5D visual analogue scale (VAS; 0–100 scale with higher scores indicating better health) was used to assess the current health state. Patient treatment satisfaction was measured using the Treatment Satisfaction Questionnaire for Medication (TSQM; 0~100 scale, with higher scores indicating higher satisfaction). The PASI (0~72 scale where 72 is considered to be maximal disease), and Nail Psoriasis Severity Index (NAPSI; 0~8 scale per nail and a cumulative score, where a high score indicates worse nail health [for patients with concomitant nail psoriasis]), were used as indicators of clinical outcomes.

Endpoints

The primary study endpoint was change in (Δ) EQ-5D index score from baseline to week 24. A key secondary endpoint was ΔEQ-5D from baseline to week 16. Other secondary endpoints were change in other PROs from baseline to week 16 and week 24 (ΔEQ-5D VAS, ΔSF-36, and ΔDLQI), number and percentage of patients who achieved a PASI of 75, 90 and 100 from baseline to week 16 and week 24, ΔPASI and ΔNAPSI for patients with nail psoriasis, from baseline to week 16 and week 24, and change in subject satisfaction questions from baseline to weeks 16 and 24.

Exploratory endpoints included subgroup analysis of ΔEQ-5D at week 24 (observed population) according to adalimumab treatment initiation (second-line or third-line), comorbidities, baseline PASI and BSA scores, sex, and the occurrence of nail psoriasis. Correlations between changes in disease severity and EQ-5D, EQ-5D VAS, SF-36 and DLQI were also assessed.

Data source and management

The study was conducted at institutions (tertiary or general hospitals) where adalimumab was prescribed as part of routine clinical practice, for the treatment of moderate to severe psoriasis. Case report forms were used to collect patient demographic data, clinical history, comorbidities, adverse events (AEs), and concomitant medications. PROs were completed by the patients, and PASI and NAPSI scores were assessed and recorded by the investigators. All patients were required to provide informed consent.

This study was approved by the institutional review boards (IRB) of the participating institutions (Supplementary Table 2).

Statistical analyses

1) Study size

In order to detect a mean change of 0.16 in ΔEQ-5D score from baseline to week 24, it was determined that a sample size of 92 patients was required, based on the findings of a previous study[13]. This value for the mean change in ΔEQ-5D was based on the assumption of a standard deviation (SD) of 0.4, a 5% significance level, statistical power of 95%, and a 10% drop-out rate.

2) The analysis populations

The safety set (SS) included patients who were administered at least one dose of adalimumab and then followed up at least once for the safety evaluation. The effectiveness set (ES) included patients in SS who had an EQ-5D score at baseline and at week 24. If adalimumab was withheld before week 24, the patient was not included in the ES after the point of treatment discontinuation, except when analyzing the percentage of patients receiving adalimumab at week 24. The statistical tests used to analyze the effectiveness endpoints and exploratory endpoints are shown in Supplementary Table 3.

Safety was assessed based on the number and incidence of AEs, adverse drug reactions (ADRs), serious AEs (SAEs), and AEs that led to study discontinuation. AEs were coded according to the Medical Dictionary for Regulatory Activities (MedDRA version 22.0) and are presented as System Organ Class (SOC) and Preferred Terms (PT). AEs were summarized by severity and causality to adalimumab. Medication histories and concomitant medications were described by anatomical group and therapeutic subgroup.

Continuous variables (the number of observed patients, mean, SD, median, minimum and maximum), categorical variables (frequency and percentage) and 95% confidence intervals (CI) were calculated with descriptive statistics. Any missing data in the questionnaires were replaced according to the recommendation of the questionnaire developer, if available. Only available data were used without any imputation for the missing data, if such recommendations were unavailable.

RESULTS

Baseline patient demographics and characteristics

Between March 31, 2017 and August 3, 2018, 97 patients were enrolled from 11 sites, of whom 77 (79.4%) completed the study and comprised the ES. One (1.0%) patient was excluded from the analysis sets due to registration during the discontinuation period. A total of 19 (19.6%) patients dropped out of the study due to adalimumab discontinuation (n=16, 16.5%) and loss to follow-up (n=3, 3.1%; Supplementary Fig. 1).

The majority (67.5%) of the ES was male with a median age of 45.4 years (range 23~74 years; Table 1). Six (7.8%) patients

Table 1. Baseline patient demographics and disease characteristics—effectiveness set (n=77)

Demographic or disease characteristic	Value
Male	52 (67.5)
Age (yr)	45.4±11.9
Family history of psoriasis	
Yes	6 (7.8)
No	59 (76.6)
Unknown	12 (15.6)
Duration of disease (yr)*	8.9±9.9
BSA score	19.2±12.4
PASI score	13.7±5.6

Values are presented as number (%) or mean±standard deviation. BSA: body surface area, PASI: Psoriasis Area and Severity Index. *A total of 65 patients in the effectiveness set were evaluable for duration of disease.

had a known family history of psoriasis. Median time since psoriasis diagnosis was 5 years (range 0~45 years). Median BSA and PASI scores were 15.00 (range 4.00~80.00) and 12.40 (range 2.70~39.40), respectively.

In the ES, 12 (15.6%) patients had a medical history with the most frequently identified conditions belonging to the SOC category of gastrointestinal disorders (n=4, 5.2%), and infections and infestations (n=4, 5.2%) (Supplementary Table 4). Previous psoriasis treatment was received by 68 (88.31%) patients, 13 (16.88%) of whom received biologics treatment (Supplementary Table 5).

Among the SS (n=96), 8 (8.33%) patients were receiving concomitant systemic treatment with methotrexate (n=4, 4.2%), cyclosporine (n=3, 3.1%), or acitretin (n=1, 1.0%), in addition to adalimumab (Supplementary Table 6).

The mean (SD) time from baseline to study data collection at week 16 and week 24 was 16.28 (1.85) weeks and 24.88 (1.92) weeks, respectively.

HRQoL outcomes

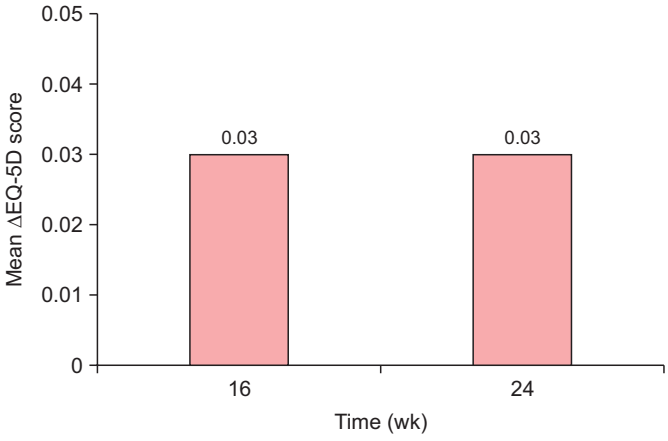
At baseline, the mean (SD) EQ-5D score was 0.88 (0.14). A statistically significant ΔEQ-5D score from baseline to week 24 (mean, 0.03; SD, 0.12; 95% CI, 0.00~0.06; p=0.0067; Fig. 1) was observed in the ES. A similar ΔEQ-5D score was observed from baseline to week 16 (mean, 0.03; SD, 0.10; 95% CI, 0.01~0.05, p=0.0288; Fig. 1). At baseline, the mean (SD) EQ-5D VAS score was 67.32 (17.53). Mean ΔEQ-5D VAS at week 16 and week 24 was +6.04 (SD, 14.72; 95% CI, 2.70~9.38; p<0.001; Fig. 2) and +8.39 (SD, 15.95; 95% CI, 4.77~12.01; p <0.0001; Fig. 2), respectively (Supplementary Table 7).

Subgroup analysis of ΔEQ-5D score at week 24 revealed that the improvement in EQ-5D scores was independent of sex, previous biologics treatment, baseline PASI and BSA scores, presence of nail psoriasis, and psoriatic arthritis (Supplementary Table 8).

A statistically significant improvement was observed at week 16 and week 24, for the Physical Functioning, Physical Role Functioning, Bodily Pain, General Health Perceptions and Social Role Functioning domain scales in SF-36, Physical Health Component score (a summary outcome measure of the SF-36), DLQI score and all domain scales of the TSQM (Supplementary Table 9~11). The Emotional Role and Mental Health domains, and the Mental Health Component scores (a summary outcome measure of the SF-36) revealed no statistically significant change from baseline to week 16 or week 24 in the SF-36 score (Supplementary Table 9).

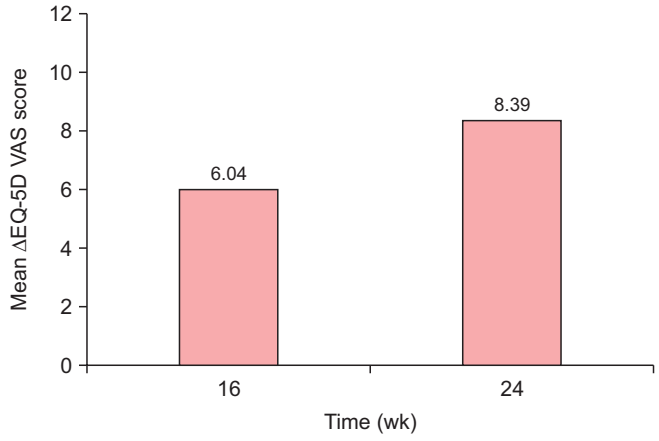
Clinical outcomes

In the ES, 65 (84.4%), 17 (22.1%), and 1 (1.3%) patient achieved a PASI of 75, 90, and 100 at week 16, respectively, compared with 64 (83.1%), 21 (27.3%), and 2 (2.6%) patients at week 24 (Fig. 3), respectively. Mean PASI in the ES improved from



95% CI	0.01~0.05	0.00~0.06
p-value	0.0288*	0.0067*

Fig. 1. Mean change in EQ-5D at week 16 and week 24—effectiveness set. EQ-5D: European Quality of Life-5 Dimensions questionnaire, Δ: change in, CI: confidence interval. *Wilcoxon's signed rank test.



95% CI	2.70~9.38	4.77~12.01
p-value	<0.001*	<0.0001*

Fig. 2. Mean change in EQ-5D VAS at week 16 and week 24—effectiveness set. EQ-5D: European Quality of Life-5 Dimensions questionnaire, VAS: visual analogue scale, Δ: change in, CI: confidence interval. *Wilcoxon's signed rank test.

13.74 (SD, 5.58) at baseline, to 2.56 (SD, 1.74) and 2.58 (SD, 2.34) at weeks 16 and 24, respectively (Table 2). Mean improvement proportions in the PASI score from baseline was 79.50 (SD, 15.20), and 77.72 (SD, 29.09) at weeks 16 and 24 respectively. A statistically significant mean ΔPASI score was observed at week 16, for all patients in the ES (–11.17; SD, 5.48), and for patients with nail psoriasis (–10.50; SD, 6.62). Statistically significant mean ΔPASI score was also observed at week 24, in patients in the ES (–11.16; SD, 5.90) and in patients with nail psoriasis (–10.45; SD, 7.09). Statistically significant mean ΔNAPSI scores were observed for patients with nail psoriasis at week 16 (–7.24; SD, 10.03) and week 24 (–9.05; SD, 15.00) (Table 2).

Correlations

Spearman's correlation coefficients indicated a significant inverse correlation between disease severity (ΔPASI scores) and improvement in EQ-5D, EQ-5D VAS, all SF-36 domains, and all TSQM domains (Supplementary Table 12). A positive correlation was found between the change in disease severity and the ΔDLQI score (R=0.6295, p <0.0001; Supplementary Table 12).

Modifying effects of baseline measures

At Week 16, the EQ-5D score at baseline, and age and sex were identified by the analysis of covariance (ANCOVA) as significant predictors of ΔEQ-5D score. EQ-5D score at baseline was the only significant predictor of change in this parameter after 24 weeks of treatment (Supplementary Table 13).

ΔEQ-5D VAS at week 16 was significantly predicted by baseline score, sex, and comorbidities, whereas at week 24 the significant predictors were baseline score, age and comorbidities (Supplementary Table 13).

Baseline value was the only significant predictor of ΔSF-36 for the Physical Functioning, General Health Perceptions, Vitality, Social Role Functioning, Emotional Role Functioning, and Physical Health Component domains, and the Mental Health Component scores at week 16 and 24. Baseline score and age were significant predictors of change at week 16 and 24 in the SF-36 Bodily Pain domain score, and the Mental Health domain score at week 16 and 24 was significantly predicted by the baseline score and age.

The ANCOVA analyses also showed that baseline score was the only significant indicator of ΔDLQI, TSQM Effectiveness and TSQM Convenience domain scores at week 16 and 24, and ΔPASI and ΔNAPSI scores were significantly predicted by baseline score at Week 16, but there were no significant predictors at week 24. ΔTSQM Overall Satisfaction score was not

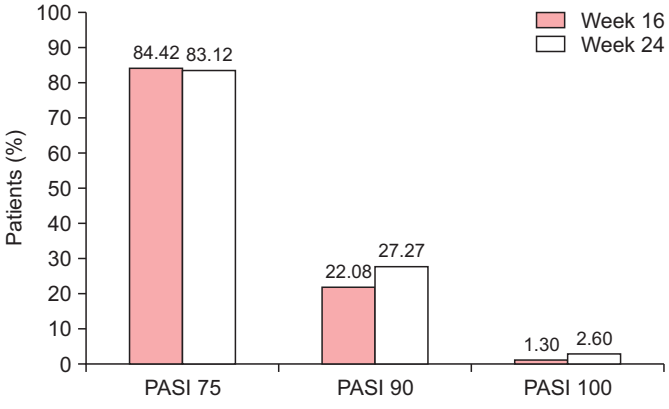


Fig. 3. Change in the proportion of patients that achieved PASI 75, 90 and 100 at Week 16 and Week 24—effectiveness set. PASI 75, 90 and 100 reflect the percentage reduction in disease severity. PASI: Psoriasis Area Severity Index.

Table 2. Improvement proportions of PASI scores, mean change in PASI scores for patients with nail psoriasis, and mean change in NAPSI scores—effectiveness set

	Value
Improvement proportions of PASI scores	n=77
Baseline to week 16 (95% CI)	79.50±15.20 (76.05~82.94)
Baseline to week 24 (95% CI)	77.72±29.09 (71.12~84.32)
ΔPASI scores	n=77
Baseline to week 16 (95% CI)	–11.17±5.48 (–12.42 to –9.93)
Baseline to week 24 (95% CI)	–11.16±5.90 (–12.50 to –9.82)
ΔPASI scores (patients with nail psoriasis)	n=26
Baseline to Week 16 (95% CI)	–10.50±6.62 (–13.18~7.83)
Baseline to Week 24 (95% CI)	–10.45±7.09 (–13.32 to –7.59)
ΔNAPSI scores	n=21
Baseline to Week 16 (95% CI)	–7.24±10.03 (–11.80~2.67)
Baseline to Week 24 (95% CI)*	–9.05±15.00 (–16.07~2.03)

Values are presented as mean±standard deviation (95% CI). Δ: change in, CI: confidence interval, NAPSI: Nail Psoriasis Severity Index, PASI: Psoriasis Area and Severity Index. *A total of 20 patients in the effectiveness set were evaluable for ΔNAPSI scores at week 24.

Table 3. Overall summary of adverse events in the safety set

AE (n=96)	Number of patients (%)	Number of events
Number of patients with AE 95% CI	12 (12.5) 7.95~22.59	14
Type of AE		
Not applicable	7 (7.3)	9
Death	0 (0)	0
Life-threatening	0 (0)	0
Hospitalization	5 (5.2)	5
Prolonged hospitalization	0 (0)	0
Congenital anomaly	0 (0)	0
Persistent or significant disability	0 (0)	0
Medically important event	0 (0)	0
Severity		
Mild	3 (3.1)	5
Moderate	6 (6.3)	6
Severe	3 (3.1)	5
AE leading to discontinuation 95% CI	11 (11.5) 7.18~21.41	13
Transiently discontinued	3 (3.1)	3
Permanently discontinued	8 (8.3)	10
Outcome		
Death	0 (0)	0
Resolved	9 (9.4)	9
Resolving	1 (1)	1
Not resolved	2 (2.1)	4
Resolved with sequelae	0 (0)	0
Others	0 (0)	0
Unable to contact patient	0 (0)	0
Adverse drug reaction 95% CI	8 (8.3) 3.55~15.30	8
Serious AE 95% CI	5 (5.2) 1.66~11.39	5
Serious adverse drug reaction 95% CI	2 (2.1) 0.25~7.11	2

AE: adverse event, CI: confidence interval.

significantly predicted by any covariates at week 16 or by age and sex at week 24.

Modifying effects of clinical variables

Change from baseline at week 16 and week 24 in EQ-5D, EQ-5D VAS, all SF-36 domains, DLQI, TSQM Effectiveness, and PASI score were not predicted by any of the clinical variables assessed (previous biologics treatment, nail psoriasis at baseline, and presence of psoriatic arthritis). Presence of psoriatic arthritis was a significant predictor of ΔTSQM Convenience score at week 16 and week 24, and for TSQM Overall Satisfaction score at week 24 (but not at week 16, for which there were no significant predictors).

Safety

No new safety signals were identified in this study (Table 3). In the SS (n=96), 14 AEs were reported in 12 (12.5%) patients, 5 of which were mild (n=3; 3.1%), 6 were moderate (n=6; 6.3%) and 3 were severe (n=3; 3.1%). Eight AEs (n=8; 8.3%) were classified as ADRs. Five SAEs (n=5; 5.2%) were reported, of which 2 (bacterial arthritis and acute myeloid leukemia) were assessed by the study investigator to be adalimumab-related. AEs led to permanent treatment discontinuation in 8 (8.3%) patients and temporary discontinuation in 3 (3.1%) patients. AEs in 10 patients were resolved or resolving during the course of the study. No deaths were caused by AEs during the study.

DISCUSSION

In this noninterventional, observational study of patients with moderate to severe psoriasis, treatment with adalimumab for 24 weeks was associated with a significant improvement in most PROs related to HRQoL (EQ-5D score; EQ-5D VAS; Physical Functioning, Physical Role Functioning, Bodily Pain, General Health Perceptions, and Social Role Functioning domain scales of the SF-36; Physical Health Component score, DLQI score; and all domain scales of the TSQM). Clinical improvement in disease severity was also observed, as evident from improved PASI scores.

Most patients experienced improvements in most HRQoL PROs, by the early assessment timepoint of week 16. These observations aligned with the results obtained in two adalimumab clinical trials where HRQoL-related PROs were used as outcome measures[14,15], and a real-world prospective observational study of patients with moderate to severe psoriasis, in the United Kingdom[16]. There were no differences in the improvement in the HRQoL measures based on sex, previous biologics treatment, baseline disease severity as expressed by PASI scores and other clinical characteristics, such as the presence of nail psoriasis, psoriatic arthritis or other comorbidities, as evident from the ANCOVA analyses. This suggests that adalimumab can improve HRQoL in patients with moderate

to severe psoriasis, independent of baseline clinical status. Spearman's correlation coefficients indicated that the mean ΔHRQoL measures and clinical outcomes after 24 weeks of adalimumab treatment were significantly correlated with decreased psoriasis severity. Together with the findings of the ANCOVA analyses, this observation reinforces the complex nature of psoriasis and its negative impact on patient well-being[17].

Depression and anxiety are more prevalent in patients with psoriasis than among patients without psoriasis[18], with psychiatric morbidity being considerably higher and QoL measures lower in comparison with patients inflicted with other skin conditions[19,20]. Patients with severe psoriasis are more likely to present with depressive symptoms, mood disturbances, anxiety and even suicidal ideation[21-23], and frequently experience low self-esteem and low self-confidence, as well as difficulty in forming intimate relationships[24]. Manifestation of these mental health symptoms can potentially have a detrimental effect on the clinical outcomes of psoriasis treatment. Psychosocial factors are likely to contribute to exacerbation of psoriatic symptoms, and the presence of skin lesions predisposes patients to further deterioration of their mental state[25]. The latter has been linked to poor treatment adherence and unsatisfactory treatment outcomes. Understanding the effect of psoriasis treatment regimens on patient mental health, and the need to prioritize psychological and emotional well-being in treatment goals, is therefore important. In this study, the baseline score for the Mental Health domain and age were identified as significant predictors of clinical outcomes in the Mental Health domain score after 24 weeks of adalimumab treatment.

Some HRQoL PROs did not demonstrate significant improvements (Vitality, Emotional Role Functioning and Mental Health domain scales of the SF-36, and Mental Health Component score) over the course of the study period. These observations are consistent with a previous study which explored well-being in patients with psoriasis, where improvement in psoriasis-related mental health symptoms was observed later than the improvement in skin symptoms, despite a favorable response to anti-psoriasis treatment[26]. In contrast, concurrent physical and psychological improvements were observed in patients with psoriasis who were treated with acetylsalicylic acid[16], which may be a reflection of TNF-α mediated psychotropic change.

HRQoL measures are widely used to quantify patient QoL, particularly in patients with psoriasis[27]. The considerable costs imposed by psoriasis on both patients and healthcare systems[28] makes it increasingly important to inform policy on reimbursement schemes and financial support. In Korea, adalimumab, a TNF-α inhibitor, is reimbursed to patients with both moderate and severe psoriasis. The patient copayment amount is higher than that for many other diseases, which poses a hurdle in the optimal access to psoriasis management. Real-world evidence is critical in the assessment of the cost-effectiveness of treatments, as it can be utilized to support local reimbursement policies. Furthermore, there is an increasing trend for the consideration of the patient's perspective in optimizing treatment access, as demonstrated in a real-world study, where patients' self-perceived disease severity was utilized to explore key challenges in using TNF-α inhibitor biosimilars[29]. Accumulation of real-world evidence on the impact of psoriasis treatments is therefore instrumental for price renegotiation and re-assessment of related copayments.

The inherent limitations of an observational study apply to this study, including limited data collection, absence of a control group, as well as the potential confounding effect of the uneven male-to-female ratio on outcome measures. Also, any partially completed questionnaires may result in an incomplete reflection of a patient's disease status. Quantification of HRQoL is complex as it is not only a reflection of the physical condition, but also of the psychological status of the patient, which can be influenced by several factors, such as interpersonal relationships, which was not explored in this study. This may explain the considerable data heterogeneity in some PROs. Future studies should include both psychological and social correlates of the HRQoL response to adalimumab and verify whether the benefits to patient mental well-being can be achieved in all patients with moderate to severe psoriasis.

This is the first study to examine the impact of adalimumab on HRQoL in Korean patients with psoriasis. Over 24 weeks of treatment, adalimumab contributed to a significant improvement of most analyzed HRQoL PROs, independent of disease severity. The results are consistent with randomized trials and observational studies that have demonstrated the safety and effectiveness of adalimumab in patients with psoriasis. No new safety signals were identified during the study. Collectively, the findings suggest that adalimumab is a well-tolerated treatment option that can facilitate a favorable effect on HRQoL for patients with moderate to severe psoriasis.

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SUPPLEMENTARY MATERIALS

Supplementary data can be found via http://anndermatol.org/src/sm/ad-22-041-s001.pdf.

CONFLICTS OF INTEREST

Sang Wook Son, Ki-Heon Jeong, Jiyoung Ahn, Il-Hwan Kim, Un Ha Lee, Joo Yeon Ko, and Kwang Joong Kim report no conflict of interest. Dong Hyun Kim has received research funding and speaker fees from AbbVie, Inc., Janssen Pharmaceuticals, Inc., Novartis Pharmaceutical Corporation, andLilly. Eun-So Lee received grants for clinical research from AbbVie, Inc., Celgene Corporation, Cell Biotech, Lilly, Janssen Pharmaceuticals, Inc., and Servier; served as an advisor or consultant for AbbVie, Inc., Celgene Corporation, Galderma Korea, Janssen Pharmaceuticals, Inc., Lilly, and Novartis Pharmaceutical Corporation. Hai-Jin Park has served as an advisor for Janssen Pharmaceuticals, Inc., and participated in clinical trials for Eli Lilly and Bristol-Myers Squibb. Byung-Soo Kim has served as a scientific adviser or clinical study investigator for Abbvie, Astellas, Boehringer Ingelheim, Eli Lilly, GlaxoSmithKline, Janssen Pharmaceuticals, Inc., Kyowa Hakko Kirin, LEO Pharma, Novartis, Regeneron, and Sanofi.

Javed Rashid and Jin Ju Kim are current and former employees of Abbvie, Inc., respectively, and may hold stock or stock options.

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This study was funded by AbbVie, Inc. AbbVie, Inc. was responsible for the study design and data interpretation, and has reviewed and approved this manuscript for submission.

DATA SHARING STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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